Advancing the evidence base for CAD/CAM insoles within orthotic practice

by

Laura Barr

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ABSTRACT

Evidence-based practice (EBP) is an essential element of safe and effective healthcare. As digital technologies advance, computer-aided design and computer-aided manufacture (CAD/CAM) is being increasingly used in orthotic practice, and it is therefore important to build an evidence base that supports its clinical application.

This thesis presents a collection of studies investigating the integration of EBP and CAD/CAM technologies within United Kingdom (UK) orthotic services. In synthesis, these studies support the use of EBP, enhance our understanding of how CAD/CAM workflows affect patient outcomes, and have contributed to the development of an Advanced Practice role in orthotics.

The first study, a cross-sectional survey of UK orthotists, found that 64.8% had accessed the Orthotics Evidence Portal, a resource designed to assist EBP, with over 80% reporting increased engagement with scientific publications. Importantly, 68.6% indicated that the Portal had influenced their clinical decisions, supporting its role in promoting EBP. The second study evaluated 3D-printed insoles for musculoskeletal conditions unresponsive to standard care. Among 36 patients, significant improvements in pain, function, and foot health were observed over eight weeks, with 26 patients requiring no additional treatment after two years. A third study reported on a national cross-sectional survey using Freedom of Information requests, examining CAD/CAM insole provision across UK National Health Service (NHS) Trusts and Health Boards. Responses from 131 services revealed widespread use of CAD/CAM (70.5%), with foam-box impression casting being the predominant shape capture method. Finally, a double-blinded randomised controlled trial compared two CAD/CAM workflows: direct foot scanning and foam-box casting. Among 112 participants, both methods yielded similar clinical outcomes at 12 weeks. However, foot scanning was associated with higher patient satisfaction, better adherence, and lower production costs.

Collectively, these findings highlight the role of EBP and CAD/CAM in orthotic practice, demonstrating their potential to enhance clinical outcomes, streamline workflows, and support orthotists in providing evidence-based care.

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ACKNOWLEDGEMENTS

The we, the us and the our.

Throughout the writing of this thesis I've been reminded, repeatedly, to focus on *my* contribution to knowledge, on *my* role in the projects presented here. And that's been one of the greatest challenges, because no project, publication, or milestone has been achieved alone. The work enclosed in these pages is a testament to the support, encouragement, and community of the brilliant people that I have so gratefully been surrounded by throughout this journey. So I am thankful to have one small section within this expanse of words, where it's OK to recognise the *we*, the *us*, and the *our* that stand behind every "I" on the next 400 pages.

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GLOSSARY OF ABBREVIATIONS AND TERMS

Abbreviations	Description
3D	3-Dimensional
AFO	Ankle Foot Orthosis
AHP	Allied Health Profession/Professional
ASTM	American Society for Testing and Materials
BAPO	British Association Of Prosthetics And Orthotics
BMI	Body Mass Index
CAD	Computer-Aided Design
CAHPO	Chief Allied Health Professions Officer
CAM	Computer-Aided Manufacture
CKP	Clinical Knowledge Publisher
CNC	Computer Numerical Control
CPD	Continuing Professional Development
DEBOP	Directory Of Evidence-Based Orthotic Practice
EBP	Evidence-Based Practice
ESP	Extended Scope Practitioner
EVA	Ethylene Vinyl Acetate
FHSQ	Foot Health Status Questionnaire
FOI	Freedom of Information
GGC	Greater Glasgow And Clyde
GRADE	Grading Of Recommendations, Assessment, Development, And Evaluations

HB	Brinell Hardness
HCPC	Health And Care Professions Council
HEE	Health Education England
HEIW	Health Education and Improvement Wales
HTML	Hypertext Markup Language
IQR	Interquartile Range
IRAS	Integrated Research Application System
MID	Minimal Important Difference
MSK	Musculoskeletal
NES	NHS Education Scotland
NHS	National Health Service
NMAHP	Nursing, Midwifery and Allied Health Professions
NMC	Nursing and Midwifery Council
NRS	NHS Research Scotland
OETT	The Orthotic Education and Training Trust
OPUS-CSD	Orthotic and Prosthetic User Survey Client Satisfaction with Device
P&O	Prosthetics And Orthotics
PE	Polyethylene
PICO	Population, Intervention, Comparison And Outcomes
PROM	Participant/Patient Reported Outcome Measure
PU	Polyurethane
RCT	Randomised Controlled Trial
RDS	Right Decision Service

REC	Research Ethics Committee
ROM	Range Of Motion
SD	Standard Deviation
TTT	Train The Trainers
UK	United Kingdom
UCLan	University of Central Lancashire
UKCC	UK Central Council for Nursing, Midwifery and Health Visiting
Terms	**Description**
Fully-digital CAD/CAM process	This describes the production of CAD/CAM insoles using a direct scan of the foot, digital modification of the scan is undertaken to produce a digital insole model, and manufacture is completed using mechanised reduction-milling or addition manufacture.
Hybrid-digital CAD/CAM process	This describes the production of CAD/CAM insoles using a physical cast of the foot which is then scanned into the CAD/CAM system, digital modification of the scan is undertaken to produce a digital insole model, and manufacture is completed using mechanised reduction-milling or addition manufacture.
Insoles	The term “insoles” is used to describe “foot orthoses” within the narrative of this thesis. It should be noted that these terms are used interchangeably throughout the published literature.
The BAPO MSK Course	The informal name “The BAPO MSK Course” is used to describe the two-day education programmed titled

	“Assessment, Diagnosis, and Treatment of MSK Foot and Ankle Problems for Orthotists” from 2015 to 2019, and “MSK Foot & Ankle: Holistic Management and treatment strategies” from 2019 to present.
The Orthotics Evidence Portal	The current name of the web-based resource described in Chapters 1 and 2, hosted on the Right Decision Service website from 2024 to present. An evolution of the Directory of Evidence-Based Orthotic Practice (DEBOP).
The Directory of Evidence-Based Orthotic Practice (DEBOP)	The previous name of the Orthotics Evidence Portal described in Chapters 1 and 2, hosted on the Clinical Knowledge Publisher website from 2015 to 2024.

CHAPTER 1. SYNOPTIC COMMENTARY

1.1. Introduction

This thesis presents the case for a PhD by Portfolio, by presenting three linked and distinct projects [Table 1.1] and highlighting their contribution to the evidence base for orthotic clinical practice. The projects focus on the use of evidence-based practice (EBP) in the UK orthotic profession, and demonstrate the position of specific research work in the area of computer-aided design and computer-aided manufacture (CAD/CAM) for insoles within this evidence base.

Throughout this thesis the term “insoles” is used to describe “foot orthoses” which are medical devices prescribed to patients as a treatment for a variety of lower limb pathologies. Within the published literature these terms are used interchangeably.

Table 1.1. A brief overview of the three projects and contribution by the author.

Project 1 [Chapter 2]: The Orthotics Evidence Portal: Supporting Evidence-Based orthotic practice in the UK
This project describes the development of "The Orthotics Evidence Portal", a unique UK-based resource, designed to facilitate EBP in the UK orthotic profession, by improving access to the evidence for orthotic treatment of musculoskeletal (MSK) and diabetic foot conditions. The project takes the form of a web-based platform, with evaluation of this platform from a cross-sectional survey.
Contribution by L Barr: The author conceived the redevelopment plan for the MSK section 2017, redeveloped and published the MSK section 2017, developed the concept of the diabetes section, developed and published the diabetes section 2017, undertook monthly literature appraisals and updated content monthly 2017 to current, developed the concept of the project evaluation, designed the methodology, undertook the data collection, analysis and write-up, developed and delivered promotional materials for the project, and contributed to the content and delivery of associated education programmes.
Project 2 [Chapter 3]: Integrating the use of hard-shell 3D-printed insoles in the MSK treatment pathway of an NHS orthotic service
This project describes the integration of 3D-printed hard-shell insoles produced using computer-aided design and computer-aided manufacture (CAD/CAM), into a treatment pathway for patients attending the National Health Service (NHS) Greater Glasgow and Clyde (GGC) orthotic service. The project takes the form of a clinical evaluation of thirty-six patients using patient reported outcome measures (PROMs), with a two-year follow-up.
Contribution by L Barr: The author developed the concept of the project, carried out the literature review, designed the methodology for the study, developed the process for integrating 3D printing into the NHS GGC CAD/CAM workflow, led the clinical evaluation, contributed to data collection and analysis, led the writing of the publication, led the review and editing of the final article, and was first author on the final publication.
Project 3 [Chapter 4]: The use of CAD/CAM in the production of insoles in the UK
This project describes a review of current practices across the UK relating to the workflow used in the manufacture of CAD/CAM insoles. This section of Project 3 takes the form of a cross-sectional study of UK orthotic services.
Contribution by L Barr: The author developed the concept for the cross-sectional survey, carried out the literature review, designed the methodology for the study, undertook the data collection and analysis, led the writing of the publication, led the review and editing of the final article, and was first author on the final publication.

Project 3 [Chapter 5]: The effectiveness of CAD/CAM insoles manufactured from foam-box casts versus direct scans in treating MSK conditions of the foot and ankle
This project explores the clinical effectiveness of two common foot shape capture methods used within the workflow for CAD/CAM insoles, related to the treatment outcomes of patients. This section of Project 3 takes the form of a single centre double-blinded randomised controlled trial (RCT)
Contribution by L Barr: The author developed the concept for the RCT, carried out the literature review, contributed to the methodology for the RCT, contributed to data collection and analysis for the RCT, led the writing of the publications for the RCT protocol and the RCT, contributed to the review and editing of the final publications, and was first author on the final publications.

The three projects are individually presented in Chapters 2, 3, 4 and 5 of this thesis, highlighting specific aims relating to each distinct project, and presenting the outcomes of formal analyses in demonstration of the original contribution to knowledge that each project offers, to further our understanding of orthotic practice. In this respect, Chapters 2 – 5 can be considered a traditional academic presentation of the projects in the form of individual studies, similar to that of a traditional PhD thesis. In contrast, the synoptic commentary which comprises Chapter 1, offers a broader view of the projects, exploring their interconnected and symbiotic relationship to each other, and their influence on the development of a clinical role in an NHS orthotic service. This synoptic commentary will synthesise the three projects, offering a retrospective narrative of their conception and evolution, while placing them in the context of a clinical career in advanced orthotic practice, by examining the projects from the perspective of the four-pillars of advanced practice, as originally defined by Kim Manley (Manley, 1997); clinical practice, leadership and management, education, and research. In doing so, this commentary will introduce additional pieces of work related to the projects in order to add context to the position of an advanced practice role. The commentary will present these adjacent areas of individual and collaborative work alongside the central focus of the three projects.

Prior to this exploration, an introduction to the three projects and their core subject matter will be made, preceded by an introduction to advanced practice

and my role as an orthotist, which aims to position myself within the advanced practice sphere, and define my focus in the research areas.

1.2. My role as an orthotist

I am an advanced practice orthotist in the National Health Service (NHS) for Greater Glasgow and Clyde (GGC), specialising in treatment of musculoskeletal (MSK) conditions of the foot and ankle. As part of my advanced practice role, I hold a MSK specialist orthotic team lead position in NHS GGC (2017 to present), a specialist clinical position within the Orthopaedic Service (2015 to 2025), and I am the National MSK lead for orthotics in Scotland (2021 to present). NHS GGC developed this advanced practice role initially in 2015 as the first Extended Scope Practitioner (ESP) orthotist position in NHS Scotland, and revised the description to Advanced Practice orthotist in 2020, in line with the Health Education England (HEE) Multi-Professional Framework for Advanced Clinical Practice in England (HEE, 2017).

The historical and continuing development of this advanced practice role has been intrinsically linked to the projects outlined in this thesis, and to the bodies of work that these projects have generated, which will be explored in this commentary.

My interest in the area of insoles has been fundamentally shaped by my clinical experience. Since 2015, over 80% of my clinical workload has focused on MSK and diabetic conditions affecting the foot and ankle, the specific orthotic treatment of which will often include the prescription of an insole. This is not unusual in the orthotic profession, two UK surveys have shown that a high proportion of orthotists treat adult MSK conditions (92.7%) and diabetic foot conditions (80.3%) in their daily practice (Eddison *et al.*, 2023), with 95.7% of orthotists prescribing insoles to patients with MSK conditions, and 94.6% to patients with diabetes (Nester *et al.*, 2018). Indeed, 43% of orthotists consider insoles to be an area of clinical expertise (Eddison *et al.*, 2023), with 47.3% spending over half of their working time providing insoles to patients (Nester *et al.*, 2018). Where my experience differs is in the area of CAD/CAM insoles. Throughout the duration of my employment in NHS GGC I have worked

exclusively with CAD/CAM when providing custom insoles, this is a contrast to the majority of the UK orthotic workforce with only 39.4% of orthotists reporting to have skills in the use of any CAD/CAM process for orthotic practice (Eddison *et al.*, 2023), and across the orthotic, podiatry and physiotherapy professions only 28.7% of custom insoles were reported to be manufactured with CAD/CAM (Nester *et al.*, 2017). My own research, as presented within this thesis, has shown that orthotic services in the UK began adopting CAD/CAM processes a median of 10 years ago, but despite this only 3.3% (3/91) of services currently use direct scanning equipment, and orthotists in only 8.8% (8/91) of services assume responsibility for the digital modelling process of CAD/CAM insoles (Barr, Richards and Chapman, 2025).

My interest in research began during my time as an undergraduate student in Prosthetics and Orthotics from 2003 to 2007, at which time I was becoming aware of the role of research in EBP, specifically how the outcomes of research were used to influence and improve clinical practice. From my first employment in NHS GGC in 2007 I knew that I wanted to retain a clinical, patient-facing healthcare role, and my observation was that research was primarily conducted in a non-clinical academic sphere. In NHS GGC, the largest health board in Scotland, there were no clinical academic positions available within the orthotic service, and no orthotists conducting research to act as a role model, while publications in my early years of practice reflected the disconnect between research and clinical application in the orthotic profession (Geil, 2008; Ramstrand and Brodtkorb, 2008; Ramstrand, 2013). However in 2015, through my involvement in Project 1, as described in Section 1.4.1 of this thesis, I began exploring the feasibility of incorporating clinical research into my clinical practice. The first steps to integrating research into a pre-existing clinical role were challenging, the underdevelopment of clinical academic pathways generally in UK healthcare (Westwood *et al.*, 2018) has resulted in a minority of any Allied Health Professionals (AHPs) working in clinical academic roles (Comer *et al.*, 2022). Given this, in combination with a recognised workforce shortage in Prosthetics and Orthotics (Chockalingam, Eddison and Healy, 2019), it was challenging to advocate for the integration of a research role within my current position at NHS GGC. However, with a minority of orthotists involved

in research and only 11.2% reporting to have published their research in peer reviewed journals (Eddison *et al.*, 2023), I recognised the importance of pursuing and championing this for our profession.

My experience in respect to these challenges is not unique in the wider context of healthcare, similar barriers are reported across various professions where advanced practice roles have been developed. In order to appreciate the wider context of advanced practice and its vital position within the healthcare system, an explorative review of advanced practice history and development in the UK healthcare system will now follow.

1.3. Advanced practice and the four pillars of practice in the UK

In UK healthcare, advanced practice is recognised as a level of practice which is demonstrated by autonomous, high level complex clinical decision making, in an environment which incorporates not just clinical expertise but a combination of leadership, education and research qualities (Gloster and Leigh, 2021). Advanced practice does not relate to a specific speciality or profession, and therefore encompasses a wide range of roles, responsibilities and professional backgrounds, within which the individual practitioner will generally be expected to demonstrate postgraduate experience at Masters level (Evans *et al.*, 2021).

The history of advanced practice in the UK began in the 1970's with acknowledgement of nurse specialists who had extended their clinical roles to mirror aspects of their medical colleagues (Castledine, 2002). However, it was not until the 1990's when, in response to shortages of medical staff, the UK Central Council for Nursing, Midwifery and Health Visiting (UKCC) published the "Scope of Professional Practice" document (UKCC, 1992), which was aimed at guiding the extension of the scope of nursing practice to suit a changing healthcare landscape, a concept which was welcomed throughout the medical community (Jowett *et al.*, 2001). Over the subsequent three decades, advanced practice nursing roles became well established in areas such as primary care (Htay and Whitehead, 2021), acute services (Jones, 2005) and emergency care (Ingram *et al.*, 2017). Studies evaluating the effectiveness of these roles consistently demonstrated equal or superior outcomes in patient care provided

by nurses substituting for doctors in primary care (Laurant *et al.*, 2005; Laurant *et al.*, 2018; Martínez-González *et al.*, 2014). This laid the groundwork for exploring the possibility of extending advanced practice roles into the AHP community in other specialist areas of healthcare practice. The first AHP advanced practice roles began in physiotherapy in the 1980's as a response to the requirement for more complex care and higher volumes of patients particularly in the areas of MSK and orthopaedics (Tawiah *et al.*, 2021). Similar to the positive impact on patient care seen in the advanced practice nursing community, the role of the advanced physiotherapy practitioner has been shown to improve accessibility of care while maintaining similar health outcomes and satisfaction for patients compared with medical counterparts (Vedanayagam *et al.*, 2021), while being a cost effective alternative to medical staff (Lafrance *et al.*, 2021). The benefits of advanced practice roles are being increasingly recognised in various non-medical healthcare professions in the UK including radiography (Hardy *et al.*, 2016), podiatry (Hardy *et al.*, 2021), and occupational therapy (O'Donnell *et al.*, 2023).

With the increasing development and uptake in advanced practice roles in the UK, the subject of regulation has been widely discussed. Nursing practice is regulated by the Nursing and Midwifery Council (NMC) but there is currently no specific regulation for advanced practice, which the NMC acknowledges may differ greatly from the usual competencies required for general nursing, and for this reason in 2023 an independent report commissioned by the NMC called for regulation of advanced nursing practice (Palmer, Julian and Vaughan, 2023). In 2021 the Health And Care Professions Council (HCPC) Advanced Practice report explored the possible requirement for regulation of advanced AHP practice, concluding that the current HCPC professional registration was sufficient without posing a risk to patients, and that members working at an advanced practice level should be doing so within the frameworks associated with their area of specialism (Hardy *et al.*, 2021). The global regulation of advanced practice remains diverse, with widespread disparity between countries who centrally regulate advanced practitioners and those who do not (Wheeler *et al.*, 2022; Mackavey *et al.*, 2024).

With UK advanced practice being locally regulated within the specific area in which the clinician works, the nation in which they work, and their regulatory body; either the NMC or HCPC, there has been a drive across the UK to develop advanced practice frameworks which can help to standardise the knowledge, skills and behaviours required to practice at this level (Gloster and Leigh, 2021). Health Education England (HEE) were the first in the UK to publish a national framework, the Multi-Professional Framework For Advanced Clinical Practice in 2017 (HEE, 2017), followed in 2019 by the Department of Health Advanced AHP Practice Framework in Northern Ireland (Department of Health, 2019), in 2021 by the NHS Education Scotland (NES) Nursing, Midwifery and Allied Health Professions (NMAHP) Post-Registration Development Framework (NES, 2021), and in 2023 by the Health Education and Improvement Wales Professional Framework for Enhanced, Advanced and Consultant Clinical Practice in Wales (HEIW, 2023). Although the four nations have developed separate frameworks, they are closely aligned, all with a key theme of the four pillars of advanced practice.

The concept of the four pillars of advanced practice was first developed by Kim Manley in 1997, published in her seminal paper titled "A conceptual framework for advanced practice: an action research project operationalising an advanced practitioner/nurse consultant role" (Manley, 1997). This work laid the foundation for the four pillars of advanced practice: clinical practice, leadership and management, education/ facilitation of learning, and research, which aimed to provide clarity, structure and optimisation of the role of advanced practitioners and nurse consultants. The outcome of her research emphasised the importance of clearly defined roles and responsibilities and the need for a structured approach to advanced practice. The concept of framing this structure within four key pillars would ensure role clarity and development areas for individuals, with the emphasis on providing safe and effective treatment in order to achieve the best possible patient outcomes. This framework has since been widely adopted by various healthcare organisations, and provides the key structure on which the four nations advanced practice frameworks are built.

Kim Manley's research proposed the benefits of this four pillar framework, based on 3 years of research at the time, which demonstrated positive

outcomes both in professional development and patient care, and hypothesised benefits in the wider healthcare setting with adoption of the framework. Since this initial work there has been widespread adoption and adaptation of the framework, with studies exploring how Manley's original findings have been instrumental in the development of advanced practice roles and the effect on patient care within the NHS as well as other international healthcare systems. Publications in both nursing and AHP practice advocate strongly for the four pillars of practice, reporting on the four pillar approach standing the test of time, providing a framework by which clinicians can optimise patient care through not just the clinical pillar but through the translation of research into practice, using strong leadership skills and facilitating the education of their teams (Gloster and Leigh, 2021). The four pillars model is generally viewed as well embedded within healthcare systems, and is examined as a standard principle of advanced practice which can even assist with the integration of additional models of healthcare advancement (Mortimore *et al.*, 2021).

Within this now well-established framework, recent studies have examined the specific balance of the four pillars within advanced practice roles. A 2021 UK scoping review raised concerns over the imbalance of the pillars, highlighting a heavily weighted focus on clinical practice which was the exclusive focus of 79% of literature pertaining to advanced practice, with only 16% of papers including any element of leadership within advanced practice roles, and only 13% and 10% including any aspect of education and research respectively (Evans *et al.*, 2021). In 2022 the largest workforce scoping review of over 4000 advanced clinical practitioners in England revealed the widespread view of the four pillars of practice as an integral aspect of advanced practice roles (Fothergill *et al.*, 2022). However despite the positive view of the requirement for the four pillars, the majority of clinicians who responded to the survey identified pressure from their service to focus predominantly on the clinical pillar, with only 11% of respondents reporting to be involved in research. A further publication identified research as a weaker pillar in terms of the advanced practitioners skill set, and advocated for the integration of clinical academic roles in advanced practice in order to improve the dissemination of knowledge and skills relating specifically to the research pillar (Fielding *et al.*,

2022). Following on from these publications, the lack of focus on the research pillar has been identified and highlighted as an area for improvement within the advanced practice community, with strategies for improvement being suggested, such as publications identifying the need for better mapping of advanced practice roles within the four pillars framework and advocating for research to be included in the day-to-day roles of advanced practitioners (Conway and Barratt, 2023). Recent publications have identified barriers faced by advanced practitioners aiming to develop the research pillar, including limited time, resource and infrastructure to support research, and advocate for the development of clinical academic posts (Dean, 2023). At the same time, positive experiences of advanced practitioners have been demonstrated by individuals making use of clinical resources already present within services and acting as a role model for disseminating and promoting evidence-based practice to drive transformative change in local services (Nie, 2025). This picture is mirrored not just throughout the UK, but internationally, with recent mapping across 22 countries showing a similar disparity in practitioner competencies, with a focus predominantly on the clinical and leadership pillars, and only 16% of competencies being linked to the education and research pillars (Kenyon *et al.*, 2024). Despite the growth of advanced practice roles in nursing and AHPs, advanced practice in the orthotic profession is still in its relative infancy. A search of multiple databases disclosed no publications relating to advanced orthotic practice [Table 1.2].

Table 1.2. Search strategy to identify publications relating to advanced orthotic practice undertaken January 2025.

Databases	**Search terms**
AMED, Embase, Medline, CINAHL	"advanced practice" or "extended scope" or "advanced practitioner" or "advanced orthotic practi*" or ESP AND orthotist or orthotic

NHS GGC remains one of the few UK orthotic services to have formally developed advanced practitioner roles, aligned initially with the Multi-

Professional Framework for Advanced Clinical Practice (HEE, 2017) and latterly with the NMAHP Development Framework (NES, 2021). Currently the number of orthotists working as advanced practitioners in the UK is unknown, and understanding the full landscape of advanced practice in the UK orthotic service has been complicated by the delayed four nations agreement of an advanced practice definition, which was only finalised in October 2024 (CAHPO, 2024), resulting in differing definitions across the UK before this time. In spite of advanced practice roles, skills, and terminology being increasingly promoted throughout the Prosthetics and Orthotics (P&O) profession and other AHP groups, it appears that the classification of advanced practitioner in orthotics remains poorly understood, leading to further uncertainty around how many orthotists are currently working in advanced practice roles in the UK. This confusion around the terminology associated with advanced practice is demonstrated in the HCPC advanced practice report where seven prosthetist/orthotists defined themselves as working at advanced practice level, five of whom stated that their role included independent prescribing (Hardy *et al.*, 2021), however the ability to independently prescribe medications is currently not within the legal authority for prosthetists and orthotists, and therefore cannot be part of an advanced practice role for those in the P&O profession. Similar disparity between the title of advanced practice and level of practice was observed in the P&O workforce survey whereby 24.1% of orthotists reported having the knowledge and skills for advanced practice, but only 13.1% reported having Masters level qualifications, a pre-requisite for advanced practice (Eddison et al., 2023). The phenomenon of conceptual confusion around advanced practice was also observed in the expansion stage of the global advanced practice nursing agenda, which resulted in wide discrepancies between the titles of advanced practitioners and the activities, skills and knowledge undertaken in their roles (Stasa et al., 2014), a variation which persisted into recent years (Fothergill et al., 2022). It is therefore important to educate the UK orthotic workforce on the role and scope of advanced practice. In this respect, the creation and subsequent development of the advanced practice role in NHS GGC has been influential in demonstrating what advanced practice positions can achieve in orthotic services. Over the

years I have liaised with the orthotic profession in various ways to support and promote the role of advanced practice orthotists, aspects of which will be explored in Section 1.5 of this chapter.

An important aspect of the four pillars of practice is not just how they shape the role for the individual, but the influence that this can have on the wider system of clinical peers, and departmental and professional processes. The next two sections will explore how the projects within this thesis have contributed to a developing advanced practice role for the author as an individual, and how the projects have contributed to improving patient outcomes, and further workstrands with a wider reach to facilitate advancing practice in the orthotic profession. In contrast to the literature highlighting discrepancy between a heavily weighted focus on the clinical pillar and universally limited focus on the research pillar, Sections 1.4 and 1.5 of this chapter will aim to demonstrate how a research specific focus has been used to strengthen the other three pillars of practice.

1.4. Introducing the projects – an overview of the history and development

In accordance with the requirements for a PhD by Portfolio, the three projects presented within this thesis comprise two historical projects that predate entry to the PhD programme [Chapters 2 and 3] and one live project conducted during my enrolment at the University of Central Lancashire (UCLan) [Chapters 4 and 5]. It should however be recognised that the first project: *Chapter 2 – The Orthotics Evidence Portal: Supporting evidence-based orthotic practice in the UK*, presents a continually evolving legacy project, and so while the evaluation of this project is retrospective, the wider discussion regarding the project will include some aspects of the contemporary project activity where relevant to the historical work.

This section aims to outline the professional journey undertaken in the development of the three projects, in order to better understand how the complete journey, and not just the specific outcomes of the projects, has shaped and influenced the position of the author as a leader in the area of advanced orthotic practice. Section 1.5 will then explore how the full spectrum

of the projects has contributed to development within each of the four pillars of practice.

1.4.1. Project 1: The Orthotics Evidence Portal: Supporting evidence-based orthotic practice in the UK

Evidence-based practice describes a systematic approach to clinical decision making in the delivery of healthcare, using methods which combine information from published clinical trials, clinician expertise and patient preference (Law and MacDermid, 2024). This approach is essential in the provision of high quality healthcare, which minimises risks and improves treatment outcomes, while also considering the best use of healthcare costs (Black *et al.*, 2015; Kumah *et al.*, 2022; Law and MacDermid, 2024). Literature from the research community also recognises EBP as a fundamental aspect of developing early research skills (Harris, Grafton and Cooke, 2020), and can be considered a stepping stone for NHS clinicians wishing to become more involved with the wider system of research (Comer *et al.*, 2022). Assisting clinicians in their use of EBP is therefore not only an important aspect of ensuring high quality healthcare, but also a gateway for clinical practitioners to become more research-active. The aim of this project was to develop and maintain a resource designed to assist orthotists and other professionals working with orthotic patients, to quickly and easily access the evidence base relevant to their clinical practice.

Since 2017 I have been the project lead for the “Orthotics Evidence Portal” formerly known as “The Directory of Evidence-Based Orthotic Practice” (DEBOP), an online resource which presents collections of publications and literature pertaining to orthotic interventions, organised into specific pathological conditions and anatomical locations, to assist clinicians navigating to the evidence relevant to them. In this respect, the Orthotics Evidence Portal is considered to be a secondary evidence source (Stevens, 2011; Highsmith, 2021), meaning that it does not produce new research, but functions as a conduit for clinicians to more easily access primary evidence sources such as clinical studies and other novel publications.

Evolution of the Orthotics Evidence Portal can be considered in three timeframes, my contribution in the various stages and their position within this

thesis is shown in Table 1.3. Given the expansive nature of this project, analysis of the period from 2017 to 2023 during which I redeveloped and maintained full leadership of the work which included conception and execution of redesign and resource publication, as well as monthly literature reviews, content updates and project evaluation, constitutes the primary focus of Chapter 2. Other aspects of the project such as my contribution to two education programmes, and conception and delivery of platform migration and modernisation are explored in this chapter - the synoptic commentary, with the aim of offering a more nuanced understanding of the project's overall trajectory and its influence on advanced practice.

Table 1.3. Timeframes and contribution to the development of DEBOP / the Orthotics Evidence Portal and associated education packages.

Timeframe	Action	Contribution by L Barr	Position in this thesis
2015	Historical development of DEBOP and initial publication	No involvement	Chapter 1
	MSK education programme	Equal contribution to course content and course delivery with two other trainers, and one coordinator	Chapter 1
2017 – 2023	Redevelopment of DEBOP MSK section	Conception of redevelopment plan, redevelopment and publication of MSK section, monthly literature reviews and content updates	Chapter 1
	Development of DEBOP diabetes section	Conception of diabetes section, development and publication of diabetes section, monthly literature reviews and content updates	Chapter 1
	Analysis of user experience and impact of DEBOP	Conception of study, study design, methodology, analysis and write-up	Chapter 2
	Diabetes education programme	Programme lead and programme coordinator: Conception of diabetes education programme, coordination of programme delivery, equal contribution to course content and course delivery with two other trainers	Chapter 1

	MSK education programme	Equal contribution to course content and course delivery with two other trainers	Chapter 1
2023 – present	Platform migration and launch of the Orthotics Evidence Portal	Conception of migration plan, redesign of content structure, development and delivery of promotional materials, monthly literature reviews and content updates	Chapter 1 and Chapter 2

1.4.1.1. 2015 – Historical development of DEBOP and initial publication

This section describes the historical development of DEBOP which predates my involvement in the project, and is included to provide context for my subsequent contributions which will be described in Sections 1.4.1.2 to 1.4.1.8.

DEBOP was developed in 2014 by six orthotists working in different areas of the UK: NHS GGC, NHS Lanarkshire, NHS Forth Valley, Buchanan Orthotics and TalarMade Ltd, and supported by the British Association of Prosthetics and Orthotics (BAPO), Munro Bolton Orthotics Ltd, and the Scottish Clinical Orthotic Leads Group. It was developed over a three month period and subsequently published in 2015 with funding from the Scottish Government as part of the MSK and Orthopaedic Quality Drive (Copland, 2014). The initial aim of DEBOP was to identify the evidence relating to orthotic treatment of MSK conditions, in order to support a case for the position of the orthotic profession within the MSK Improvement Agenda (Borthwick and Cree, 2014). At this time, the MSK Improvement Agenda had highlighted five workstrands [Appendix 1] to improve patient access to MSK care, and in order to ensure that orthotics was recognised at the appropriate point in the patient care pathway, the orthotic profession along with other AHPs were asked to provide the evidence for the treatments that their profession offered. The development of DEBOP sat within

workstrand A: “AHP MSK Redesign – Getting patients on the right pathway”. The purpose of this workstrand was to facilitate new referral pathways whereby patients would be directed to the appropriate AHP service for their care, rather than the historical route from community GP services, via orthopaedics, and latterly to AHP services.

Before the initial publication of DEBOP there was no centralised EBP directory for the orthotic profession to use in the presentation of their case as a service to which MSK referrals could be directed. The funding received from the Scottish Government allowed this work to be undertaken, beginning with identification of the relevant evidence base over a 10 year period from 2004 to 2014, which was achieved through the creation of a clinical question using the “population, intervention, comparison and outcomes” criteria (PICO) (Methley *et al.*, 2014) after which two orthotists undertook critical appraisal using the “Grading of Recommendations, Assessment, Development, and Evaluations” (GRADE) (Siemieniuk and Guyatt, 2019) methodology to determine the quality of the evidence. DEBOP was designed to contain individual sections for specific areas of the body [Figure 1.1], within which the evidence was presented as an algorithmic-style pathway, with the intention of indicating the most appropriate treatment for each presenting condition [Figures 1.2 and 1.3].

Figure 1.1. Screenshot of the first iteration of DEBOP showing the landing page for the MSK directory, with sections for each area of the body.

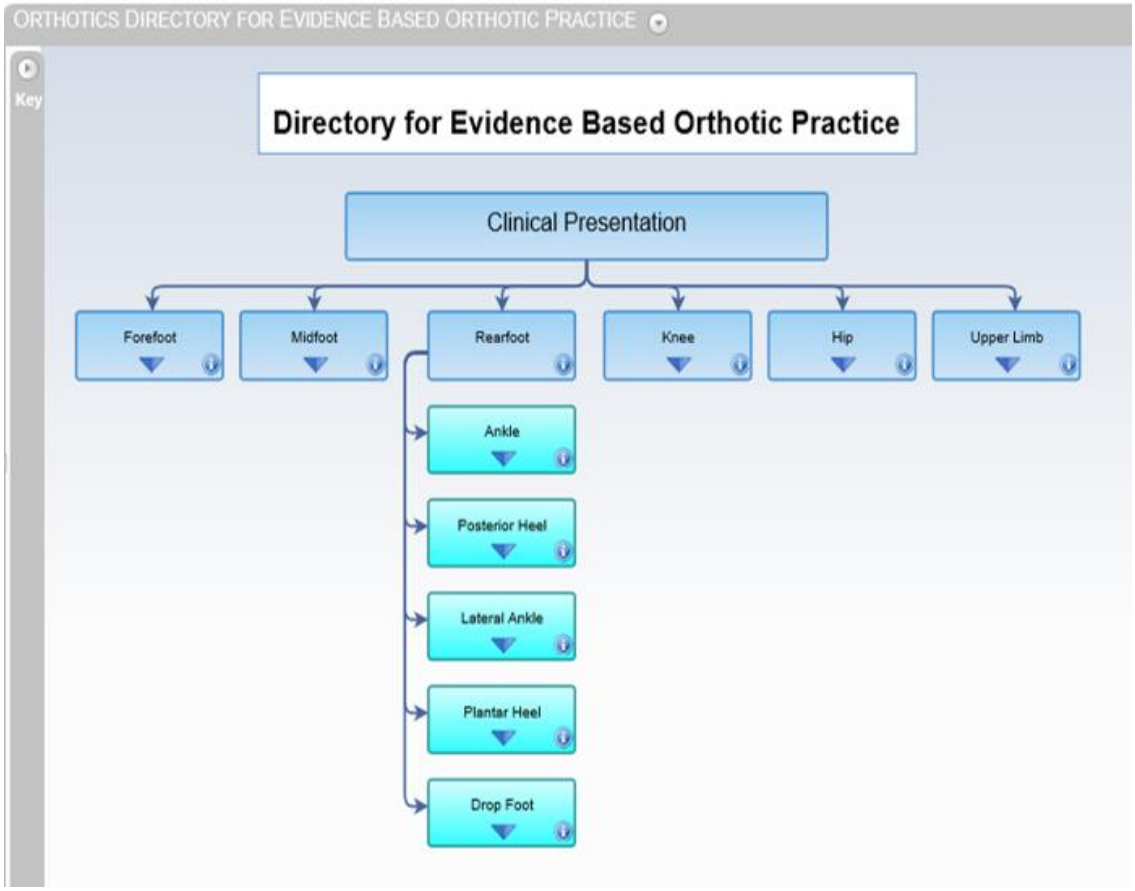


Figure 1.2. Screenshot of the first iteration of DEBOP showing the pathway for orthotic treatment of the lateral ankle.

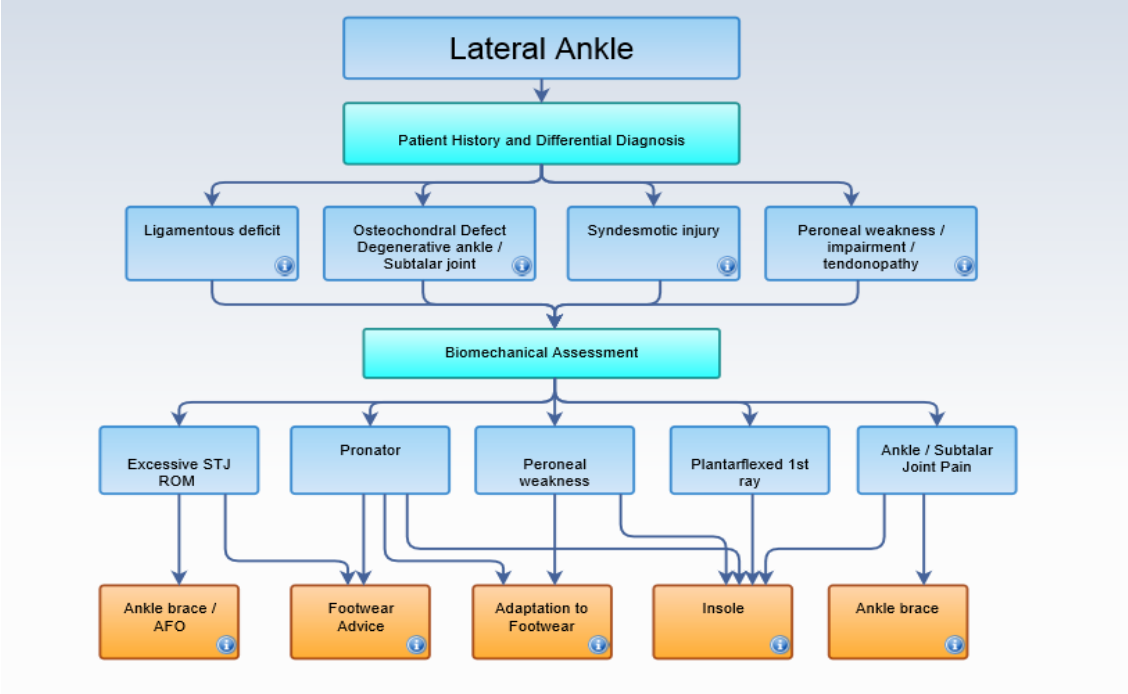
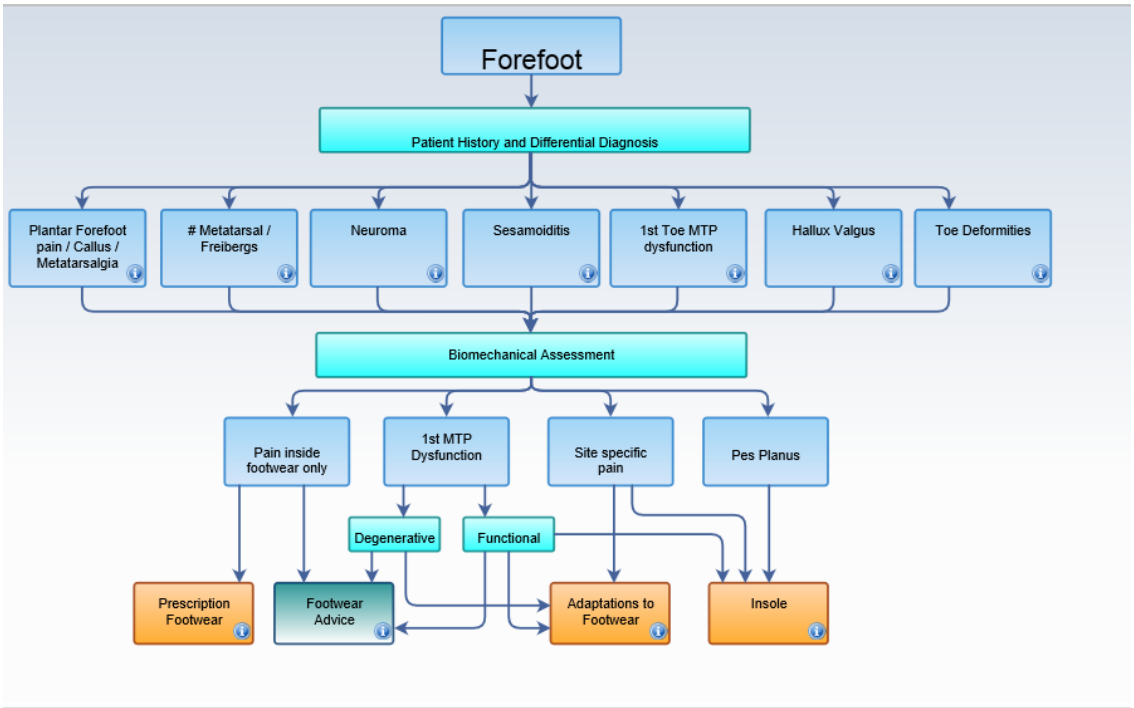


Figure 1.3. Screenshot of the first iteration of DEBOP showing the pathway for orthotic treatment of the forefoot.



At the conclusion of the three-month funding period from the Scottish Government, DEBOP was published on the Clinical Knowledge Publisher (CKP)

platform. In NHS GGC, DEBOP was used to evidence the position of the orthotic service in the MSK Foot and Ankle Treatment Pathway alongside physiotherapy and podiatry (Munro, 2014), fulfilling the original aim of its development.

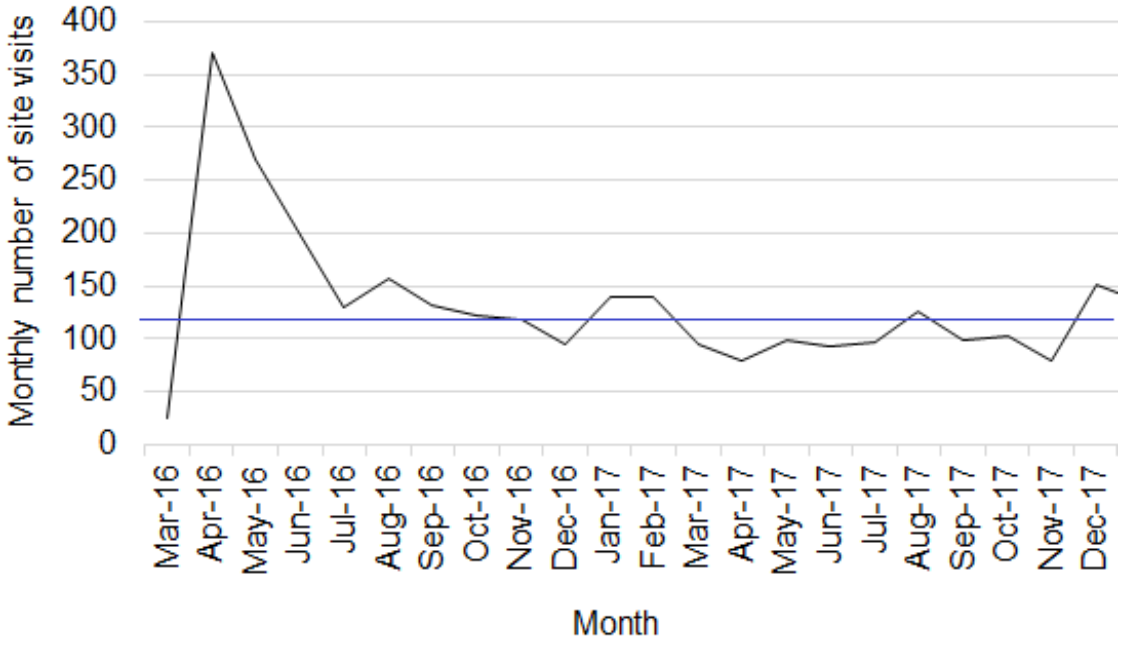
1.4.1.2. 2015 – MSK education programme

My involvement with the DEBOP project began in 2014, when the development group identified the need for additional training for orthotists in the UK due to the proposed new position of orthotists within the MSK foot and ankle treatment pathway. This training was intended to accompany the publication of DEBOP, aiming to educate orthotists on incorporating the latest evidence-based practice for MSK foot and ankle conditions into their daily clinical routines. Specific EBP training has been shown to improve clinical belief in, and implementation of, EBP in health services (Abu-Baker *et al.*, 2021), and is more positively received from peer-peer delivery as opposed to learning from written sources alone (Ramstrand, 2013). As such, expressions of interest were sought from orthotists who wished to become trainers in the area of MSK foot and ankle, to deliver courses on behalf of BAPO to orthotists in Scotland. I was one of seven trainers who volunteered to participate in a train the trainers (TTT) programme from November 2014 to February 2015 which was taught by a course coordinator. In healthcare, TTT programmes are commonly used to disseminate information to healthcare staff and shown to be an effective way of improving the knowledge of both trainers (Poitras *et al.*, 2021) and trainees (Nexø *et al.*, 2024). On the 9th and 10th of March 2015, I, along with four other probationer trainers, delivered the inaugural BAPO educational programme titled "Assessment, Diagnosis, and Treatment of MSK Foot and Ankle Problems for Orthotists" (informally termed “the BAPO MSK course") to 15 orthotists from across the UK. Two other courses followed in April and May 2015 allowing each probationer trainer the opportunity to teach on one course. After this probation period myself and two other trainers took on permanent positions as trainers alongside the course coordinator, in the ongoing contribution of course content and delivery of the education programme. An article outlining my TTT experience and early years teaching on the BAPO MSK course is presented in Appendix 2.

1.4.1.3. 2017 - 2023: Redevelopment of DEBOP MSK section

From 2015 until 2017, maintenance of DEBOP was relatively dormant due to the lack of funding, and this in tandem with the high rate at which new evidence is published resulted in the directory quickly becoming outdated. This is a common phenomenon among online secondary evidence sources which have been shown to incorporate less than 50% of new publications after 9-months (Banzi *et al.*, 2011). In spite of this, monthly visitor numbers collected from NHS GGC Knowledge Services via Google Analytics demonstrated consistent use of DEBOP throughout this period, with a median of 120.5 (IQR 95.8, 143.0) views per month [Figure 1.4] [full analysis is explained in Chapter 2]. Throughout this period, my personal interest in DEBOP grew, due in part to my role as a trainer on the MSK course, but predominantly due to my interest in the importance of EBP. I identified that the intended algorithmic flow was not fit for purpose due to conflicting and a lack of evidence in various areas of DEBOP, meaning that specific treatment recommendations could not be made. Furthermore, there were inconsistencies in the grading of evidence as well as missing or inaccurate links to publications. Following discussions between myself and the initial DEBOP development team it was acknowledged that these limitations were a product of the restricted three-month timeframe associated with the initial development.

Figure 1.4. Number of monthly page views on the Directory of Evidence-Based Orthotic Practice from March 2016 to December 2017, as collated by NHS GGC Knowledge Services from Google Analytics. Blue line represents the median number of views.



On the 17th February 2017, those involved in the delivery of the BAPO MSK course and those who were involved in the initial development of DEBOP were invited by the Chair of BAPO to meet and discuss the future of DEBOP, a meeting which included seven orthotists in total. The popularity of the BAPO MSK course, which by this time had been delivered on 11 occasions throughout the UK, was publicising DEBOP across the profession, and in conjunction with the consistency in visitor numbers, the group agreed that DEBOP had proven to be a valuable resource which was worth maintaining. At this meeting I discussed my concerns regarding the structure and content, as well as stating my interest in fully redeveloping DEBOP from its current format, which could be considered a “proof of concept”, into a more sustainable user-friendly resource. I envisioned that DEBOP would be specifically redesigned with the aim of guiding clinicians to the evidence, allowing them to appraise the relevance of the literature for themselves, without endorsing specific treatments, and displaying this in a way which would be intuitive to clinicians. In order for this to

be successful in the long-term there would need to be continual appraisal of the emerging evidence base to maintain an up-to-date resource. This was discussed in detail as a group, with agreement that this vision aligned with informal feedback from colleagues and attendees on the BAPO MSK course who had used DEBOP. The group agreed on the proposal for me to take on the role of project lead to redevelop and maintain DEBOP, with professional oversight from BAPO, and agreed on the proposed actions to resolve the issues discussed. A summary of this discussion, and the actions agreed by the group are documented in Table 1.4. The issues are grouped into two interconnected categories; the requirement for the directory to be fully redeveloped and maintained, and the requirement for securing ongoing financial resource to facilitate this long-term.

Table 1.4. Overview of the issues and actions agreed regarding the redevelopment of DEBOP in February 2017.

Issues identified	Categorisation	Actions
No dedicated time available to review and update the evidence contained within	Acquisition of ongoing financial resource	○ Funding bid to be made to the Orthotic Education and Training Trust (OETT) by the Chair of BAPO ○ Funding should be sufficient to support a project lead to redevelop and maintain DEBOP long-term
No ongoing funding to support maintenance of the project long-term		
The initial search strategy and initial time limitations resulted in publications being excluded	Redevelopment and long-term maintenance of DEBOP	○ My position as project lead agreed by the group ○ Redevelopment and long-term maintenance to be undertaken by project lead: • All evidence to be presented by study type • All evidence to be arranged in Harvard referencing format • New search strategy to be designed • Ongoing maintenance with monthly literature reviews • Links to lead to PubMed where possible • Algorithmic flow to be removed • Reformatting for aesthetic improvement • Development of DEBOP diabetes section
Inconsistent grading of evidence		
Algorithmic style of the pathways unfit for purpose		
Navigation difficulties owing to evidence presented by the date added to the directory		
Practicality of GRADE methodology not ideal for users or long-term maintenance		
Links to some evidence sources were broken, incorrect, or in breach of publisher's copyright		
Aesthetic issues due to formatting within CKP		
DEBOP currently limited only to MSK conditions		

A funding bid was made to the Orthotic Education and Training Trust (OETT) by the Chair of BAPO, and long-term funding was approved to support the project lead to undertake the agreed actions required to redevelop the directory, and to

maintain this on a monthly basis long-term. The actions undertaken to redevelop DEBOP were carried out from February 2017 to December 2017, with ongoing monthly updates thereafter. The detail of this transitional period of development is outlined below.

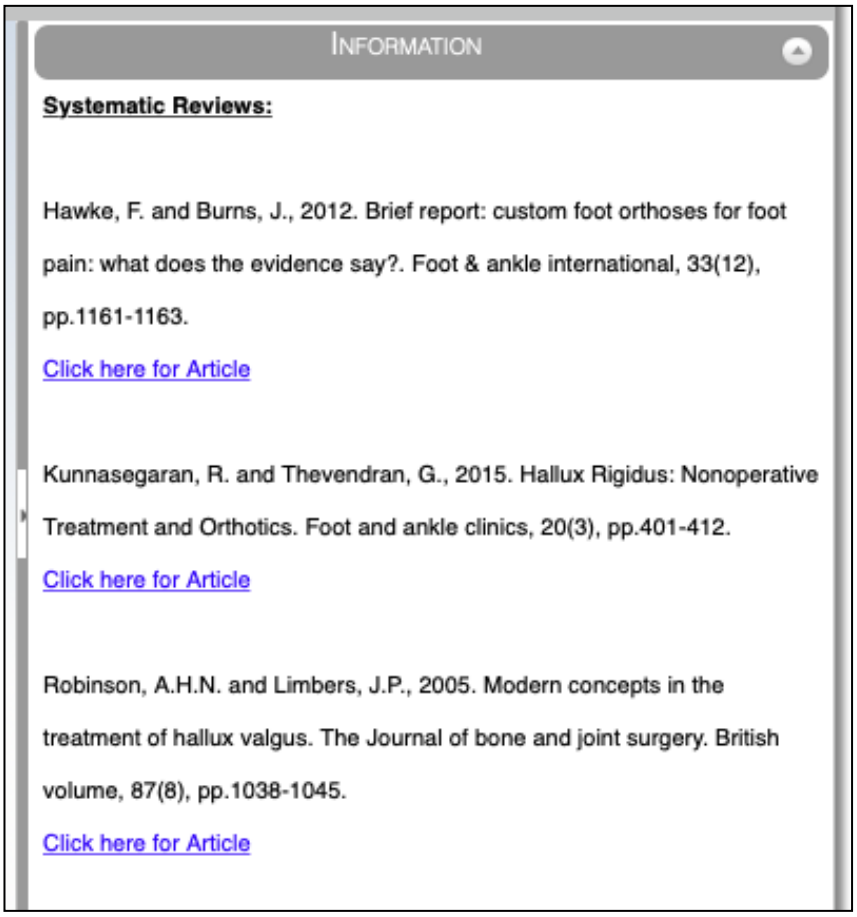
- **All evidence to be presented by study type.**

This decision was made based on feedback from users who advised that the GRADE methodology was unhelpful to those inexperienced in critical appraisal, and therefore limited their ability to know which paper(s) to select to support a specific area of clinical practice. As a key goal of the directory was to assist orthotists in the translation of evidence into clinical practice, it was important to simplify this area, particularly given that publications on translational research advocate for research to be presented in a way which makes the subject easy to understand (Dillon and Fatone, 2018). In conjunction, the GRADE criteria although robust in terms of appraisal, was too time consuming for an individual to undertake for every paper in the ongoing monthly literature reviews within the time supported by the funding. As such, every piece of evidence hosted on DEBOP in February 2017, comprising 326 articles, was re-assessed by study type, and then presented within the relevant section in descending order according to the evidence hierarchy (Evans, 2003).

- **All evidence to be arranged in Harvard referencing format.**

Initially the evidence within DEBOP was presented in the order in which it was added to the directory, from newest to oldest, making it challenging to locate individual items or grouping evidence. To assist with ease of locating articles, the evidence within each section of DEBOP, which was now categorised within the evidence hierarchy, was then further updated to be presented in alphabetised Harvard format [Figure 1.5]. Harvard format was chosen due to its recognition as one of the most common referencing styles (Weerawardane and Byrne, 2021), and its use at the two higher education institutes who provided UK P&O education at the time, meaning that this style would be familiar to the majority of orthotists accessing DEBOP.

Figure 1.5. Screenshot of the evidence presented in Harvard referencing format on DEBOP in accordance with the evidence hierarchy.



- **New search strategy to be designed.**

With DEBOP now presented in such a way that it could be consistently and uniformly updated in future, a full review of all literature from the period of dormancy from 2014 to 2017 had to be undertaken and relevant papers added to the pathways. In addition to this, the original search strategy derived from the PICO question was reviewed, identifying that certain keywords and Boolean operators had limited the results leading to the exclusion of important evidence from DEBOP. It was therefore agreed that a new search strategy would be developed and extended to include the initial 10 year period covered by the 2014 development team to ensure that no evidence had been missed, meaning that the new search would include all papers returned from 2004 to 2017. The new search strategy was designed in partnership with NHS GGC Knowledge Services [Appendix 3] and carried out across Medline, AMED and CINHAL

databases. This involved the review of 1872 journal articles which I undertook independently throughout a four month period in 2017, with financial support from OETT.

- **Ongoing maintenance with monthly literature reviews.**

In order to ensure inclusion of the most current evidence it was agreed that DEBOP would be maintained continually on a monthly basis. The project lead would take primary responsibility for the review of all literature on a monthly basis, while also presenting this as a continuing professional development (CPD) opportunity for any UK orthotist to develop their critical appraisal skills by participating in the appraisal processes. The search criteria was set up by NHS Knowledge Services to produce monthly alerts from which the literature reviews would be made, and each month from 2017 to present, the search results are reviewed by an orthotist. In order to ensure uniform decision making on the inclusion or exclusion of evidence from DEBOP, a standard process was designed to identify appropriate evidence for DEBOP [Appendix 4], alongside a guide on categorising the relevant publications in terms of the DEBOP hierarchy structure [Appendix 5]. In the interests of futureproofing, visibility and accountability, it was important that the search results for DEBOP were accessible to the BAPO secretariat and executive committee, rather than being linked to an individual account. With assistance from NHS Knowledge Services the recurring monthly searches were designed to disseminate to the project lead and a shared email account at BAPO (Evidence@BAPO.com). This email account would also be used for all enquiries regarding DEBOP and all expressions of interest from those wishing to participate in the ongoing maintenance.

- **Links to lead to PubMed where possible.**

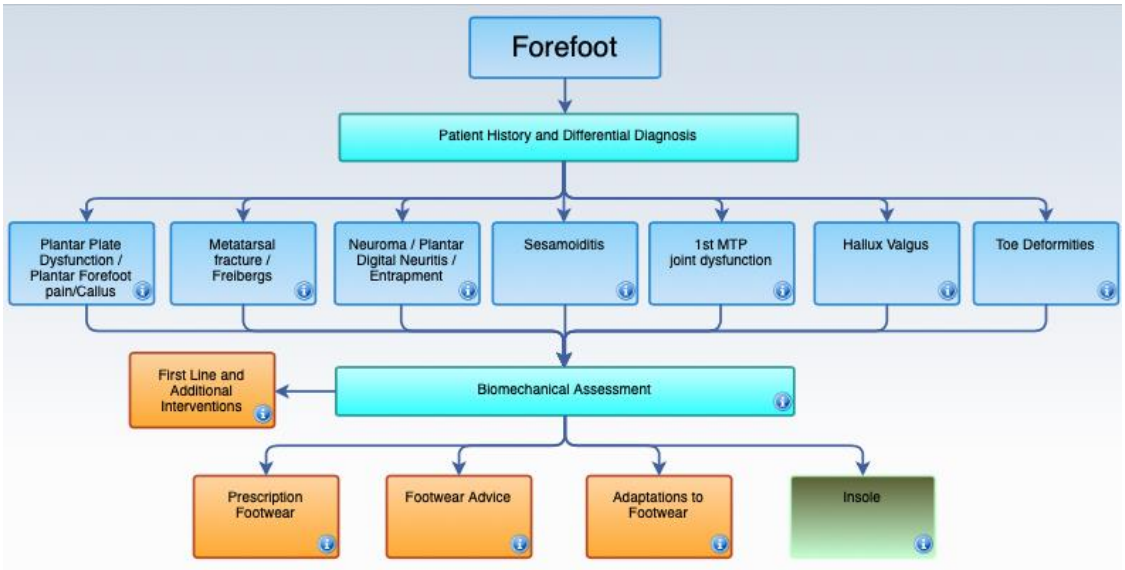
With DEBOP initially envisioned as a tool for NHS access only, all in-text hyperlinks were initially targeted at users with Athens access to journal articles, and some PDF files which had been hosted on proxy sites, which on review were found to be in breach of publishing access rights. One of the most frequent queries sent to the Evidence@BAPO.com email address were comments regarding the inability to access the links from international

countries, and for UK users without NHS access. As such the link to each publication was replaced with the relevant hyperlink to the publication reference on the National Centre for Biotechnology Information PubMed archive site where available, which would instead allow users to view potential locations for journal access, to which they could navigate dependent on their preferences and access rights.

- **Algorithmic flow to be removed.**

At the initial conception of DEBOP there had been a vision of presenting the project as a treatment algorithm, with evidence for orthotic interventions linked to specific pathology. In reality it was not possible to create a treatment algorithm for the entirety of MSK orthotic practice due to the limitations, complexity and variation in published literature relating not just to the orthoses but also the pathologies under investigation throughout multiple different studies, some of which presented contradictory findings. This led to concerns over the possibility of clinicians assuming that a treatment was evidenced for a certain condition due to the algorithm flow rather than reading the study to assess the relevance of the evidence for themselves. In order to mitigate this, and to encourage those visiting the site to read and appraise the relevance of the literature for themselves, DEBOP was restructured to simply present the evidence under orthoses type, within a broader category of body area. This would give orthotists the opportunity to assess the relevance of the evidence based on their own appraisal, in relation to the patients under their care. In order to support orthotists in critically appraising the literature that they accessed from DEBOP, a section was added signposting to The Critical Appraisal Skills Programme, a tool endorsed by the Cochrane Qualitative and Implementation Methods Group, and known to be the most commonly used critical appraisal tool in healthcare (Long, French and Brooks, 2020). I completed the restructure of all MSK DEBOP sections independently in 2017, an example of which can be seen in Figure 1.6.

Figure 1.6. Screenshot of the restructured forefoot pathway created by the author in December 2017.



- **Reformatting for aesthetic improvement**

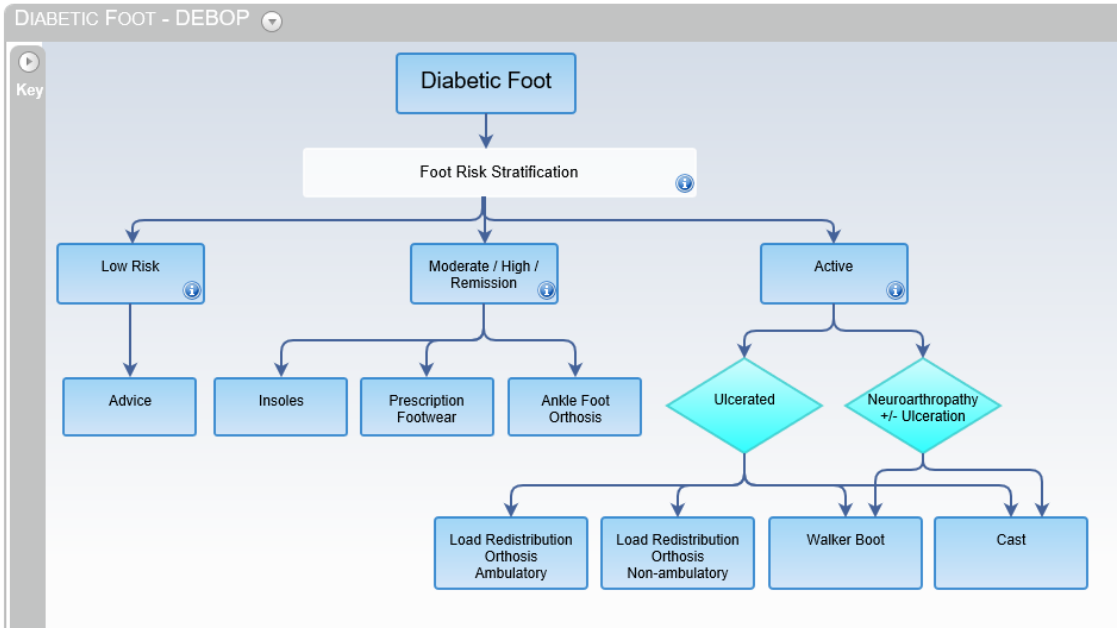
Clinical Knowledge Publisher presented some stylistic issues when used in rich text format which resulted in a non-uniform aesthetic throughout the DEBOP sections. In order to achieve a uniform appearance to every section within the directory, the evidence sections were coded in hypertext markup language (HTML) to avoid any visual discrepancies, helping to improve user experience by offering a more professional aesthetic.

1.4.1.4. 2017 – 2023: Development of DEBOP diabetes section

With the redevelopment of the MSK section completed and published, development of the diabetes section was undertaken throughout 2017 to 2018. This was first conceptualised following the completion of my MSc in Diabetes Care and Management in 2015, and the subsequent publication of two narrative literature reviews linking evidence to the orthotic treatment of specific diabetic foot conditions (Barr, 2015). I hoped to do more to explore the evidence base regarding orthotic treatment of the diabetic foot, to support the 80.3% of UK orthotists who also work in this area (Eddison *et al.*, 2023), and in 2017 my leadership of DEBOP provided the opportunity to develop a resource for this. Having developed an initial layout for the proposed DEBOP diabetes section, I consulted with orthotists from NHS GGC, BAPO, NHS Forth Valley, the

University of Strathclyde, Buchanan Orthotics and TalarMade Ltd to review and refine the concept, and undertook patient and public involvement through the delivery of a diabetes education programme which is discussed in the next section. Similar to the DEBOP MSK development, advice was sought from NHS GGC Knowledge Services regarding the construction of an appropriate search strategy for the recurring monthly searches [Appendix 3], with the initial evidence appraisal from 2004 to 2018 being undertaken by two orthotists from NHS GCC including myself as the project lead. The DEBOP diabetes section was published and made live for public access in December 2018, the front page of which can be seen in Figure 1.7. As will be discussed in Section 1.4.1.7., the 2017 version of DEBOP is no longer accessible, having now migrated to a modernised platform, links to the current live version of this resource are presented at the end of this section.

Figure 1.7. Screenshot of the DEBOP diabetes section in December 2018.



1.4.1.5. 2017 – 2023: Diabetes education programme

During the development stage of the diabetes section of DEBOP, and prior to its publication, I put forward a proposal to BAPO to develop and run a diabetes education programme for orthotists [Appendix 6]. The course was intended to disseminate the information from the literature appraisals, presenting a guide to evidence-based orthotic practice in the area of diabetes foot care, while

simultaneously providing an opportunity for stakeholders from across the UK to engage with the development of the diabetes section in the form of patient and public involvement. Diabetes foot care is generally undertaken in multidisciplinary partnership with podiatry colleagues (Buggy and Moore, 2017), and to reflect this in the diabetes education programme, I collaborated with an experienced podiatry educator from Glasgow Caledonian University, and two orthotists from NHS GGC, to deliver the course in Glasgow on two occasions to a total of 44 orthotists in 2016 to 2017. Feedback and discussion from attendees on these courses were used to inform the direction and final structure of the diabetes DEBOP section. A review of the course is shown in Appendix 7.

1.4.1.6. 2017 – 2023: MSK education programme

By the conclusion of 2018 I had been a trainer on 18 of the 22 BAPO MSK courses run across the UK and New Zealand, training 272 of the total 315 attendees. The course content had evolved significantly throughout the first four years in tandem with the growing publication of evidence in the orthotic field and the associated expansion of DEBOP. As such, by the end of 2018 only 7% of the original content from the 2015 version of the course remained, and the course content had expanded by just over 50% and was now being delivered by only three trainers. The training group agreed that the original course proposal approved by BAPO in 2014 was no longer fit for purpose, and together submitted a new course proposal in 2019 rebranding the course as “MSK Foot & Ankle: Holistic Management and treatment strategies”. This proposal approved the expansion of the attendee criteria to all registered healthcare practitioners and was no longer restricted only to orthotists, as well as clarifying the equal contribution of the three trainers in terms of the course content and delivery [Appendix 8]. The BAPO MSK course has run under this new name since 2019, and to date I have been a trainer on 13 of the 16 UK courses. Therefore, across both iterations of the MSK course, I have been a trainer on a total of 31 of the 38 courses, training 462 of the 555 total attendees from 2015 to 2024 [Table 1.5].

Table 1.5. BAPO MSK Course dates and participation of L Barr from 2015 to 2024.

Date	Location	L Barr participation	Number of attendees
9-10 March 2015	Glasgow – probation course	Trainer (probation)	10
15-16 April 2015	Glasgow – probation course	No participation	11
20-21 May 2015	Glasgow – probation course	No participation	9
6-7 July 2015	Glasgow	Trainer & course content	11
14-15 September 2015	Dundee	Trainer & course content	17
5-6 October 2015	Leeds	Trainer & course content	13
4-5 November 2015	Edinburgh	Trainer & course content	18
1-2 December 2015	Mansfield	Trainer & course content	19
15-16 January 2016	Sheffield	Trainer & course content	16
15-16 April 2016	Wellingborough	Trainer & course content	19
12-13 May 2016	Blackburn	Course content	8
24-25 June 2016	Oxford	Trainer & course content	18
27-28 April 2017	London Croydon	Trainer & course content	16
11-12 May 2017	Cardiff	Course content	15
9-10 June 2017	Newcastle	Trainer & course content	19
27-28 July 2017	London	Trainer & course content	15
2-3 October 2017	Birmingham	Trainer & course content	9
23-24 October 2017	Glasgow	Trainer & course content	17
3-4 February 2018	Auckland, New Zealand	Trainer & course content	18
5-6 April 2018	Abingdon	Trainer & course content	12
13-14 November 2018	East Midlands	Trainer & course content	8
6-7 December 2018	Glasgow	Trainer & course content	17
17-18 January 2019	Glasgow	Trainer & course content	11
4-5 February 2019	Newcastle	Trainer & course content	9
23-24 May 2019	Manchester	Trainer & course content	10

27-28 June 2019	Nottingham	Trainer & course content	18
12-13 September 2019	Roehampton	Trainer & course content	17
23-24 September 2019	Edinburgh	Trainer & course content	15
28-29 January 2020	Manchester	Trainer & course content	17
9-10 September 2021	Chesterfield	Trainer & course content	13
30 Sept - 1 Oct 2021	Glasgow	Trainer & course content	16
24-25 March 2022	Chesterfield	Trainer & course content	15
26-27 November 2022	Southampton	Trainer & course content	17
25-26 September 2023	Chesterfield	Trainer & course content	18
7-8 December 2023	Borders	Course content	15
26-27 February 2024	Preston	Trainer & course content	14
7-8 October 2024	Chesterfield	Course content	16
9-10 December 2024	Newcastle	Course content	19

1.4.1.7. 2023 – present: Platform migration and launch of the Orthotics Evidence Portal

In 2023, I conceptualised a study to examine the use of DEBOP by orthotists in the UK in order to understand its influence on EBP and its impact on clinical practice. This study was designed with the aim of understanding if DEBOP was fulfilling its purpose as envisioned during the 2017 redevelopment, as well as to gather feedback on any suggested updates to improve its use. A full discussion of the development of the cross-sectional survey, analysis and results are presented in Chapter 2. In summary, feedback was gathered from 108 orthotists in the UK via a cross-sectional survey, with questions related to their use of EBP and their experience of using DEBOP. The respondents who used EBP in their clinical work (92.6%, 100/108) and also used DEBOP (70.0%, 70/100) were asked about their experiences in accessing evidence using DEBOP: the majority identified that using DEBOP made them more likely to access published research (82.9%, 58/70), made it easier for them to locate and access published research (87.1%, 61/70), made it less time consuming to access published research (87.1%, 61/70), made it easier for them to identify meaningful research which is relevant to their clinical practice (85.7%, 60/70),

with 71.4% (50/70) stating that in their day-to-day clinical practice they chose to access published research through DEBOP rather than other sources, and over two thirds said that using the Portal had changed their clinical practice (68.6%, 48/70). The majority of respondents 52.9% (37/70) had only ever used the post-2017 version of DEBOP, and the remaining 47.1% (33/70) were asked questions comparing the pre-2017 and post-2017 versions, with the majority reporting that the post-2017 version made it easier to locate relevant evidence (84.9%, 28/33) and was easier to navigate (78.8%, 26/33). In addition the median number of monthly page views had increased by 49.0% from 120.5 to 179.5 after 2017.

Unexpectedly, the positive results from this survey highlighted the importance that the UK orthotic profession placed on DEBOP and increased my sense of responsibility for ensuring that it was fit for purpose. Some of the barriers expressed by respondents initially resulted in a feeling of failure on my part to present this resource in the most appropriate format, and lead to reflection on the changes that could have been made over the years to improve this for users. Thus having reflected on the survey results, the information gathered from respondents was ultimately used to plan the evolution of DEBOP into its current format as the Orthotics Evidence Portal, with the aim of addressing some of the concerns raised by its users primarily related to interface issues on mobile and desktop devices, and promotion. The original CKP platform was limited in terms of updating the DEBOP structure, and prevented integration with mobile applications which are increasingly used to access information (Stocchi *et al.*, 2022). As such, the decision was made to move to the Right Decision Service (RDS), a platform which offered a more accessible interface which is optimised not only for desktop use but also for mobile devices. In conjunction with the move to RDS, the decision to rebrand from the name DEBOP to the Orthotics Evidence Portal was undertaken to better align the resource’s name with its evolving purpose; while the original 2015 concept functioned primarily as a directory aimed at collating and categorising evidence to support the role of orthotic interventions within MSK treatment pathways, the resource had since transitioned to fulfil a broader objective: to facilitate orthotists' access to a wide range of evidence-based resources and associated

services through a unified interface. The migration on to the RDS platform was undertaken in collaboration with NHS GGC Knowledge Services, and prior to its launch stakeholders from healthcare services across the UK were invited to review the Portal and provide comment on navigation, functionality, and content quality. Stakeholder engagement from 17 orthotists and podiatrists from NHS Scotland, NHS England, higher education institutes and private services was used to test and refine the Portal prior to its launch. The full user feedback report can be viewed in Appendix 9.

Consideration was given to the most effective way of advertising the launch of the Portal, advice was gathered from the BAPO Professional Affairs Committee, with agreement that a combined approach of written promotion, conference promotion, and dissemination on social media would provide appropriate reach across the profession. In addition, I sought the option of using animation as a tool to both advertise the Portal and to assist users in navigating the site, by making a successful funding application to OETT in 2024 [Appendix 10]. This allowed me to produce a script, and work with an animator to create animated assets which provide a cohesive and recognisable brand for the Portal on the RDS platform, in written promotional articles, and at conference events. The Orthotics Evidence Portal was formally relaunched on the RDS platform in January 2025 and has been advertised utilising the animated assets within the conference programmes at the Forth Conference in Gateshead on 1st February 2025, and the BAPO Regional Conference in Wigan on 16th May 2025, as well as a promotional publication in BAPOConnect [Appendix 11], and shared on LinkedIn and Twitter/X social media platforms. The Portal is also shared during all BAPO MSK courses both verbally and within the course handouts, and has been promoted to apprentices and students in the University of Derby Orthotics Practice 1 Module, as well as the undergraduate Prosthetics and Orthotics programme at the University of Strathclyde. Usage analytics for the Orthotics Evidence Portal will be collected by NHS Knowledge Services on a quarterly basis, and data on viewership of the animated assets, hosted on the YouTube platform, will also be gathered to assess engagement levels. This monitoring will facilitate the identification of optimal time points for re-promotion and re-advertising efforts in the future.

The value of this project was recognised by the Advancing Health Care awards in May 2025 when it won the category for “British Association of Prosthetists and Orthotists award for evidencing impact and excellence in Prosthetics and Orthotics” [Appendix 12].

The Orthotics Evidence Portal, full animation, and conference presentation can be found using the following links or QR codes:

Orthotics Evidence Portal: https://rightdecisions.scot.nhs.uk/the-orthotics-evidence-Portal/

Full animation: https://www.youtube.com/watch?v=ogfya0SIWa8

Conference presentation: https://www.youtube.com/watch?v=xo4udKS6Ibo

Orthotics Evidence Portal

Full Animation

Conference Presentation

1.4.1.8. How DEBOP work led to Projects 2 and 3

The nature of the DEBOP project increased my awareness of the gaps in the literature; the process of undertaking monthly literature reviews since 2017, involving all upper limb and lower limb MSK conditions and diabetic foot care, had helped me to understand the landscape of unexplored research areas. However it was the education programmes which guided the direction of the following project work presented in this thesis. By 2021 when I formally commenced my PhD journey, I had taught 27 MSK and diabetes courses, personally being involved in the training of 418 attendees. These courses incorporated many case studies from myself and the other trainers used to demonstrate treatment methodologies for specific and often complex patient conditions, linking back to the evidence base. These case studies usually serve as pivotal moments in the course, enabling attendees to connect scientific evidence with the complex reality of clinical practice, therefore generating substantial discussion within the cohorts. With my own case studies predominantly demonstrating treatment with CAD/CAM insoles, recurring

themes of questions emerged over the years, with the most common inquiries not relating to the details of treatment plans for specific complex conditions, but rather to the fundamentals, what we might consider the basics of what we do; “Does scanning work better than casting”, “Would a 3D-printed insole have a different outcome”, “Do harder materials make a difference”. The wholesale adoption of CAD/CAM in the NHSGGC orthotic service had given me an arguably a biased view of CAD/CAM workflows, and the literature relating to CAD/CAM tended to have a focus on the morphology of digital shape capture (Farhan *et al.*, 2021), the speed of manufacture (Anggoro *et al.*, 2020), and the cost of the system (Ngan *et al.*, 2022), rather than focusing on the fundamental question asked by clinicians from many services that I spoke with – does CAD/CAM affect the patient outcomes. Furthermore, where published studies did explore the clinical application of CAD/CAM, they did so by presenting a narrowly defined clinical scenario (Bishop, Thewlis and Hillier, 2018; Parker *et al.*, 2019), one which is not always reflective of, and therefore transferable to, the reality of clinical practice; a phenomenon not exclusive to the field of orthotics (Paraskevas, de Borst and Veith, 2019). Through a desire not to repeatedly answer these questions with the prefix “in my opinion” or “in my experience” I began to explore ways in which I could assist with providing more robust answers to these questions. This began my back-to-basics approach to what would become Projects 2 and 3 [Chapters 3 and 4] in this thesis. I wanted to explore the fundamentals of CAD/CAM insole use in orthotic practice and, within the limitations of research, undertake this in a way that most closely reflected a realistic clinical environment.

1.4.2. Project 2: Integrating the use of hard-shell 3D-printed insoles into the MSK treatment pathway of an NHS orthotic service

There is a lack of comprehensive clinical guidance for orthotists when it comes to choosing harder or softer insole materials based on specific patient characteristics, a subject which was raised many times throughout the education courses. While research has emphasised the influence on comfort, kinematics, and pressure reduction in relation to material hardness (Anderson, Williams and Nester, 2020; Van Alsenoy *et al.*, 2023; Melia *et al.*, 2021), these studies fail to provide consistent recommendations for clinicians in evaluating

patient suitability for harder insoles, and do not focus on patient outcomes in treating foot and ankle conditions.

Ethylene-vinyl-acetate (EVA), a type of compressible foam, is the most commonly used material in custom insole production (Nilsen *et al.*, 2022) and is acknowledged to be standard care (Nickerson *et al.*, 2024). Reduction milling, which is utilised in CAD/CAM insole manufacture, is limited to the milling of softer materials such as EVA as opposed to harder materials such as plastics, due to the complex relationship between material hardness and the speed of the milling spindles relating to vibration and surface roughness (Anggoro *et al.*, 2019). Such reduction milling machines are used to produce custom CAD/CAM insoles in the NHS GGC orthotic service, and therefore prior to 2018, hard-shell insoles could not be manufactured using this system. Therefore it was challenging to make a case for the use of hard-shell insoles in our service, due to the limited clinical guidance, and the requirement to deviate from our standard workflow. Project 2 outlines my journey to increasing the evidence base for the use of hard-shell insoles with the aim of informing clinical practice, and describes the process undertaken to integrate hard-shell insole production into the existing CAD/CAM workflow in NHS GGC.

1.4.2.1. Background to the project

The NHS GGC orthotic service were early adopters of CAD/CAM insole systems, introducing this in 2006 at which time CAD/CAM systems were infrequently used in NHS orthotic services. A cross-sectional study which forms part of Project 3 in this thesis, collected information using freedom of information (FOI) requests and disclosed that at this time NHS GGC was one of only six UK orthotic services using CAD/CAM for insoles, with the median time of introduction being 10 years ago (Barr, Richards and Chapman, 2025). CAD/CAM training was not provided within the undergraduate P&O programme when I graduated from university, and even in recent years the UK P&O profession have identified that CAD/CAM training is lacking with over a third stating that they do not have CAD/CAM skills (Eddison *et al.*, 2023). During my first few years in NHS GGC there was no formal training for the CAD/CAM system in use in the service, and information was relayed peer to peer which

led to differing design methods, confidence and competence among clinical teams, as is known to be the case with non-standardised training (Guthrie, 2009). In 2013 I was offered the opportunity to take on the role of project lead for the clinical aspects of the Paromed Paromanager CAD/CAM modelling system used in the NHS GGC orthotic service, a role which I still hold today. As part of my role as the clinical CAD/CAM lead in the NHS GGC orthotic service, I developed a suite of staff resources including a standardised modelling training process, a competency-based framework, and standard operating procedures for clinical and technical staff, with written and video resources; with the aim of standardising the CAD/CAM scanning, modelling and manufacture processes across the department [Appendix 13]. Section 1.5.4 of this chapter explores the techniques used to develop these resources from a leadership perspective in more detail. Over the past 12 years these resources have been used to train 34 orthotists in NHS GGC, as well as being delivered to bi-annual practice placement students from the University of Strathclyde. They have also been shared with neighbouring Health Boards in NHS Forth Valley and NHS Tayside as well as commercial companies Renace Ltd and Paromed Australia. Quality improvement projects have been undertaken over the years and training resources updated according to the outcomes to ensure the consistency of CAD/CAM insole modelling, manufacture and quality [Appendix 14], as well as offering fortnightly drop in sessions which can be accessed by any staff member requiring additional one-to-one support. By the financial year 2021/22, 99.9% (n=3054.94) of all insoles manufactured in NHS GGC were produced using the Paromed Paromanager v6.00 and Paro360 modelling systems, with 100% of these insoles being modelled by an orthotist who had undertaken the NHSGGC standardised CAD/CAM training [Appendix 15].

In terms of insole materials, the Paromed CAD/CAM reduction-milling system is limited to the manufacture of shore hardness A70 EVA or softer, and so prescribing insoles from a harder material than A70 EVA required deviating from the standardised NHS GGC CAD/CAM method and undertaking manufacture by a traditional process. Throughout my orthotic practice the question of when to prescribe harder insole materials and how to clinically justify the material selection was one of the most challenging to answer, and

one of the most frequently raised both by the team in NHS GGC and from the wider profession during the education courses described in the previous section. Softer materials are more conforming and some studies have suggested a link between softness and patient comfort (Anderson, Williams and Nester, 2020; Lo *et al.*, 2018). However a limitation of these studies is the lack of treatment outcome measures to inform clinical practice or to guide on material selection when softer insoles do not produce the desired outcomes. In a recent study, the supination resistance test was evaluated to determine how the outcome of the test could inform clinical decisions relating to insole prescription, however this did not extend to how the test could be used to determine the best choice of insole material (Moisan *et al.*, 2023). Studies specifically investigating the use of hard-shell compared to soft shell insoles tend to do so by measuring either the effect on balance and posture (Martínez-Córcoles *et al.*, 2024; Iglesias, de Bengoa Vallejo and Peña, 2012) or the effect on plantar foot pressures (Goske *et al.*, 2006; Tang *et al.*, 2014), but these do not provide a satisfactory clinical guide to assist clinicians in making the most effective choice for their patients based on treatment outcomes. While my work on Project 1 highlighted the lack of evidence to guide clinical decisions on the use of harder materials, I gained further insights into gaps in the patient treatment pathway while collaborating on an aligned project in the NHS GGC health board: AHP MSK Foot and Ankle Treatment Pathways (Munro, 2014). My involvement in the NHS GGC MSK Foot and Ankle Treatment Pathways helped me to identify that there was no interim step between orthotic treatment with custom EVA insoles, and the use of escalated treatments such as ankle foot orthoses (AFOs), or escalation referral to other services such as orthopaedics. In order to address these three issues (1) the inability to manufacture hard-shell insoles using our CAD/CAM system, combined with (2) a lack of clinical outcomes relating to harder material choices, and (3) no evidenced place in the NHS GGC MSK treatment pathway for harder insoles; I began exploring possible hard-shell options which would integrate with our current CAD/CAM system. In doing so, this would allow us to test the viability of hard-shell manufacturing options, while simultaneously investigating clinical outcomes for patients within the NHS GGC orthotic service. Depending on the

outcomes, this would therefore determine the possibility of clarifying a clinical decision-making process for using harder insoles, in order to position this as a treatment option for patients within the NHS GGC MSK foot and ankle pathway.

1.4.2.2. Designing the clinical evaluation process

In 2018, all suitable hard-shell custom CAD/CAM insole products available commercially in the UK were considered in terms of the ability to manufacture from the Paromed Paromanager V6.0.2 CAD insole system used within the department at the time. Podfo Ltd were considered to be the most suitable manufacturer offering a compatible interface with the Paromanager modelling system, providing the opportunity to use our standard orthotist-led CAD design process, with additive manufacture (3D printing) to produce hard-shell insoles. Additive manufacture has been shown to be a viable method of insole production (Wang *et al.*, 2020; Barrios-Muriel *et al.*, 2020), with superior outcomes in terms of cost and lead-times when built using selective laser sintering, the technique used by Podfo (Saunders, 2017), compared with other rapid manufacturing techniques (Jumani, 2013).

Having identified a suitable manufacturer, the next steps were to design the process for prescribing the hard-shell insoles and gathering outcome data to measure the effectiveness in order to inform future practice. At this time the NHS GGC orthotic service was not research-active, with no experienced team members able to guide the development of a research study, as such I liaised with the NHS GGC Research and Innovation Department to determine what actions we could take to measure the effectiveness of the hard-shell insoles that we were proposing. It was agreed that as hard-shell insoles were not a novel product, and were already arbitrarily used within the service, we could proceed within the remit of a clinical evaluation. This evaluation would involve using the standard treatment processes in place at NHS GGC, which would include evaluating the effect of the insoles using validated outcome measures, as stipulated by the HCPC standards of proficiency (HCPC, 2013). In doing so, this would fulfil the desire to evaluate the insoles within a standard clinical environment providing a true reflection of clinical practice, as opposed to a

narrowly defined clinical scenario as is often represented in research, described in Section 1.4.1.8.

I developed and conducted a study, leading a team of four orthotists, who would be involved in the project which ran from 2018 to 2021. Consideration was first given to the use of outcome measures, despite the HCPC requirement for orthotists in the UK to use appropriate outcome measures for their patients, studies at the time demonstrated their use to be inconsistent, concluding that only 28% of orthotists and prosthetists were routinely using outcome measures (Young, Rowley and Lalor, 2018), and identifying barriers such as time and a lack of training (Hall, Parker and Williams, 2020). Therefore, prior to the evaluation commencing, I assigned responsibility to one member of the team to identify the range of outcome measures being used in the NHS GCC orthotic service and to determine any appropriate options for the evaluation of hard-shell insoles. Following this, and with reference made to relevant publications at the time, I reviewed the options and decided to use the validated Foot Health Status Questionnaire (FHSQ) to measure changes in pain, function, foot health and footwear (Menz *et al.*, 2014; Healy *et al.*, 2018), alongside the Orthotic and Prosthetic User Survey Client Satisfaction with Device module (OPUS-CSD) to gauge patient satisfaction with their insoles (Peaco, Halsne and Hafner, 2011). Myself and the two remaining members of the team, were responsible for the assessment and prescription of hard-shell insoles and gathering the outcome measures. These three team members all attended a Podfo Ltd biomechanics and prescription workshop from 02/05/2019 – 03/05/2019 to ensure they were appropriately informed on the properties and limitations of the insoles.

As the project lead, I liaised with the Podfo Ltd business development manager and managing director, as well as the professional lead for orthotics in NHS GGC to agree the process for the evaluation, and Podfo Ltd agreed to supply 40 pairs of insoles at a reduced cost of 50%. This evaluation required new processes both for Podfo Ltd, who would usually receive un-modelled scans from their customers, and for ourselves who would not usually transfer the digital insole files outside our own service. We agreed and tested the digital insole file transfer process, complying with general data protection regulations, and the manufacture process, for two pairs of insoles prior to commencing the

formal evaluation. From a clinical perspective, in conjunction with the technical processes I also designed clinical processes [Appendix 16] by which any orthotist in NHS GGC could identify patients who may be suitable and willing to try hard-shell insoles if custom CAD/CAM EVA insoles had not met their treatment goals. These patients could then be offered an appointment with one of the three project team members, who could then assess, discuss and proceed with the hard-shell insoles if appropriate. As part of this process, quality control measures were taken to reduce the risk of unsuitable digital models being sent to Podfo Ltd for manufacture, this required myself to review the prescription and modelled insole files for all patients prior to manufacture, to ensure there were minimum discrepancies in the modelling process. In total 39 patients were fitted with a total of 41 pairs of Podfo insoles, due to two patients requiring repeat manufacture resulting from problems with their first pairs. Full detail of the clinical evaluation, analysis and outcomes of this project are described in Chapter 3, and were published in 2024 (Barr *et al.*, 2024). In summary, the results demonstrated high satisfaction scores with significant improvements in pain, function and foot health across the cohort, and after two years 26 of the 39 patients had not required any further additional treatment for their original condition. Therefore it was concluded that custom hard-shell 3D-printed insoles were an effective treatment option for patients with lower limb musculoskeletal conditions who had not improved with custom EVA insoles, which showed the potential to improve pain, function, foot health, and provide satisfaction.

1.4.2.3. Reflecting on the clinical evaluation and next steps

For the orthotic team in NHS GGC this was the first time we had undertaken the process of translating a clinical evaluation into a journal article, a process which was assisted by expertise from my supervisory team at UCLan who were working on the advisory team at Podfo. The process of publishing the study in a peer-reviewed journal resulted in a more intense feeling of scrutiny than I had anticipated, reviewers feedback highlighted the importance of ensuring rigorous clarity, methodological transparency and relevance of contribution in ways I had not fully anticipated. Some of the reviewers' comments triggered a self-reflective feeling of failure: should I have anticipated these questions before submission?

Could I have included more critical details, written more convincingly, or structured my writing more carefully? This effect of peer-review, particularly on early career researchers, is not unique and has been discussed widely in recent years (Jiang, 2021; Mavrogenis, Quaile and Scarlat, 2020; Heesen and Bright, 2021). Understanding that this was all part of the normal process, along with support from my academic supervisory team, allowed me to translate this discomfort into constructive revision of the manuscript, ultimately leading to a successful publication, and better preparing me for repeating the process again for the future publications which would follow in Project 3.

Due to the constraints of a clinical evaluation structure combined with the NHS GGC orthotic team's lack of experience in clinical research processes, there were aspects of the final analysis and outcomes of this project which were limited, particularly in terms of the clinical data gathered in the assessment stage and the inconsistency in follow-up time. This somewhat limited our ability to carry out further analyses to provide a more robust prescription guide for the use of hard-shell insoles, the main limiting factor being the lack of consistent outcome measures gathered prior to the use of hard-shell insoles during the use of the initial EVA insoles. Despite these limitations, the outcome of the evaluation was sufficient to support the use of custom CAD/CAM 3D-printed hard-shell insoles for patients with lower limb MSK conditions who did not improve with custom CAD/CAM EVA insoles, and was integrated into the MSK Foot and Ankle Pathway in NHS GGC as an alternative treatment option for patients who would otherwise be offered escalation, either to proximal orthoses such as AFOs, or other services such as orthopaedics.

For myself and the wider orthotic team in NHS GGC, this project provided perspective on possibilities of widening our influence on clinical practice in the research sphere. The project generated enthusiasm from the team who participated directly in the process, and also from other team members who were able to see the influence of this work on our service. Collaborating with Professor Richards and Dr Chapman from UCLan during the later stages of the project offered valuable insight and exposure to the complexities of the research process. It was at this stage that I approached them regarding the possibility of further academic engagement, which led to my introduction to the PhD by

Portfolio pathway. This doctoral route would not only allow me the opportunity to review and analyse the work of the first two projects from a retrospective position, but it would also provide the necessary academic support and infrastructure to initiate a formal research trial in the NHS GGC orthotic service for the first time, a process which I hoped would also provide a foundation for further research activity in the future.

1.4.3. Project 3: The use of CAD/CAM in the production of insoles in the UK and the effectiveness of CAD/CAM insoles manufactured from foam-box casts versus direct scans in treating MSK conditions of the foot and ankle

Much like Project 2, the conceptualisation of Project 3 stemmed from my work on the Orthotics Evidence Portal; identifying limited evidence for the standard processes associated with foot shape capture used in CAD/CAM insole production, and reinforced by queries from colleagues in NHS GCC and attendees on the BAPO education programmes. I identified that research investigating the most effective method of shape capture would be of clinical relevance not just to our own service, but to other services using, developing and introducing CAD/CAM. In addition to the clinical aspect, there were also economic and environmental considerations, as a key advantage of CAD/CAM technology is its potential to minimise waste production (Kumar and Chhabra, 2022), particularly in insole manufacturing, where single-use materials such as foam-box casts used to capture the shape of the foot, can be replaced with direct scanning. However, CAD/CAM systems enable clinicians to continue using these traditional physical shape capture methods, by allowing the casts to be scanned into the system, rather than directly scanning the foot. This approach is widely documented in the industry (Barrios-Muriel *et al.*, 2020), with existing studies on CAD/CAM insole production showing interchangeable use of foam-box casts and direct scanning, or simply not specifying the method used (Coheña-Jiménez, Pabón-Carrasco and Pérez Belloso, 2021; Rasenberg *et al.*, 2021; Bishop, Thewlis and Hillier, 2018; Trotter and Pierrynowski, 2008), leading to the potential for unnecessary waste production. It was therefore important to understand how widely these different methods were being used in

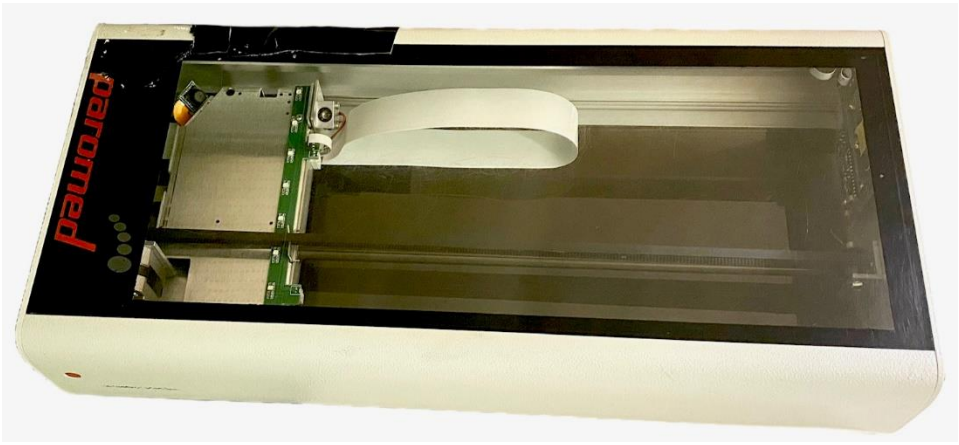
the orthotic profession, and what effect they may have on the outcomes of patient treatment.

1.4.3.1. The history of foot shape capture in the NHS GGC orthotic service

When considering the possible reasons for variation in practice, the literature suggests both clinical preference and expense to be potential influences (Kogler and Hovorka, 2021; Ngan *et al.*, 2022; Binedell *et al.*, 2020), and with a lack of evidence to guide services and clinicians, this variation is likely to persist. From the perspective of working in my own service, I observed this variation and gained many years of experience using both methods, due to clinical circumstances. The first version of the Paromed CAD/CAM insole system used in NHS GGC in 2006 was introduced with large static scanners [Figure 1.8] installed on two of the eight clinical sites covered by the orthotic service. These scanners had the capacity to produce direct foot scans or to scan foam-box casts. However, the physical size of the scanners, measuring 650mm in height, breached the health and safety allowances of the health board, meaning that patients were not permitted to stand directly on them in order to scan their feet. These health and safety concerns in conjunction with six clinical sites not having direct access to the scanners, meant that for the first seven years the majority of CAD/CAM insoles were produced using foam-box casts. This workflow describes a “hybrid-digital” process whereby an element of traditional manufacture is integrated into digital CAD/CAM production; in this instance traditional shape capture with a foam-box cast is used, as opposed to taking a direct scan of the foot, which would constitute a “fully-digital” process. The introduction of mobile foot scanners (Figure 1.9) across the service from 2013 onward made direct foot scanning more accessible and convenient, with foam-boxes now only being used due to individual clinician preference, or in situations where the scanners were unavailable. This meant by the time of commencing the PhD programme I had spent an equal proportion of my clinical career using both a hybrid-digital workflow and a fully-digital workflow in the production of CAD/CAM insoles. This experience meant that I understood the nuances of working with both methods and was therefore well positioned to construct a protocol to explore the differences between the methods, while replicating a routine clinical environment.

Figure 1.8. Photograph of the first static foot scanners used in the NHS GGC orthotic service.

Figure 1.9. Photograph of the mobile foot scanners currently used in the NHS GGC orthotic service.



1.4.3.2 Developing research capacity in the NHS GGC orthotic service

With the experiences gained from undertaking Project 2, I determined that in order to develop and conduct a high quality research study I would require not only academic guidance which would come from my PhD supervisors, but also

dedicated clinical time. Having consulted with the professional lead for the NHS GGC orthotic service and explained my vision to carry out a randomised controlled trial (RCT) which would as closely as possible reflect the standard practices in routine orthotic care; we agreed that if a study protocol was designed to reflect the current service provision, then participants could be recruited from the orthotic waiting list, therefore not increasing waiting list pressures. This would satisfy the purpose of the research without affecting clinical capacity in the department. However, in order to ensure sufficient time for aspects of the research beyond the clinical interactions; such as development of the research protocol, supporting documents, and the later stages of analysis and write-up, additional time would need to be secured to allow me to step back from my clinical duties. This led me to apply for dedicated funding via the NHS Education Scotland (NES) AHP Careers Fellowship Scheme, for which I successfully secured a Fellowship at the maximum allowance of two days per week for 12 months commencing in April 2022 [Appendix 17]. This funding permitted dedicated time for me to undertake the necessary non-clinical aspects of the intended studies by providing backfill for my role, which simultaneously allowed another member of the team an opportunity to work alongside me in the clinical contact stage of the proposed RCT. The fellowship also provided a support network of peers from across Scotland as well as monthly education sessions designed to provide exposure to project management and leadership techniques.

1.4.3.3. Project development and ethical approval

With staff resource secured and agreement from the professional lead of the orthotic service to commence with the clinical trial, I was able to undertake the activities required to carry out the planned research, which involved two distinct aspects to the project.

Firstly, in order to understand the potential impact of the work it was important to gauge the clinical landscape in terms of current practice across the UK. I initially planned to undertake a cross-sectional survey of orthotists in the UK, using a questionnaire enquiring about the current practices in their service, regarding the use of CAD/CAM insole production and the specific elements

used in the CAD/CAM workflow. This posed various challenges including the risk of multiple orthotists from a single service completing the questionnaire and skewing the results, and the possibility of low response rates which can be a barrier to clinical studies involving online questionnaires (Scott *et al.*, 2011). Therefore I engaged with fellow researchers in the field of orthotics to determine the most effective ways to gather this type of service information, and decided to conduct the study using Freedom of Information (FOI) requests (Fowler *et al.*, 2013). This method would ensure that there would not be multiple responses received from individual services, and due to the terms of the FOI Acts in the UK there would also be a high response rate from the requests, however this approach did limit the type of questions which could be included, such as opinion based queries, according to the terms of the FOI Acts across the UK (Walby and Larsen, 2012). After gathering contact details for all 214 UK Trusts and Health Boards, requests were sent in November and December 2022. The return rate from the FOI requests was predictably high with 186 responses received, but with the inconvenience of requests being sent in multiple different formats, requiring additional time to collate. Furthermore despite the FOI act stipulating that a reply should be made within 20 working days, many of the Trusts and Health Boards responded outside of this window, with the latest response received 12 months following the initial request, delaying the final analysis.

Secondly, I planned to undertake a double blinded RCT, comparing the patient reported outcomes of CAD/CAM insoles produced using a hybrid-digital workflow with foam-box casts, and CAD/CAM insoles produced using a fully-digital workflow with direct foot scans. Following discussions with the NHS GGC Research and Innovation Department who would act as the sponsor for the study, I produced the study protocol, and supporting documents including the patient information sheet, consent form and case report form in line with NHS GGC research protocols. This process presented one of the first, and greatest challenges that I faced after formally entering the PhD programme, as I learned how to navigate the various integrated online platforms that encompassed all the elements of ensuring an ethically sound study; including the Integrated Research Application System (IRAS), Health Research Authority system,

clinical trials registration, Research Ethics Committee (REC) paperwork as well as ethics approval forms from the sponsor at NHS GGC and host institute at UCLan. At times these platforms felt overwhelming, particularly for an early career-researcher, having to understand the language and the timings which felt contradictory, as elements of the IRAS system required prior clinical trial registration, but the clinical trials registry could not be completed until research ethical approval had been received, and this would not be received until the IRAS forms had been submitted. Despite the frustrations throughout this lengthy process, during the nine months from protocol development to ethical approval, navigating these platforms led me to make useful contacts within the orthotic industry and the sponsor site, as well as deepening my understanding of these processes so that they may be less daunting in the future. The various documents associated with the trial development were approved by the REC review panel in September 2022, permitting the trial to formally commence in October 2022. Prior to commencement of the trial, I sought expressions of interest from the orthotic team at NHS GGC who would be involved in the recruitment, assessment and randomisation of participants in the trial, and arranged for completion of the required Good Clinical Practice modules.

With ethical approval received to proceed with the RCT, and with the cross-sectional survey design changed from a questionnaire to an FOI request, more time would be required to fully complete and analyse both studies. I was therefore required to source additional funding to extend beyond the NES Fellowship which concluded in 2023. This led me to apply for a three-year NHS Research Scotland (NRS) Career Research Fellowship, for which my application was successful, and secured ongoing support for the projects in the form of backfill for one day per week for three years, commencing on the day that the NES Fellowship concluded in April 2023 [Appendix 18].

1.4.3.4. Outcomes and reflections on the studies

The full analysis and publications associated with this project are documented in Chapters 4 and 5. In summary, the cross-sectional survey using FOI requests disclosed that 86.8% (79/91) of UK orthotic services predominantly used a hybrid-digital workflow with foam-box casts when producing CAD/CAM insoles,

resulting in the disposal of over 36,000 foam-boxes in the 2021/22 financial year as a result of CAD/CAM insole production alone. The RCT demonstrated similar patient outcomes relating to pain improvement and function improvement regardless of shape capture method, but importantly, significantly better outcomes relating to patient satisfaction, adherence and cost of insole manufacture were observed when using direct scanning as opposed to foam-box casts. One of the unexpected challenges arising from this project was the limitation placed on publishing the final two studies due to journal word count restrictions. This resulted in many months of condensing three years of work into a written format that met journal guidelines without sacrificing too much detail – a struggle familiar to many clinical researchers, which led to a sense of frustration when certain aspects of the studies had to be omitted from the final publications. Fortunately, following publication of the two studies, I was able to utilise alternative methods of dissemination, such as conferences and social media, to share additional supporting information with the profession.
Ultimately, the outcome of these two studies provide services and clinicians with important information to guide their clinical practice in the area of CAD/CAD insole production, with the overall message that the use of direct scanning has the potential to improve patient outcomes, reduce waste production, and reduce production costs compared with the use of foam-box casts.

1.5. The Projects and their influence on the pillars of practice

Having described the process associated with the conception, development, and execution of Projects 1, 2 and 3 in the previous sections of this chapter, this section will now explore how the three projects described in this thesis have contributed to the development of my advanced practice role, and to the profile of advanced orthotic practice in the UK P&O profession; aligning specifically to the four pillars of advanced practice. My position as an advanced practitioner based in Scotland necessitates that my current role is aligned with the NES NMAHP Development Framework (NES, 2021). As discussed in Section 1.3, outlining the history of advanced practice development in the UK, there is an agreed overarching definition of advanced practice across the four nations, but there are nuances within the individual national frameworks. Therefore, the

alignment of the specific project work discussed in this commentary, in relation to the four pillars of practice, should not vary significantly across the four frameworks. However, for the purposes of this narrative, the projects have been specifically aligned with the Scottish national development framework.

The following is taken from the common definition agreed across the four UK countries from the Chief Allied Health Professions Officers (CAHPO) in 2024:

“Advanced Practice in Allied Health Professions involves complex decision making, underpinned by a post-registration master’s level award or equivalent undertaken by an experienced practitioner that encompasses all four pillars of practice: clinical practice, leadership and management, education, and research. It is delivered by skilled and experienced registered health and care professionals who exercise significant autonomy, judgement and responsibility in their roles. Advanced practitioners manage complex care in partnership with individuals, families and carers, analysing and synthesising complex problems, often as part of multi-professional teams. They handle clinical risk and uncertainty across significant areas of work, in various settings, developing innovative solutions to expedite access to care, optimise people’s experiences, drive population health and prevention and improve outcomes.” - *Advanced practice in the Allied Health Professions*, CAHPO 2024.

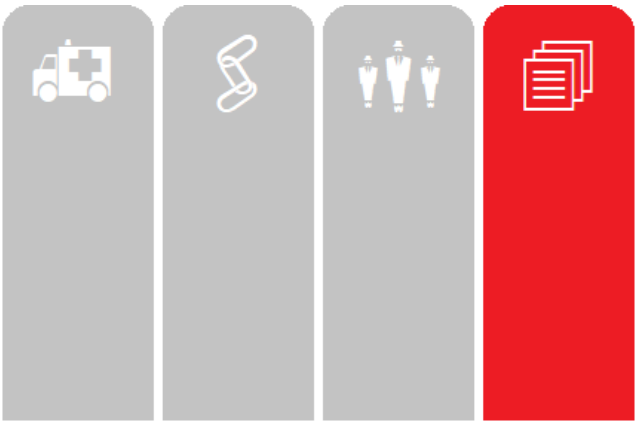
Within the NES NMAHP Development Framework advanced practice is defined as Level 7 practice, with the four pillars of practice at this level encompassing Clinical Practice, Facilitation of Learning, Leadership, and Evidence, Research and Development. A reproduction of the NES NMAHP pillars of practice diagram [Figure 1.10] will be used throughout the following sections as a visual indicator to highlight the specific pillar to which the section relates. Where there are differences in the titles of the four pillars across the four nation’s frameworks, this has been acknowledged in the introduction for each section for the sake of clarity for the reader.

Figure 1.10. Reproduction of the four pillars of practice from the NES NMAHP Development Framework, 2021.

1.5.1. Pillar of practice – Evidence, Research and Development

Within the NES NMAHP Development Framework the research pillar is titled "Research, Evidence and Development" and provides the following definition - "The knowledge, skills and behaviours needed to use evidence to inform practice and improve services" (NES, 2021). This pillar relates to the aforementioned "research pillar" as initially described by Manley in 1997, and its title differs across the four nations, with the English and Northern Irish frameworks using the title "Research", and the Welsh framework using the title "Research and Audit".

Figure 1.10a. Evidence, Research and Development Pillar.



As discussed in Section 1.3, the research pillar is recognised to be the most underdeveloped area in global advanced practice roles, with practitioners describing barriers such as a lack of access to research expertise and time limitations. The project work undertaken and described in this commentary serves to offer an alternative perspective, whereby a specific focus on the research pillar; starting with the integration the early research skills of critical appraisal (Long, French and Brooks, 2020; Lee, Hu and Bilszta, 2020) and clinical evaluation (Hughes, 2005) into an advanced practice role, can act as a stepping stone into formal research studies in the form of cross-sectional studies and an RCT, and ultimately act as a facilitator to strengthen the clinical, leadership and education pillars of practice.

My research journey has been fuelled by a professional interest in the integration of EBP with the aim of providing the highest quality healthcare, and within this led me to exploring ways in which I could contribute to the evidence base to support orthotists like myself with specific day-to-day aspects of clinical practice. The activities outlined in Project 1 [Section 1.4.1] provided me with a perspective on the evidence base in conjunction with the privileged position of having a forum in which to explore and promote this with colleagues from across the UK. The feedback received from the BAPO education courses [Appendices 19 and 20] in conjunction with the outcomes from the survey undertaken for the Orthotics Evidence Portal [Chapter 2] demonstrate the positive influence of this work in enhancing EBP in the UK orthotic profession. This positioned me to present a case to the orthotic professional lead in NHS GGC, as well as the AHP Director, regarding the feasibility of integrating research into the service, with the aim of both informing important aspects of clinical practice, but also strengthening our research profile as a profession. Their support of my applications to the NES and NRS Fellowship programmes allowed these research activities to proceed. Both fellowship programmes provided a specific focus on my career progression, through the pursuit of project work and research, paralleling my desire to explore the scope of advanced orthotic practice through the specific lens of research. The NES Fellowship provided a National forum to present my research activities on 20th June 2023 when I was asked to present both a Poster [Appendix 21] and a

podium presentation to an audience of AHP leaders and health board directors, including the Chief Allied Health Professions Officer for Scotland, and the NMAHP Director for NES, providing the opportunity to showcase the projects being undertaken to a national audience. Undertaking the live research studies within Project 3 provided not just a personal research development opportunity, but one which was shared with other members of the NHS GGC orthotics team who were involved directly in the clinical aspects of the RCT. Projects 2 and 3 [Chapters 3 and 4] demonstrated the benefit of research in a clinical environment, with our findings directly influencing clinical processes such as the integration of hard-shell insoles into the MSK Foot and Ankle pathway which followed Project 2 (Munro, Tougher and Barr, 2024), and supporting our position on the use of direct scanning which followed Project 3. It also provided a wider network of support from the NHS Research and Innovation Department with whom I had not previously worked, improving my knowledge, skills and awareness of the necessary systems in the area of research development. Liaising with a wider network of researchers both through the NES and NRS Fellowships, as well as pursuing contact with other researchers in the field of orthotics, improved my awareness of data gathering through the use of FOI, a process of which I was previously unaware. This in turn allowed me to share this information through publications in professional magazines such as the Institute of Health and Social Care Management and BAPO Connect [Appendix 22], to promote the use of FOI as a research tool which has historically been underutilised (Fowler *et al.*, 2013). Through the NRS Fellowship I have been given the opportunity to share my research story with various professions outside of orthotics, as an invited speaker at the NHS GGC Knowledge Services Research Room on 24th August 2023, a 30 minutes virtual presentation intended to demonstrate the accessibility of research in the NHS environment, a vital aspect of developing advanced practice roles. My work on Project 1 [Chapter 2] provided invaluable links with the P&O professional body, allowing me to liaise with the BAPO research committee to review and promote the dissemination of the questionnaire to the orthotic membership, with their endorsement of this research increasing the reach of the questionnaire [Appendix 23]. This relationship built with BAPO over the years, in conjunction

with the promotion of my research activities on all three projects, provided me the opportunity to share my research story with a wider audience, promoting the position of research in an advanced practice role through a case study published in a “Research Training and Career Guide” in 2024 [Appendix 24].

The culmination of the research activities and projects described in this thesis has been the publication of four original research articles in peer-reviewed journals. These publications, associated with Projects 2 and 3 [Chapters 3 and 4], are presented for discussion in the individual project chapters, and summarised here in Table 1.6. The process of peer review for these publications was itself a learning experience, providing the opportunity to strengthen aspects of the research and to defend decisions made throughout the studies, the details of which are presented in the individual project chapters.

Table 1.6. Peer reviewed publications and their position within the project chapters.

Publication reference	Chapter location
Barr, L., Munro, N., Watters, K., McCaig, R., Richards, J. and Chapman, G.J., 2024. The effectiveness of custom hard-shell 3D-printed foot orthoses in a cohort of patients who did not respond to treatment with custom ethylene-vinyl-acetate (EVA) foot orthoses. *The Foot*, *61*, p.102142.	Chapter 3
Barr, L., Richards, J. and Chapman, G.J., 2025. The use of computer-aided design and manufacture for foot orthoses: A cross-sectional study of orthotic services in the UK. *Journal of Foot and Ankle Research*, *18*(1), p.e70031.	Chapter 4
Barr, L., Richards, J. and Chapman, G.J., 2024. Comparing the effectiveness of computer-aided design/computer-aided manufacturing (CAD/CAM) of insoles manufactured from foam box cast versus direct scans on patient-reported outcome measures: a protocol for a double-blinded, randomised controlled trial. *BMJ open*, *14*(4), p.e078240.	Chapter 5
Barr, L., Richards, J., Dickson, C., Tawse, J., Munro, N., Scott, H., Holland, A. and Chapman, G.J., 2025. To scan or not to scan? Comparing the effectiveness and cost differential of insoles manufactured from foam-box casts versus direct scans in treating musculoskeletal conditions of the foot and ankle: A double-blinded, randomised controlled trial. BMC Musculoskeletal Disorders, 26(1), p.282.	Chapter 5

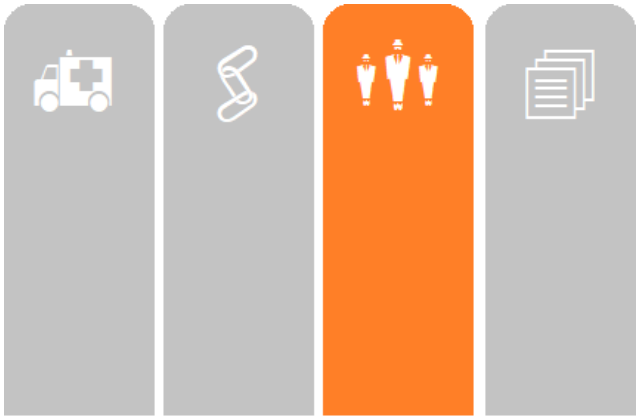
Publication of research work is undoubtedly a vital aspect of the research process, offering an opportunity for academic scrutiny to validate the robustness of the work undertaken and to strengthen the academic stance on the research outcomes (Guraya *et al.*, 2016). However, this section has additionally demonstrated the influence of research beyond academic publication by showcasing local opportunities and associated work which has contributed to developing a career path that is both shaped by, and a conduit for, research.

1.5.4. Pillar of practice – Leadership

Within the NES NMAHP Development Framework the leadership pillar has the following definition - “The knowledge, skills and behaviours needed to lead and to fulfil management responsibilities” (NES, 2021). The title of this pillar differs across the four nations, with the English framework using the title “Leadership

and Management", and the Northern Irish and Welsh frameworks using the title "Management and Leadership".

Figure 1.10b. Leadership Pillar.



The definition of healthcare leadership and leadership styles have been studied and documented in a variety of ways throughout the literature, but frequently acknowledge the involvement of processes that influence and enable others (Gottlieb, Gottlieb and Bitzas, 2021). Leadership is a vital element of the healthcare model and, as highlighted in Section 1.3, a key element in advanced practice positions, being recognised as an influencing factor on the translation of evidence into practice (Stevenson *et al.*, 2021). Leadership in research plays a crucial role in enhancing the research culture within healthcare (Evans, 2012; Browning, Thompson and Dawson, 2017). This aspect is intrinsically connected to the deficiency of research skills reported among advanced practitioners (Evans *et al.*, 2021; Fielding *et al.*, 2022), as it consequently implies that research leadership capabilities are also likely to be insufficient. Often, clinical professionals such as myself are promoted into leadership roles without targeted leadership training (Stanley *et al.*, 2017), based on clinical accomplishments in their professional careers (Perez, 2021). The activities undertaken throughout Projects 1, 2 and 3 [Chapters 2 to 4] have directly influenced my growth as a clinical leader, and are directly attributed to the translation of evidence and research into practice, by the demonstration of leadership theory in various ways.

Behavioural leadership theory describes behaviours associated with effective leaders within three categories: (1) relation-oriented leadership - relating to

behaviours which involve the development and recognition of others through supportive actions to achieve team commitment, (2) task-oriented leadership - relating to behaviours which include the clarification of roles within projects and teams, and planning to ensure optimum use of resources and (3) change-oriented leadership - relating to behaviours which provide vision and direction to support change (Gifford *et al.*, 2018). In order to clarify the development of leadership through research and the demonstration of specific leadership styles used throughout the projects in this thesis, various aspects of my advanced practice development have been organised according to the three categories of leadership behaviour described above.

- **Relation-oriented leadership**

Social capital in healthcare, defined by the notion of team strengthening through networking and collaboration (Scott and Hofmeyer, 2007) is known to be most strongly associated with relation-oriented leadership (Strömgren *et al.*, 2017). Using change-oriented leadership, by utilising my knowledge and experience to support the development of others, has been a key feature of my involvement in the historical development of the project work presented in this thesis, underpinning all aspects of my research work. From my early leadership role of the Paromed CAD/CAM system in NHS GGC commencing in 2013 as described in Section 1.4.2a, I recognised the importance of developing a standardised approach to the design of CAD/CAM insoles. Without which, we would have been unable to progress to the clinical evaluation in Project 2, and the clinical trial in Project 3, both of which required consistency and competency in the use of CAD/CAM insole design. The development of standardised training required the concurrent development of a competency framework, which is promoted in healthcare as a means of assuring confidence, consistency and quality of processes (Batt, Tavares and Williams, 2020). In order to engage the orthotic team in this process of change, I encouraged individual members of the orthotic team to consult as stakeholders in the development stage, offering individuals from across the clinical and technical teams the opportunity to contribute ideas to the proposed processes; a method which has been shown to positively influence team commitment (Murray *et al.*, 2022). Extending stakeholder engagement beyond those who actively use the final resources has

also been shown to positively influence the development of competency based frameworks (Lepre *et al.*, 2021). In this respect, over the years I have sought additional stakeholder involvement to refine the training and frameworks, by engaging with orthotic and podiatry colleagues from Canada, Germany, the Netherlands and Australia, by attending and participating in the annual International Paromed Orthotic Summits from 2014 to 2017. Since 2013 I have continued to support all orthotic team members in NHS GGC in use of the Paromed CAD/CAM system, to create a community of support and commitment, offering weekly one to one sessions to any team members seeking extra training, as well as delivering regular continuing professional development (CPD) sessions both virtually and in person. I have also engaged with the clinical and technical teams by utilising quality improvement methodology to measure the consistency of CAD/CAM insole production, ensuring visibility of the efforts undertaken by all team members by sharing such information at monthly CPD events and by the dissemination of written materials within the department [Appendix 14]. In order to support NHS GGC orthotists in their own development into advanced practice roles, I have been responsible for the creation of a professional development framework which is now used within the health board [Appendix 25]. This framework covers the four pillars of advanced practice and career progression specific to orthotics in the area of MSK practice. It was developed with stakeholder engagement from the full clinical team in NHS GGC orthotic service as well as multi-professional input from the NHS GGC podiatry and physiotherapy team leads. This framework now forms part of the annual professional development review undertaken by all orthotists in NHS GGC, and serves as a guide for those aiming to develop to advanced level practice by helping to inform the direction of CPD activities.

- **Task-oriented leadership**

When examining influential leadership behaviours related to research, a systematic review specifically highlighted the importance of task-oriented behaviour in the work environment (Gifford *et al.*, 2018). This area of leadership has been of significance throughout all three projects in planning the specific activities to be carried out by each team member to support the projects as a whole, and the development of those within the teams. My ongoing leadership

of the Orthotics Evidence Portal has involved liaising with, and supporting a variety of orthotists across the UK who have volunteered to be involved in the project. In the development stages of the diabetes section of the Portal this involved leading and overseeing the activities of a group of orthotists from NHS GGC and the University of Strathclyde, while also seeking feedback from stakeholders including orthotists in NHS Forth Valley, Buchanan Orthotics, TalarMade Ltd, and BAPO. Ensuring that all members of the team were supported in their activities and providing timescales for individual tasks resulted in a positive outcome, with the publication of the diabetes section after 8 months as described in Section 1.1.1d. On an ongoing basis, I lead volunteers who are involved in the monthly literature appraisals, providing guides to assist with consistent methods of appraisal, maximising resources by using shared documents where possible, and providing open communication with team members by phone, email and Microsoft Teams. The leadership skills developed throughout the work on the Orthotics Evidence Portal assisted in the leadership of Project 2 [Chapter 3] undertaking the clinical evaluation, and Project 3 [Chapter 5] undertaking the RCT. These projects involved the leadership of clinical tasks, which I defined in the associated process for Project 2 [Appendix 16] and study protocol for Project 3 (Barr, Richards and Chapman, 2024). These task-based processes provided a supportive environment for the team members involved in these projects, none of whom had previously engaged in a research trial. Leadership using a task-based approach is shown to be beneficial in healthcare when supporting staff in learning new processes (Papkiadeh *et al.*, 2024), and this was reflected in the use of task-based leadership utilised throughout these projects, helping to support the team in an unfamiliar research landscape.

- **Change-oriented leadership**

The outcome of healthcare research is often to suggest a change to clinical practice, with the uptake of these changes requiring specific leadership skills (Eccles *et al.*, 2005). When managed well, change-oriented leadership is shown to be positively related to job satisfaction in the healthcare setting (Øygarden, Olsen and Mikkelsen, 2020). In terms of managing change within the NHS GGC orthotic service based on the outcomes of Projects 2 and 3, using this

leadership approach to demonstrate how research carried out in the department has informed clinical practice, resulted in staff embracing these changes within the MSK foot and ankle treatment pathway. In a broader sense, undertaking the three projects within this thesis has provided opportunities to develop and enhance my leadership skills not just at a local level, but also nationally. Project 1 provided me with a national forum to support change in the profession, through the Orthotics Evidence Portal supporting EBP, and through the education programmes where I could share the wider vision of the project and support change in practice across the UK. Through working on these projects, which were imperative to the development of my advanced practice role, I have been invited on multiple occasions to share my advanced practice journey, with the specific aim of providing vision and direction to other individuals and services who wish to change aspects of their role or service to integrate advanced practice. Table 1.7 provides a summary of some of these activities. The delivery of these presentations, written articles and interviews have all been carried out with a focus on the core leadership principles of integrity and honesty, ensuring to share both the successes and challenges of this journey, values which are consistently highly rated in successful healthcare leadership (Hargett *et al.*, 2017; Hemberg and Salmela, 2021).

Table 1.7. Publications and presentations related to the authors advanced practice role development.

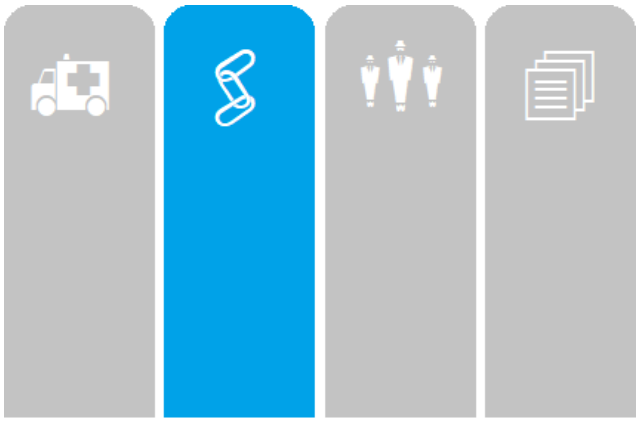
Title	Output type and location	Date
“Extending Practice: The Role of an Orthotist”	Presentation. International Society for Prosthetics and Orthotics (ISPO) Symposium, Glasgow	1st October 2016
“Extended Scope Practice - The Role of an Orthotist Within the Orthopaedic Clinic”	Presentation. British Association of Prosthetics and Orthotics Annual Conference, Ricoh Arena, Coventry	18th March 2017
“Interview with Laura Barr, Advanced Orthotic Practitioner”	Interview. British Association of Prosthetics and Orthotics - Tea Time Talk, virtual	29th April 2021
“Empowering Professional Development Beyond the Standard P&O Role”	Presentation. International Ossur Summit, Women in Innovation: Empowering the Future of O&P Innovation in Practice presentation, virtual	10th June 2021
“My Journey To Advanced Orthotic Practice In The UK”	Publication. O&P Edge, Colorado, October 2021, pp. 30-35 [Appendix 26]	29th September 2021
“Advanced Practice in Prosthetics and Orthotics. Case Study: Advanced Level Practice - Laura Barr”	Case Study. Publication: Asoluka, C and Guthrie, M. Advanced Practice in Prosthetics and Orthotics. British Association of Prosthetics and Orthotics. 2024. Version 2, pp.19-20 [Appendix 27]	Published July 2024
“Exploring Advanced Practice: Insights from Laura Barr and Susie Hughes”	Webinar. British Association of Prosthetics and Orthotics, virtual, accessible from: https://youtu.be/ZnH5TcSzEo0 [accessed: 5th February 2025]	5th March 2025
“Advanced Orthotic Practitioner, Laura Barr”	Case Study. Publication: BAPO. Exploring a Career in Prosthetics and Orthotics. Version 1, pp.19 [Appendix 28]	Published March 2025

Through the exposure provided by these various channels, I have been asked to consult with orthotic services in NHS Scotland regarding service changes with a view to the development of advanced practice roles. This has included NHS Argyll and Bute who successfully developed an advanced practice orthotist post in February 2021, for which I consulted in the development stage and acted as peer support to the successful candidate. More recently I have also provided written and verbal consultation to NHS Ayrshire and Arran and NHS Grampian who are in the early stages of advanced practice Development.

1.5.3. Pillar of practice – Facilitation of Learning

Within the NES NMAHP Development Framework the facilitation of learning pillar has the following definition - “The knowledge, skills and behaviours needed to enable effective learning in the workplace” (NES, 2021). The title of this pillar differs from the other three nations who all use the title “Education”.

Figure 1.10c. Facilitation of Learning Pillar.



Orthotists, as with all registered healthcare professionals, are expected to participate in continual learning as part of their registration requirements (HCPC, 2023), due to the proven benefits that CPD offers in terms of patient care associated with the developing knowledge and skills of the clinician (Mlambo, Silén and McGrath, 2021). As outlined by the NES NMAHP Development Framework, a key role of the advanced practitioner is to facilitate and support the education of other professionals in recognition of the benefits of peer-to-peer learning (Ramstrand, 2013). Maintaining pace with the constantly evolving evidence associated with clinical care means that education methods require to be both accessible and varied in terms of their delivery (Chaker, Hajj-

Hassan and Ozanne, 2024). The variety of education techniques proven to be effective in the ongoing education of healthcare professionals include both virtual and face-to-face delivery, using written reference materials, lectures and presentations (Ramani, McMahon and Armstrong, 2019). In specific reference to e-learning, when education content is accessed remotely, there are benefits to the techniques of synchronous learning, which is a method connecting learners together at a defined time, and asynchronous learning which allows learners to access pre-developed materials at a time of their choosing (Lawn, Zhi and Morello, 2017). The asynchronous technique is proving to be particularly effective for healthcare staff who can therefore access the materials within their individual work schedules (Kimura *et al.*, 2023). The education techniques used to support other orthotists throughout the development and delivery of Projects 1 to 3 demonstrate a variety of these techniques.

The BAPO education programmes in which I have been involved throughout Project 1 for MSK and diabetes are peer-to-peer, face-to-face education courses, using both written, verbal, and practice education techniques, and have been shown to be effective through post-course evaluation forms [Appendices 19 and 20] and written testimonials [Appendices 7 and 29]. The MSK course has also been condensed into conference programmes and workshops which have also received positive feedback from learners [Appendix 30]. As well as providing face-to-face education, I have also produced written material advertising the benefits of the Orthotics Evidence Portal in the area of EBP for BAPO Connect [Appendix 11]. In order to produce variety in the methods of delivering educational information about the Orthotics Evidence Portal to healthcare professionals, I explored the option of animation, a method which can aid education and enhance knowledge in healthcare practitioners (Knapp *et al.*, 2022), and facilitate a deeper understanding of subject areas (Stadlinger *et al.*, 2021), while also being an effective public relations tool (Srimala, Aueng and Chatwattana, 2023). After making a successful funding application to deliver an animation, I worked directly with an animator to produce an instructional guide to using the Portal and promoting the benefits related to EBP [Appendices 31 and 32].

In response to my involvement in Project 1 in terms of the Orthotics Evidence Portal, the MSK education programme, and my development of the diabetes education programme, I was contacted by the University of Derby in 2022 and asked to author the new undergraduate apprenticeship module for “Orthotic Practice 1”, as part of the new Prosthetics and Orthotics Degree Apprenticeship launching at the University in 2023. Creating this module, which comprised 10 units, involved expanding my knowledge from my work in Project 1, in order to create a module that would both deliver elements synchronously and asynchronously to undergraduate students, and use various methods of delivery including written material and visual material such as diagrams, photographs and videos. This module has been delivered to the first apprenticeship cohort and received positive feedback via the module evaluation survey submitted anonymously by students on completion of the module in 2024 [Appendix 33].

In consolidation of my own learning on specific aspects of Projects 1 to 3, and in my role as a local educator to members of the NHS GGC team, I aimed to expand my reach by being involved in the production of evidence-based education materials to the wider UK P&O profession. In the early stages of my education journey I wrote an article for BAPOMag to share my experiences as an educator on the BAPO MSK course and the impact this had had on my development as an advanced practitioner, the aim of this article was to encourage other clinicians to integrate education into their own practice in order to facilitate their career journeys and the learning of others [Appendix 2]. From the learning that I undertook regarding FOI in the early stages of Project 3, I published an article on my experience learning about the FOI Acts and their purpose and use in research, the aim of this article was to share the knowledge of the act with orthotic healthcare practitioners who may consider using the FOI Acts in research in future [Appendix 22]. Given my leadership role in the continual literature evaluations associated with Project 1, I was asked to co-author a guide to assist clinicians to undertake literature reviews “Keeping up to date with evidence-based practice: A guide to searching research databases” [Appendix 34], and given my experience with conference presentations I was also asked to co-author a guide to support clinicians in developing poster

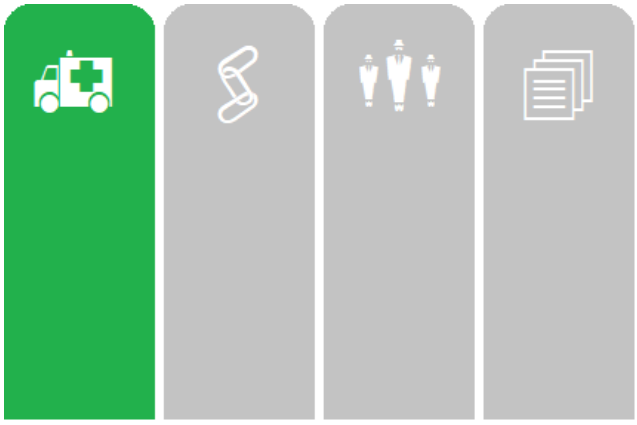
presentations for conferences “A Guide For Preparing and Presenting Posters at Conferences” [Appendix 35].

Learning through teaching has long been recognised as a powerful education tool (Duran, 2017; Grymonpre *et al.*, 2010; Kondo *et al.*, 2024), and my own experience as an educator throughout this journey is testament to this, having strengthened my own knowledge and skills as a researcher, and ultimately strengthening my position as an advanced practitioner.

1.5.2. Pillar of practice – Clinical Practice

Within the NES NMAHP Development Framework the clinical practice pillar has the following definition - “The knowledge, skills and behaviours needed to provide high quality healthcare that is safe, effective and person centred” (NES, 2021). The title of this pillar is ubiquitous across the four nations.

Figure 1.10d. Clinical Practice Pillar.



As discussed throughout this commentary, every part of the project work in this thesis was undertaken with the specific intention of developing and delivering outputs which would directly relate to realistic clinical practice. I have strived throughout my journey as a researcher, leader and educator, to support my fellow colleagues in the use of EBP, and delivering novel research with the intention of improving clinical practice. The outcomes from the three distinct projects relate directly to improving clinical practice, with Project 1 providing a resource to support EBP, and Projects 2 and 3 presenting published information to fill a gap in the knowledge base specifically relating to CAD/CAM insoles. The impact of Project 1, following the redevelopment of DEBOP, has been evidenced by survey respondents from across the UK, demonstrating the

clinical impact of facilitating access to the orthotic evidence base. Project 2 has directly influenced clinical practice in NHS GGC relating to the treatment of MSK foot and ankle conditions, by providing evidence to support the use of hard-shell insoles in the AHP MSK Foot and Ankle pathway, and has the potential to influence other services with this publication being shared through professional and social media channels. Project 3 has provided new evidence to assist clinicians and orthotic services in the area of CAD/CAM insole workflow, for the first time providing evidence directly related to patient outcomes, service cost and sustainability in this area. The publications associated with Projects 2 and 3, and the resource associated with Project 1, all have a relevance to other AHP services, particularly podiatry, as well as the potential to influence individuals and services beyond the scope of orthotics. Effective dissemination of project and research findings is a crucial aspect in promoting EBP and advancement of clinical practice (Marín-González *et al.*, 2017; Budden and Michener, 2017). In undertaking these three projects, with the aim of ensuring clinical relevance, throughout the 10 year duration of Projects 1 to 3 I have continually been involved in the dissemination of information to support the clinical practice of my fellow multidisciplinary healthcare colleagues, by promoting the use of EBP in various aspects of orthotic clinical practice to local, national and international forums. Table 1.8 provides a non-exhaustive selection of these conference and event presentations.

Table 1.8. Examples of presentations disseminating clinical information regarding orthotic care throughout the duration of Projects 1, 2 and 3.

Presentation Title	Organiser and location	Date
"Biomechanical Function of Foot Orthoses. Prosthetics and Orthotics Biomechanics"	International Society of Biomechanics Congress, Glasgow	12th July 2015
"Adult Acquired Flat Foot Non-operative management, what can be achieved?"	Foot and Ankle Scotland conference, Glasgow	26th September 2016
"The Minefield of Metatarsalgia - An Evidence-based Approach to Conservative Treatment"	West of Scotland Foot and Ankle Society Meeting, Glasgow	6th September 2017
"A Day in The Life of an Extended Scope Orthotist in the Orthopaedic Foot and Ankle Clinic"	NHS Scotland - Reporting Radiographers Study Day, Glasgow	10th March 2018
"Evidence-Based Conservative Management in the Orthopaedic Clinic"	NHS Greater Glasgow and Clyde Advanced Practice Physiotherapy Workshop, Glasgow	24th May 2018
"Principles for Evidence-Based Orthotic Treatment of The Foot and Ankle"	West of Scotland Orthopaedic Surgical Trainee Study Day 2018, Glasgow	14th September 2018
"Orthotic Treatment of Midfoot Pathologies"	Scottish Podiatry MSK Conference, Glasgow	26th April 2019
"Orthotic Treatment of Hindfoot Pathologies"	Scottish Podiatry MSK Conference, Glasgow	26th April 2019
"Updated Principles for Evidence-Based Orthotic Treatment of The Foot and Ankle"	West of Scotland Orthopaedic Surgical Trainee Study Day 2021, virtual	7th September 2021
"Non-Operative Treatment of the Forefoot"	Scottish Ankle and Foot Education, Glasgow	7th February 2023
"Conservative Management of Plantar Fibroma"	Foot and Ankle Scotland conference, Glasgow	29th September 2023
"Evidence-Based Conservative Management in the Orthopaedic Clinic"	NHS Greater Glasgow and Clyde Advanced Practice Physiotherapy Workshop, Glasgow	17th October 2023

“An Update on Evidence-Based Principals of Orthotic Treatment for the Orthopaedic Patient”	West of Scotland Foot and Ankle Society Meeting, Stirling	30th November 2023
“An Evidence-Based Approach to Material Selection for Custom Foot Orthoses”	NHS Greater Glasgow and Clyde Orthotic CPD Session, virtual	18th December 2024
“The Tale of the Orthotist, the Foam-Box and The Scanner”	UCLan Research Centre for Applied Sport, Physical Activity and Performance Coffee Morning, virtual	19th December 2024
“Research in the Orthotic Service – Results of an RCT and Cross-Sectional Survey”	NHS Greater Glasgow and Clyde Orthotic CPD Session, virtual	15th January 2025

In addition to these clinically focused presentations, I have produced written guidance on specific aspects of advanced clinical practice, to act as a resource for other orthotic services wishing to develop the clinical pillar of advanced practice roles [Appendix 36], as well as outlining how research activities can influence clinical practice through a fellowship route [Appendix 37].

The combination of activities described within these four pillars of practice has demonstrated the importance of not just undertaking and publishing research in the field of orthotics, but the vital aspect of sharing these research findings with the profession through additional mediums, such as conferences, professional networks, and social media, as a means to increase the reach and impact of these studies in the wider field of orthotics. Conferences can act as a hub for clinical collaboration and innovation, allowing researchers to present their findings to audiences who may not have accessed published versions of the work, allowing for a wider exchange of information which can advance not just individual clinical knowledge, but also drive the overall development of the field (Klamma, Cuong and Cao, 2009). The opportunity to share my research in conference settings has allowed me to present the findings in more engaging ways than simply through the medium of academic publication, by verbalising casual anecdotes from the reality of clinical experience to engage with clinical audiences, and using graphics to draw attention to clinically important aspects

of the research work which may have been overlooked in the journal publications [Appendix 21].

The use of social media platforms can further enhance the dissemination and discussion of research findings, with a recent international study suggesting that 66% of healthcare professionals view platforms such as LinkedIn as advantageous for accessing new research findings, by allowing clinician-to-clinician communication and enabling the swift transfer of professional content (Guerra *et al.*, 2022). The growing use of professional video content on social networking platforms has also been found to contribute to enhancing the reach of research findings and educational information in healthcare professions (Fehring et al., 2017) (Mclawhorn et al., 2016). Sharing the outputs of all three projects on social media using written and video content has allowed me the opportunity to discuss my research findings with members of the orthotic profession on an international scale, which would otherwise not have been possible, and has also permitted open discussion of project details which were not included in the journal publications. The reach of posts on LinkedIn can be observed in user analytics, which have shown that posts relating to journal publications for projects 2 and 3 have reached over 4500 individual users, and similarly analytics of video content relating to Project 1 have shown over 500 views.

By maximising the visibility of research using such platforms as conferences and social media which encourage clinician-to-clinician information sharing, it is possible to increase the integration of evidence-based practice into everyday clinical settings in the orthotic profession (Ramstrand, 2013), an important aspect of increasing research impact, which will be discussed in more detail in Chapter 2, section 2.2.1. In this way, promoting the projects described within this thesis increases the visibility of the work, and has the potential to help the wider profession to fulfil specific drivers for orthotic practice; such as the NHS England “Getting it Right First Time” improvement programme which calls for services to use best evidence to improve patient care and reduce treatment variation (Duncan and Sayers, 2023), and sustainability drivers such as “NHS Net Zero” which aims to reduce unnecessary waste and emissions through

sustainable supply chains and workflows (Torjesen, 2020; van Hove *et al.*, 2024).

1.6. Conclusion

This commentary has provided the opportunity to reflect on and synthesise project work undertaken over a 10 year period, providing new perspectives on many aspects of the work, and positioning them within the wider context of evidence-based orthotic practice, to which the projects support and contribute. In combination with the detailed description and output of the projects in the following chapters, this thesis demonstrates an original contribution to the knowledge base of orthotic practice and establishes the author's position as a champion of EBP in the orthotic profession. By exploring this journey through the context of the four pillars of practice; research, leadership, education and clinical practice, the author offers a new perspective to utilising research in an advanced practice role, providing significant contributions to the increasing discussions around the development of advanced practice in the orthotic profession.

In summary, the project work described in this thesis and synthesis thereof, provides a unique contribution to the knowledge base and impacts the orthotic profession in the following ways:

- Project 1 facilitates the use of EBP in the UK orthotic profession, by providing a platform which improves ease of access to evidence which is relevant to orthotic practice, while simultaneously improving the critical appraisal skills of users.
- Project 2 provides a unique insight into the use of hard-shell insoles as a treatment option for patients with lower limb MSK pathology, and offers clinical guidance on the position of this treatment within an MSK foot and ankle treatment pathway.
- Project 3 provides evidence for the use of direct foot scanning in the workflow for CAD/CAM insoles, demonstrating the benefits over foam-box casting in terms of patient outcomes, cost and sustainability. This

project suggests the potential impact of this new evidence by offering an overview of current UK CAD/CAM insole workflow, which currently favours the use of foam-box casts.

- The synoptic commentary presents a unique advanced orthotic practice role, strengthened by the integration of research, providing insight to other orthotic services as a potential pathway for developing advanced practice positions within their own service. The synthesis of the project work from the unique perspective of the author demonstrates the potential of such advanced practice pathways to benefit the individual practitioner, the local service, and the wider profession.

In conclusion this combined body of work demonstrates a significant contribution by the author to the field of orthotic practice, providing new perspectives on the use of research to develop advanced practice, demonstrating impact on the use of EBP in the UK profession, and contributing directly to the clinical knowledge base.

CHAPTER 2. THE ORTHOTICS EVIDENCE PORTAL: SUPPORTING EVIDENCE-BASED ORTHOTIC PRACTICE IN THE UK

2.1. Chapter structure and statement of contribution

This chapter describes an evaluation of The Orthotics Evidence Portal, formerly known as the Directory of Evidence-Based Orthotic Practice (DEBOP), a historical project initially developed in 2015, which continues to evolve today. The Orthotics Evidence Portal is a digital resource designed to facilitate access to the evidence base regarding the orthotic treatment of patients with musculoskeletal (MSK) pathology or diabetic foot conditions. A full account of the background and development of this project over the past 10 years is described in Chapter 1, Section 1.4.1, which fully describes the author's contribution to all stages of the project. A summary of the author's contribution is also included in Section 2.1.2 of this chapter.

This chapter begins with an introduction to the subject area of evidence-based practice (EBP) in the healthcare setting, and describes how resources, such as the Orthotics Evidence Portal, are designed to facilitate access to the evidence base, with the aim of improving patient care and promoting continuing professional development. In order to understand the perception of EBP by orthotists in the UK, and how the Orthotics Evidence Portal has influenced access to the evidence base, a cross-sectional survey is described. The analysis and results of this evaluation are described in conjunction with the existing body of literature on this subject, as well as considering how the project is positioned in relation to the UK orthotic workforce. The chapter concludes with a description of ongoing developments of the Orthotics Evidence Portal with consideration given to the feasibility of future developments.

2.1.1. Terminology

Throughout this chapter this project will be referred to as "The Orthotics Evidence Portal" which is the current name of the live resource, this may also be abbreviated to "the Portal". The full history of the Orthotics Evidence Portal and its evolution from DEBOP is outlined in Chapter 1. When referring to the

period from 2015 to 2024 it should be understood that the resource was called DEBOP at that time.

2.1.2. Contribution by L Barr

The author conceived the redevelopment plan for the MSK section of the Portal in 2017, redeveloped and published the MSK section in 2017, developed the concept of the diabetes section, developed and published the diabetes section in 2017, undertook monthly literature appraisals and updated content monthly from 2017 to present, developed the concept of the project evaluation for the Orthotics Evidence Portal, designed the methodology, undertook the data collection, analysis and write-up, developed and delivered promotional materials for the project, and contributed to the content and delivery of associated education programmes.

2.2. Introduction

2.2.1. Evidence-based practice and the translation of research into practice (TRIP) model

Evidence-based practice describes the delivery of healthcare to patients using treatments that are known to be safe and effective, employing best-practices which combine information from published clinical trials and other relevant studies in synthesis with clinician expertise and patient preference (Abu-Baker *et al.*, 2021). EBP is increasingly recognised as essential in the delivery of high quality healthcare, due to the ability of this approach to reduce treatment variance, decrease healthcare costs and time-to-treatment, improve patient safety and improve overall treatment outcomes (Black *et al.*, 2015; Kumah *et al.*, 2022). Given this positive impact across various aspects of healthcare, there has been an increasing effort to integrate EBP in health policy decisions (Bornstein *et al.*, 2017). In the UK, Government and NHS policies encourage clinicians to use EBP in daily practice. However, it has long been accepted that implementing EBP can be an arduous and daunting task for clinicians given the scope of the evidence base. In 1992, the evidence-based medicine working group acknowledged the onerous nature and limitations of practicing evidence-based healthcare (Guyatt *et al.*, 1992), and many publications have since

outlined the barriers faced by healthcare staff, as well as highlighting several failed examples of EBP implementation (Aarons *et al.*, 2009; Grimshaw and Russell, 1993; Zillich *et al.*, 2008). In 2018, the National Institute for Health and Care Research released their guide on the "principles for putting evidence-based guidance into practice" (NIHCE, 2018), which calls attention to the importance of identifying requirements for specific professions to create an environment conducive to change.

Clinicians recognise the importance of research in enhancing clinical practice, but they often encounter practical challenges when attempting to incorporate EBP, suggesting that there are obstacles to effective implementation (Clarke *et al.*, 2021). As with all areas of healthcare, EBP is recognised as essential for enhancing the quality of services in the Prosthetics and Orthotics (P&O) profession (Jafarian, Rahimi and Sadeghi-Demneh, 2021). Nonetheless, specific barriers to the implementation of EBP in the orthotics industry have been described in various publications discussed below, which can be broadly categorised into three areas:

1. Access

Lack of knowledge to access and appraise the available literature. A 2011 survey by Andrysek et al found that over half of orthotists did not feel they had the necessary skills to identify, appraise and implement research findings in their clinical practice (Andrysek, Christensen and Dupuis, 2011).

2. Relevance

As recently as 2020, a lack of high-level, relevant research into orthotic practice has been highlighted (Falbo and Brinkmann, 2020), and within the existing body of published research the question of relevance has been raised in terms of the clinical applicability of the orthotic research being undertaken (Ramstrand and Brodtkorb, 2008).

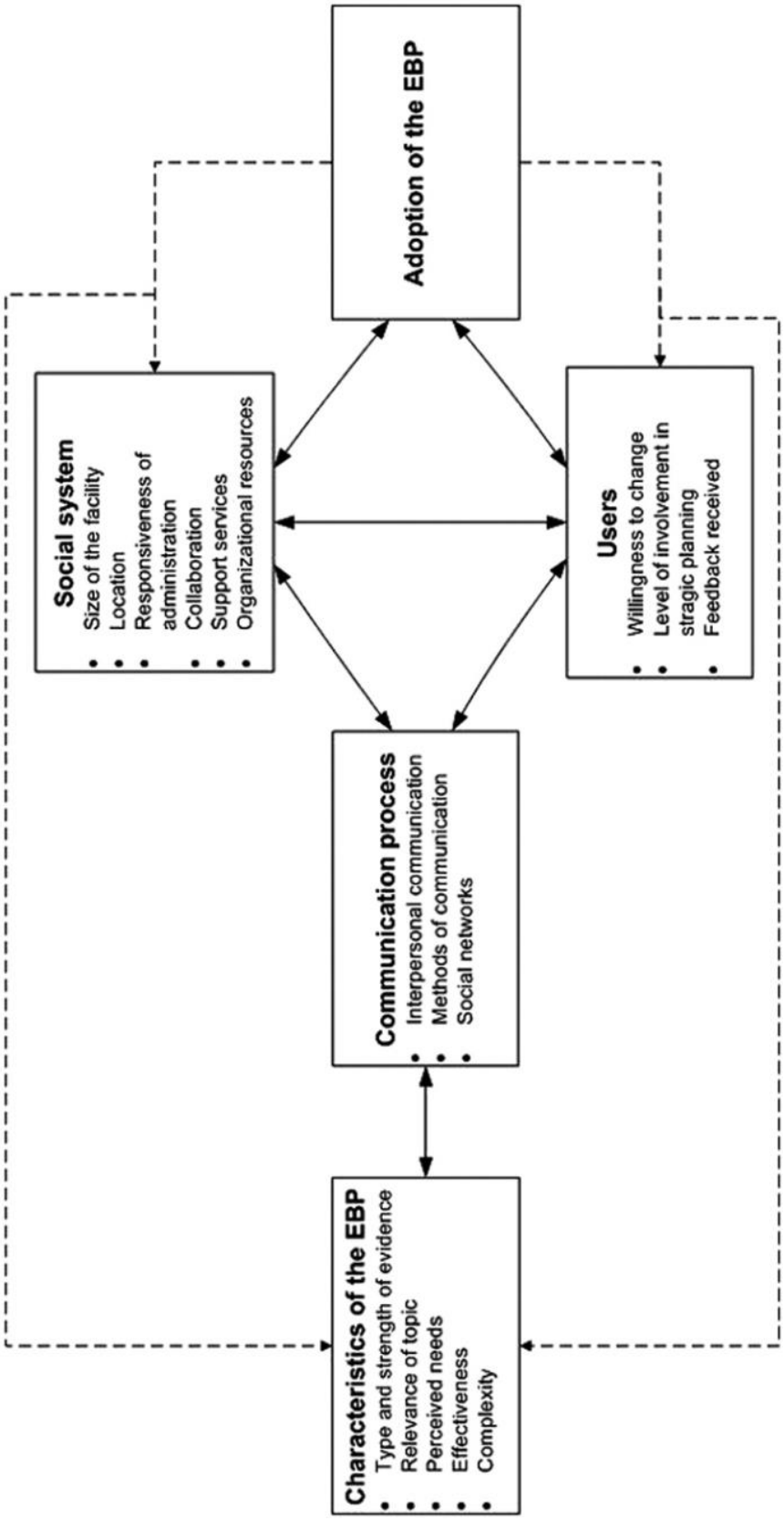
3. Collation

In 2011, having concurred with the issues relating to access and relevance, Stevens identified the importance of developing "secondary sources" of collated evidence to facilitate orthotists in their implementation of EBP (Stevens, 2011),

a recommendation which has continued to be advocated in recent years (Highsmith, 2021).

Having identified the areas of Access, Relevance and Collation in relation to EBP, it is important to consider the requirements necessary to overcome these barriers and support orthotists in the successful implementation of EBP. Researchers across various areas of healthcare have explored the use of defined implementation models and strategies, tailored to professional needs, finding these to be more effective than traditional methods such as lectures and scientific publications (Sales *et al.*, 2006; Stergiou-Kita, 2010). In 2013, Ramstrand presented the theoretical concept of an implementation model to facilitate the “translation of research into practice” (TRIP) [Figure 2.1] specifically in the P&O profession (Ramstrand, 2013). Ramstrand theorised that the TRIP model, based on a concept originally presented in the critical care profession (Titler and Everett, 2001), could offer a possible approach to overcome some of the barriers observed in the orthotics industry, having already been shown to be an effective means of encouraging EBP in adjacent healthcare settings (Titler *et al.*, 2009; Carlfjord *et al.*, 2010; Brooks *et al.*, 2009).

Figure 2.1. TRIP model as adapted by Ramstrand (Ramstrand, 2013), conceptualising the main areas of consideration for the introduction of EBP to the prosthetics and orthotics industry.



2.2.2. The Orthotics Evidence Portal and the TRIP model

The Orthotics Evidence Portal was first published under the name DEBOP in 2014, as part of the MSK and Orthopaedic Quality Drive [Appendix 1] funded by the Scottish Government, with the initial aim of repositioning orthotic services in the treatment pathway for MSK patients in NHS Scotland. The Portal was fully rebuilt and re-published in December 2017 with the aim of providing orthotists with easy access to the evidence base for orthotic practice relating to MSK and diabetic foot pathology. Since this time, the Portal has continued to be maintained and further developed by orthotists in the UK with professional oversight from the British Association of Prosthetics and Orthotics (BAPO) and support from the Orthotic Education and Training Trust (OETT), and now functions as a centralised “secondary” evidence resource, as previously described (Stevens, 2011).

The full development history of the Portal is described in Chapter 1 of this thesis, but in summary, since 2017, recurrent monthly literature reviews have been undertaken, the publications from which are reviewed by an orthotist following a standard set of appraisal criteria [Appendices 4 and 5], and relevant publications are manually added to the Portal. The Portal contains evidence relating specifically to the areas of MSK pathology and diabetic foot conditions, which are two of the primary areas in which orthotists practice in the UK (Eddison *et al.*, 2023). The continual evidence evaluation undertaken in the development of the Portal has also highlighted areas of everyday clinical practice lacking a robust evidence base, some of which will be addressed in Chapters 3 and 4.

In terms of the TRIP model (Ramstrand, 2013), the Orthotics Evidence Portal specifically addresses the first two key areas: Characteristics of EBP and the Communication Process, highlighted as imperative for the successful implementation of EBP in clinical practice, in the following ways:

1. Characteristics of EBP

The extent to which EBP is adopted by clinicians is affected by the perception of simplicity and relevance, in the context of P&O, priorities are considered to be a focus on clinical areas in which the profession specialises, and the involvement

of the profession in the dissemination of the EBP resources (Ramstrand, 2013). The Orthotics Evidence Portal addresses these priorities by focusing on two of the largest single areas of orthotic practice; MSK care, treated by 92.7% of the UK orthotic workforce, and diabetes care, treated by 84.8% of dual practicing orthotists and prosthetists and by 80.3% of orthotists (Eddison *et al.*, 2023).

The implementation of decision-making tools, such as treatment algorithms and guidelines, to simplify the process of clinical decision making has been shown to have a positive impact on promoting EBP in the orthotic profession (Sadeghi-Demneh *et al.*, 2018). At the same time, the involvement of orthotists in reviewing the evidence base and assessing this in terms of relevance to the context of their own local practice, has been shown to maximise EBP adoption (Ramstrand, 2013). The Orthotics Evidence Portal has been designed to present the evidence base in terms of condition-specific and treatment-specific headings, which allows orthotists the opportunity to review the evidence relevant to their clinical assessment, and to select the course of treatment most appropriate to the individual patient and local service in which they work. Furthermore, the Portal presents the opportunity for any orthotist to be involved in the content review, maintenance, and development of the Portal through expressions of interest on the Orthotics Evidence Portal “About” page, communication through BAPO, as well as social media channels.

2. Communication process

When evaluating clinician’s responses to EBP, dissemination of information through social channels is known to be a preferred communication method (Panahi, Ghalavand and Sedghi, 2021), with information shared from peers being more positively received in the clinical setting (Titler, 2008). Therefore the role of EBP facilitators in P&O acting in the capacity of “opinion leaders”, has been suggested, with the aim of promoting EBP practices, disseminating information, and providing peer support to departments and individuals (Ramstrand, 2013). In a similar vein, “Education Outreach” including staff training sessions, conference presentations, and delivery of workshops are thought to be instrumental in enhancing orthotists’ clinical practices (Forghany *et al.*, 2018). In this respect, the promotion of the Orthotics Evidence Portal has

been an essential aspect of its implementation within the orthotic profession in the UK. The Orthotics Evidence Portal has been and continues to be promoted widely by BAPO both through social media, written communications to members, and at national conferences. At the initial conception of DEBOP, an education programme was developed as described in Chapter 1, based on promoting EBP in clinical practice, teaching clinicians about the scope of EBP in orthotics, and the use of the Orthotics Evidence Portal to support easy access to EBP in a clinical setting. This education programme has been delivered as standalone courses in the areas of MSK and diabetes, and in the form of conference presentations and workshops since 2015. This education programme provides peer-to-peer education in terms of supporting orthotists in using EBP, and promoting the importance of EBP in the clinical setting.

The remaining two areas in the TRIP model focus specifically on the social system and individual clinicians who are using EBP. The “social system” in this context refers to the organisational facility in which the individual clinician is situated. Within various areas of healthcare, the specific environment in which EBP is implemented in one facility is known to differ when compared with other facilities (Abelsson, Karlsson and Morténius, 2022; Leeman *et al.*, 2021) and in this respect the most important aspect to supporting EBP in orthotic practice is focused on the leadership roles within the individual department (Ramstrand, 2013). Similarly, the characteristics of the individual clinician will ultimately determine their mode of clinical practice, meaning that the willingness to embrace EBP is incumbent on the individual orthotist. Given this symbiotic relationship between individual orthotists and their interactions within their own local clinical environment, the Orthotics Evidence Portal is unlikely to influence this directly, however by focusing on the first two components of the TRIP model in relation to EBP characteristics and communication, it is likely that the Orthotics Evidence Portal has the potential to contribute to the resolution of EBP challenges within both the broader orthotic environment and in terms of individual user access.

2.3. Objectives

The primary aim of this study was to evaluate the impact of the Orthotics Evidence Portal on facilitating the use of EBP in the UK orthotic workforce. The secondary aim was to improve understanding of how EBP is perceived by orthotists in the UK.

2.4. Hypotheses

It was hypothesised that the Orthotics Evidence Portal would facilitate easier access to the evidence base, and that users would find the post-2017 version of the Portal to be more user friendly than the 2015 version, and therefore users would be more likely to use the Portal in the future.

2.5. Methods

A cross-sectional survey was undertaken using an online questionnaire intended to be completed by orthotists registered with the Health and Care Professions Council (HCPC) and final year P&O students in the UK, and was reported in accordance with the STROBE cross-sectional reporting guidelines (Von Elm *et al.*, 2007). Approval for the study was received from the health ethics review panel at the University of Central Lancashire (HEALTH 0365 Phase 2). From 26 May 2023 to 29 September 2023 participants were invited to complete the survey via social media platforms including LinkedIn, X (formerly known as Twitter) and shared by BAPO and authors through email and MS Teams. In keeping with prior studies which have shown that response rates of healthcare professionals can be increased by follow-up requests (Cho, Johnson and VanGeest, 2013; Meyer *et al.*, 2022), BAPO sent out one follow-up email to members, and the author followed up with personal contacts on one further occasion after the initial request.

The survey comprised of 35 questions [Appendix 38] including quantitative and qualitative items, with adaptive routing which directed respondents to the next question dependent on their previous answers. The survey covered three main areas; (1) the use of evidence-based practice, (2) the use of the Orthotics

Evidence Portal and (3) a comparison of the Portal from pre-2017 and post-2017.

(1) Use of Evidence-based practice

The aim of this section was to gather information on the use of EBP in UK orthotic practice, this included questions on the use of primary evidence sources, critical appraisal of literature and clinical decision making based on primary evidence.

(2) Use of the Orthotics Evidence Portal

The aim of this section was to understand how the Orthotics Evidence Portal is used by orthotists in the UK and included questions on the ease of accessing evidence and applying it into practice, and how use of the Portal has influenced clinical practice and project work.

(3) Comparison of the Portal pre-2017 and post-2017

The aim of this section was to understand if the development of the Portal from 2017 onwards, as undertaken by the author and described in Chapter 1, has positively affected user experience.

The target number of responses for this survey was 100 participants, in keeping with prior P&O surveys which received response rates of 83 (Binedell *et al.*, 2020); and 119 (Chockalingam, Eddison and Healy, 2019). Given the known number of orthotists working in the UK as of 2022, reported to be 631 (Eddison *et al.*, 2023), this response target would account for approximately 15.8% of the UK orthotic workforce.

In addition to the survey, monthly page views on the Orthotics Evidence Portal were collected by NHS GGC Knowledge Services using Google Analytics from March 2016 to December 2023, and used to demonstrate the frequency of page visits during this period.

2.5.1. Inclusion criteria

- Orthotists based in the UK, working and registered with HCPC.

- Student orthotists who have completed their orthotic clinical placement based in the UK.

2.5.2. Data analysis

Descriptive analysis was undertaken, with responses presented as percentages (%), or median with interquartile range (IQR) where relevant. Open-ended responses were analysed using an inductive, thematic approach (Braun & Clarke, 2006), the identified themes of which were compiled by the author. Where questions directly compared the experience of respondents in two areas of practice, statistical analysis was undertaken with SPSS (version 29) using Wilcoxon signed rank tests to identify differences between areas of practice. The frequency of monthly site visits to the Portal was checked for normality using Kolmogorov-Smirnov tests, and the difference in the frequency of site visits before and after the 2017 rebuild were analysed using a Mann-Whitney U test.

2.5.3. Patient and public involvement

No patients or members of the public were involved in the design of this study. Before dissemination across the UK, the questionnaire was piloted by six orthotists in three NHS Trusts/Health Boards and by the BAPO Professional Affairs Committee, who provided comment on the content and structure of the questions, all comments were addressed in the final version of the questionnaire and these pilot responses were not included in the final analysis.

2.6. Results

2.6.1. Responses

There were 126 survey responses, 18 were not HCPC registered orthotists working in the UK or P&O students who had completed their orthotic clinical placement, therefore 108 responses were included in the final analysis. The demographics of respondents are shown in Table 2.1.

Table 2.1. Demographics of respondents.

Demographics	Number of Respondents	Percentage of responses*
Type of orthotic service in which respondents work:		
NHS in-house service	53	49.1%
NHS contracted service	46	42.6%
Private Practice – Commercial Company	9	8.3%
Private Practice – Own practice / Jointly owned practice	0	0.0%
UK region in which respondents work:		
England	68	63.0%
Northern Ireland	2	1.9%
Scotland	36	33.3%
Wales	2	1.9%
Work status:		
Orthotist	105	97.2%
Dual practice prosthetist / orthotist	2	1.9%
Student orthotist	1	0.9%

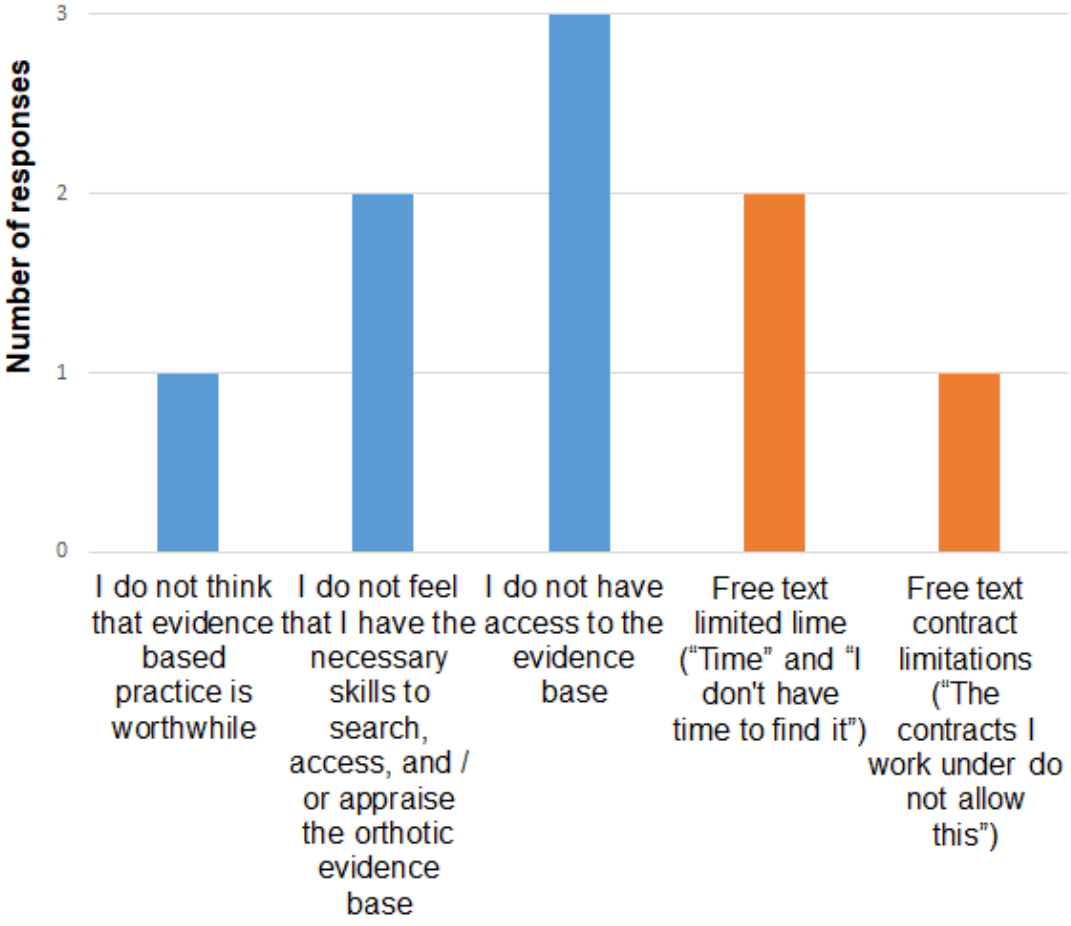
*percentages are rounded to one decimal place and therefore the sum may not equal 100%

2.6.2. Use of evidence-based practice

Respondents were asked if they used EBP in their clinical work, 92.6% (100/108) answered “yes”, and 7.4% (8/108) answered “no”. The eight respondents who did not use EBP in their clinical work were asked to describe what prevents them from using EBP by selecting from a list of reasons and/or providing a free-text answer; five barriers were identified by respondents, and

one respondent selected two answers, giving a total of nine responses from eight respondents. Access to the evidence base was the greatest barrier accounting for 33.3% (3/9) of responses, limitations on time accounted for 22.2% (2/9) responses, as did limitation of skills (22.2% (2/9)), contract limitations accounted for 11.1% (1/9) of responses, one respondent answered that they did not think that EBP was worthwhile (11.1% (1/9)) [Figure 2.2].

Figure 2.2. Responses to the question "What prevents you from using evidence-based practice in your clinical work". Blue bars represent responses selected from a list of options, orange bars represent free text responses grouped into themes.



The 100 respondents who did use EBP in their clinical practice were asked a series of questions about their experience of searching for and utilising evidence from primary sources, respondents were asked to grade their experiences on a five-point Likert scale [Table 2.2]. Across all four questions the

majority of respondents indicated that there was a difficulty in using primary sources to access the evidence base, with 44 respondents (44.0%) finding it somewhat difficult or extremely difficult to search for and locate evidence from primary sources, while only 30 respondents (30.0%) found it easy to search for and locate evidence from primary sources, and the remaining 26 (26.0%) were neutral. Forty-five respondents (45.0%) expressed difficulty in critically appraising the evidence that they found from primary sources, with less than a quarter (24.0%) finding this easy, and 31 (31.0%) being neutral. In terms of finding relevant evidence from undertaking literature searches, 44 (44.0%) found this to be difficult, with 27 (27.0%) finding this easy, and 29 (29.0%) being neutral. The vast majority of respondents 90 (90.0%) found it time consuming to perform their own literature searches, with 8 (8.0%) being neutral and only 2 (2.0%) finding this not too be time consuming. The final question had a similar number of respondents for each answer with about a third finding that making clinical decisions based on their own literature searches was easy (35.0%), difficult (33.0%) or neutral (32.0%).

Table 2.2. Experiences of orthotists using evidence from primary sources.

Experiences	Total (n=100)	Percentage of total
How easy do you find it to search for and locate evidence from primary sources?		
Extremely easy	3	3.0%
Somewhat easy	27	27.0%
Neutral	26	26.0%
Somewhat difficult	39	39.0%
Extremely difficult	5	5.0%
How easy do you find it to critically appraise evidence that you find from primary sources?		
Extremely easy	2	2.0%
Somewhat easy	22	22.0%
Neutral	31	31.0%
Somewhat difficult	36	36.0%
Extremely difficult	9	9.0%
How easy do you find it to identify relevant evidence from undertaking your own literature searches?		
Extremely easy	2	2.0%
Somewhat easy	25	25.0%
Neutral	29	29.0%
Somewhat difficult	39	39.0%
Extremely difficult	5	5.0%
How time consuming do you find it to undertake your own literature searches?		
Extremely time consuming	53	53.0%
Somewhat time consuming	37	37.0%
Neutral	8	8.0%
Somewhat not time consuming	1	1.0%
Extremely not time consuming	1	1.0%

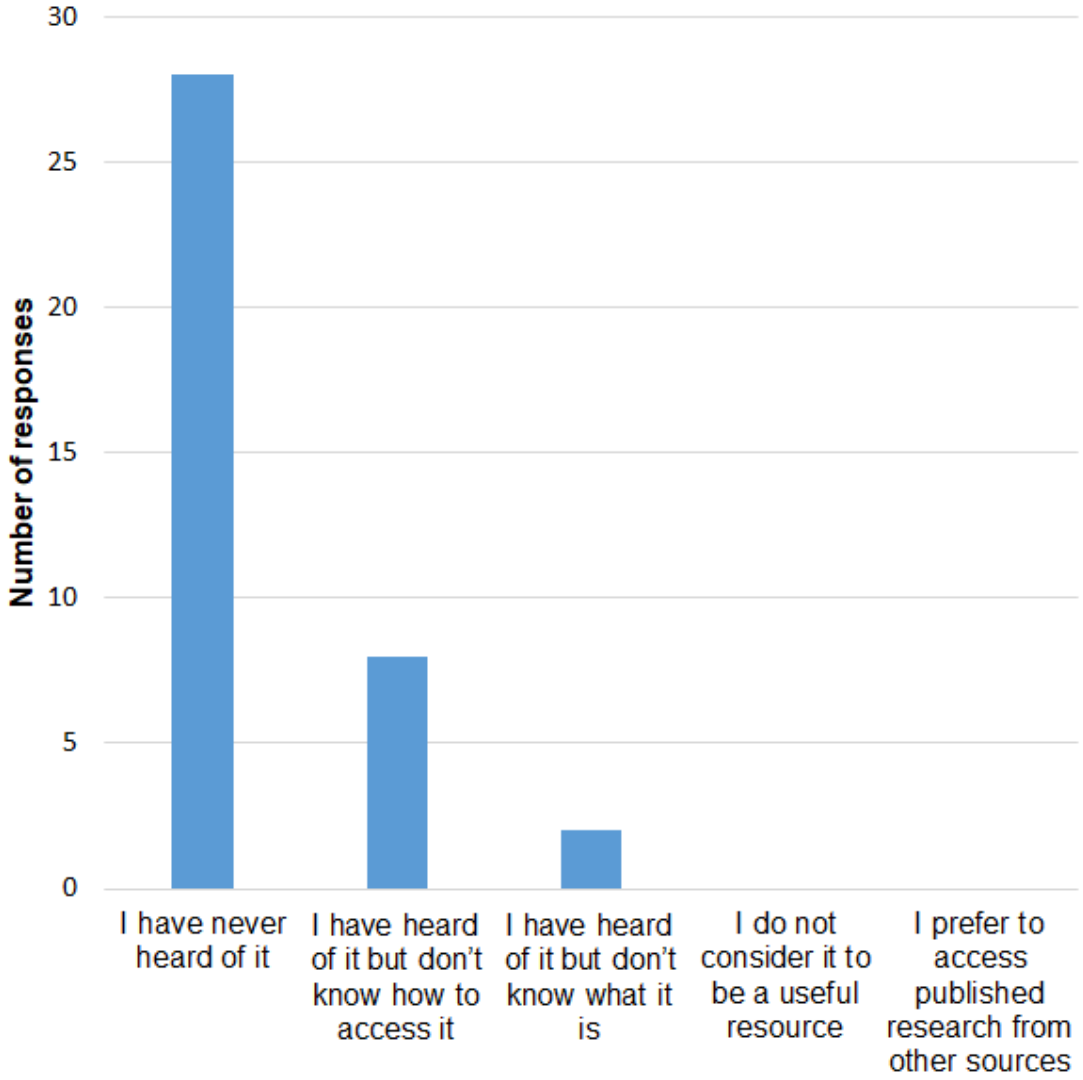
How easy do you find it to base clinical decisions on the published research that you find when you undertake your own literature searches?		
Extremely easy	6	6.0%
Somewhat easy	29	29.0%
Neutral	32	32.0%
Somewhat difficult	32	32.0%
Extremely difficult	1	1.0%

Finally those who did use EBP were asked about their involvement in the publication of orthotic research, only 22 (22.0%) had been involved in publication, while the majority (78.0%) had not.

2.6.3. Use of the Orthotics Evidence Portal

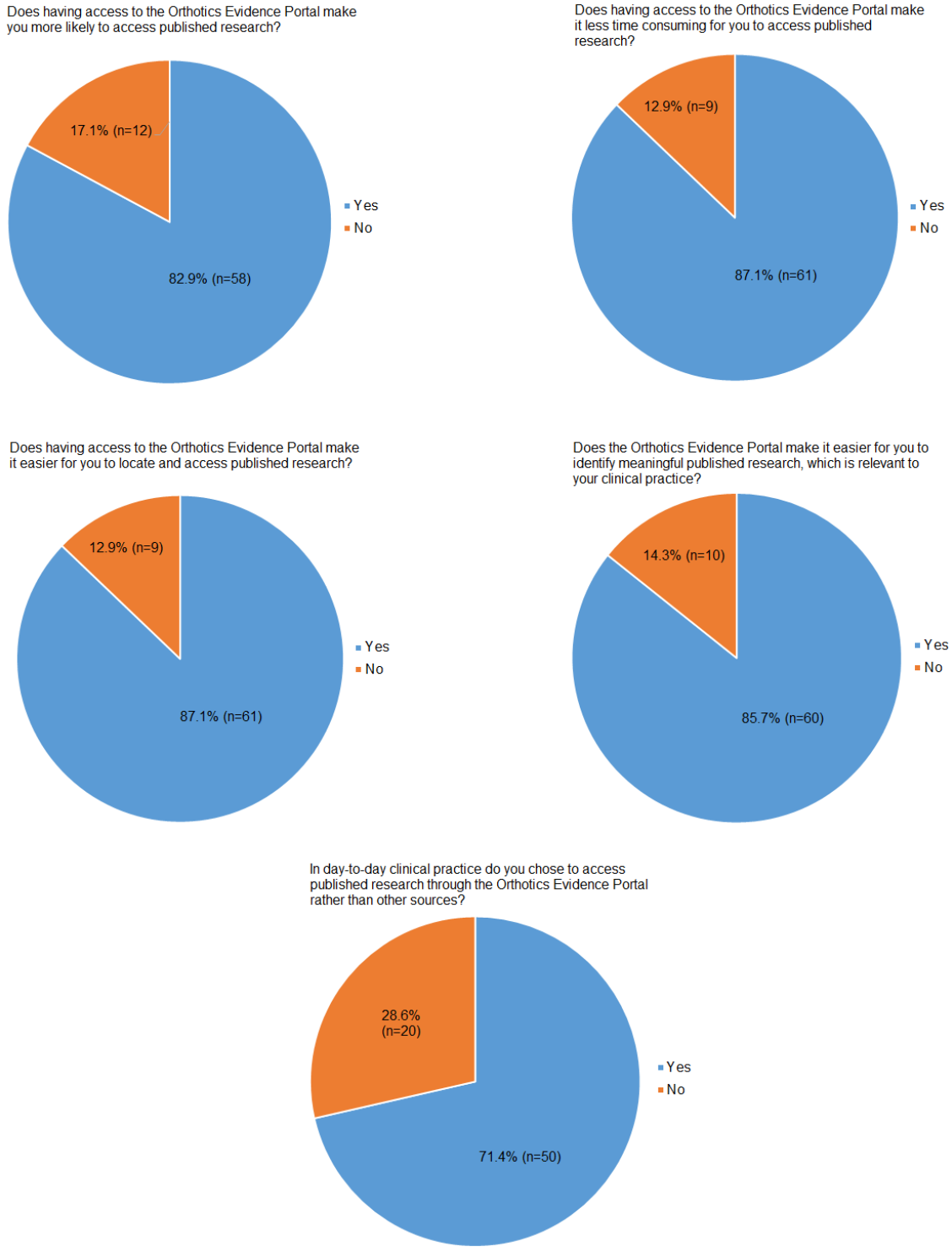
In this section respondents were asked if they had ever used the Orthotics Evidence Portal, with 64.8% (70/108) stating that they had, and the remaining 35.2% (38/108) saying they had not. Seventy-five percent (6/8) of those who did not use EBP in their clinical practice had also never used the Orthotics Evidence Portal. Those who had never used the Portal were asked to describe what prevents them from using this resource, respondents could choose from a pre-selected list or they could complete a free-text answer; the majority of this group 73.7% (28/38) stated that they did not use the Portal because they had never heard of it, 21.1% (8/38) did not know how to access it, and 5.3% (2/38) had heard of it but did not know what it was, no respondents entered a free-text response and no one selected the options that they preferred to access published research from other sources or that they did not consider the Portal to be a useful resource [Figure 2.3].

Figure 2.3. Responses to the question “What prevents you from using the Orthotics Evidence Portal?”



The 70 respondents who had used the Orthotics Evidence Portal were asked questions about their experiences in accessing published research using this resource. Respondents said that having access to the Portal made them more likely to access published research (82.9%, 58/70), made it easier for them to locate and access published research (87.1%, 61/70), made it less time consuming to access published research (87.1%, 61/70), made it easier for them to identify meaningful research which is relevant to their clinical practice (85.7%, 60/70), and 71.4% (50/70) stated that in their day-to-day clinical practice they choose to access published research through the Portal rather than other sources [Figure2.4].

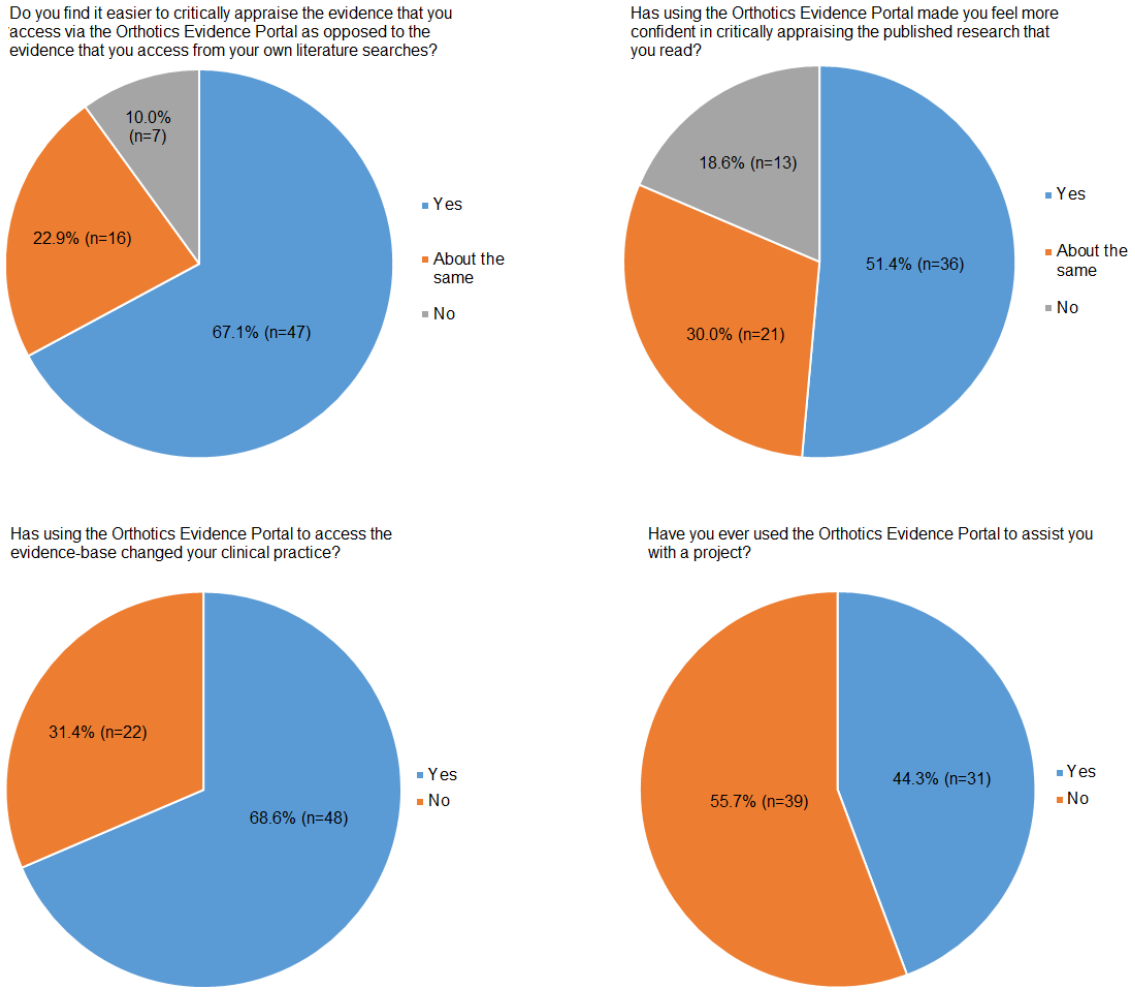
Figure 2.4. Respondents experience of accessing published research using the Orthotics Evidence Portal.



Respondents were asked a series of questions relating to the impact of using the Orthotics Evidence Portal on their clinical practice and their confidence in the area of critical appraisal. 67.1% (47/70) found it easier to critically appraise

the evidence that they accessed via the Portal as opposed to evidence accessed from their own literature searches, just over half (51.4%, 36/70) felt that having access to the Portal increased their confidence when critically appraising published research, 68.6% (48/70) said that using the Portal had changed their clinical practice, and 44.3% (31/70) had used the Portal to assist them with a project [Figure 2.5].

Figure 2.5. Impact of the Orthotics Evidence Portal of the clinical practice and critical appraisal skills of respondents.



Respondents were asked to complete a five-point Likert scale regarding how easy or hard they found it to base clinical decisions on the published research that they accessed via the Orthotics Evidence Portal, 30% (21/70) found this extremely easy, 54.3% found this easy (38/70), 11.4% were neutral, 4.3% found this somewhat difficult, and no-one selected the option for extremely difficult. Of these participants, 68 had also answered the previous question regarding the

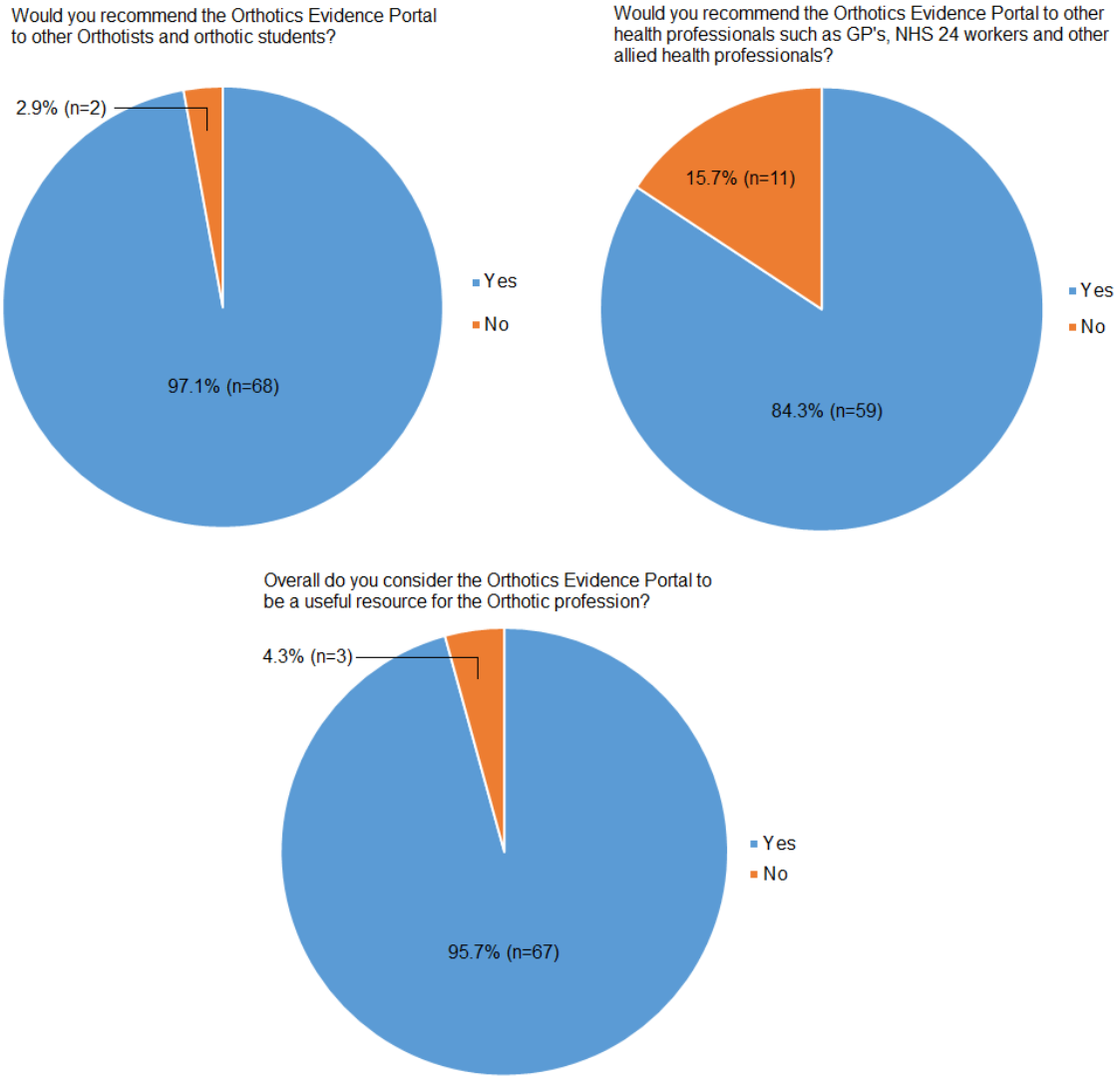
difficulty of making clinical decisions based on their own literature reviews, the results of these two questions were compared for this group using a Wilcoxon signed rank test, a significant difference was found, with 73.5% (50/68) of the group finding it easier to make clinical decisions using the Orthotics Evidence Portal compared with their own literature searches, 22.1% (15/68) reported no difference and 4.4% (3/68) found it easier to make decisions based on their own literature searches ($p<0.001$).

The final set of questions in this section related to general use of the Portal. Respondents were asked how frequently they used the adult MSK pathway, the majority of respondents 38.6% (27/70) accessed this on a monthly basis, with 28.6% (20/70) accessing yearly, 21.4% (15/70) weekly, 10% (7/70) never, and 1.4% (1/70) daily [Table 2.3]. Participants were also asked how frequently they access the diabetes section of the Portal which was published in 2018, about a third of participants accessed this on a monthly basis (32.9%, 23/70), with 28.6% (20/70) accessing yearly, 24.3% (17/70) never, 12.9% (9/70) weekly, and 1.4% (1/70) daily [Table 2.3]. The vast majority of respondents 97.1% (68/70) said they would recommend the Portal to other orthotists and orthotic students, and consider the Portal to be a useful resource for the orthotic profession (95.7%, 67/70). 84.3% (59/70) of respondents would also recommend the Portal to other healthcare professionals such as GP's, colleagues working in specialist Health Services such as NHS 24 (Scotland’s equivalent of NHS 111), and other Allied Health Professionals (AHPs) [Figure 2.6].

Table 2.3. Overall use of the Orthotics Evidence Portal.

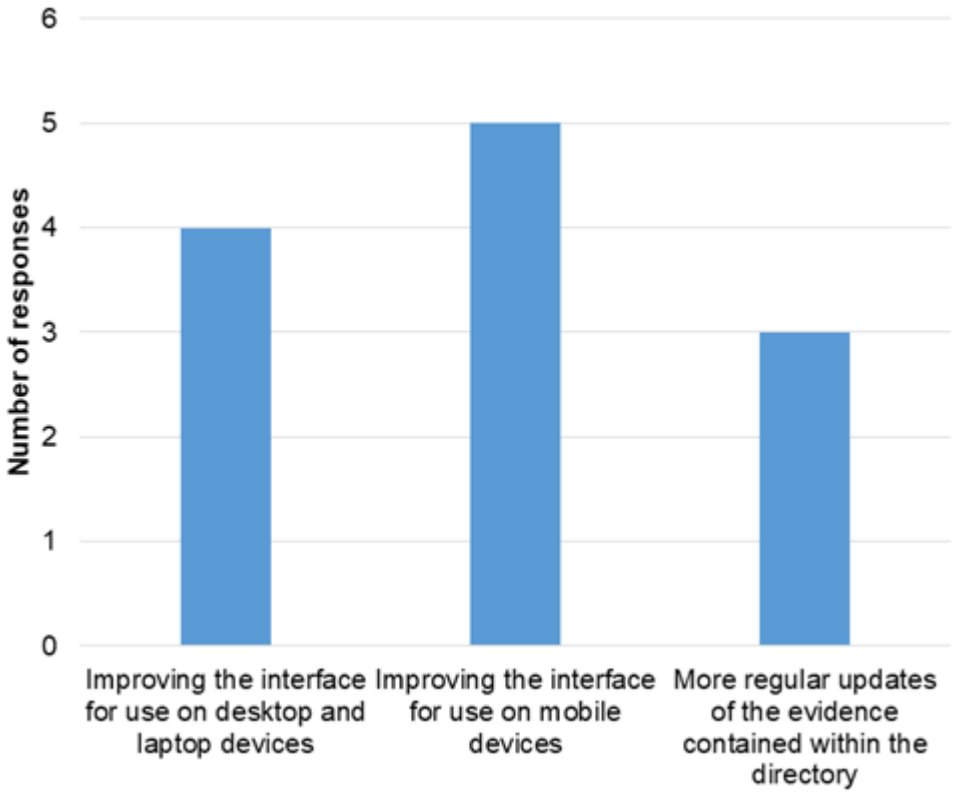
Usage	Total (n=70)	Percentage of total
How often do you access the Orthotics Evidence Portal MSK pathway?		
Daily	1	1.4%
Weekly	15	21.4%
Monthly	27	38.6%
Yearly	20	28.6%
Never	7	10.0%
How often do you access the Orthotics Evidence Portal Diabetes pathway?		
Daily	1	1.4%
Weekly	9	12.9%
Monthly	23	32.9%
Yearly	20	28.6%
Never	17	24.3%

Figure 2.6. Overall use of the Orthotics Evidence Portal.



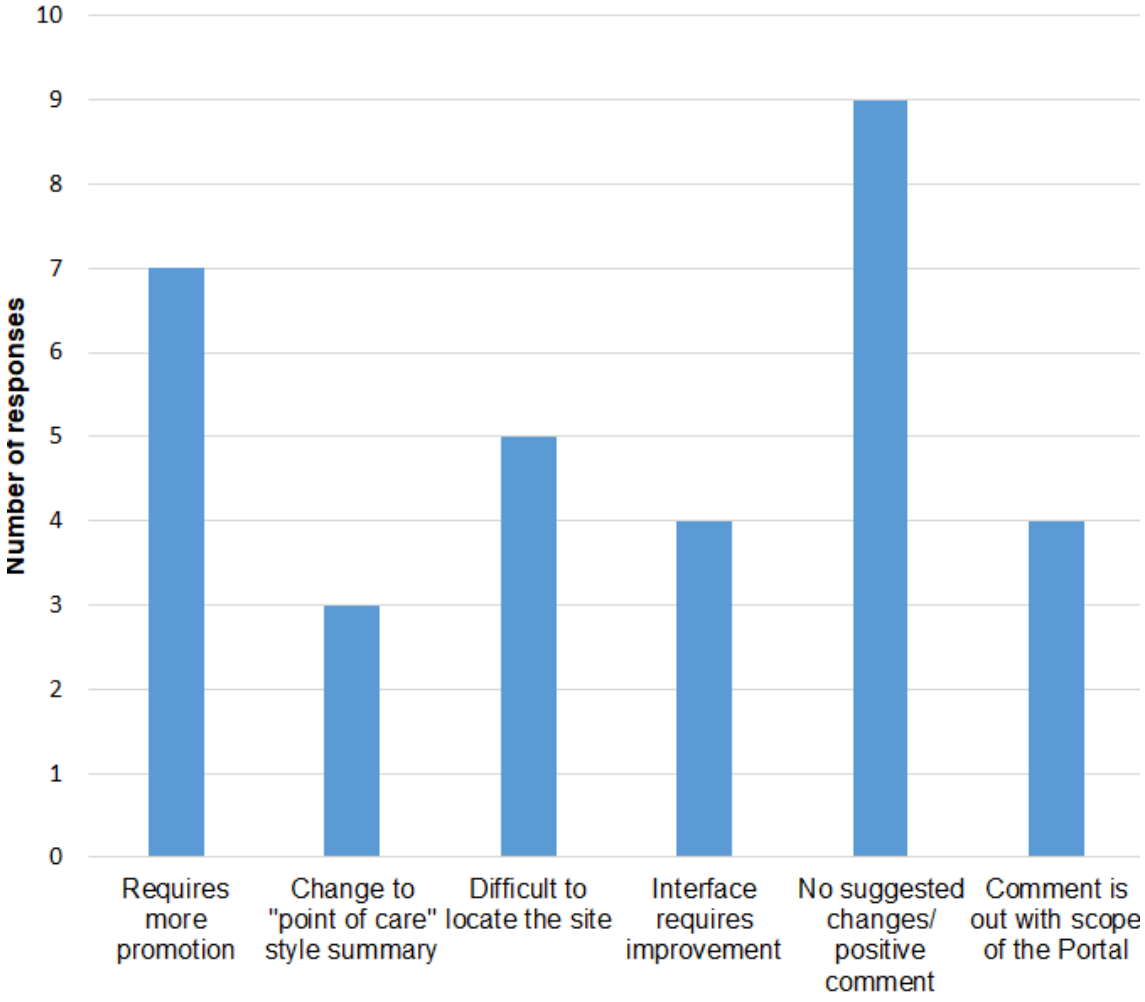
Respondents were asked what they felt could be done to improve the usefulness of the Orthotics Evidence Portal, respondents could select from a list of options and provide free text comments, 10.0% (7/70) of respondents completed this question and only 1 participant provided a free text comment, as such this comment was collated with the free text comments in Appendix 39. The remaining responses, all of which were selected from the list of options, are shown in Figure 2.7, the most common response was “Improving the interface for use on mobile devices” which was selected by 5 respondents.

Figure 2.7. Responses to the question “What do you feel could be done to improve the usefulness of the Orthotics Evidence Portal?”



For the final question in this section participants were invited to provide any free text comments about the Orthotics Evidence Portal which had not been covered in the survey, 29 anonymous comments were received from 25.7% (18/70) of respondents and these were collated into themes as shown in Figure 2.8, with the individual comments shown in Appendix 39. The majority of free text comments were positive with no change suggestions (9/29). The most common theme relating to possible areas of improvement was the requirement for better visibility of the Portal in terms of promoting this resource (7/29) and optimising the ability to search for and locate the site (5/29) [Figure 2.8]. The remaining two areas for suggested improvement related to the layout of the site, with four responses indicating issues with the platform interface, and three responses suggesting a layout change to a “point of care summary” style interface. The remaining four comments related to a lack of time within individual clinical settings, which was considered to be outside of the scope of the Portal’s influence.

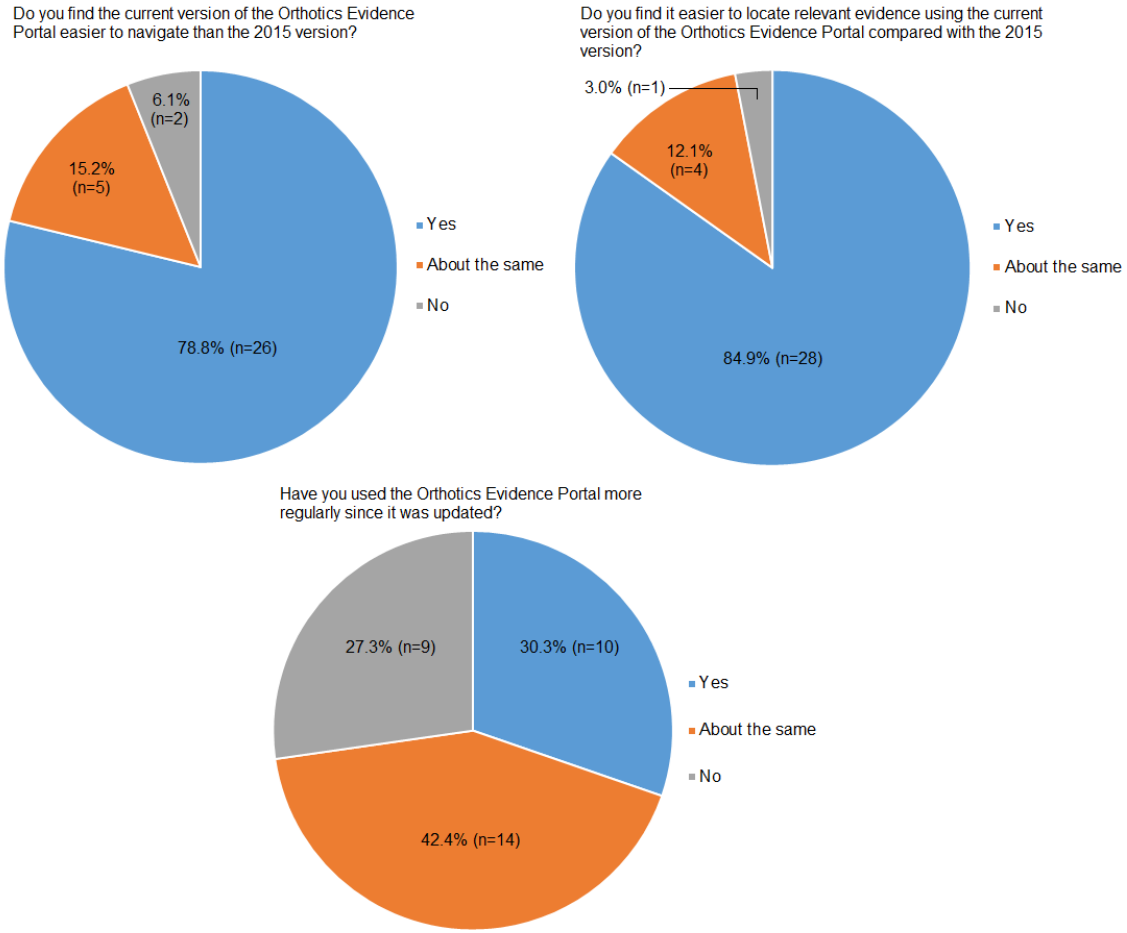
Figure 2.8. Thematic responses collated from free text comments regarding any aspect of the Orthotics Evidence Portal.



2.6.4. Comparison of the Portal pre-2017 and post-2017

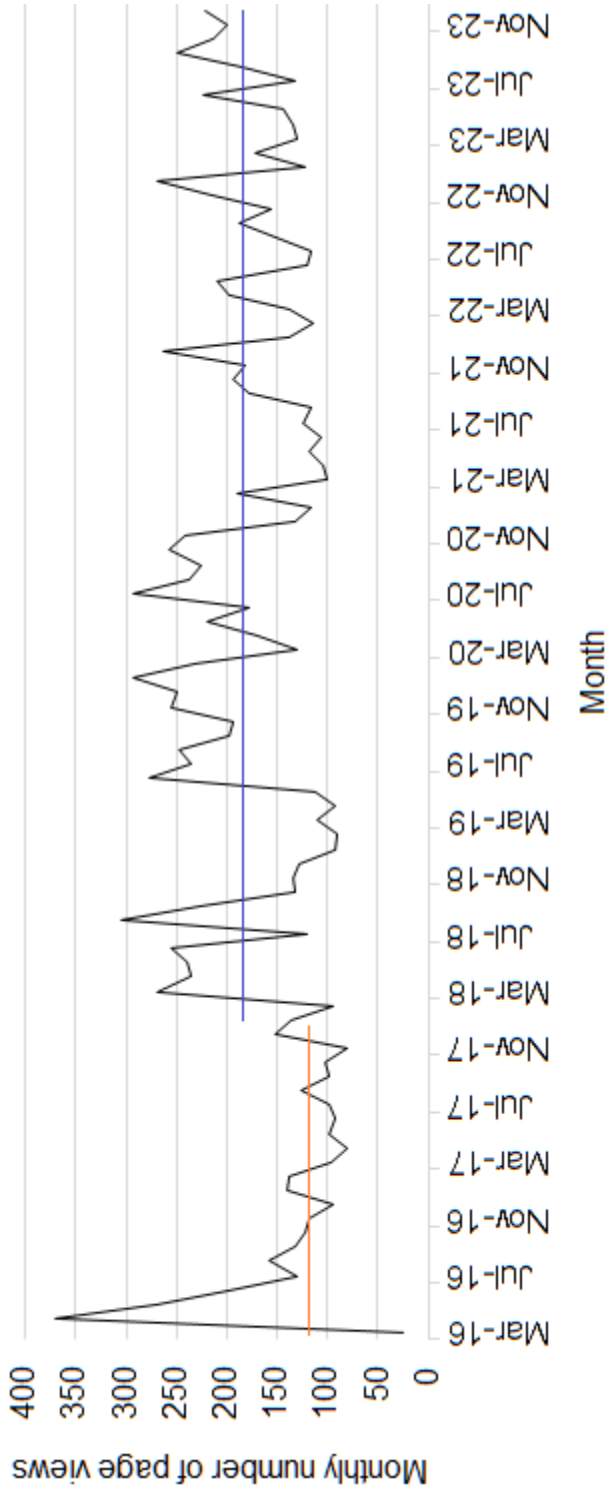
In this section respondents were asked if they had used the Orthotics Evidence Portal prior to the rebuild in 2017, just under half of the respondents (47.1%, 33/70) had used the Portal between 2015 and 2017, and were invited to answer further questions comparing the Portal before and after the rebuild. 78.8% (26/33) reported that the post-2017 version was easier to navigate than the pre-2017 version, 84.9% (28/33) found it easier to locate relevant evidence using the post-2017 version than the pre-2017 version, and about a third said they had used the Portal more regularly since it was updated in 2017 (30.3%, 10/33) with 42.4% (14/33) continuing to use it with similar frequency as they did prior to 2017 [Figure 2.9].

Figure 2.9. Responses to questions comparing the pre-2017 and post-2017 versions of the Orthotics Evidence Portal.



Kolmogorov-Smirnov tests showed that that monthly number of page views on the Portal from March 2016 to December 2017 (pre-2017 rebuild), and January 2018 to December 2023 (post-2017 rebuild) were not normally distributed. The median number of views pre-2017 was 120.5 (IQR 95.8, 143.0) and post-2017 was 179.5 (IQR 125.3, 234.8) [Figure 2.10]. A Mann Whitney U test demonstrated that there was a significant difference in the frequency of monthly views before and after the 2017 rebuild ($p<0.001$) with the site being visited approximately 48.9% more frequently after 2017.

Figure 2.10. Number of monthly page views on the Orthotics Evidence Portal from March 2016 to December 2023, as collated by NHS GGC Knowledge Services from Google Analytics. Orange line represents the median number of views before the 2017 rebuild, Blue line represents the median number of views after the 2017 rebuild.



2.7. Discussion

2.7.1. Statement of principle findings

This study explored the experiences of UK-based orthotists accessing the Orthotics Evidence Portal and the impact this has had on their use of EBP in clinical practice The majority of respondents (64.8%) had used the Orthotics Evidence Portal, with over 80% of users confirming that having access to the Portal meant they were more likely to access published research, they found that the Portal made it easier and less time consuming to access research, and using the Portal made it easier to identify research which was relevant to their clinical practice. 71.4% of those who use the Portal said they would choose to access evidence via the Portal rather than using other sources such as undertaking literature searches on scientific databases, and 68.6% said that using the Orthotics Evidence Portal had changed their clinical practice.

Over 75% of those who had used the Portal prior to the rebuild in December 2017 found that the updated site was easier to navigate and made it easier to locate relevant evidence, with about a third of those users also using the Portal more frequently since the rebuild. The Portal also experienced a significant increase in volume of monthly page views after the 2017 rebuild.

The majority of orthotists who completed the survey were using EBP, but did express difficulties with conducting their own literature searches to support EBP, with the majority of respondents finding it difficult rather than easy to search for and locate evidence, critically appraise evidence, identify relevant evidence, and base clinical decisions on that evidence, as well as the majority finding this to be a time consuming process. These experiences align with the two main barriers experienced by other AHPs when undertaking EBP, such as physiotherapists; with 31.2 to 93.8% (da Silva *et al.*, 2015) and 53% (Paci *et al.*, 2021) identifying time pressures related to EBP processes, and 30.4 to 54.3% (da Silva *et al.*, 2015) and 27.0 to 31.0% identifying a lack of skills when appraising literature.

2.7.2. Response rate and response bias

The survey received a good response rate; as of 2022 there were known to be 631 orthotists and dual practicing prosthetists and orthotist's working in the UK (Eddison *et al.*, 2023), meaning that the survey was completed by approximately 17.1% (n=108) of the UK orthotic workforce, exceeding the target number of responses for the study. However it is acknowledged that response bias and non-response bias can be a potentially limiting factor in the results of any survey-based study (Groves, Cialdini and Couper, 1992), and the implication of this must be considered in tandem with the conclusions of this study. The potential of response bias exists in terms of respondents being pre-disposed to answer questions in a way that they consider the researchers to view positively (Sedgwick, 2014), steps were taken to mitigate this by ensuring the survey responses were anonymous and respondents were made aware of their anonymity prior to completing the survey. The majority (92.6%) of orthotists working in the UK who completed this survey were using EBP in their clinical work, which is on the higher end of prior surveys involving other AHPs such as physiotherapy where systematic reviews have shown that 48 to 93.2% of physiotherapists consider EBP to be necessary in clinical practice and 78.1 to 90.3% consider scientific literature to be important in clinical practice (da Silva *et al.*, 2015). The high proportion of respondents using EBP in the current study may be a product of response bias in terms of "topic interest" (Groves and Peytcheva, 2008) as the survey was titled "Evidence-Based Practice in the UK Orthotics Industry" therefore it is anticipated that those with an interest in the subject area were more likely to respond. Notably however it is anticipated that this may have minimised the response bias in terms of the primary aim (to evaluate the impact of the Orthotics Evidence Portal on facilitating the use of EBP in the UK orthotic workforce) as the Orthotics Evidence Portal was not mentioned in the title of the survey.

2.7.3. Interpretation within the wider context of the literature and the context of the orthotic workforce

The results of this study suggest that the Orthotics Evidence Portal has had a positive effect on the way in which UK-based orthotists are using EBP,

specifically in terms of the main barriers of access, relevance and collation that orthotists are likely to face when implementing EBP, which were identified at the start of this chapter. When considering access limitations, which were known to be related to a lack of skills in locating and appraising evidence (Andrysek, Christensen and Dupuis, 2011), this study confirms that using traditional literature searches to locate evidence was a difficulty for 44% of orthotists, whereas having access to the Portal made this easier for 87.1% of respondents. Similarly, 45% of orthotists confirmed that appraising literature from their own searches was difficult, whereas using the Portal made this easier for 67.1%. The use of EBP is intrinsically linked to clinicians having the skills to critically appraise the evidence that they read (Katrak *et al.*, 2004) and although the primary function of the Portal is not to teach critical appraisal, it is reassuring to see that it has positively affected orthotists in this area. This study did not explore the specific ways in which the Portal improved the critical appraisal skills and confidence of its users, and so pragmatic consideration is given as to the possible reasons for this change.

Since December 2017 the Portal has been structured to present the evidence by pathology and body area, and study type in accordance with the hierarchy of evidence (Evans, 2003), and it also provides links to critical appraisal tools in addition to the literature. In doing so, the Portal provides a simplified indication of the study's strength while encouraging users to read and appraise the quality for themselves. There has long been doubt in the literature as to the benefits of formal courses teaching critical appraisal skills to healthcare practitioners (Coomarasamy and Khan, 2004; Taylor *et al.*, 2000; Taylor *et al.*, 2004), suggesting that these skills are better learned within a clinical environment, and the current study supports the notion that presenting the evidence base to orthotists in a clinically relevant way, as is done on the Portal, can indeed be beneficial in improving their critical appraisal skills.

Providing easier access to the evidence is one of the main purposes of the Portal, but the ability of clinicians to translate the evidence that they read into their clinical practice is recognised to be of the utmost importance throughout healthcare at all career stages (Kumah *et al.*, 2022; Saunders *et al.*, 2019; Abu-Odah *et al.*, 2022). For this reason we compared how easy or hard respondents

found it to make clinical decisions based on the evidence that they find from their own literature searches compared with those they found from the Orthotics Evidence Portal, there was a significant difference in the ease of translating the evidence into practice between the methods, with 73.5% finding it easier to translate evidence into practice using the Orthotics Evidence Portal ($p<0.001$). This in combination with over two thirds of respondents confirming that using the Portal had changed their clinical practice, provides confirmation that the Portal is fulfilling its aim of supporting the translation of evidence into practice to facilitate EBP. Again, respondents were not asked to clarify the ways in which the Portal improved this ability, and so it is suggested that the structure of the Portal is addressing the aforementioned barrier of relevance (Falbo and Brinkmann, 2020; Ramstrand and Brodtkorb, 2008) by guiding clinicians to the evidence relating only to the area of the body or pathology that they have selected. Presenting the evidence within such sections also addresses the barrier of “collation” (Highsmith, 2021), whereby clinicians tend to find EBP less challenging when they have access to collated secondary evidence sources, such as the Portal, as opposed to undertaking their own literature searches from primary databases and journals (Stevens, 2011; Highsmith, 2021).

This study has shown that giving UK-based orthotists access to relevant and collated evidence sources has improved their use of EBP and influenced their clinical practice, and this is supported by prior studies investigating AHP groups who engage with the evidence base, which show that this can positively affect care processes (Chalmers *et al.*, 2023). Having investigated the positive impact that the Portal has had on clinical practice in the UK orthotic profession, it is important to recognise the potential of the Portal from a wider perspective in terms of the global orthotic community and other AHPs who may be involved in the care of orthotic patients. In the UK it is recognised that orthotic patients are treated by a variety of professions including orthotists, podiatrists and physiotherapists (Nester *et al.*, 2018), as well as professional variation among orthotists, pedorthists and podiatrists in the global community (Guldemond *et al.*, 2005; Chapman *et al.*, 2018; Ahmed *et al.*, 2024). The current survey was limited only to UK orthotists however the Portal is internationally accessible, and therefore has the potential to influence the use of EBP among these groups as

well, this is of particular relevance in the current clinical climate as a recent systematic review of international education in P&O found a lack of emphasis on EBP and highlighted the need for this to change (McDonald, Kartin and Morgan, 2020). Lack of knowledge and use of EBP in the international orthotic workforce was also recently emphasised in a survey of prosthetists and orthotists in Turkey who found that the skills and knowledge of EBP in this community was low in those who did not hold higher degrees (Ak, Elverişli and Atılgan, 2025), and a further recent review of orthotic education history discussed the importance of upskilling the global profession in critical inquiry and EBP (Spaulding *et al.*, 2020). As such, wider promotion of the Portal in both the UK and to international audiences should be considered a future priority, and is supported by the UK orthotists who completed this survey, 97.1% of whom would recommend the Portal to other orthotists and students, and 84.3% would recommend the Portal to other healthcare professions.

One of the aspects explored in this survey was the use of the Portal for specific clinical purposes, the two main areas covered by the Portal being MSK practice and diabetes foot care. Among the orthotists who were surveyed, 61.4% (43/70) visited the MSK pages at least monthly, and 47.1% (33/70) visited the diabetes pages at least monthly, the higher frequency of MSK usage is expected in terms of the UK workforce profile whereby about 10% more orthotists work in the area of MSK than diabetes (Eddison *et al.*, 2023). Given that the orthotics UK regulatory body, the HCPC, does not specify any time allocation for continuing professional development (CPD) activities (Karas *et al.*, 2020), it is encouraging to see that UK orthotists are engaging with CPD in the form of accessing evidence for their practice on a regular basis via the Portal. This is of particular relevance given prior studies have shown UK orthotists to have limited CPD time in their clinical schedule (Prosser and Achour, 2023), suggesting that the Portal provides a convenient means of undertaking CPD in terms of accessing literature. When comparing this to physiotherapists, a global systematic review found that 10 to 40% of physiotherapists reported reading scientific literature on a monthly basis (da Silva *et al.*, 2015), which is lower than we found in the orthotic population surveyed in this study. However as the population size of

6411 (da Silva *et al.*, 2015) was significantly greater than the population of the current study, the results may not be directly comparable.

When considering the usefulness of the 2017 rebuild, a high proportion of respondents felt this had improved navigation (78.8%) and improved ease of locating relevant evidence (84.9%). Of those surveyed, 42.4% had continued to use the site with the same frequency as they did prior to the rebuild, and 30.3% were now using the site more frequently. Due to a limitation in the survey question, it was not possible to say if the remaining 27.3% had used the site with equal frequency or less frequency than they did prior to the update, therefore comparison with the site visits recorded from Google Analytics was made which suggests that the frequency of visits had increased after 2017. However, due to limitations in the information available regarding website traffic from Google Analytics it was not possible to determine the specific reason for this increase, and it is recognised that this could be related to more individual users visiting the site rather than established users visiting more frequently.

In order to understand barriers to the use of the Orthotics Evidence Portal, responses were gathered from those who did not use the Portal, the majority of whom (73.7%, 28/38) did not use the Portal because they had never heard of it, 21.1% did not know how to access it and 5.3% did not know what it was. These responses were complimented by the free text suggestions for improvement which were received from those who do use the Portal (29 comments total); stating that the Portal requires more promotion (n=7) and identifying that it is challenging to locate the site (n=5). Similarly, improving the interface for computers and mobile devices were key areas selected by users of the Portal both from the pre-written list of options and free text comments. Although not specific to the use of EBP, studies on UK healthcare practitioners using web-based CPD resources revealed similar barriers to those faced by Orthotics Evidence Portal users, which were mainly web infrastructure issues and limited training (Willman, 2020). Other studies which have surveyed users of online healthcare library resources found similar requests from users to provide a more intuitive interface and include appropriate training to assist with use (Wilson and Neilson, 2011). At the time of initial publication of the Orthotics Evidence Portal in 2015, the option of web-host interfaces for the Orthotics

Evidence Portal were limited, however in light of the subsequent increased availability of newer platforms which can offer interface options which are optimised for both desktop and mobile use, future development of the Portal to improve the interface and accessibility is indicated as a priority for this project, as well as considering the issue of promotion and training for users; key themes which will be explored in Section 2.10 “Concurrent work and future directions”.

As a final consideration, in the free text sections of this survey a small number of respondents raised the issue of insufficient clinical time to undertake EBP (n=2) and insufficient time to use the Orthotics Evidence Portal (n=4). Although the subject of timetabling and CPD allowances within individual clinical environments is outside of the scope of the Orthotics Evidence Portal, it is nonetheless important to acknowledge this concern, which is not unique to orthotists. Restrictions on CPD time is a concern raised internationally by various healthcare professions such as nurses; with an international study showing that 50% of nurses undertook CPD activities in their personal time (Vázquez-Calatayud, Errasti-Ibarrondo and Choperena, 2021), a view confirmed by a UK systematic review where nurses identified management expectations to carry out CPD in their personal time (Walter and Terry, 2021). Similarly, physiotherapists have identified time pressures related to EBP processes, with 31.2 to 93.8% (da Silva *et al.*, 2015) and 53% (Paci *et al.*, 2021) of physiotherapists experiencing such pressures. As previously stated, it is also challenging for individual orthotists to make a case for increasing CPD time in the UK as there is no recognised minimum time allowance advised from HCPC. Despite these challenges, it does appear that the Portal is helping to maximise the CPD time that UK orthotists are given, as 87.1% (61/70) of users reported it was less time consuming to access published research via the Portal compared with their own literature searches. However it is important to explore the feasibility of alternatives to further improve this. As well as improving the overall interface and optimising for mobile use which could improve ease of access to the Portal, an alternative option for the Portal is to expand the site to provide a summary of the evidence for each section, an option which was suggested in free text comments by three survey respondents. This would involve changing the Portal to a “point of care summary” – this describes resources which collate

the evidence in a subject area and present a written summary for healthcare professionals to access, and have been shown to be effective for physicians using such tools as DynaMed and UpToDate (Baxter *et al.*, 2022; Viegas Dias *et al.*, 2022). However one important limitation to recognise is that these tools become quickly outdated (Banzi *et al.*, 2011; Campbell *et al.*, 2015), and converting the Orthotics Evidence Portal to this style would require significantly more resource to allow those updating the Portal to read, synthesise, write and update the summaries. Given that the Portal is currently updated on a monthly basis with no spare resource, changing to a point of care summary is more likely to result in the Portal becoming outdated and ultimately less clinically useful. If more resource can be attained in future however then the option to include a point of care summary could certainly be considered.

2.8. Limitations

Some limitations of this study have been explored in the discussion, including the influence of responder bias in conjunction with the proportion of UK based orthotists who completed the survey, as well as the survey being limited to UK orthotists only.

Additional limitations are recognised due to the wording of questions 15, 16, 17, 24 and 25 [Appendix 38 and Table 2.5] where respondents were given the option of answering “yes, no, or about the same”. For these questions defining the intended meaning of respondents who answered “no” was not fully possible, as this could have meant that respondents noticed no difference in the task, or that the task in question was more difficult.

Table 2.5. Survey questions 15, 16, 17, 24 and 25.

Question number	Wording of question
15	Do you find the current version of DEBOP easier to navigate than the 2015 version?
16	Do you find it easier to locate relevant evidence using the current version of DEBOP compared with the 2015 version?
17	Have you used DEBOP more regularly since it was updated?
24	Do you find it easier to critically appraise the evidence that you access via DEBOP, as opposed to the evidence that you access from your own literature searches?
25	Has using DEBOP made you feel more confident in critically appraising the published research that you read?

The quality of information which could be gained from Google Analytics was a further limitation when evaluating the monthly site visits to the Orthotics Evidence Portal. By working with NHS GGC Knowledge Services, who owned the domain for the Portal at the time of data collection, the page visits for the landing page of the Portal were collated, but this did not include the count number for visitors who used direct links to access other pages of the Portal bypassing the landing page. It was also not possible to gather accurate information on the activity of users accessing the Portal such as the specific pages that they visited or time spent on the site. In combination, these factors may have led to an inaccurate representation of the actual use of the Portal. However, by using the same methodology of data collection for the full time period from March 2016 to December 2023 it was possible to present a reasonable comparison of the pre-2017 and post-2017 periods.

In addition to these limitations, there are a number of further practical and methodological considerations that may have influenced the findings of this study. Firstly, the cross-sectional design of the survey captures only a snapshot of orthotists' engagement with the Orthotics Evidence Portal and their perceptions of its impact on EBP at a single point in time. This approach does not allow for the exploration of how behaviours and attitudes towards EBP evolve over time, or how continued use of the Portal may influence clinical

decision-making in the longer term. A valuable avenue for future research would be to conduct a longitudinal study following orthotists over several years, assessing whether increased familiarity with the Portal leads to sustained changes in EBP engagement and patient outcomes. Such an approach would also help to identify if improvements in ease of access and critical appraisal translate into durable behavioural change.

A further limitation relates to the self-reported nature of the data. Respondent's claims about using EBP or changing clinical practice as a result of the Portal cannot be objectively verified. This may lead to over-estimation or under-estimation of the true impact of the Portal, particularly if respondents wished to present their practice in a favourable light. Future studies could complement self-reported surveys with objective measures, for example, by incorporating usage analytics from the Portal itself, or qualitative interviews exploring specific examples of how research evidence has been applied in practice. Mixed-methods approaches combining quantitative usage data with qualitative insights would offer a more comprehensive understanding of how orthotists interact with and apply evidence.

Another important consideration is that of potential imposter participants, which is a recognised risk of any open access, anonymous survey, where respondents' identities cannot be verified (Morrow *et al.*, 2025). Steps were taken to review respondent responses with regard to completion time and free-text comments, with the aim of identifying any responses that may have been bot-generated or inconsistent with professional knowledge. No responses were excluded on this basis; however, the possibility remains that individuals who were not qualified orthotists may have contributed data. Future studies could mitigate this risk further by distributing surveys only through verified professional channels, employer networks, or password-protected portals, and excluding social media, thereby maximising the possibility that responses are drawn exclusively from verified members of the professional group only, however this does risk limiting potential reach. In addition, incorporating CAPTCHA verification at the point of survey access could help to minimise automated or bot-generated responses, providing further assurance that all data collected originate from genuine human participants.

Practical limitations were also evident in the recruitment and sampling strategy. The study relied primarily on voluntary participation, disseminated via professional networks and online channels. This may have inadvertently excluded orthotists who are less engaged with professional organisations or less confident using digital technologies, thereby skewing the sample towards more research-interested or digitally literate practitioners. Future follow-on studies could employ a mixed digital and in-person sampling approach to encourage representation from different employment sectors, levels of experience, and geographical regions, or collaborate directly with NHS Trusts and private providers to ensure wider and more inclusive recruitment.

Finally, the study focused exclusively on orthotists practicing within the United Kingdom. While this was appropriate for the scope of the research, it limits the generalisability of findings to international contexts, particularly where professional structures, education standards, and digital access vary considerably. Since the Orthotics Evidence Portal is accessible globally, there would be considerable value in undertaking cross-national comparative studies to explore how practitioners in different countries engage with the resource, and to identify whether similar barriers and facilitators to EBP exist across health systems.

2.9. Conclusion

This project described in this chapter has been the product of a 10-year effort to improve access to the orthotic evidence base and to facilitate EBP in the UK orthotic profession. The evaluation described herewith has demonstrated the positive impact of the Orthotics Evidence Portal in terms of improving ease of access to the evidence base relating to orthotic treatment of MSK and diabetic conditions, as well as demonstrating that those orthotists who use the Portal are more likely to access published research and find it less time consuming to do so. The Portal has been shown to have the additional effect of improving the critical appraisal skills of those who use it, a vital aspect of EBP and one which is also considered to be an important element in early career research. Undertaking this evaluation has helped to demonstrate the position of the Orthotics Evidence Portal as a valuable resource for orthotists in area of EBP.

Some limitations have been described in terms of the evaluation and also regarding the Orthotics Evidence Portal as a resource, however as an ongoing project the ability to address these aspects provides the opportunity to continually develop, improve and maintain the Portal for the benefit of the user and to assist implementation of current EBP approaches.

2.10. Concurrent work and future directions

The evaluation described in this chapter was conducted at the end of 2023 following completion of the survey on 29th September 2023. Following this evaluation, the Orthotics Evidence Portal was transferred from its previous host site onto the Right Decision Service. The decision to transfer the Portal was made following user feedback from this survey, regarding the outdated interface and lack of mobile device integration, which has now been addressed. The Orthotics Evidence Portal was formally relaunched in January 2025, and further evaluation is planned for June 2025 to gather feedback from users to assist in evaluating the current changes and guiding the direction of future developments.

The project evaluation identified some barriers to using EBP in clinical practice, one of which was a reported lack of access to the evidence base. This survey was open only to registered orthotists working in the UK, and therefore the vast majority should have access to library services allowing them to read scientific literature. This suggested a possible education issue rather than an access issue, and to address this an additional page has now been added to the Orthotics Evidence Portal which directs users in each of the four UK nations to the relevant library and/or knowledge service for their area.

One of the main barriers which was identified both by users of the Portal and those who did not use the Portal, was the lack of promotion of this resource. In order to address this, the relaunch in January 2025 was designed to coincide with a written advertorial for the professional magazine BAPOConnect [Appendix 11], as well as conference presentations beginning with the Forth conference on 1st February 2025. Social media also offers a prime opportunity to advertise and continue promoting the Orthotics Evidence Portal, with

previous studies demonstrating this method to be associated with accelerated knowledge dissemination (Panahi, Ghalavand and Sedghi, 2021).

Consideration has been given to methods of improving user experience in conjunction with promotion, and in November 2024 the author made a successful funding bid to work with an animator to create a series of animated explainer videos for the Portal, to assist with advertising and also to assist users in navigating the Portal. In keeping with previous studies, it is hoped that this animation will aid education and enhance knowledge of healthcare practitioners using the Portal (Knapp *et al.*, 2022), while also being an effective public relations tool (Srimala, Aueng and Chatwattana, 2023), which will be more effective than the use of static text and images alone (Ploetzner, Berney and Bétrancourt, 2020), and will facilitate a deeper understanding of the subject area (Stadlinger *et al.*, 2021). The completed animation was embedded in the Orthotics Evidence Portal in three parts for the relaunch in January 2025, and has been used to promote the Portal in conference presentations; the animation and conference presentation links can be found in Section 1.4.1.7. of this thesis.

Further development of the Orthotics Evidence Portal is being planned for future, stakeholders from across the UK have already been invited to contribute to an expansion of the subject areas contained within the Portal to include Neurological conditions and Paediatrics, which will maximise the reach of the Portal by covering four of the main subject areas in which UK orthotists specialise (Eddison *et al.*, 2023). However, further expansion will only be viable if the rate of literature reviewing and inputting to the Portal remain up to date. As such, options are being explored to engage more members of the profession to become involved in the process of the monthly literature reviews. One possible option is the development of an associated appraisal club, this would have the intended benefit of offering members the opportunity to improve their critical reading skills (Hohmann and Tetsworth, 2016; McLeod *et al.*, 2010) as a CPD activity (Mohamed *et al.*, 2024), while contributing to an important resource for the orthotic profession. In future it may also be possible to explore the use of automated appraisal, which has not yet proven to be viable (Dos Santos *et al.*, 2023) but with the rate of expansion in artificial intelligence targeted to evidence

synthesis (Fatalla *et al.*, 2023), this may be an option to explore in years to come.

CHAPTER 3. INTEGRATING THE USE OF HARD-SHELL 3D-PRINTED INSOLES INTO THE MSK TREATMENT PATHWAY OF AN NHS ORTHOTIC SERVICE.

3.1. Chapter structure and statement of contribution

This chapter describes a historical project which ran from 2018 to 2021 in the NHS Greater Glasgow and Clyde (GGC) orthotic service, which aimed to integrate the use of computer-aided design and computer-aided manufacture (CAD/CAM) 3D-printed hard-shell insoles into the treatment pathway for patients with lower limb musculoskeletal (MSK) pathology. The project takes the form of a clinical evaluation with two-year follow-up. The project work described within this chapter has been published as an original peer-reviewed research article which is presented as a full PDF in Appendix 40.

Article publication: *The effectiveness of custom hard-shell 3D-printed foot orthoses in a cohort of patients who did not respond to treatment with custom ethylene-vinyl-acetate (EVA) foot orthoses. Barr L, Munro N, Watters K, McCaig R, Richards J, Chapman GJ. The Foot. 2024 Dec; 61:102142. doi: 10.1016/j.foot.2024.102142.*

This chapter presents an extended version of this publication, offering additional details and context to the project.

The chapter begins with an introduction to the subject area, followed by a description of how the project was designed to fill a gap in this knowledge base. The specific objectives and hypotheses of the project are described, and the methods and results of the clinical evaluation and two-year follow-up are then presented. The chapter concludes with a discussion of the study findings and their relevance to the existing evidence base, along with suggestions for future research to build on the knowledge generated by this project.

3.1.1. Contribution by L Barr

The author developed the concept of the project, carried out the literature review, designed the methodology for the study, developed the process for integrating 3D printing into the NHS GGC CAD/CAM workflow, led the clinical

evaluation, contributed to data collection and analysis, led the writing of the publication, led the review and editing of the final article, and was first author on the final publication.

3.2. Introduction

3.2.1. Insole materials

Considerable variation exists in the orthotic profession in relation to the types of materials from which insoles are constructed. In order to understand the relationship of these materials to the clinical outcomes associated with treatment, it is first important to outline the most common materials used in practice.

In the orthotic profession, materials will often be referred to by their trade name rather than the chemical compound or material type, an example of this is "Poron ®" which is the trademarked name of a foamed form of polyurethane (PU) widely used as a cushioning material for various purposes in the orthotic profession (Eddison *et al.*, 2022; Faulí *et al.*, 2008). In order to disambiguate the use of materials in this chapter, Table 3.1 lists the compound names which will be used to describe the associated tradenames throughout. This table has been adapted from the schematic figure presented by Nilsen *et al*. (2022), and expanded and verified against the individual data sheets from the associated manufacturers.

Table 3.1. Material types and their commonly used trade names (adapted from Nilsen *et al*., 2022).

Material type / compound	**Trade name**
Foamed polyurethane (PU)	Poron®, PPT®, AstroShock®
Foamed polyethylene (PE)	Pe-lite®, Plastazote®
Thermoplastic PE	Ortholene
Foamed ethylene vinyl-acetate (EVA)	Evazote®, Algefoam, Lunalight®
Foamed rubber	Spenco®, Spencore®

Three recent systematic reviews have described the materials associated with insole prescriptions for different areas of orthotic practice. Mendes *et al*. (2020) conducted a systematic review specifically investigating the use of insoles in the treatment of MSK conditions, and reviewed the material properties used for each study. This review found that the majority of studies (n=8) used foamed EVA as a material in their insole design, three used cork, and one study each investigated insoles constructed with other materials including polypropylene, foamed PE, and silicone gel, and seven studies did not quantify the material that they used to manufacture the insoles. A further systematic review in 2020 investigating the effect of material choice of insoles on plantar pressures of the foot, identified five studies, each investigating a different material which included; foamed PU, foamed PE, foamed EVA, thermoplastic polypropylene, and carbon composite (Gerrard *et al.*, 2020). Following these publications Nilsen *et al*. (2022) conducted a systematic review specifically investigating materials used in the prescription of insoles for diabetic foot conditions. This review identified 37 studies which used a variety of materials, the most common being foamed EVA which was used in 16 of the studies, with other materials including cork, thermoplastic PE, thermoplastic polypropylene, thermoplastic Nylon, foamed PU, foamed PE, and foamed rubber. With a specific focus on the UK, two cross-sectional studies have shown a the majority of insoles to be prescribed from foamed EVA as opposed to harder materials; in a study of orthotists, podiatrists and physiotherapists across the UK it was found that the majority (62.3%) of respondents most frequently used foamed EVA for custom insoles, and this was the most commonly used material among all three professions (Nester *et al.*, 2017), and in the orthotic UK profession a total number of 51326 foamed EVA insoles were prescribed between 2015-2016 compared with only 4514 insole prescribed from harder plastics (Chockalingam, Eddison and Healy, 2019).

These studies show a commonality of material types used in the production of insoles, with foamed EVA being the most common in the treatment of MSK and diabetes, but despite this there is a clear demonstration of variation in the materials being used, suggesting that different materials may be required for

different treatment scenarios. Within all studies using EVA, and all but two studies using PU, the foamed version of these materials is used, and as such for the duration of this chapter they will simply be referred to as EVA and PU. However both the thermoplastic (harder) and foamed (softer) versions of PE are described frequently in the studies, and therefore the terms “thermoplastic PE” and “foamed PE” will be used to differentiate these where relevant.

3.2.2. Material hardness

In mechanical terms, hardness is defined as the resistance to surface deformation exhibited by a material under load (Gilman, 2009). Given the application of insoles as devices which are placed under the foot and exposed to repetitive compressive load, material hardness should be one of the primary considerations in the prescription of insoles. Hardness can be classified on various scales, but with insoles primarily being constructed from foamed rubbers, plastics and composites, the most common classification is Shore hardness testing (Zhao, Allanson and Ren, 2015). The Shore hardness durometer test can be performed using different scales dependent on the hardness of the material, with Shore OO scales being used for very soft materials, Shore A scales for soft and medium materials, and Shore D scales for hard and extra hard (Mohamed and Aggag, 2003). The outcome of the test is presented on a scale of 0 to 100, with higher values indicating harder materials, with a degree of overlap between the Shore OO, Shore A and Shore D scales (Qi, Joyce and Boyce, 2003), allowing for an approximate comparison of materials measured using different scales (Esteves *et al.*, 2021). The hardness of the material is written as Shore OO/A/D to denote the type of test undertaken, followed by the numerical outcome of the test, for example “Shore A70”, which would have an approximate value of Shore D20 on the equivalent durometer D test [Figure 3.1]. The hardness of materials can be altered by production aspects such as composite blending and heat treatments (Eroglu, 2007; Junior *et al.*, 2021; Sasikala and Kala, 2018), resulting in a variety of hardness options for individual materials, for example, EVA Shore A25 to A70 and PU Shore A15 to A30, all of which have wide commercial availability. The precision of the Shore testing method is highlighted by its compliance with the American Society for Testing and Materials standards D2240 and F1957, which

offer guidelines for assessing the hardness of foams and plastics (Zhao, Allanson and Ren, 2015). In light of the standardisation of these tests, manufacturers of orthotic materials will generally provide the Shore values to the customer, allowing these values to be presented in publications of studies investigating orthotic devices, but also allowing investigators the opportunity to systematically test the materials themselves (Peng *et al.*, 2023; Chatzistergos *et al.*, 2017). Studies investigating common materials used in insole manufacture have also demonstrated Shore hardness to correlate with other mechanical properties which are routinely considered when prescribing insoles, such as tensile strength and energy absorption (Pabón-Carrasco *et al.*, 2021), further highlighting the importance of considering material hardness when prescribing insoles.

Figure 3.1. Comparison of durometer scales for Shore OO, A and D tests, adapted from Qi, Joyce and Boyce, 2003.

Shore A test							10	20	30	40	50	60	70	80	90	100					
Shore D test										10			20		30	40	50	60	70	80	90	100
Shore OO test	10	20	30	40	50	60	70	80		90					100							

3.2.3. Materials in clinical practice

Despite the relevance of hardness to the prescription of insoles, there remains little clinical guidance when it comes to deciding on the most effective material hardness associated with patient outcomes in the treatment of MSK conditions. The aforementioned systematic review conducted by Mendes *et al*. (2020), investigating insole properties in the treatment of lower limb MSK pathology, concluded that variation in the types of insoles used, inconsistency in documenting the material type, and a lack of material evaluation linked to the outcome of treatment, means there is little discernible criteria by which clinicians can be guided in their clinical decision making regarding material choice.

Sections 3.2.3.1 to 3.2.3.11 of this chapter will consider the existing literature on the subject of insole hardness and its relevance to the treatment of patients with MSK lower limb pathology.

3.2.3.1. Insole hardness and the effect on plantar pressures in those with diabetes

Throughout the body of literature, certain pathologies such as diabetes, or themes such as plantar pressure measurements are more commonly investigated in relation to material choices, and should be considered for their potential relevance to MSK pathology.

In 2014, a randomised controlled trial (RCT) compared plantar pressures for diabetes patients using custom soft (EVA Shore A35) insoles and custom harder (EVA Shore A55) insoles, concluding that both types of insole were equally effective at reducing the heel pressure compared with a flat control, and found no difference between the two custom EVA insoles in terms or pressure reduction or patient satisfaction after 2 years (Tang *et al.*, 2014). This clinical study contrasted with an earlier theoretical study using computational foot models to estimate the effect of insole materials on plantar pressure in the diabetic population, which concluded that softer material tested from a range of Shore A30, A40 and A50 insoles, were more likely to reduce plantar pressures than harder materials (Cheung and Zhang, 2008). Despite the contradictory findings between these two studies, a further clinical study in 2022 invested the effectiveness of plantar pressure reduction in diabetic patients aged 50-70 comparing soft insoles (PU Shore A18 and EVA Shore A25) and hard insoles (foamed PE Shore A30 and EVA Shore A58), and found that softer materials did reduce plantar pressures more than the harder materials (Shi *et al.*, 2022). However comparison between this study and the former clinical study is limited as the insoles used in the later study (Shi *et al.*, 2022) were not custom made to the patients feet, and the insoles used in the earlier study (Tang *et al.*, 2014) corresponded more closely to the hard condition used by Shi *et al*. (2022). Plantar pressure has been shown to correspond with the progression of diabetic neuropathy and the development of foot ulceration (Abri *et al.*, 2019), and is therefore considered an important aspect in the care of the high risk diabetic

foot, in this respect studies have also investigated the cushioning effect of simple flat insoles in relation to plantar pressures, finding that insoles spanning from very soft (Shore OO2 and OO53) to soft (Shore A 15 and A30) all had the ability to reduce the minimum and maximum plantar pressures of the foot, but with the firmer material being the most effective (Tong and Ng, 2010). The effect of plantar pressures on the development of diabetic foot ulceration is well understood (van Netten *et al.*, 2024), however the effect of pressure on the development and treatment of MSK foot pathology is less clearly defined, with the development of MSK conditions thought to be more closely associated with biomechanical issues and physiological factors such as age, physical activity level, and health characteristics (Haas *et al.*, 2023). Therefore measuring the effect of insole materials on plantar pressures is not indicated to be the most relevant outcome when treating lower limb MSK pathology.

3.2.3.2. Insole hardness and the effect on plantar pressures in those with MSK foot pathologies

In relation to a specific MSK pathology of plantar fasciopathy, the relevance of plantar pressures has also been considered. In 2024 a RCT investigated the clinical outcomes associated with the use of moulded pre-fabricated carbon fibre vs prefabricated thermoplastic PE vs prefabricated PU in the treatment of patients with plantar fasciitis (Taseh *et al.*, 2024). The Shore hardness of the prefabricated insoles used by Taseh *et al*. (2024) are unknown, but classified by the authors as ranging from carbon fibre and thermoplastic PE being the hardest, to PU being the softest. This study concluded that carbon fibre and thermoplastic PE were the most effective due to improved pain outcomes compared with the softer PU; which is in contrast to a prior study by Gerrard *et al*. (2020) who found that PU was superior to PE in terms of plantar pressure reduction, and therefore calls into question the relevance of plantar pressure reduction in the treatment of plantar fasciitis. However it is relevant to note that Taseh *et al*. (2024) used the thermoplastic version of PE which is harder than the foamed PE version discussed by Gerrard *et al*. (2020) and is not directly comparable. It is important to note that the harder materials in this MSK scenario produced improved patient reported outcomes to those observed with the softer materials. This study by Taseh *et al*. (2024) is also consistent with the

findings of a prior RCT which compared the effect of three types of insoles on the outcome of pain, which included soft insoles manufactured from EVA, duel foamed PE and PU, and hard thermoplastic insoles (Walther *et al.*, 2013), concluding superior pain reduction with the hardest insoles. The results are however not directly comparable due to the addition of targeted heel cushioning included in the thermoplastic insole design, coupled with a failure to disclose the Shore hardness of any of the insoles used in the trial. A study comparing the use of hard contoured carbon fibre insoles compared with soft contoured PU insoles in healthy participants (Ko, Ma and Xiong, 2023), found that the harder insoles were more likely to improve power generation during sports, and also increased muscle activation but were subjectively less comfortable than the softer insoles. Although this study examined healthy participants, the findings could be of relevance to patients with plantar fascia pathology when combined with previous studies which found full length carbon fibre insoles to reduce plantar fascia tension (Lin *et al.*, 2013). However the effect of harder full length insoles does not necessarily consistently relate to superior outcomes, with a further study finding greater improvements in plantar fascia pain after 6 months when using moulded EVA and cork insoles, compared with full length thermoplastic insoles (Coheña-Jiménez, Pabón-Carrasco and Pérez Belloso, 2021). The clinical relevance of this study is unknown, as the insoles were not directly comparable in terms of design, with the hard insole being a prefabricated flat design, compared with a custom moulded softer EVA and cork. Furthermore the specific materials used and their related hardness was not disclosed, making it difficult to determine the clinical relevance of the material choices.

In further consideration of insole materials in the treatment of specific MSK pathology, one study investigated patient reported outcomes and plantar pressures in the treatment of patients with midfoot osteoarthritis (Rao *et al.*, 2009). The study compared flat full length hard carbon fibre insoles with softer moulded 3/4 length insoles, the hardness values of which were not specified, and concluded improved symptomatic relief with flat carbon. As considered previously, it is possible that the biomechanical effect of the carbon fibre insole on muscle activation and plantar tissue tension (Lin *et al.*, 2013; Ko, Ma and

Xiong, 2023) could be a causative factor in the positive patient reported outcomes observed in this study. It is however not possible to ascertain if the outcomes of the study were exclusively related to the harder material choice, as the moulded dimensions of the softer insoles were not used in the construction of the harder carbon insoles, and were therefore not directly comparable.

3.2.3.3. Insole hardness and the effect of flat and contoured designs

The outcome of studies investigating the use of flat, non-contoured insoles as described in various studies above (Rao *et al.*, 2009; Lin *et al.*, 2013; Coheña-Jiménez, Pabón-Carrasco and Pérez Belloso, 2021), should be considered in relation to the differing effects of plantar tissue compression observed with the use of contoured orthoses compared with flat orthoses. The relevance of plantar tissue compression can be considered in relation to various MSK pathologies including plantar fasciopathy, fat pad atrophy, nerve impingement and bone marrow oedema (Landorf, 2015; Rosenbaum, DiPreta and Misener, 2014). Studies investigating compression of the plantar heel tissues have shown that contoured devices reduce compression of the plantar tissues more than flat devices constructed with materials of the same shore hardness (Shore A59) (Telfer, Woodburn and Turner, 2014). This effect is further enhanced by reducing plantar heel pressure when a soft top layer is overlaid on a harder contoured insole (PE Shore A50 and top layer Shore A25), compared with a flat softer insole (PU Shore A20) (Bonanno, Landorf and Menz, 2011). The effect of reduced heel compression and heel pressure seen in these studies has also been observed by a study investigating hard-shell plastic heel cups, whereby compression of the plantar heel pad was reduced during weight bearing when wearing a contoured plastic heel cup as opposed to standing on a hard flat surface with no insole (Lin *et al.*, 2022). The effect of the reduced compression and pressure observed in these studies is assumed to be related to increased mediolateral containment of the heel tissues in harder insoles preventing “spread” of the plantar tissues on weight bearing, but it is unknown if this mechanism positively influences patient reported outcomes relating to MSK pathology, such as pain and function.

3.2.3.4. Insole hardness and the effect on patient reported outcome measures

As highlighted previously, the use of plantar pressure measurements may not be the most relevant consideration when aiming to determine the effectiveness of insoles in the treatment of patients with MSK conditions, and thus using outcome measures which evaluate insole materials in terms of patient reported outcomes may be of greater clinical significance. Several studies have considered the outcome of patient reported comfort related to material choice for insole prescriptions, with varying outcomes. One study invested three contoured prefabricated EVA insoles of Shore hardness A52, A60 and A75 and a flat EVA Shore A52 insole and found that there was no relation to hardness and comfort (Mills, Blanch and Vicenzino, 2011). These findings were contradicted by a previous study involving asymptomatic military recruits using custom and prefabricated soft insoles manufactured from PU Shore A45 vs harder thermoplastic PE insoles, and found increased comfort reported with the use of softer insoles (Finestone *et al.*, 2004). The contradiction in these studies makes it difficult to draw any clinical conclusions, and the use of healthy participants is not necessarily reflective of those who present with MSK conditions. Similarly, other studies involving non-symptomatic participants have demonstrated differences in comfort related to material hardness, with one studying reporting that harder insoles were rated lowest for comfort among a full cohort of military recruits, but that sub group analyses showed hard insoles were preferable to participants who had lower medial arch heights (Mündermann, Stefanyshyn and Nigg, 2001). In contrast a study by Lo *et al*. (2018) investigated the use of triple layer insoles varying from Shore A18 to A28 hardness, and concluded that the hardest insole was perceived as the least comfortable, with these findings corresponding to a greater reduction in plantar pressures with the softer insoles. Another study also investigating multi-layered insoles, with a triple layer design of nine insole variations constructed from three materials (soft Shore A23, medium Shore A45, and hard Shore A59), concluded that healthy participants preferences were related to the hardness in the arch area specifically, preferring a differential of harder arch and softer forefoot/hindfoot; therefore increased arch pressure resulted in the perception of a more comfortable insoles (Anderson, Williams and Nester, 2020). This finding

may correspond to the conclusion drawn by Mündermann, Stefanyshyn and Nigg (2001), whereby participants with lower arch heights reported better comfort scores when wearing insoles manufactured from harder materials, which it is assumed would increase pressure in the arch area. Studies which link comfort outcomes to material hardness in participants with MSK conditions are scarce, one study investigating anterior knee pain using insoles of varying hardness (hard Shore A75, medium Shore A60, and soft Shore A52) found a similar distribution of comfort ratings with the use of all insoles, with the only significant finding being an increase in muscle activity of vastus lateralis in participants who reported discomfort with any insole, but as this was not linked specifically to material hardness, the relevance of this change in muscle activity is unclear (Mills, Blanch and Vicenzino, 2012).

3.2.3.5. Insole hardness and the effect on pes cavus and pes planus foot types

Foot type, as classified by systems such as the Foot Posture Index (Redmond, Crosbie and Ouvrier, 2006), may not necessarily be associated with the development of MSK pathology (Shultz *et al.*, 2017; Nester *et al.*, 2014), but can nonetheless be a useful aspect of patient assessment to identify joint mobility and soft tissue stresses when MSK pathology is present (Kerr *et al.*, 2019; Menz *et al.*, 2013; Burns *et al.*, 2005). One study investigated the use of insoles manufactured from different materials in the treatment of individuals with a chronically painful pes cavus foot type, comparing custom contoured hard 3/4 length polypropylene insoles and soft flat foamed latex, concluding that the hard insoles improved foot pain, foot function, and plantar pressures (Burns *et al.*, 2006). However as the insoles in this study were not comparable in terms of morphology it is not possible to conclude if the use of the harder material or the use of the custom contoured design was the most relevant factor in the outcomes. A further study investigated the use of insoles manufactured from Shore A30, A35 and A42 with varying arch heights in a cohort of participants with a pes plaus foot type, and undertook additional finite element modelling to determine intra-joint stresses and ligament stresses of hindfoot and midfoot joints, all of which were found to increase with harder materials (Su *et al.*, 2017). This study may provide some insights into the biomechanical effects of harder insoles in the treatment of patients with MSK foot pathology in terms of

the effect on increasing soft tissue and intra-joint stresses, but it is relevant to note that although the participants in this study presented with a pes planus foot type, this was not necessarily indicative of any underlying MSK pathology, and so the possibility of clinical improvements in a symptomatic cohort cannot be determined.

3.2.3.6. Insole hardness and the effect of body mass index

Some MSK conditions of the foot are known to be associated with higher body mass index (BMI) (Butterworth *et al.*, 2012), with higher BMI also being shown to affect foot function with regard to plantar loading forces in gait (Telfer and Bigham, 2019; Walsh *et al.*, 2017), thus the consideration of BMI in the prescription of insoles is a possible area of relevance. Two studies by Chatzistergos *et al*. (2017 and 2023), investigated the relationship of material hardness to BMI, using gait analysis and plantar pressure measurements, with participants wearing insoles varying in hardness from PU Shore A10 to Shore A40. The first study in 2017 concluded that optimal offloading of the foot in participants with higher BMI was achieved with harder materials however, as the cohort was comprised of healthy volunteers this did not necessarily correspond to optimising treatment outcomes (Chatzistergos *et al.*, 2017), however the subsequent study in 2023 did investigate a pathological cohort of participants with diabetic neuropathy (Chatzistergos *et al.*, 2023). The cross-sectional follow-up study was undertaken using the same insole designs from Shore A10 to Shore A40, and concluded that the results from the healthy volunteers were indeed consistent with the results in a diabetic patient group, recommending the use of harder insoles to optimise offloading properties in patients with diabetic neuropathy. It is however important to note that these studies involved the use of flat insoles, and as previously discussed, the use of contoured insoles can present different outcomes in relation to material hardness which may be of relevance to MSK pathologies.

3.2.3.7. Insole hardness and the effect on shock attenuation

Shock attenuation, which describes the magnitude of an impact as it travels from the point of contact through the limb (Edwards, Derrick and Hamill, 2012) has been suggested as contributing factor in the development of some MSK

pathologies of the lower limbs (Reenalda *et al.*, 2019; Grech, Formosa and Gatt, 2016), and is therefore an aspect of consideration in the selection of materials for insoles. Butler *et al*. (2003) compared the effect of different insole materials on shock attenuation and hindfoot motion in healthy runners, and found no significant difference between custom soft insoles manufactured from EVA Shore A60 and custom hard thermoplastic PE. A previous study demonstrated a positive improvement in shock attenuation using a variety of soft flat PU insoles measured during running in healthy volunteers (Windle, Gregory and Dixon, 1999). However, differences in the methods demonstrated by the two studies, coupled with the lack of disclosure of Shore hardness values of materials in the Windle, Gregory and Dixon (1999) study, means it is not possible to draw firm conclusions between the effect of material hardness on shock attenuation and the possible implications in the treatment of MSK pathologies. In a more recent study, the ability of different insole materials to absorb shock was measured in laboratory conditions, investigating 21 different types of materials including EVA, PU, foamed PE, cork and foamed Latex, with the material hardness ranging from the softest (foamed latex) Shore A14 to the hardest (foamed PE) Shore A62 (Pabón-Carrasco *et al.*, 2021). Contrary to the earlier findings by Windle, Gregory and Dixon (1999), this study found that softer materials performed more poorly in terms of their ability to dampen shock than harder materials. However there were also differences in the shock absorption abilities of different material types with similar hardness values, for example EVA generally absorbed shock better than PU of equivalent hardness. These results suggest that the consideration of harder materials may be of benefit when shock absorption is a factor in insole prescription, but the hardness should be considered in tandem with the type of material in order to maximise dampening effects (Pabón-Carrasco *et al.*, 2021).

3.2.3.8. Insole hardness and the effect on balance, posture and stability

Dynamic postural balance is known to be related to foot and ankle function (Wei *et al.*, 2022) and has an implication in the development of lower limb injuries (Cobb *et al.*, 2014), as such the effect of insole materials on balance, posture and stability should be a consideration in the prescription of insoles for MSK pathology. In 2015, a study investigating healthy adults compared the use of flat

thermoplastic PE insoles with the same design of flat soft PU and flat soft EVA, finding that hard insoles had a more positive effect on dynamic postural stability than soft insoles (Qu, 2015). The results of this study aligned with a previous study which compared the use of soft gel insoles with prefabricated hard EVA A50 insoles, and determined that the hard insoles were more effective in reducing postural sway (Iglesias, de Bengoa Vallejo and Peña, 2012). In a more recent cross-over trial, prefabricated soft gel insoles were compared with hard prefabricated thermoplastic insoles with a soft top cover, and found that hard insoles provided greater stability than soft insoles, suggesting that soft insoles may actually impair balance and stability (Martínez-Córcoles *et al.*, 2024). These studies all suggest that the use of harder materials has a more positive effect on posture, balance and stability, however the healthy participant cohorts used in all three studies mean that the results may not be applicable to those with lower limb pathology.

3.2.3.9. Insole hardness and the effect on active, sporting and military populations

There is known to be a high prevalence of MSK pathology in active, sporting and military populations through overuse or traumatic injury, leading to the requirement for effective treatments both in the long and short term (de la Motte *et al.*, 2019; Goes *et al.*, 2020). As such, studies investigating the effect of different materials in the treatment of these populations is important in the consideration of optimising outcomes. Several studies have investigated the effect of insole materials specific to the environments experienced during sporting and military activities, with conflicting results. In a study by Peng *et al*. (2023), healthy participants were asked to undertake hiking in mountaineering conditions while wearing backpacks, and plantar foot pressures were measured comparing hard insoles manufactured from Shore A50-52, with soft insoles manufactured from Shore A16-22. The study concluded that higher plantar pressure values were observed when wearing the hard insoles, but were unable to relate this to patient outcomes in relation to pathology or injury to support clinical guidance (Peng *et al.*, 2023). A similar study measured plantar pressures and perceived comfort associated with soft PU insoles compared with harder duel material PU and viscoelastic composite insoles when walking with

loaded backpacks (Melia *et al.*, 2021). Findings showed that soft insoles were more effective in reducing plantar pressure than harder insoles, but with no effect in the perceived comfort of wearers. This was tested under normal gait conditions while wearing a backpack, in healthy individuals, and therefore could not conclude any relationship to foot pathology and patient outcomes. This study attributed the pressure differences to greater deformation of the material when using soft insoles, an effect which has been described as both desirable and undesirable in the literature. Prior studies have described this effect as "enveloping" whereby the insole conforms around the foot resulting in pressure reduction (Tsung *et al.*, 2004; Butler *et al.*, 2003; Rome, 1991) but also in terms of "over deformation" which negatively influences the shock absorbing properties of softer materials resulting in negative performance of shock attenuating properties (Melia *et al.*, 2021). In a subsequent study which built on the findings from Peng *et al*. (2023), mountaineers wore prefabricated contoured medium hardness insoles (Shore A30 at the arch) and hard insoles (Shore A44 at the arch), measuring plantar pressures and perceived comfort, and in contrast to the prior studies, found superior results both in terms of comfort and plantar pressure reduction with the harder insoles (Tai *et al.*, 2024). All three of these studies used healthy volunteers which limited the ability to reliably inform clinical practice for MSK pathology, and presented contradictory results in terms of the outcomes measured, suggesting that further investigation will be required to guide clinicians in clinical decision making. As a final consideration to the effect of insole hardness and sports injuries, one study investigated the effect of prefabricated contoured insoles manufactured from Shore A32-36 and Shore A44-49 hardness on the occurrence of haemolysis in runners, which is thought to occur as an result of high impact forces, concluding that hard insoles more effectively reduce haemolysis in runners compared to soft insoles (Janakiraman, Shenoy and Sandhu, 2011). As the development of haemolysis is suspected to be related to impact forces, this study supports the previous findings that suggest harder insoles may more effective in absorbing shock than softer materials (Pabón-Carrasco *et al.*, 2021). However, as with the majority of publications discussed in terms of the sporting population, this study

used healthy participants, making it difficult to translate these findings into the clinical setting.

3.2.3.10. Clinical tests and the prescription of insole material hardness

When assessing patients in a clinical environment, the use of clinical tests can help to guide prescriptions for treatment, however there are a lack of clinical tests shown to guide the material choices for clinicians prescribing insoles for MSK conditions. The supination resistance test is a validated clinical assessment used to quantify the force required to supinate the foot in stance (Griffiths and McEwan, 2012). It has been suggested that there is a relationship between greater supination resistance of the foot, and the ability of insoles to affect midfoot and hindfoot moments with medial hindfoot wedging in terms of lower limb biomechanics (Payen *et al.*, 2024). Studies have also shown that the use of insoles with medial wedging can reduce the supination resistance of the foot when treating MSK pathologies of the foot and ankle (Moisan *et al.*, 2023), and suggests that the ability to reduce supination resistance can have a positive effect on midfoot power generation in gait (McBride *et al.*, 2019). Despite the relevance of these prior studies in providing clinical guidance to clinicians when prescribing insoles, the researchers did not extend their investigations to the use of material choice, and so it is not possible to determine if different material hardness would affect supination resistance.

3.2.3.11. Categorisation of “hard” and “soft” insole materials

One of the themes noted throughout the review of the literature is the inconsistency in the terminology describing materials as “hard” and “soft”, with variation in studies classifying soft from Shore OO2 (Tong and Ng, 2010) to Shore A52 (Mills, Blanch and Vicenzino, 2011), and hard from Shore A15 (Tong and Ng, 2010) to Shore D58 and 60HB (Casado-Hernández *et al.*, 2023). This wide variation in terminology could be a confounding factor for clinicians trying to interpret and translate the findings in to clinical practice, as the results are often not directly comparable, and can appear contradictory. This is compounded by a failure by some researchers to disclose a description of the materials being used in the studies, adding further to difficulties in appraising the applicability of the outcomes to clinical practice. In conjunction, this literature

review has shown a lack of studies investigating the effectiveness of insole materials on patient reported outcomes of those with MSK foot and ankle pathology, meaning there is little guidance for clinicians as to the most appropriate materials to use to improve common MSK complaints such as pain and impact on lower limb function. In general there requires to be more transparency of insole prescription throughout the literature, in conjunction with clinically relevant studies which investigate insole material hardness from the perspective of a standard clinical caseload in patients with MSK pathology.

3.2.4. Insole materials and computer-aided manufacture

The choice of material hardness can be limited by the method of insole manufacture. In CAD/CAM systems there are two main manufacture options; reduction manufacture with computer numerical control (CNC) milling which involves creating an insole by carving it out from a block of material, or addition manufacture also known as 3D printing where the insole is constructed by building material in layers. CNC milling machines used in insole manufacture have to be calibrated to accurately mill the most common materials without distorting the materials (Watasuntonpong, Pimsarn and Tantrapiwat, 2019). The drill bits, spindles and base plates used to mill and stabilise the materials during manufacture therefore have to withstand the specific forces applied to them, while permitting manufacture from materials with a range of hardness values (Anggoro *et al.*, 2021). Studies testing the parameters of CNC milling for insoles have shown a complex relationship between material hardness and spindle speed, vibration and surface roughness, meaning that CNC machine tolerance is limited to mill a finite range of material hardness values, which in a 2019 study was shown to be optimal between EVA Shore A20 to A60 (Anggoro *et al.*, 2019). A follow-up study experimented with optimising CNC milling for different material hardness using alternating spindle speeds, and showed increased vibration with harder materials up to a tolerance of EVA Shore A66 (Anggoro *et al.*, 2022).

Additive manufacture can offer opportunities to integrate harder materials into the CAD/CAM insole workflow, without the restrictions of CNC milling. Harder 3D-printed materials such as Nylon Shore D58 (Mo *et al.*, 2019) and

thermoplastic PU Shore A92 (Iacob *et al.*, 2024) have been shown to be effective in clinical practice, and have positive outcomes in terms of durability (Shaikh, Jamdade and Chanda, 2023). The precision of additive manufacture using honeycomb architecture can also be used to manipulate the properties of materials to vary the Shore hardness, for example thermoplastic PU Shore A97 can be printed to achieve a final insole hardness of Shore A40 to A70 (Allado *et al.*, 2021), demonstrating that 3D printing has a wide application to print the same material hardness values used in reduction CNC milling, as well as allowing for the production of harder materials.

Despite the manufacturing advantages, 3D printing remains a less common method of insole manufacture than reduction milling for UK health professions, with a UK mixed-methods cross-sectional survey showing that less than 3.0% of Allied Health Professionals (AHPs) prescribing insoles had ever used 3D-printed materials (Nester *et al.*, 2017). The results of studies investigating the use of 3D-printed insoles for MSK conditions are encouraging, showing that hard thermoplastic PU 3D-printed insoles Shore A90-95 are effective in alleviating pain (Shaikh, Jamdade and Chanda, 2023), but unfortunately it is not possible to determine if the outcome of such studies are due to specific material choice, or simply the prescription of a custom insole, a conclusion which was also determined from a recent systemic review of 3D-printed insoles (Daryabor *et al.*, 2023). As such, more evidence is needed to assist clinicians in decision making when it comes to the use of 3D printing for insoles, specifically to understand the possible benefits of increasing material hardness and the opportunities that 3D printing offers in this regard within CAD/CAM workflows.

3.3. Background to the project

As described in Chapter 1, the NHS GGC orthotic service had exclusively used CAD/CAM with reduction milling to manufacture custom insoles since 2006. This meant the service was restricted to the manufacture of insole hardness values between Shore A25 and Shore A70, due to the limitations of CNC reduction milling machines as discussed in Section 3.2. The NHS GGC foot and ankle treatment pathway at this time advocated the use of custom insoles if first and second line interventions such as stock insoles and exercises were

unsuitable or ineffective (Munro, 2014), meaning that patients treated in the orthotic service would be offered custom EVA insoles manufactured from Shore A25 to Shore A70. Within this pathway, if these custom insoles were ineffective then patients would be escalated either to more restrictive proximal interventions such as ankle-foot-orthoses (AFOs) or referred to other services for consideration of more invasive treatments such as surgery. Models of care focusing on improving patient outcomes for MSK conditions and minimising pressures on health services has been highlighted as a global priority (Blyth *et al.*, 2019), and in this respect it is important that patients are guided to the right care at the right time, avoiding unnecessary invasive treatments. In the UK, the NHS set out the RightCare agenda, which aimed to optimise treatment pathways including those for musculoskeletal services. By focusing on patients receiving the right care, in the right place, at the right time, adoption of the RightCare approach has facilitated a reduction in secondary care referrals by 30% (NHS Merton, 2017), and highlights the importance of ensuring that treatment pathways are optimised.

3.4. Knowledge gap

A potential gap in the NHS GGC MSK treatment pathway was identified as a result of the CAD/CAM workflow limitations, meaning that custom hard-shell insoles were not included in the standard treatment pathway. The RightCare agenda highlighted the importance of ensuring that the NHS GGC foot and ankle treatment pathway was optimised to reduce the patient journey through the healthcare system, and thus investigating the potential effectiveness of additional non-invasive treatments such as hard-shell insoles was important in order to understand if this could offer an alternative to escalation for more invasive treatments. Making a case to introduce hard-shell insoles as a treatment option was limited by the lack of evidence relating to insole hardness above Shore A70, as discussed in Section 3.2, as well as the conflicting outcomes relating to the benefits of both harder and softer insole materials in terms of MSK treatment outcomes.

3.5. Objectives

Given the knowledge gap, there was a need to simultaneously address the gap in the MSK treatment pathway by identifying a means of introducing hard-shell insoles into the CAD/CAM workflow, while also determining the effectiveness of hard-shell insoles in the treatment of MSK lower limb conditions for patients who did not respond to standard treatment with custom EVA insoles. The combination of these two objectives would help to evidence the best position of hard-shell insoles within the MSK foot and ankle treatment pathway, in order to assist with clinical decision making.

3.6. Hypotheses

In order to meet these objectives, the study described in this chapter explored the hypothesis that 3D printing could be used within the existing CAD/CAM workflow in NHS GGC orthotic service as an alternative to reduction manufacture. In doing so, hard-shell insoles could be manufactured, providing the opportunity to evaluate if insoles manufactured from harder materials would be effective in improving outcomes for those patients with lower limb MSK conditions who had not responded to treatment with custom CAD/CAM EVA insoles. It was hypothesised that if harder insoles were effective then patients would not require escalation to more proximal orthoses or to other services within the MSK treatment pathway after two years.

3.7. Methods

3.7.1. Patients

Patients were treated by three orthotists from the orthotic service in the NHS GGC Health Board. Patients were eligible to be fitted with custom hard-shell 3D-printed insoles if they were; aged ≥ 16 years old, presented with a musculoskeletal pathology of the lower limb, and did not report an improvement in pain following 12 weeks of treatment with custom EVA insoles; this is in keeping with standard practice, with previous studies identifying that improvements with insoles are expected within this time scale (Rasenberg *et al.*, 2021; Bishop, Thewlis and Hillier, 2018; Trotter and Pierrynowski, 2008; Xu

et al., 2019). There were no limitations regarding the specific clinical presentations or musculoskeletal pathology, resulting in a heterogeneous patient cohort, which represents a general orthotic clinical case-load. Patients were not eligible to be fitted with custom 3D-printed insoles if they required full length insoles as the 3D printing system was limited to the manufacture of ¾ length orthoses, had an active ulceration, or required insoles with a top cover as it was not possible to attach a top cover to the 3D-printed insole. All data were collected as part of routine patient care, in keeping with standard NHS GGC orthotic service processes, and approved by the orthotic professional lead for NHS GGC.

3.7.2. Clinical assessment

Patients' age, sex, and musculoskeletal pathology were collected at baseline followed by a biomechanical assessment which included the validated manual supination resistance test (Noakes and Payne, 2003), to establish the force (high, moderate or low) required to manually supinate the foot. Using a goniometer, passive ankle dorsiflexion range of motion (ROM) was measured at the position of first detectable resistance when passively moving the ankle into dorsiflexion from a plantigrade position. Ankle ROM was considered limited if less than 10° and considered normal if over 10° (Araújo *et al.*, 2011). To assist with insole prescription, other biomechanical assessments were carried out if deemed clinically relevant for individual patients including visual gait analysis, Jacks test or the modified Jacks test for functional hallux limitus (Sánchez-Gómez *et al.*, 2020), and palpation to determine subtalar joint axis location (De Schepper *et al.*, 2012).

3.7.3. Intervention

Podfo Ltd offered a compatible interface with the Paromanager V6.0 computer-aided design modelling system in use at the study site. Custom 3D-printed hard-shell insoles were manufactured to the same functional specification as the EVA orthoses by using the patients' pre-existing scan of their feet contained within the CAD/CAM system, from which their previous EVA insoles had been manufactured. Custom 3D-printed insoles were manufactured from Nylon 11 material, built through a selective laser sintering 3D printing process (Saunders,

2017) which provides harder insoles (Shore D67.2) (MatWeb, 2024) compared to the previous custom EVA insoles (ranged from Shore A40 to Shore A70 [Shore D10 to Shore D20]) (Qi, Joyce and Boyce, 2003). Figure 3.2a and 3.2b show an example of the custom EVA insoles and the custom 3D-printed hard-shell insoles.

Figure 3.2.a. Example of a custom CAD/CAM EVA insole. **b.** Example of a custom 3D-printed hard-shell insole.

At baseline (pre-intervention), all eligible patients were consulted by one of three orthotists who were trained in the use of custom 3D-printed insoles, and offered verbal and written information on the custom 3D-printed insoles before commencing treatment. Patients were all provided with footwear advice from their orthotist prior to commencing treatment, and their footwear were checked by the orthotist at the fitting appointment and confirmed to be suitable for use with insoles. Clinical and biomechanical assessments of each patient were carried out by the orthotist who then converted the pre-existing CAD/CAM insole models into the format for 3D printing using the NHS GGC computer-aided design system (Paromanager V6.0.2, Paromed). The orthotist confirmed that the functional elements used in the patient's original EVA insoles remained appropriate for each patient's specific clinical presentation. Functional insole features included hindfoot and forefoot wedging (Desmyttere *et al.*, 2018), medial heel skiving (Bonanno *et al.*, 2012), and heel raises (Ellison, Molloy and Mason, 2017) which were included in the insole designs depending on the individual clinical presentation and biomechanical assessments. All computer-aided design models were reviewed by the orthotic service's musculoskeletal

team lead prior to manufacture of the custom 3D-printed insoles. Patients were asked to wear their custom 3D-printed insoles at all times when wearing footwear and were asked to contact their orthotist for an interim review if any issues arose that prevented them from using their insoles before their scheduled follow-up. The scheduled follow-up was then extended accordingly for those patients requiring an interim review. Follow-up was conducted by telephone or in a face-to-face clinic depending on patient preference, at a minimum of eight weeks after insole fitting.

3.7.4. Data collection and Outcome measures

To investigate the effect of custom 3D-printed insoles on self-reported foot health, patients completed the validated Foot Health Status Questionnaire (Bennett and Patterson, 1998) at baseline and again at a minimum of eight-week follow-up. Baseline data was defined as data collected prior to any 3D-printed insoles being fitted. For the Foot Health Status Questionnaire, patients answered all four subdomains; pain, function, general foot health and footwear, providing a score between 0 and 100, with higher scores representing less pain, better function, better foot health and more satisfaction with footwear. To measure patient satisfaction, at the follow-up, patients also completed the validated Client Satisfaction with Device module of the Orthotics and Prosthetics User Survey, where satisfaction is measured on a scale of 0-36, with higher scores indicating greater satisfaction (Heinemann, Gershon and Fisher Jr, 2006). Adherence was not directly measured but patients were asked to contact the orthotic service if they had been unable to use their insoles at all times within their footwear, and in these instances the insoles were reviewed and redesigned until they could be worn at all times within the footwear. Two years following fitting of custom 3D-printed insoles, relevant medical records were reviewed for all patients to establish if any further intervention was required for the initial presenting condition. Relevant medical records included review of orthotic service records, referrals, clinical records relating to the foot and ankle orthopaedic service, podiatry service, musculoskeletal physiotherapy service and rheumatology service. In instances where a patient's treatment pathway was unclear after review of the medical records, patients were re-

contacted via telephone to establish if or when they ceased using their orthoses, and if further treatment was required for their original condition.

3.7.5. Sample size

This study's primary aim was powered based on a previous study that explored the effectiveness of custom insoles (de Oliveira *et al.*, 2019). Forty patients were required to detect a difference of 18.5 in the FHSQ subdomain for pain, with a standard deviation of 23.9, at the 5% significance level, with 90% power, allowing for 10% drop out rate.

3.7.6. Statistical analysis

All data were analysed using Shapiro-Wilk tests and found to be not normally distributed. Wilcoxon signed rank tests were performed to determine any whole group changes between the baseline and eight-week follow-up in Foot Health Status Questionnaire scores for pain, function, foot health and footwear. To explore response to 3D-printed insoles, patients were also categorised as responders or non-responders to the custom 3D-printed insoles based on each patients change in Foot Health Status Questionnaire pain scores from baseline to eight-week follow-up using the minimal important difference (MID) threshold of 13 points (Landorf, Radford and Hudson, 2010). Responders were defined as patients that exhibited a positive change of 13 points or greater and non-responders as those patients that exhibited a change of 12.99 or less. Mann Whitney U tests were used to explore differences between responders and non-responders for Foot Health Status Questionnaire scores, satisfaction score, ankle dorsiflexion range (limited or normal), and supination resistance test scores (low, moderate, high), and separate within-group differences between baseline and eight-week follow-up were explored using Wilcoxon signed rank tests. Incidences where patients required additional interventions post-custom 3D-printed insoles are presented. All statistical analyses were performed using SPSS version 29 (IBM Corp, Armonk, NY).

3.8. Results

Thirty-nine consecutive patients who met the inclusion criteria were fitted with custom 3D-printed insoles from the NHS GGC orthotic service, however two

withdrew from treatment before the end of the minimum eight-week evaluation period, and one was lost to follow-up, the data for these three participants were not included in the final analysis. Two patients reported problems with their first pair of custom 3D-printed insoles and were subsequently fitted with a new pair of custom insoles which were successfully worn for the minimum eight-week period before follow-up. Thirty-six patients (18 females) were included in the final analysis, keeping the sample size above the 10% allowance for dropout, with a mean age of 50 years (range 19 to 75) and a median follow-up of 118 days (range of 61 to 340). Table 3.2 shows patients' primary musculoskeletal presentation and the clinical assessment of ankle dorsiflexion ROM and supination resistance.

Table 3.2. Primary presentation, ankle dorsiflexion range of motion (ROM) and supination resistance.

Primary Presentation **Responders*/Non-Responders^**	**Ankle dorsiflexion ROM**	**Supination resistance**
Knee		
Anterior knee pain & sciatica (n=1^)	Limited (n=1)	Low (n=1)
Posterior knee pain & stroke (n=1*)	Limited (n=1)	Unable to assess
Leg		
Recurrent calf strain (n=1^)	Limited (n=1)	High (n=1)
Ankle		
Lateral ankle instability (n=2^)	Limited (n=1); Full range (n=1)	High (n=1); Low (n=1)
Deltoid tear (n=1*)	Full range (n=1)	Low (n=1)
Subfibular impingement (n=3*)	Limited (n=2); Full range (n=1)	High (n=3)
Lateral ankle pain (n=1^)	Full range (n=1)	Moderate (n=1)
Dorsal impingement pain (n=1*)	Limited (n=1)	High (n=1)
Poster tibial tendon dysfunction (n=3*, n=4^)	Limited (n=6); Full range (n=1)	High (n=7)
Poster tibial tendon dysfunction & ankle osteoarthritis (n=1^)	Limited (n=1)	High (n=1)
Poster tibial tendon dysfunction & dorsal midfoot interosseous compression syndrome (n=1*)	Not documented	High (n=1)
Poster tibial tendon dysfunction & lateral impingement pain (n=1^)	Limited (n=1)	High (n=1)
Poster tibial tendon dysfunction & rheumatoid arthritis (n=1*)	Limited (n=1)	High (n=1)
Rearfoot		
Plantar heel pain (n=1*, n=2^)	Limited (n=2); Full range (n=1)	High (n=1); Moderate(n=2)
Midfoot		

Midfoot osteoarthritis (n=3*, n=2^)	Limited (n=4); Full range (n=1)	High (n=3); Moderate (n=2)
Midfoot pain (post-midfoot fusion) (n=1^)	Limited (n=1)	High (n=1)
Dorsal midfoot pain (n=1^)	Limited (n=1)	High (n=1)
Rheumatoid arthritis & Midfoot & hindfoot pain (n=1^)	Full range (n=1)	Moderate (n=1)
Forefoot		
First metatarsal pain (inc. hallux valgus) (n=1*, n=2^)	Limited (n=2); Full range (n=1)	High (n=1); Moderate (n=1); Low (n=1)

When the patients were pooled together, significant improvements were seen for the Foot Health Status Questionnaire pain, function and foot health subdomains from baseline to follow-up (Table 3.3, $p<0.001$) which exceeded the MID threshold (Landorf, Radford and Hudson, 2010). However, there was no significant change between baseline and follow-up for the Foot Health Status Questionnaire footwear subdomain ($p=0.101$).

Table 3.3. Overall sample changes in Foot Health Status Questionnaire (FHSQ) subdomain scores between baseline and follow-up.

FHSQ subdomain	Median	25th	75th	p value Wilcoxon
Pain at baseline	41.9	29.4	74.2	**<0.001**
Pain at follow-up	75.3	43.4	87.5	
Function at baseline	56.3	31.3	85.9	**<0.001**
Function at follow-up	87.5	43.8	100	
Foot Health at baseline	25	12.5	42.5	**<0.001**
Foot Health at follow-up	60	25	85	
Footwear at baseline	75	41.7	91.7	**0.101**
Footwear at follow-up	70.8	33.3	83.3	

Further analysis of pain subdomain scores showed there were 16 responders and 20 non-responders to custom insoles [Table 3.4, Figure 3.3]. The differences in ankle dorsiflexion ROM, supination resistance, satisfaction scores, and Foot Health Status Questionnaire scores were examined between the responders and non-responders. Mann-Whitney U tests revealed significant differences between responders and non-responders for the Foot Health Status Questionnaire pain and foot health subdomains at baseline ($p=0.008$, $p=0.029$), with the responders reporting significantly more pain prior to treatment escalation. For the responders, Wilcoxon Signed Rank test revealed that there was a significant improvement between baseline and follow-up in Foot Health Status Questionnaire pain ($p<0.001$), function ($p<0.001$) and foot health ($p=0.008$). There was no significant difference in Foot Health Status Questionnaire footwear between time points ($p=0.288$). For the non-responders, there was a significant improvement between baseline and follow-up for foot health ($p=0.043$) and a trend towards significance for improved function ($p=0.071$). However, there were no significant changes in pain ($p=0.842$) nor footwear ($p=0.195$) between baseline and follow-up [Table 3.5]. At follow-up,

there was a significant difference in satisfaction scores between responders and non-responders (p=0.025) with responders reporting significantly more satisfaction compared to non-responders [Table 3.4]. However, no significant differences were seen between the responders and non-responders for the supination resistance or ankle dorsiflexion range (p=0.213, p=0.831), respectively.

Table 3.4. Median and inter-quartile range between responders and non-responders differences in clinical outcomes and trial period**.**

Measurement / Clinical outcome measure	**Responders (n=16)**	**Non-Responders (n=20)**	**p value (2-tailed)**
Trial Period (days)	118.5 (87.5; 147.5)	115.5 (93.5; 149.75)	0.987
Satisfaction score*	35 (32.5; 36.0)	30.5 (27.0; 34.0)	**0.025**
Ankle dorsiflexion ROM (1, 2)	2 (1; 2)	2 (1; 2)	0.831
Supination Resistance (1, 2, 3)	3 (3; 3)	3 (2; 3)	0.213

* significant difference p<0.05 from Mann-Whitney U Test; 1 = low/limited; 2=normal/moderate and 3 = high

Figure 3.3. Responders and non-responders based on change in Foot Health Status Questionnaire pain response after wearing insoles defined as a minimal important difference (MID) of ±13. Pain responders (black) demonstrate a positive change of 13 points and non-responders (grey) demonstrate a ≤12.99 change in pain between baseline and minimum eight-week follow-up.

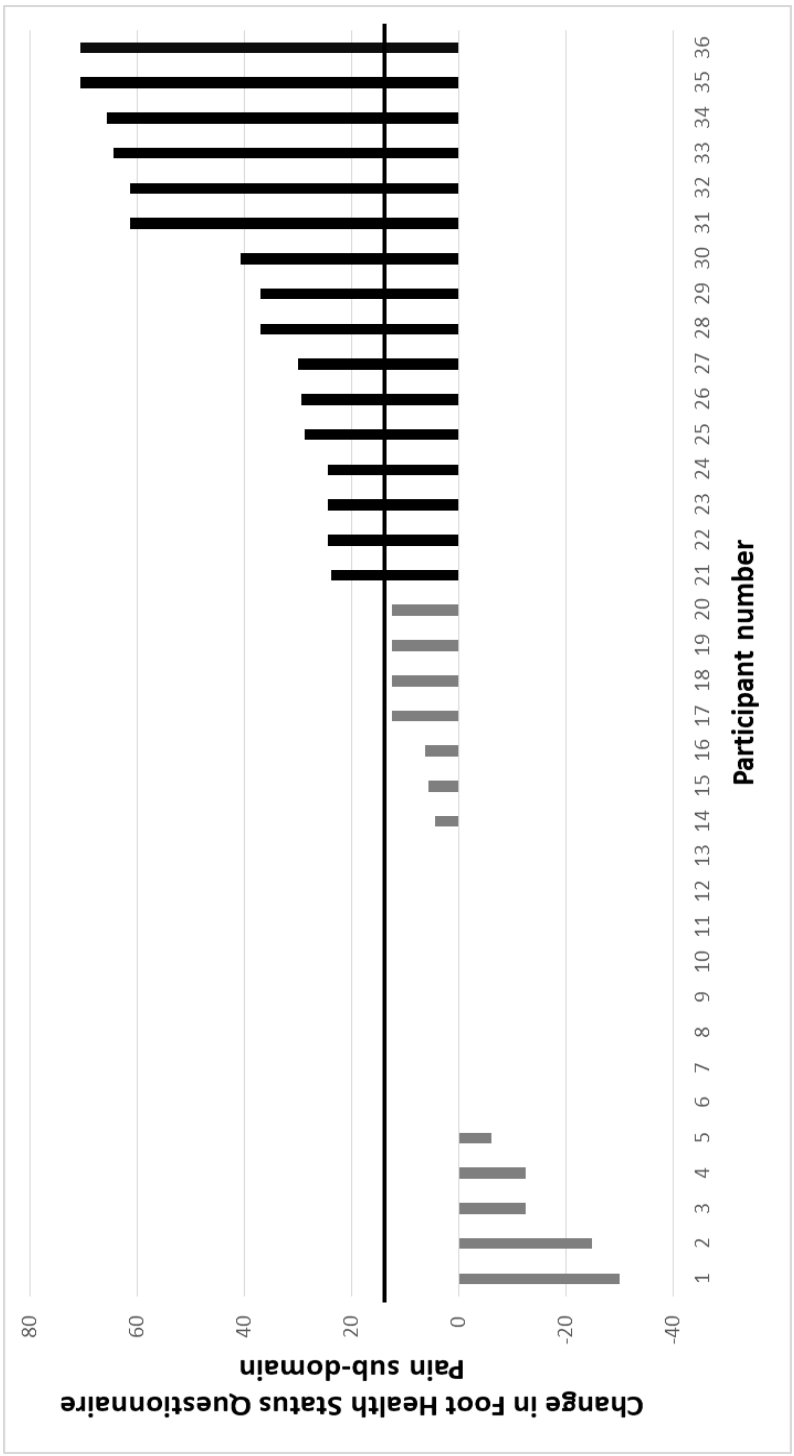


Table 3.5. Median and inter-quartile range, and Wilcoxon Sign Rank test within the responders and non-responders, and Mann-Whitney U-tests for between groups for Foot Health Status Questionnaire (FHSQ) subdomain scores.

FHSQ subdomain	**Responders (n=16)**		**Non-Responders (n=20)**		**p value**	
	Baseline	**Follow-up**	**Baseline**	**Follow-up**	**Between group baseline**	**Between group follow-up**
Pain	29.4 (26.1, 41.9)	78.1 (66.3, 89.1)	66.3 (35.6, 83.6)	48.1 (30.9, 87.5)	**0.008***	0.117
Baseline vs. follow-up (p-value)	**<0.001***		0.842			
Function	46.9 (25.0, 67.2)	87.5 (70.3, 98.4)	62.5 (37.5, 93.8)	84.4 (37.5, 100.0)	0.093	0.591
Baseline vs. follow-up (p-value)	**<0.001***		0.071			
Foot Health	25 (0, 25.0)	60 (45.6, 81.9)	27.5 (25.0, 72.5)	60 (15.6, 85.0)	**0.029***	0.795
Baseline vs. follow-up (p-value)	**0.008***		**0.043***			
Footwear	75 (37.5, 81.2)	66.7 (27.1, 83.3)	75 (41.7, 91.7)	75 (35.4, 89.6)	0.747	0.872
Baseline vs. follow-up (p value)	0.288		0.195			

* significant difference p<0.05

Of the 36 patients included in the initial analysis, 26 (n=14 non-responders and n=12 responders) patients did not receive any further intervention for their original presenting condition in the two years following custom 3D-printed insole

prescription. Nine patients ceased using their custom 3D-printed insoles after their original condition fully resolved (n=6 non-responders; n=3 responders) and 13 patients continued to use their custom 3D-printed insoles (n=7 non-responders; n=6 responders). One responder continued intermittent use of their 3D-printed insoles in conjunction with an off-the-shelf insole for sports participation, three patients did not require further treatment for their original presenting condition but were unable to confirm if they continued to use their 3D-printed orthoses (n=1 non-responder; n=2 responders).

Ten patients required escalation for treatment of their original lower limb musculoskeletal condition within two years of being fitted with custom 3D-printed insoles (n=6 non-responders; n=4 responders). Four patients were escalated to treatment with a custom ankle foot orthosis (n=3 non-responders; n=1 responder). Four patients were escalated to Orthopaedics and were listed for surgery (n=3 responders; n=1 non-responder). Of the remaining two patients (both non-responders); one was escalated to Orthopaedics and received corticosteroid injections and the other was converted to a different style of custom insole.

3.9. Discussion

3.9.1. Statement of principle findings

This study explored the effectiveness of custom hard-shell 3D-printed insoles to reduce pain, improve function and improve foot health, when used for patients with lower limb MSK conditions that had not improved with the use of custom EVA insoles. The study involved an eight-week clinical evaluation of thirty-six patients with lower limb MSK pathology who were fitted with custom hard-shell 3D-printed Nylon Shore D67.2 insoles. A review of medical records was conducted after two years to determine if patients had required treatment escalation for their original presenting condition after being fitted with 3D-printed insoles. The study concluded that there were significant improvements in self-reported pain, function and foot health across the full cohort after eight-weeks, and 26 patients required no further treatment for their original presenting condition after two years. The outcome of this study supports the hypothesis that 3D-printed insoles can be integrated into existing CAD/CAM workflows to

produce hard-shell insoles, which are effective in improving patient reported outcomes when used in the treatment of MSK conditions which did not improve with custom CAD/CAM EVA insoles. The further hypothesis that patients receiving hard-shell insoles would not require further treatment escalation within two years is also supported by this study, providing evidence for the position of hard-shell 3D-printed insoles within the MSK treatment pathway as an alternative to escalation for more proximal orthotic devices or escalation to other healthcare services.

3.9.2. Interpretation within the wider context of the literature

Following eight weeks of intervention with hard-shell 3D-printed insoles, reported pain scores demonstrated considerable variability, which is consistent with past research examining insoles on symptomatic lower limb musculoskeletal conditions (Whittaker *et al.*, 2017; Hoang, Chen and Chou, 2021). We therefore split the full cohort into responders and non-responders using MID threshold based on baseline to follow-up pain scores (Landorf, Radford and Hudson, 2010) to determine if pain response influences custom 3D-printed orthoses effectiveness. At baseline, responders reported significantly worse pain compared to non-responders ($p=0.008$). However, at follow-up, responders reported significant improvements in pain (<0.001) resulting in a similar pain score to non-responders ($p=0.117$). These findings suggest patients presenting with worse pain scores prior to treatment may respond better to custom 3D-printed insoles. This is consistent with previous research demonstrating worse pain scores to be indicative of improved outcomes with insoles (Collins *et al.*, 2007; Rome *et al.*, 2017). Conversely better pain scores have been shown to be predictive for successful treatment with insoles (Rasenberg *et al.*, 2022). Therefore, more research is required to determine if reported pain scores can determine the effectiveness of insoles across cohorts of non-specific musculoskeletal pathologies.

The responders also demonstrated significant improvements in function ($p<0.001$), foot health ($p=0.008$) and significantly greater satisfaction scores compared to the non-responders ($p=0.025$). These findings support our hypothesis that custom hard-shell 3D-printed insoles may be a viable treatment option for patients with musculoskeletal lower limb pathology that do not report

improvements with their initial custom EVA insoles. Interestingly, the non-responders demonstrated significant foot health improvements (p=0.043) and a trend towards improved function (p=0.071) suggesting some benefits to treatment escalation despite no change in self-reported pain scores. Despite only 16 patients demonstrating improved pain scores after 8-weeks, a two-year follow-up disclosed that 26 of the 36 patients did not require any further intervention, therefore shortening their healthcare journey. However future research is required to understand why a sub-group of 10 patients did require further treatment escalation and additional intervention for their original musculoskeletal condition.

Ankle dorsiflexion range was not found to be clinically important when considering patient outcomes in this study, despite past research demonstrating increased pain to be associated both with increased ankle dorsiflexion range (Irving *et al.*, 2007; Pohl, Hamill and Davis, 2009) and conversely decreased ankle dorsiflexion range (Sullivan *et al.*, 2015; Mickle *et al.*, 2011). In addition, we found no significant between-group differences for supination resistance despite reports suggesting those with higher supination resistance may benefit from the harder orthotic material (Payne, Oates and Mitchel, 2002). The lack of significant clinical findings suggests these clinical tests may not be sufficiently sensitive to detect response to orthotic treatment. Further research is therefore required to identify more sensitive clinical measures that may predict response to orthotic prescription.

After eight weeks, the non-responders' satisfaction scores were comparable with previous studies reporting benefits of insoles (Amer, Jarl and Hermansson, 2014; Jarl, Holmefur and Hermansson, 2014) suggesting positive treatment perceptions despite no pain improvements. These satisfaction scores in addition to improved foot health (p=0.043) and foot function scores (p=0.071), could possibly explain why 14 non-responders did not require any further escalation for treatment within two years despite no significant pain improvement.

We found no significant difference in the FHSQ footwear subdomain from baseline to follow-up in both the responder and non-responder groups. It is widely accepted that insoles can reduce internal footwear volume by the nature

of their physical position within the shoe, and although our results were not significant, we did find a worsening of outcomes in the FHSQ footwear subdomain in the responder group from 75 to 66.7, which was more than the MID of -2 reported by Landorf, Radford and Hudson (2010). In clinical practice, as demonstrated in this study and in the previous study by Landorf, Radford and Hudson (2010), we anticipate that patients may experience a negative impact on their footwear due to the use of an insole, but this does not necessarily affect the overall outcome of the treatment, as demonstrated by the improved FHSQ results that we observed for pain, function and foot Health in the responder group. Nor does this negative impact on footwear appear to affect the overall satisfaction of patients as demonstrated by the high satisfaction values observed in the responders OPUS scores. We also observed a relatively high median baseline value of 75 across the cohort, which may be explained as these existing orthotic patients had already received footwear advice with their prior course of treatment, and had therefore been guided toward more appropriate footwear choices before being escalated to treatment with custom 3D-printed insoles.

It is interesting to observe that the OPUS Satisfaction with device scores in the non-responders group (30.5) at the minimum eight-week follow-up was comparable with previous studies reporting on the success of insoles (Amer, Jarl and Hermansson, 2014; Jarl, Holmefur and Hermansson, 2014). This finding suggests that although the non-responders pain scores did not improve, their perception of their treatment was positive. These satisfaction scores in addition to the improved FHSQ foot function and foot health scores ($p=0.071$ and $p=0.043$, respectively), could offer a possible explanation as to why 14 non-responders did not require any further intervention within two years despite having no significant improvement in pain after initial eight-week follow-up. It is plausible to suggest that pain may not have been the primary treatment objective for these patients, and as such analysing the groups in terms of pain response could have caused a misrepresentation regarding the number of patients who considered their treatment to be successful.

The full cohort's median baseline values for the FHSQ across the four subdomains for pain (median=41.9, IQR 29.4; 74.2), function (median=56.3,

IQR 31.3; 85.9), foot health (median=25, IQR 12.5; 42.5) and footwear (median=75, IQR 41.7; 91.7) were comparatively worse than the baseline FHSQ pain (mean=52.6 ± SD 15.7) and function (mean=60.7 ± SD 20.4) previously reported for non-specific lower limb MSK pathologies (Chuter, Searle and Spink, 2016). This is likely due to the recalcitrant nature of the conditions presented in this study which had not previously responded to standard orthotic care with custom EVA insoles, as opposed to a baseline pre-treatment group more typically presented in the published literature. In contrast, the baseline results from the present study were comparatively better across the pain, function and footwear subdomains than those found in a study investigating multimorbidity MSK conditions (median pain=29.38; IQR 48.75, median function=31.25; IQR 53.13, median footwear=25.0; IQR 39.58), and similar for the foot health subdomain (median general foot health =25.5; IQR 42.5) (Hendry *et al.*, 2019). While it is acknowledged that the current study did not exclude multimorbidity, the presence of coexisting psychological factors such as depression which are known to impact negatively on foot and ankle pain (Cotchett *et al.*, 2022), depression scores were not recorded, and therefore it was not possible to isolate an analysis for this group to establish if there was a similarity in poorer baseline values with the existing evidence base.

3.9.3. Limitations

This study had a number of limitations which should be considered. Patients' adherence to insole use was not recorded and it is unknown whether increased adherence leads to improved outcomes. There was significant variance seen in the follow-up period across the patient cohort which may have affected the outcomes, this was due to patient cancellations and failure to attend initial follow-up appointments, which is a true representation of day-to-day clinical NHS practice. Within this analysis we only considered responders and non-responders to treatment, and not those who showed a negative change lower than -13 FHSQ subdomain for pain who could be described as a third group of "negative responders". Although this is an important group to consider a much larger sample size is required to perform a robust analysis.

The study design was that of a clinical evaluation and as such there was no control group or blinding, which can lead to potential bias in terms of patient

expectations of treatment. Steps were taken to mitigate this by conducting a review at two years, rather than basing the results simply on the initial eight-week evaluation period.

The study did not monitor adherence to treatment and as such it was not possible to evaluate any treatment effects associated with the amount of time the insoles were worn. Without precise data on how often each patient used their custom hard-shell 3D-printed insoles, it remains unclear whether the observed outcomes were influenced by differential usage. Prior studies of orthotic devices for various pathological conditions including MSK, have demonstrated the viability of using embedded sensors, temperature or pressure monitors, or wearable tracking devices to objectively measure adherence and usage patterns (Ehrmann *et al.*, 2018; Nurse *et al.*, 2024; Bus *et al.*, 2024; Devanand and Kedgley, 2023). Future follow-up research could integrate such wear-time monitoring to more accurately associate outcomes to actual device usage and investigate threshold doses of wear associated with clinical benefit. This would provide a deeper understanding of the dose-response relationship between insole use and treatment effect, and allow differentiation between perceived “treatment failure” due to non-adherence and failure due to ineffectiveness of the device.

The cohort size meant that it was not possible to perform subgroup analyses for specific clinical presentations, and so it was not possible to determine if particular patient characteristics were more or less responsive to the treatment. Addressing these limitations through larger, longitudinal, multi-centre, and mixed-methods studies would substantially enhance the evidence base surrounding hard-shell 3D-printed orthoses by allowing for analysis of individual pathologies with homogenous groups as opposed to the heterogeneous cohort sampled in the current study. In doing so, future research could refine the clinical indications for the use of hard-shell insoles, establish clearer predictive factors for treatment success, and support the integration of digital manufacturing technologies within routine MSK care. This could also allow for additional analyses based on patient characteristics such as BMI or foot posture, which were not possible in the current study due to inconsistencies in the information gathered by orthotists during the clinical assessments. Future

studies should aim to standardise the clinical assessment criteria and recording of patient characteristics in order to allow further exploration of these factors in terms of relevant outcomes, which could help to refine clinical decision making in the future.

As documented in the study publication there were also limitations associated with variation in follow-up times due to appointment cancellations and non-attendance of patients, as well as limitations in the information gathered during the two-year follow-up which only included NHS records and did not include any additional interventions that may have been received privately. Future research could strengthen this by incorporating patient follow-up interviews, which could highlight specific case examples within the cohort, or by utilising digital patient-reported outcome monitoring systems to record any additional care pathways pursued beyond the NHS. This would not only improve data completeness but also offer valuable insights into patient behaviour, satisfaction, and long-term management of chronic MSK conditions.

Further methodological consideration should be given to the influence of the manufacturing process itself, specifically the use of 3D printing, which could have affected the outcomes separate to the material hardness. In this study, the hard-shell insoles were produced via a 3D-printed process, whereas the prior comparator were custom EVA insoles produced by reduction milling. It is therefore possible that some of the observed effect is attributable not solely to the increased hardness of the material but to differences in manufacturing method, digital design variability, shell geometry and surface finish. Indeed, reviews of 3D-printed orthoses highlight that additive manufacture introduces unique structural and mechanical properties, such as interlayer bonding effects, anisotropy, and infill pattern influence which may affect performance (Atallah *et al.*, 2025; Jonnala and Kumar, 2023). A follow-up study could control for this by 3D-printing both the intervention and the comparator EVA insoles, thereby removing manufacturing method as a confounding variable and allowing a clearer isolation of the effect of material stiffness.

Another consideration is that the study did not explore cost-effectiveness or time-efficiency of the 3D-printed insoles in comparison to the reduction-milled EVA insole manufacture. Given that NHS services must balance clinical benefit

with economic sustainability, understanding the comparative costs of producing and maintaining 3D-printed insoles is critical for future clinical adoption, particularly in the advancing landscape of digital technologies. A follow-on health economic analysis could model the costs of production alongside the improvements in pain, function, foot health and treatment escalation reported in this study. This would add practical value for service commissioners and could guide evidence-based procurement decisions in orthotic service delivery.

3.9.4. Conclusion

In conclusion this study suggests that custom hard-shell 3D-printed insoles have the potential to improve pain, function, foot health and provide patient satisfaction, when used as a treatment in the musculoskeletal Foot and Ankle pathway for patients who did not improve with custom EVA orthoses and were being considered for escalation to other services. The option of custom hard-shell 3D-printed insoles for patients who do not report symptom improvement with custom EVA insoles could offer a long-term alternative to medical or surgical treatment, minimise healthcare services pressures by limiting onward referrals, and ultimately minimise patients' journey through the healthcare system. Given the heterogeneous patient cohort described in this study, we have been unable to conclude if any specific pathologies or clinical presentations should be considered for hard-shell 3D-printed insoles as a first line treatment, and therefore we suggest their use only if custom EVA insoles have been unsuccessful in reducing pain. Further studies should focus on determining if specific characteristics affect the response to hard-shell 3D-printed insoles. Although this study considered pain response to treatment, the longer-term follow-up highlights the need to develop clinically relevant and implementable predictors of treatment success.

3.7.2. Contribution to knowledge

This project provides an original contribution to knowledge by offering evidence on the effectiveness of hard-shell insoles related to patient reported outcomes, and relating these outcomes specifically to the use of the harder insole material, thus providing clinicians with an alternative treatment option if EVA insoles are not effective. This study has further contributed to knowledge by offering

evidence for the specific position of hard-shell insoles within an MSK treatment pathway, demonstrating that using hard-shell insoles prior to escalation to more proximal orthoses or other services can reduce the need for these treatments, ultimately minimising the patient's healthcare journey. This project has added to the existing body of evidence around the use of hard-shell insoles by offering these insights from the perspective of a standard orthotic service patient cohort, rather than focusing on a single pathology, and by focusing on patient specific outcomes rather than other forms of analysis such as plantar pressures which may not be reflective of the effectiveness of treatment.

3.7.4. Recommendations for further research

This project has helped to identify the relevance of material hardness associated with patient outcomes when treating lower limb MSK conditions with custom insoles. Further larger controlled studies are recommended to allow subgroup analyses in order to determine if certain specific pathologies or patient characteristics respond more or less favourably to harder insoles.

Various studies have examined the effects of using full length hard insoles on the biomechanics of the foot related to tensile forces and muscle activation, but fail to reach a conclusion about the use of full length hard insole designs in terms of clinical outcomes in the treatment of MSK pathology (Coheña-Jiménez, Pabón-Carrasco and Pérez Belloso, 2021; Ko, Ma and Xiong, 2023; Lin *et al.*, 2013). The project described in this chapter limited the prescription of hard-shell insoles to 3/4 length only, and therefore it is unknown how much of an effect the insoles were likely to have on muscle activation and tensile stresses of the foot and ankle, and indeed if this is of relevance to the positive outcomes observed in the current project. Future studies may wish to investigate the effect of a full length design on the outcomes associated with MSK pathology.

This study conducted a two-year follow-up of patients and within this period no replacement hard-shell insoles were required due to wear or breakage. Prior studies have advocated for the use of hard-shell insoles due to increased durability requiring less replacements than soft materials (Tang *et al.*, 2014). Future studies should focus on the patient outcomes in conjunction with long-

term sustainability and possible environmental benefits of hard-shell insoles in terms of waste reduction, which is a priority for health services (Torjesen, 2020).

The literature review associated with this project has specifically identified a lack of clinical tests which may help to guide clinicians in decision making with regard to material hardness, and therefore suggests that further studies should be undertaken to understand if tests such as the supination resistance test can help to determine the most appropriate material choice for treating patients with MSK conditions.

The literature review has also highlighted inconsistencies associated with the terminology for “hard” and “soft” insole materials, and it is therefore recommended that future studies provide full transparency around the type of material used in the prescription of insoles as well as the hardness of those materials.

CHAPTER 4. THE USE OF CAD/CAM IN THE PRODUCTION OF INSOLES IN THE UK

4.1. Chapter structure and statement of contribution

This chapter describes part of the live project work that was undertaken during my enrolment at the University of Central Lancashire as a PhD by Portfolio student, from 2022 to 2025. This project aimed to contribute to the understanding of the current workflow used in the production of computer-aided design and computer-aided manufacture (CAD/CAM) for insoles in the UK. This was achieved by undertaking a cross-sectional survey of UK National Health Service (NHS) orthotic services. The study described within this chapter has been published as an original peer-reviewed research article which is presented as a full PDF in Appendix 41.

Article publication: *The use of computer-aided design and manufacture for foot orthoses: A cross-sectional study of orthotic services in the UK. Barr L, Richards J, Chapman GJ. Journal of Foot and Ankle Research. 2025 Feb; 18(1). doi: 10.1002/jfa2.70031.*

This chapter presents an extended version of this publication, offering additional details and context to the project.

The chapter begins with an introduction to the subject area to set the scene for the research, followed by a description of the cross-sectional study and how this was developed to fill a gap in the knowledge base. The objectives and hypotheses associated with the study is described, and the methods and results of the cross-sectional study is then presented. The chapter concludes with a discussion of the study findings and their relevance to the existing evidence base, along with suggestions for future research to build on the knowledge generated by this project.

4.1.1. Contribution by L Barr

The author developed the concept for the cross-sectional survey, carried out the literature review, designed the methodology for the study, undertook the data collection and analysis, led the writing of the publication, led the review and editing of the final article, and was first author on the final publication.

4.2. Introduction

4.2.1. CAD/CAM insole production.

As discussed in previous chapters, the use of CAD/CAM for insole production offers an alternative to traditional manufacture processes, and has been increasingly introduced to orthotic services since the 1980's (Smith and Burgess, 2001; Haleem and Javaid, 2019). Traditional manufacture of insoles involves taking a physical cast of the foot, most often using materials such as phenolic foam-box impression casts, which are then filled with materials such as plaster of Paris or gypsum to create a physical model of the foot over which the insole material is then draped (Cheng and Wang, 2024); a process which involves the use of single-use materials which create waste products (Laughton, McClay Davis and Williams, 2002; Binedell *et al.*, 2020). CAD/CAM systems are designed on the premise that each step in the traditional process can be replaced with a digital counterpart, such as directly scanning the foot to create a digital model, and in doing so CAD/CAM processes have conceptualised advantages over traditional methods in terms of waste reduction, quality, accuracy of shape capture, repeatability, and faster production times (Gatt, Formosa and Chockalingam, 2016; Oldfrey *et al.*, 2022; Binedell *et al.*, 2020), and can have equivalent outcomes compared with traditional manufacture in aspects such as plantar pressure reduction and foot kinematics (Ki, Leung and Li, 2008; Dombroski, Balsdon and Froats, 2014). The digital storage of models and repeatability also creates the opportunity to integrate CAD/CAM systems into virtual services, potentially reducing the need for travel and reducing patient contact time (Sedigh *et al.*, 2020; Gatt, Formosa and Chockalingam, 2016; Binedell *et al.*, 2020).

Despite these reported benefits, there are known barriers to the implementation of CAD/CAM systems, which include costs associated with equipment, the requirement for additional staff training to use the systems, and for staff to adapt from a traditional to a digital workflow (Silva *et al.*, 2024). Furthermore there is a self-reported lack of CAD/CAM expertise in the global orthotic workforce (Kogler and Hovorka, 2021; Alireza, Tahereh and Shahram, 2019), a concern which is shared by UK orthotists whereby a recent workforce demonstrated that only 39.4% of orthotists reported having skills in CAD (Eddison *et al.*, 2023).

Publications have acknowledged the additional skills required by clinicians to integrate CAD/CAM into their clinical workload, framing the positive aspects of this in terms of clinicians having control of the insole design (Dickinson *et al.*, 2019), however it has also been suggested that the lack of upskilling by clinicians in order to undertake the design aspects of CAD/CAM insoles, has led to a tendency for services to employ technicians to undertake the digital design process, thereby negating the need for clinicians to learn these digital skills (Gatt, Formosa and Chockalingam, 2016). At the same time Gatt, Formosa and Chockalingam aimed to support services in integrating CAD/CAM systems by highlighting barriers such as a cost and upskilling and demonstrating step by step methods to assist services in order to overcome these (Gatt, Formosa and Chockalingam, 2016). Despite such suggestions in the literature, the specific barriers relating to CAD/CAM and the extent of CAD/CAM skills and usage throughout the UK is unknown, partially due to a lack of research in the area, but also due to prior cross-sectional survey questionnaires covering all aspects of CAD/CAM in both P&O care, rather than insoles alone, coupled with low response rates from UK orthotic services (Ngan *et al.*, 2022; Binedell *et al.*, 2020).

In spite of the barriers, the importance of CAD/CAM technology is increasingly recognised by those who prescribe insoles in the UK; in 2017, 12.5% of UK Allied Health Professionals (AHPs) who prescribed insoles felt that the integration of CAD/CAM technologies to clinical practice would be an important requirement for the future (Nester *et al.*, 2017), and in 2023 a far greater proportion of orthotists felt the same, with 76.4% saying that digital scanning for shape capture would be a requirement for the future of the profession (Eddison *et al.*, 2023). These findings were supported by a UK focus group in 2024 which included experienced podiatrists who were involved in the prescription of custom insoles, who stated that the elements of CAD/CAM manufacture including digital shape capture could revolutionise the prescription of insoles and the services who provide them (Leach, Cowley and Bowen, 2024). In line with this vision for the future, the anticipated increase in the use of CAD/CAM technology has been reported across various aspects of the medical field (Smith and Burgess, 2001; Haleem and Javaid, 2019), and with CAD/CAM technologies becoming increasingly available and increasingly cost effective in

the orthotic profession (Dickinson *et al.*, 2019), it is important to understand how they can be most effectively integrated into the orthotic workflow.

Few studies have explored the difference in treatment outcomes with insoles comparing traditional versus CAD/CAM workflows. In a recent systematic review of digital scanning versus traditional manufacture, five studies were identified which investigated the prescription of insoles using these two methods (Farhan *et al.*, 2021), concluding that there was potentially greater accuracy, improved time benefits and improved repeatability with the scanning methods. However four of the five studies focused primarily on the physical dimensions of the foot models (Laughton, Davis and Williams, 2002; Carroll, Annabell and Rome, 2011; Telfer *et al.*, 2012; Lee, Lin and Wang, 2014), with the remaining study focusing only on the cost implications comparing plaster casts and digital scans (Payne, 2007), however none of these studies compared the effects of the traditional and digital workflows on treatment outcomes. The morphological differences between traditional and digital insole manufacture were considered again in a recent study where the surface geometry of direct foot scans and digitalised foam-box casts were compared, disclosing differences in length, width and depth of the shape capture method, but did not extend this to the production of insoles to determine the clinical effect (Nickerson *et al.*, 2025). In a randomised controlled trial (RCT) undertaken in 2019, the outcomes relating to plantar pressures in a diabetic patient cohort were found to be no different when comparing custom traditional and CAD/CAM insoles, however there was an increased cost associated with the CAD/CAM supply chain (Parker *et al.*, 2019). Notably however the increased cost associated with the CAD/CAM workflow was primarily incurred by the clinical staff undertaking the CAD design of the insole, whereas the traditional insoles were designed by a technician, a cost which was not accounted for in the study.

The proportion of custom insoles produced using CAD/CAM is unclear in the literature, as studies examining prescription patterns by custom insole providers do not always differentiate between traditional and CAD/CAM manufacture techniques (Chapman *et al.*, 2018). A UK study in 2017 suggested the number of CAD/CAM insoles produced by orthotic, podiatry, and physiotherapy services was still significantly lower than other types of insoles, with only 28.7% of

custom insoles reported to be manufactured with CAD/CAM (Nester *et al.*, 2017), but there is a lack of more recent studies to show if this figure has changed over the years.

4.2.2. Hybrid-digital vs fully digital CAD/CAM workflows.

The existing knowledge base on CAD/CAM insoles is based on the assumption of a fully digital workflow, whereby every step in the traditional manufacture process has been replaced with a digital equivalent. However, throughout the literature there is reference made to the use of foam-box casts within the CAD/CAM workflow (Cheng and Wang, 2024; Anggoro *et al.*, 2021; Watasuntonpong, Pimsarn and Tantrapiwat, 2019), creating a process which can be considered a hybrid-digital workflow. The extent of fully digital and hybrid-digital workflows in CAD/CAM production have been suggested in the literature but not fully explored. In 2024 a study exploring the proportion of research publications which focused on fully digital workflows and hybrid-digital workflows found a three-fold increase in research involving fully digital workflows compared with hybrid-digital (Cheng and Wang, 2024). However a UK mixed-methods cross-sectional survey of orthotists, podiatrists and physiotherapists, suggested that a fully digital workflow was not used by the majority of clinicians prescribing CAD/CAM insoles; in this study the majority of clinicians reported that they provided custom insoles using foam-box casts (54.1%) or plaster casts (39.9%) and only 14.2% used scanners, however the same study reported that 28.7% of custom insoles were manufactured by CAD/CAM, therefore indicating that a high proportion of CAD/CAM insoles were produced using a hybrid-digital workflow (Nester *et al.*, 2017).

In 2024, Cheng and Wang also investigated the environmental impact of CAD/CAM insole workflows, exploring the use of both direct scanning and foam-box shape capture, concluding that the use of the traditional foam-box capture method negatively impacted on environmental outcomes related to waste production and disposal (Cheng and Wang, 2024). In addition to disposal, the environmental impact of foam-boxes should also be considered in terms of the carbon emissions required for the production of the phenolic foam material from which they are constructed (Tingley *et al.*, 2017). Furthermore, the environmental burden associated with physical foam-box casts should also be

considered in terms of the transportation of casts, a step which is eliminated in the fully digital workflow, and one which is often not considered in the literature. With NHS services being steered towards minimising their environmental impact and achieving net zero targets (van Hove *et al.*, 2024; Torjesen, 2020), the production and disposal of foam-box waste products should be scrutinised in terms of their place in a CAD/CAM workflow where alternative options, such as direct scanning exist. However, guidance for clinical services is lacking in terms of the most effective workflow for maximising patient outcomes. Some researchers have indicated clinical preferences for direct scanning as opposed to foam-box casts when manufacturing CAD/CAM insoles (Anggoro *et al.*, 2021; Watasuntonpong, Pimsarn and Tantrapiwat, 2019), attributing their preferences to the aforementioned studies which investigated the accuracy and repeatability of direct scanning, however these benefits have not yet been explored in the context of clinical practice relating to their effect on patient outcomes.

No prior studies have been undertaken to compare the clinical outcomes of patients treated with insoles produced by a fully digital workflow compared with a hybrid digital workflow. Indeed, studies which investigate the clinical outcomes associated with insoles manufactured using CAD/CAM, often give little consideration to the workflow which was used in their production, despite recommendations in 2010 that researchers should clarify and standardise the process of foot shape capture in clinical studies (Telfer and Woodburn, 2010), and this issue continues to be raised by researchers as an ongoing inconsistency in studies in recent years (Allan *et al.*, 2023). One RCT which investigated custom insoles and placebos, describes the use of a CAD/CAM system in the production of placebo insole, but fails to identify the method or methods of foot shape capture beyond the description of a “3D imprint” (Rasenberg *et al.*, 2021). Furthermore in this study the custom insoles were manufactured according to the podiatrist’s preference, which will presumably have resulted in a mix of methods which is not considered in the final outcomes, making it challenging to interpret the potential influence of a hybrid or fully digital workflow. Similar uncertainty was seen in a study by Shojai et al, where CAD/CAM insoles were manufactured from “compression scans” which leads to uncertainty about the type of scanner used, and if the compression element was embedded within the scanner or achieved by use of a physical cast (Shojaie *et*

al., 2020). Other studies comparing CAD/CAM insoles provide a lack of information relating to the shape capture method with some not identifying this at all (Zequera, Stephan and Paul, 2007), and others describing the use of one consistent method of shape capture either using a direct scan (Sahoo and Satheeshwari, 2023; Wang *et al.*, 2021; Wyndow *et al.*, 2021; Pallari, Dalgarno and Woodburn, 2010) or a foam-box cast (Hsu *et al.*, 2022; D'Amico *et al.*, 2021), but not providing any clinical reasoning for this choice, therefore not allowing analysis of the potential relevance of the shape capture method on the patient outcomes. In a further study which aimed to assess the differences in plantar foot pressures on diabetic patients associated with different CAD/CAM insole manufacture techniques, foam-box impressions were used to create 3D foot scans, with the insoles then designed based on additional static and pressure measurements; however, the mix of methods in the design stage, coupled with the small number of participants, meant that it was not possible to attribute patient outcomes to the method of foot shape capture, and the use of a hybrid-digital workflow as opposed to a fully digital workflow which was not discussed (Zwaferink *et al.*, 2020). One study did provide clinical reasoning for the foot shape capture method, using a foam-box cast to create insoles for a single patient with club foot due to the patient being unable to attend the hospital site for direct scanning, but due to the single case study design, lack of outcome measures and unusual patient presentation, it is not possible to place this into the wider context of the general musculoskeletal (MSK) population (Anthony *et al.*, 2019).

Despite studies advocating for the use of direct scanning for many years (Telfer and Woodburn, 2010; Allan *et al.*, 2023), and the associated benefits of fully digital workflows as discussed, the prevalence of fully digital workflows in the production of insoles in the UK is uncertain.

4.3. Background to the project

As highlighted by this literature review, prior to undertaking this project there was a lack of information available regarding the prevalence of CAD/CAM for insoles being used by orthotic services in the UK, and very little information as to the specific processes used within the CAD/CAM workflow. As described in

Chapter 1, discussions with orthotists from across the UK over many years of working as a trainer on the British Association of Prosthetics and Orthotics (BAPO) MSK education courses, had highlighted a lack of clinical certainty around the most effective processes for attaining shape capture of the foot when prescribing CAD/CAM insoles, and had suggested variation in techniques being used across the UK. In order to assist orthotists in making evidence-informed choices for their patients, the cross-sectional study described in this chapter was designed, following by a clinical trial which will be described in Chapter 5.

4.4. Knowledge gap

The literature demonstrated a lack of evidence relating to how widely CAD/CAM had been adopted by the UK orthotic profession for the manufacture of bespoke insoles, and how specific elements of the CAD/CAM workflow, such as foot-shape capture, had been integrated into insole production.

4.5. Objectives

Given the knowledge gap, this project aimed to understand how widely CAD/CAM insoles were used by UK NHS orthotic services, and to investigate the volume of CAD/CAM insoles prescribed by UK NHS orthotic services, as well as exploring any variations in the workflow and any barriers to the use of CAD/CAM. In combination with the clinical trial described in Chapter 5, this would therefore provide clinical services with valuable insights into the most effective methods for shape capture within the CAD/CAM workflow, while demonstrating the breadth of services for which this information is likely to be relevant.

4.6. Hypotheses

In order to meet the objectives, the cross-sectional study explored the hypotheses that CAD/CAM insoles were being used routinely by orthotic services across the UK, but that there was variation in the production workflows. These hypotheses were explored in the publications described in Sections 4.7, 4.8 and 4.9.

4.7. Methods

4.7.1. Survey design

A cross-sectional study was undertaken using the UK freedom of information (FOI) act to gather data (Fowler *et al.*, 2013) and reported in accordance with the STROBE cross-sectional reporting guidelines (Von Elm *et al.*, 2007). From 11 November 2022 to 2 December 2022 FOI requests were sent to all 214 NHS Trusts and Health Boards (HB) across the UK. The request comprised 22 questions [Appendix 42] designed to gather information relating to UK National Health Service (NHS) orthotic services during the 2021/22 financial year from 6 April 2021 to 5 April 2022. Not all questions required an answer, and Trusts/HBs were instructed on which specific questions they should answer depending on their particular responses. The request focused on two main areas: (1) CAD/CAM insoles and (2) barriers / facilitators to using CAD/CAM.

(1) CAD/CAM insoles

The aim of this section was to gather information on the volume of bespoke insoles prescribed by the Trust/HB, the methods used for manufacture, and the proportion of insoles manufactured by traditional and CAD/CAM methods. Further questions then explored the workflow relating to manufacture of CAD/CAM insoles; this included questions on the methods used to acquire digital foot models, the transportation of foot models, the design, and the manufacture of the insoles.

(2) Barriers / facilitators to using CAD/CAM

The aim of this section was to understand the reasons why services chose to use or not to use CAD/CAM as part of their insole manufacture process. Using previous publications which examined barriers and drivers for the use of any CAD/CAM systems in the prosthetics and orthotics industries (Binedell *et al.*, 2020; Hovorka, 2021; Ngan *et al.*, 2022), a list of options was compiled from which respondents could either choose their answers, or provide a free text comment. Given recent considerations to the use of digital technology in supporting health services following the Covid-19 pandemic (Binedell *et al.*, 2020), we also chose to include options regarding any benefits that CAD/CAM insole systems provided to Trusts/HBs during and following the pandemic.

Approval for the study was received from the health ethics review panel at the University of Central Lancashire (HEALTH 0365 Phase 2).

4.7.2. Data analysis

An analysis was undertaken and presented in terms of response rate for the individual questions. Where free text responses were provided, the answers were reviewed and an inductive approach was used to form a thematic analysis (Braun and Clarke, 2006), the themes of which were agreed by the authors and presented alongside anonymised quotations. Where questions required a numerical answer, if a respondent provided a range of values then the mean of those values was used in the analysis. Where numerical answers were provided, distribution of those values was analysed using Kolmogorov-Smirnov tests and presented as median values when data was not normally distributed. Where Trusts/HBs were asked to select one preferred method of shape capture, analysis was made on the assumption that a minimum of 51% of their CAD/CAM insole production would be manufactured using this method, and where two options were selected the subsequent analysis was based on the assumption that 50% of their CAD/CAM insole production would be manufactured using each method.

4.7.3. Patient and public involvement

No patients or members of the public were involved in the design of this study. Before dissemination across the UK, the FOI request was piloted by orthotists in three Trusts/HBs who provided comment on the content and structure of the questions, all comments were addressed in the final version of the FOI request.

4.8. Results

4.8.1. Response rate

Complete or partially complete responses were received from 186 (86.9%) Trusts/HBs, two (0.9%) declined to respond, and 26 (12.2%) provided no response. On preliminary review of the responses, 60 stated that they did not have an orthotic service in their Trust/HB and were excluded from the analysis. Within the received responses one was excluded due to lack of information as only one question was answered despite prompting to complete further

questions. Three Trusts/HBs provided separate responses for their adult and paediatric services, three provided individual responses for two separate geographical areas within their Trust/HB, and one provided individual responses for three geographical areas within their Trust/HB. Therefore the total number of responses included in the analysis was 131 [Figure 4.1]. The geographical regions of the respondents are presented in Table 4.1. Not all Trusts/HBs provided answers to all questions requested of them, with the variation in response rate documented in Appendix 43.

Figure 4.1. Study flow chart.

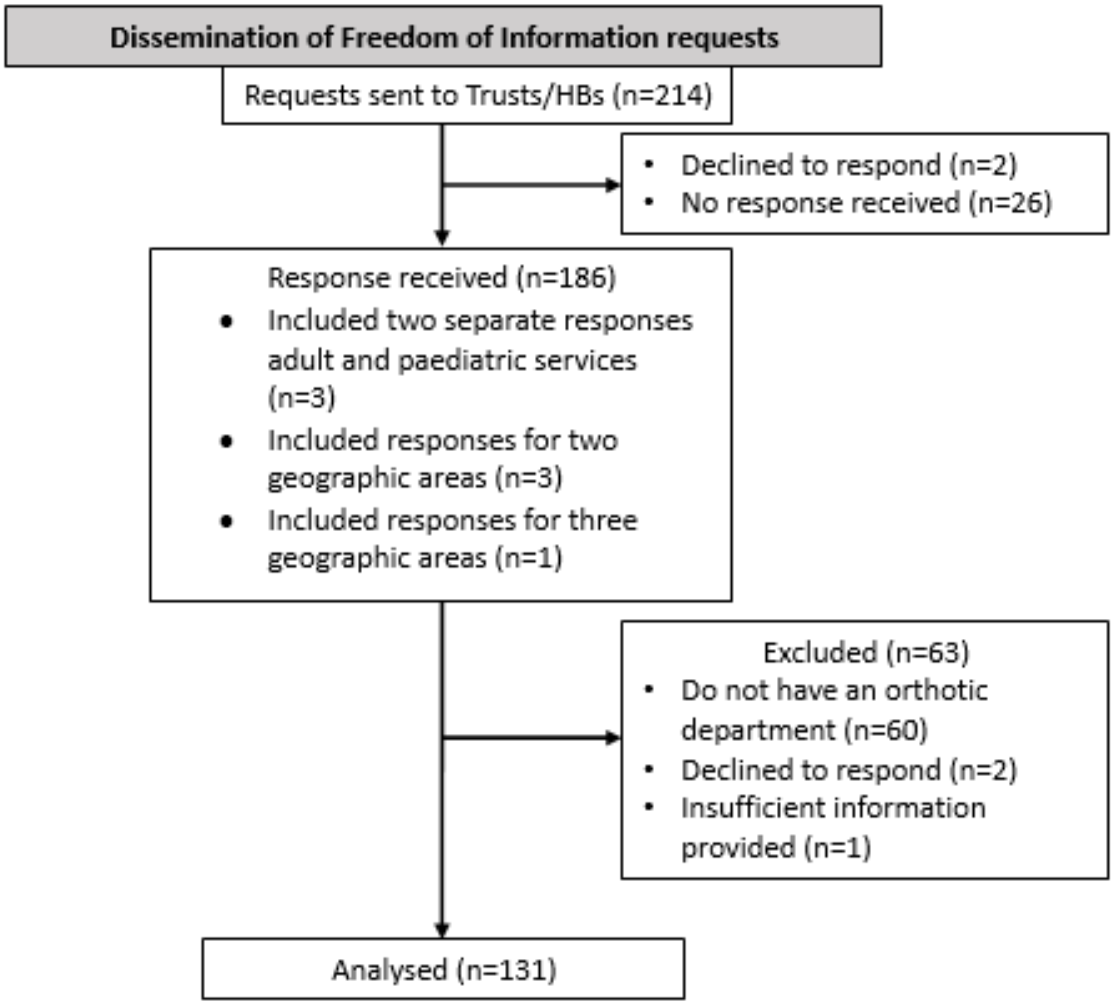


Table 4.1. Responses by geographical region.

Region	Number of respondents	Percentage of total (131)
Scotland	11	8.4%
Northern Ireland	4	3.1%
Wales	7	5.3%
England:		
North East	7	5.3%
North West	14	10.7%
Yorkshire and Humber	11	8.4%
East Midlands	7	5.3%
West Midlands	10	7.6%
East	11	8.4%
London	17	13%
South East	19	14.5%
South West	13	9.9%

4.8.2. Overview of bespoke insole provision

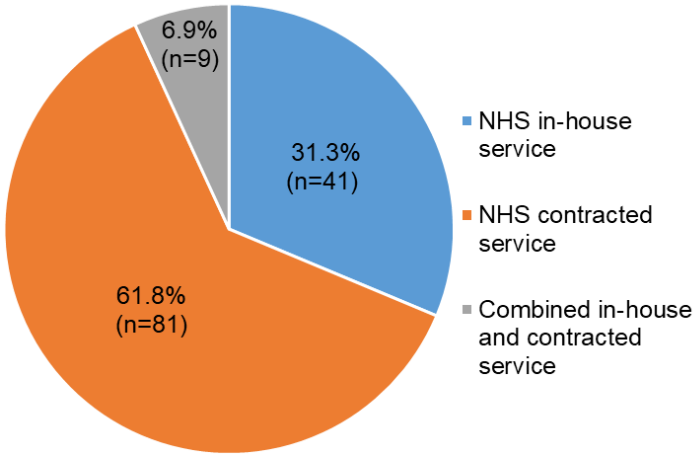
Responses showed that a greater proportion of Trusts/HBs (61.8% (81/131)) provided a contracted orthotic service, whereby the NHS pays for orthotic services from an external company, with approximately 30% (31.3% (41/313)) of Trusts/HBs using an in-house service where orthotists are employed directly by the NHS, and a small number (6.9% (9/131)) used a combined contracted and in-house service [Figure 4.2a].

Of those Trusts/HBs that provided insoles, the majority (93.1% (122/131)) confirmed that they provided bespoke insoles to patients and a small number (5.3% (7/131)) did not respond [Figure 4.2b]. Those Trusts/HBs who did provide bespoke insoles, the majority (80.6% (104/129)) provided details of the number of bespoke insoles ordered for patients in the 2021/22 financial year. Fifteen of the 129 Trusts/HBs provided an estimated number or a range of values. The total number of bespoke insoles provided by Trusts/HBs was 144,414 (median

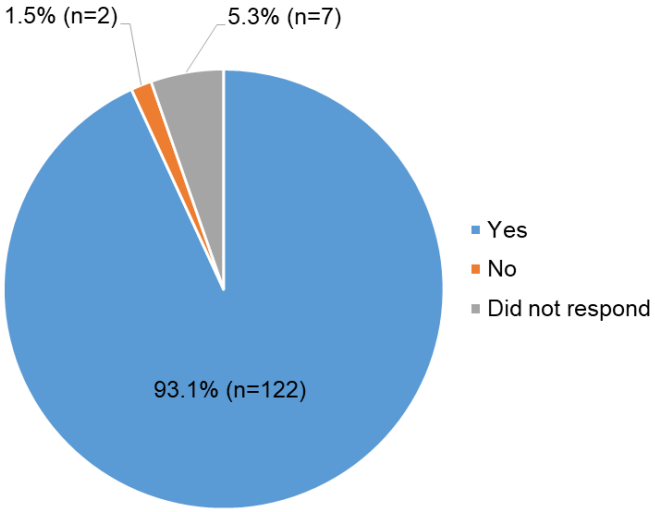
904.50, IQR 360.50 to 1652.25). Of those Trusts/HBs who provided bespoke insoles, 70.5% (91/129) used CAD/CAM whereas ~20% (25/129) did not use CAD/CAM to manufacture the bespoke insoles and 10.1% (13/129) did not respond.

Figure 4.2. Proportionate answers to individual questions from Trusts and Health Boards (HBs).

(a) Which of the following best describe your orthotic service?



(b) Does your orthotic service provide bespoke insoles to patients?



4.8.3. CAD/CAM insoles

Of the 91 Trusts/HBs that used CAD/CAM for insole manufacture, the response rate varied from 79.1% to 86.8% for the breakdown of the manufacture methods used in their services. Six (6.6%) Trusts/HBs were unable to provide specific details due to the insoles being manufactured externally without the Trust/HB

having knowledge of the external processes. A full breakdown of the manufacture methods are shown in Table 4.2.

Table 4.2. Techniques used to manufacture bespoke insoles

Method of insole manufacture (respondents)	**Volume of insoles: Median percentage†**	**Volume of insoles: Total**	**Volume of insoles: total**	**Volume of insoles: Median total†**
In-house Traditional (79/91)	0.0 (0.0 – 0.0)	11,006.89	27,296.65 (traditional manufacture)	0.00 (0.00 – 0.00)
Outsourced Traditional (72/91)	3.0 (0.0 – 9.1)	16,289.76		11.71 (0.00 – 942.90)
In-house Computer-Aided Manufacture using Reduction Manufacture (79/91)	0.0 (0.0 – 0.0)	22,044.63	76,381.25 (CAD/CAM manufacture)	0.00 (0.00 – 0.00)
In-house Computer-Aided Manufacture using Additive Manufacture (79/91)	0.0 (0.0 – 0.0)	5,373.27		0.00 (0.00 – 0.00)
Outsourced Computer-Aided Manufacture using Reduction Manufacture (72/91)	78.0 (17.8 – 95.0)	44,320.25		400.00 (0.00 – 942.90)
Outsourced Computer-Aided Manufacture using Additive Manufacture (77/91)	0.00 (0.0 – 10.0)	4,643.10		0.00 (0.00 – 49.61)

†Median (IQR 25 – 75)

With regard to the number of years that CAD/CAM had been used as part of their insole manufacture process, 85.7% (78/91) Trusts/HBs reported a median of 10.00 years (IQR 7.50 to 15.00).

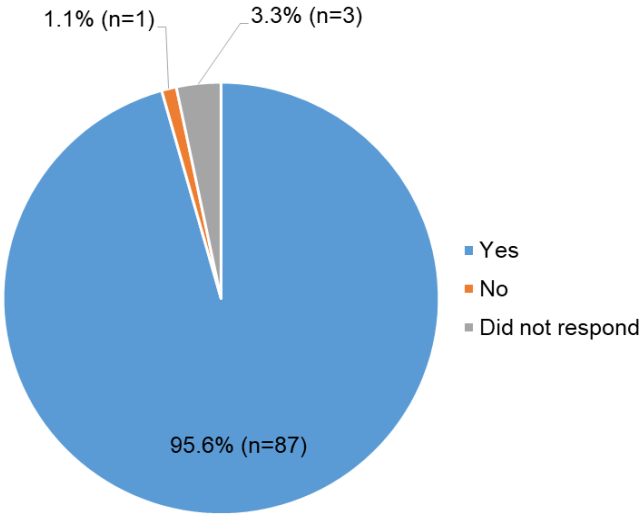
The final set of questions in this section were designed to understand details of the CAD/CAM workflow. A high majority (95.6% (87/91)) of Trusts/HBs confirmed they sometimes used foam-box impression casts when prescribing CAD/CAM insoles, and 3.3% (3/91) did not respond [Figure 4.3a]. Of those who used foam-box impression casts, 81.6% (71/87) scanned the cast directly into the CAD/CAM system, 1.4% (1/87) filled the cast with plaster before scanning, and 17.2% (15/87) did not know the specific processes due to this being undertaken by external manufacturers [Figure 4.3b]. With regard to the location of scanning, 90.8% (79/87) reported that the foam-box impression casts were transported and scanned into the CAD/CAM system on another site, 8.1% (7/87) reported that the casts were scanned on the site where the patient was seen, and 1.2% (1/87) provided an invalid response by selecting more than one option [Figure 4.3c]. Just over half (58.2%,(53/91)) of Trusts/HB reported they occasionally used slipper/plaster casts to capture patients' foot shape when prescribing CAD/CAM insoles, and 3.3% (3/91) did not respond [Figure 4.3d]. With regard to the location of scanning, 96.2% (51/53) of Trusts/HBs confirmed that the plaster/slipper casts would be transported to another site to be scanned into the CAD/CAM system, 1.9% (1/53) scanned the casts on the site where the patient was seen, and 1.9% (1/53) provided an invalid response by selecting more than one option [Figure 4.3e].

The majority of Trusts/HBs (86.8% (79/91)) confirmed that they most commonly used foam-box impression casts when manufacturing CAD/CAM insoles, 2.2% (2/91) did not respond, 1.1% (1/91) provided a free text answer of “direct scanner”, 1.1% (1/91) selected direct 3D scan using a handheld scanner, 1.1% (1/91) chose direct 3D scan using a flatbed scanner, 1.1% (1/91) chose slipper cast / plaster cast, and 6.6% (6/91) selected two options [Figure 4.3f]. For the 2021/22 financial year, the minimum total number of CAD/CAM insoles produced using foam-box impression casts was 36,316, with 3,252 produced with direct scanning, and 1,288 produced using slipper casts.

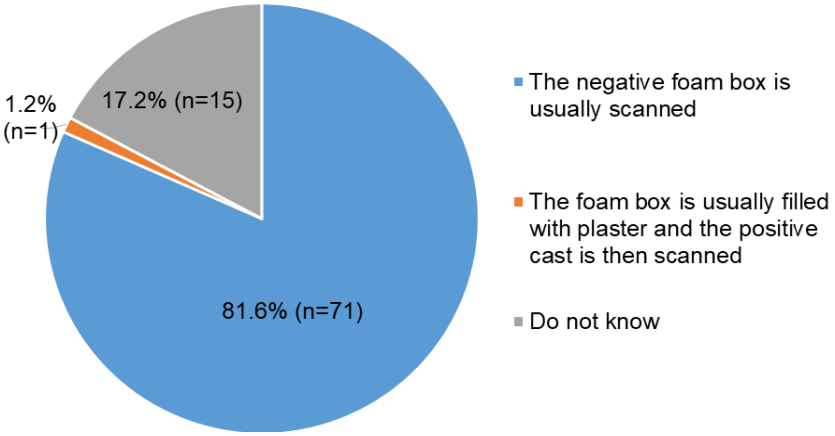
With regards to rectifying/modelling the CAD/CAM insoles, 73.6% (67/91) were conducted by a technician, 8.8% (8/91) confirmed the modelling was completed by the orthotist who assessed the patient, 1.1% (1/91) used a clinical assistant, 1.1% (1/91) reported two options, 12.1% (11/91) did not know due to an external manufacturer being responsible for the process, 1.1% (1/91) entered a free text answer of “podiatrist”, and 2.2% (2/91) did not respond [Figure 4.3g].

Therefore the summation of responses from this section of the FOI request shows that the most common workflow for CAD/CAM insoles in UK NHS orthotics services is a hybrid workflow, comprising elements of traditional manufacture and digital techniques [Figure 4.4].

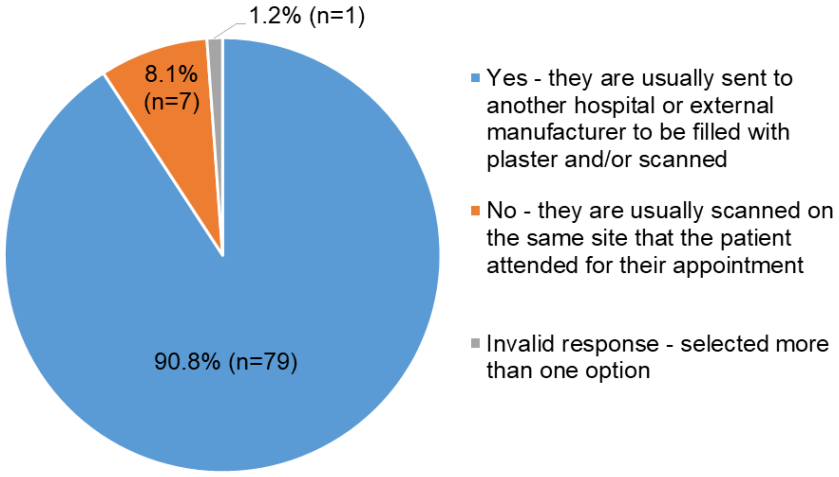
Figure 4.3. Proportionate answers to individual questions from Trusts and Health Boards (HBs).
(a) “Does your orthotic service ever use foam-box impression casts to capture the shape of the patient’s foot, when prescribing CAD/CAM insoles?”



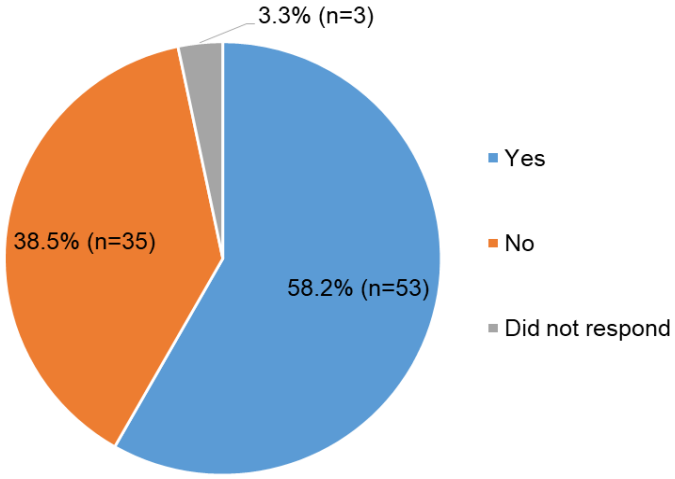
(b) “Is the negative foam-box impression cast usually scanned into the CAD/CAM system, or is it filled with plaster first and then the positive model scanned?”



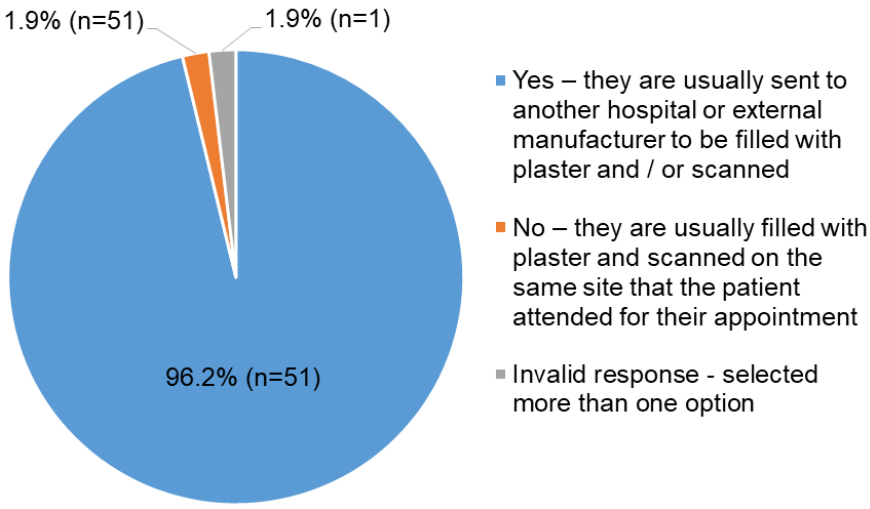
(c) “Are the foam-box impression casts usually transported to another site to be scanned into the CAD/CAM system?”



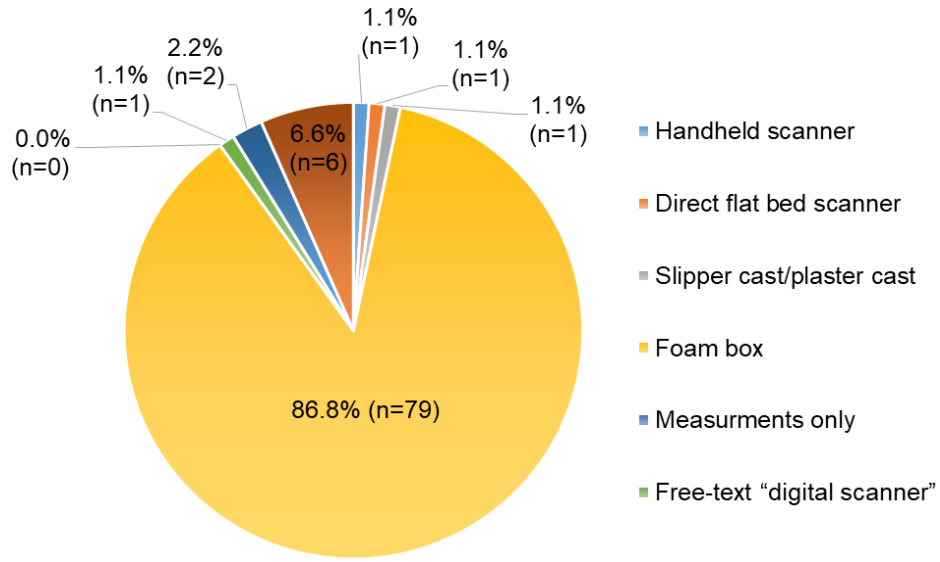
(d) “Does your orthotic service ever use slipper casts / plaster casts to capture the shape of the patient’s foot, when prescribing CAD/CAM insoles?”



(e) “Are the slipper casts / plaster casts usually transported to another site to be filled with plaster and scanned into the CAD/CAM system?”



(f) “In your orthotic service, which is the most common method used to capture the shape of the patient’s foot, when prescribing CAD/CAM insoles”



(g) “Who is usually responsible for performing the modelling/rectification of the CAD/CAM insoles that your orthotic service provide?”

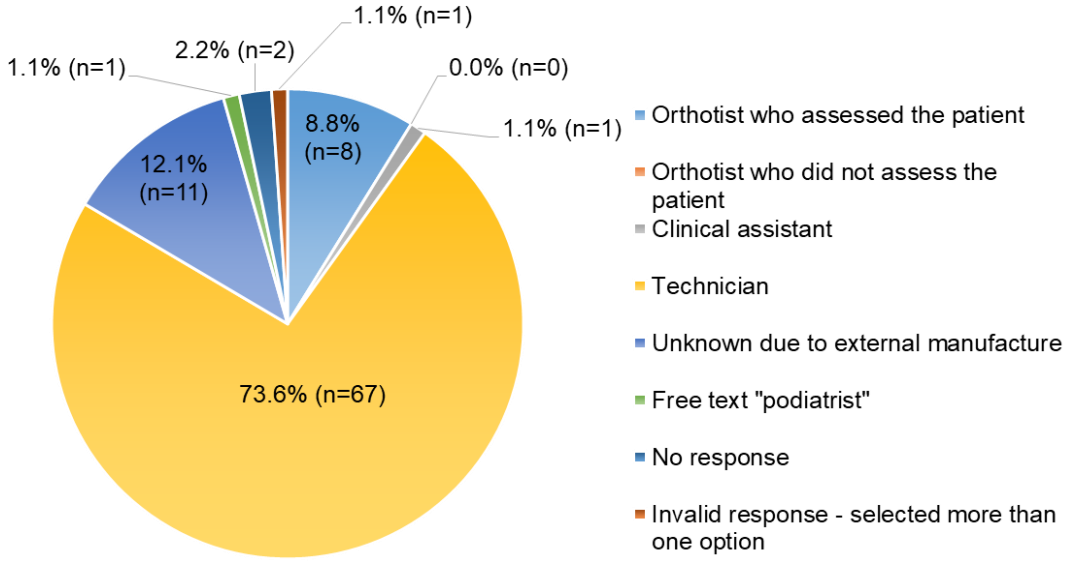
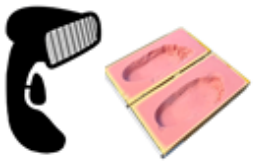


Figure 4.4. The most common workflow for CAD/CAM insole production in UK orthotic services.

Shape capture - 86.8% (79/91) of services most commonly used foam box impression casts when manufacturing CAD/CAM insoles
The patient's foot is pressed into a phenolic foam box to produce a negative cast of their foot

Scanning - 90.8% (79/87) of services reported that the casts were transported and scanned into the CAD/CAM system at another site
The foam box cast is physically transported to a site with a digital scanner



Digital upload - 81.6% (71/87) of services scanned the negative cast into the CAD/CAM system
The negative foam box cast is scanned directly into the digital scanner without being filled with plaster

Insole design – in 73.6% (67/91) of services a technician modelled the CAD/CAM insole
The digital foot model is modified in the CAD/CAM system in order to create the final insole deign

Manufacture – 86.9% (66364.88/76381.25) of all CAD/CAM insoles were produced by reduction milling
The physical insole is produced by a milling machine from the digital insole design which is milled into a block of material such as ethylene-vinyl acetate

4.8.4. Barriers and facilitators for CAD/CAM

In order to understand the barriers and facilitators that services experience when considering the use of CAD/CAM for insole manufacture, we asked those respondents who did not use CAD/CAM (25 of the 129 Trusts/HBs) to provide reason(s) for not using CAD/CAM. Multiple responses were permitted, and

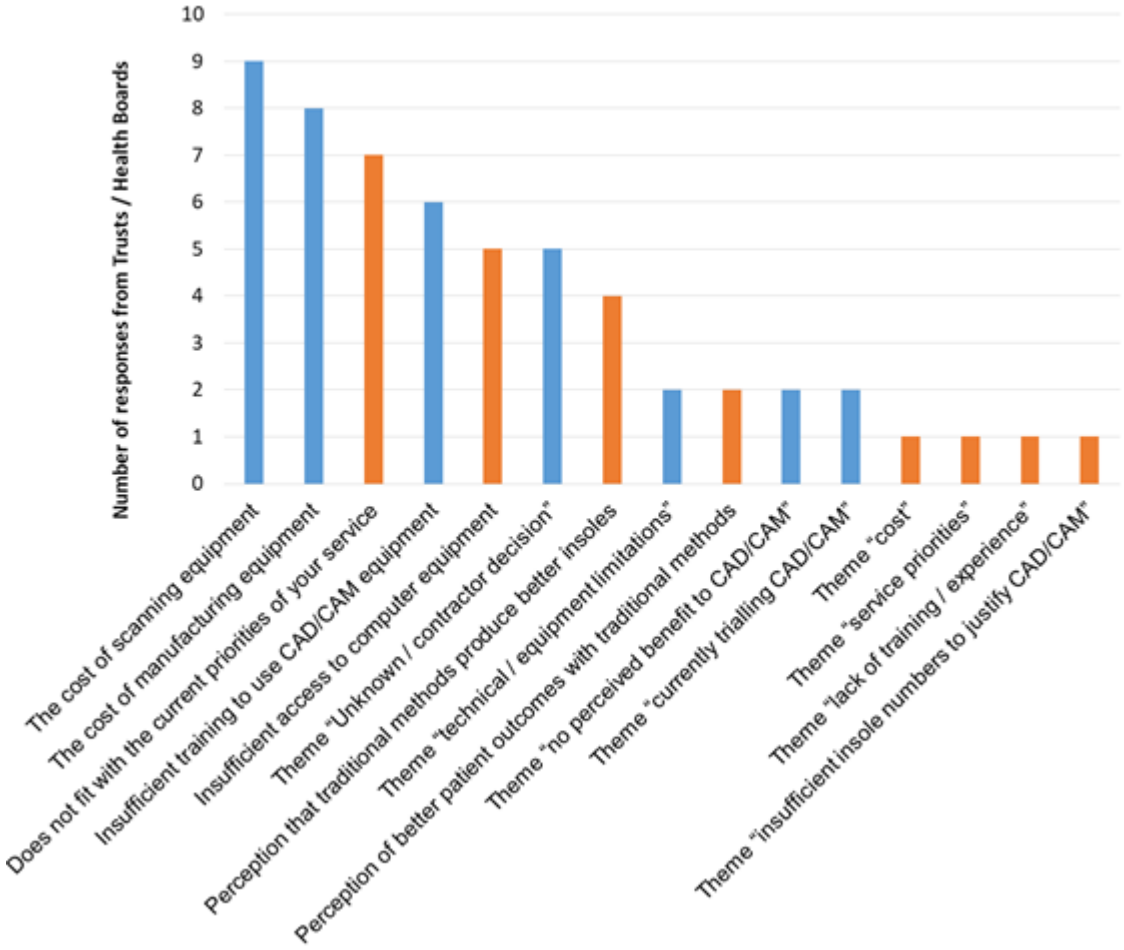
where a free text response was provided (48% (12/25)), these responses were collated into themes [Table 4.3]. Responses were received from 88% (22/25) Trusts/HBs, with the most common barriers being the cost of scanning equipment (40.9% (9/22), and the cost of manufacturing equipment (36.4% (8/22)), with all selected and thematic responses shown in Figure 4.5.

Table 4.3. Thematic breakdown of free text responses describing barriers to CAD/CAM from individual Trusts and Health Boards

Trust / Health Board response	Cost	Lack of training / experience	Service priorities	Technical / equipment limitations	No perceived benefit to CAD/CAM	Insufficient insole numbers to justify CAD/CAM	Unknown / contractor decision	Currently trialling CAD/CAM
"We have equipment to consider using CAD/CAM but due to this not being top priority, lack of experience, cost for technical support and time, this has been put on hold."	•	•	•					
"They are currently trialling this"								•
"…the numbers of specialist custom made foot orthoses required are lower and thus the cost benefits and time saving of foot only CAD CAM systems are less."						•		
"Our current supplier does not use scanning"							•	
"Unable to answer as this would be a contractor decision"							•	
"This is being considered however the current computer set up may provide difficulties in supporting scanning devices"				•				
"Not offered by the company"							•	
"A good service is provided via the methods currently use."					•			
"We use a company who are just testing the technology"							•	•
"Sharing of information electronically with third parties, not a limiting factor, but one to be considered"				•				
"Poor results with previous CAD systems"					•			

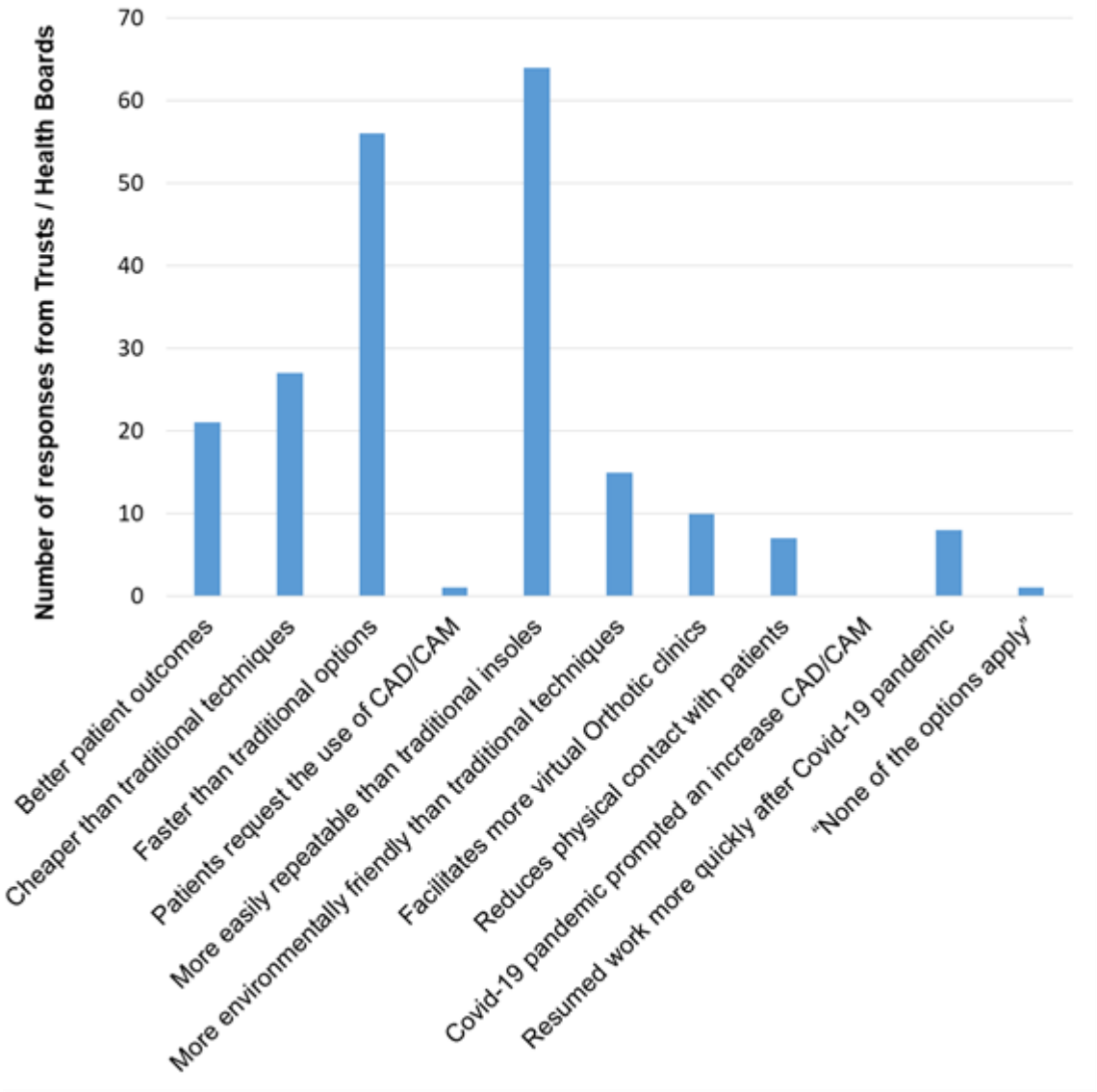
"Unsure, as external contractor"							•	
Totals	**1**	**1**	**1**	**2**	**2**	**1**	**5**	**2**

Figure 4.5. "What are the barriers for using computer-aided manufacture for custom insoles in your orthotic service?"



Those services who did use CAD/CAM (n=91) were asked to select any relevant options from a list of facilitators. Responses were received from 86.8% (79/91) Trusts/HBs with one respondent stating that none of the options applied. The most popular reasons for using CAD/CAM were the perception that CAD/CAM insoles are more easily repeatable than traditional insoles (81.0% (64/79)) and CAD/CAM is faster than traditional options (70.9% (56/79)) [Figure 4.6].

Figure 4.6. “In your orthotic service, what are the reasons for using CAD/CAM insoles?”



4.9. Discussion

4.9.1. Statement of principle findings

This chapter describes a cross-sectional study which was undertaken using freedom of information requests sent to all NHS Trusts and Health Boards across the UK, in order to gain an understanding of the current practices associated with the provision of CAD/CAM insoles in UK orthotic services. Respondents were asked to answer 22 questions relating to the use of CAD/CAM insoles in their orthotic service. The data collected was predominantly quantitative, but respondents were also offered the opportunity to

provide free-text responses to some questions, which provided some qualitative data as well. The response rate was high with responses received from 186 (86.9%) Trust and HBs, and 131 responses were included in the final analysis. 70.5% (91/129) of Trusts/HBs used CAD/CAM to manufacture bespoke insoles. The most common workflow associated with CAD/CAM insole production was foot-shape capture with a foam-box impression cast (86.8% (79/91)); casts transported to another site (90.8% (79/87)); foam-boxes scanned into a CAD/CAM system (81.6% (71/87)); insoles designed by a technician (73.6% (67/91)) and CAD/CAM insole produced with reduction milling (86.9% (66364.88/76381.25)). The survey confirmed the hypothesis that CAD/CAM insoles are being used widely by NHS UK orthotic services, and confirmed variation in the workflow. With a specific focus on shape capture methods, the majority of Trusts and Health Boards confirmed that they predominantly used foam-box impression casts rather than direct foot scanning in the production of CAD/CAM insoles. The greatest barriers to the use of CAD/CAM were those of equipment costs and staff experience and training.

4.9.2. Interpretation within the wider context of the literature

The majority of NHS Trusts/HBs confirmed they did use CAD/CAM as part of their bespoke insole manufacture process, which is in keeping with the anticipated increase in CAD/CAM technology reported in the literature (Smith and Burgess, 2001; Haleem and Javaid, 2019). However, the workflow predominantly used by UK orthotic services [Figure 4.5] constitutes a hybrid-digital process rather than a fully-digital process, whereby some steps associated with traditional manufacture remain. This would potentially reduce some of the reported benefits associated with CAD/CAM such as waste production and speed of manufacture.

Past research has shown that hybrid digital processes, equivalent to the most common process used in the UK as described in this paper, produce greater waste products and pollution, and score less favourably in terms of sustainability than fully digital processes (Cheng and Wang, 2024). Furthermore, services using plaster casts and slipper casts within their CAD/CAM insole workflow, as well as those choosing to fill foam-box casts with plaster prior to digital upload, further decrease sustainability of the insole

production (Cheng and Wang, 2024). Although some studies have identified the potential for recycling of both gypsum and plaster of Paris, these techniques are not currently part of routine medical or industrial processes (Tawade *et al.*, 2024; Shangali, Shiyo and Nagels, 2020; Geraldo *et al.*, 2017). The production of such avoidable waste products should be strongly considered by orthotic services wishing to improve their environmental impact in terms of carbon emissions, and for those services in the UK to meet NHS net-zero goals (van Hove *et al.*, 2024; Torjesen, 2020). Future studies comparing patient outcomes using hybrid digital and fully digital workflows may help to better inform orthotic services about the clinical impact of these different methods, in order to support the case for best practice in terms of clinical goals alongside sustainability policies. Despite the increasing development of additive manufacture techniques in the orthotic profession in recent years (Chansoda, Chookaew and Suvanjumrat, 2024; Claybrook, 2024; Daryabor *et al.*, 2023), this study found that additive manufacture was the least used manufacture method for insoles in UK NHS orthotic services. As this is still a relatively new manufacturing technique it is possible that health services have not yet had the opportunity to fully explore the position of additive manufacture in treatment pathways, and future studies will be required to demonstrate any change in practices in the years to come.

With the majority of orthotic services physically transporting casts externally prior to digital upload into the CAD/CAM system, consideration should be given not only to the manufacture delay incurred by this step, but also to the possible carbon emissions associated with transportation (Aydemir *et al.*, 2023; Allahyari *et al.*, 2023; Dagay, 2021). It would therefore be advantageous to compare this with alternative fully-digital workflows which remove the need for transportation, such as direct scanning, to assess if these processes produce equivalent outcomes in terms of patient treatment, in order to establish best practice for CAD/CAM insole production. The size of the medical foot orthotic industry is expected to increase globally with a compound annual growth rate of 4.6%, in excess of $3.9 billion by 2030 (Cheng and Wang, 2024), establishing the optimal CAD/CAM processes in terms of clinical effectiveness and sustainability should be a research priority for the orthotic profession.

The greatest barrier to the use of CAD/CAM for insole production was related to equipment costs [Figure 4.5], which was in keeping with the barriers identified in previous reports (Binedell *et al.*, 2020; Ngan *et al.*, 2022; Silva *et al.*, 2024). Despite this, cost was also identified as a facilitator to the use of CAD/CAM, with 34.2% (27/79) of Trusts/HBs reporting that using CAD/CAM for insole production was cheaper than traditional techniques. It is possible that those who had not yet introduced CAD/CAM into their service model were limited by start-up costs associated with the integration of equipment and training of the workforce which has historically incurred high in-house costs (Smith and Burgess, 2001; Silva *et al.*, 2024). However, the contradiction observed in this study between the perceptions of cost both as a barrier and a facilitator suggests that services may well be basing their cost concerns on a legacy of historical CAD/CAM prices, which have reduced significantly in recent years such that CAD/CAM technologies are now being recommended as the lowest cost option for low income countries (Dickinson *et al.*, 2019).

Lack of experience and training related to the CAD/CAM process were highlighted as a barrier by 6 of 25 Trusts/HBs, accounting for 12.7% of the total reasons given by services for not using CAD/CAM for insole production. This lack of skills in the UK orthotic profession was also highlighted in the recent prosthetic and orthotic workforce survey, in which only 30% of orthotists reporting that they had CAD/CAM skills (Eddison *et al.*, 2024). Although within the current study, services who did use CAD/CAM were not asked to identify any barriers to their use of CAD/CAM processes, it is possible that the lack of clinical skills relating to scanning and digital modelling could partly explain why the current workflow in the UK favours a hybrid-digital model, whereby the scanning and modelling are undertaken at a central fabrication centre rather than by the orthotist in charge of the patients' care. In 2020, research on fully-digital workflows was more than three times greater than that on hybrid-digital workflows (Cheng and Wang, 2024). Workforce reviews have identified that improving clinicians CAD/CAM modelling skills could be a strategic advantage for the profession (Kogler and Hovorka, 2021), and over 70% of orthotists believe that CAD/CAM skills will be required by the profession in the future (Eddison *et al.*, 2024). As such, additional training and support will be necessary before UK orthotic services can transition to fully digital workflows.

In spite of the published benefits that CAD/CAM could offer during the time of the Covid-19 pandemic (Gatt, Formosa and Chockalingam, 2016; Binedell *et al.*, 2020; Sedigh *et al.*, 2020), none of the Trusts/HBs in our study reported increased use of CAD/CAM for insole production as a result of this, although eight Trusts/HBs were able to resume services more rapidly following the pandemic when they used CAD/CAM. These findings highlight that CAD/CAM processes were already established within these Trusts/HBs at the time of the pandemic, with a median of 10 years duration of use and as such the benefits were already established. Despite the access to digital modelling systems, and increased speed of CAD/CAM modelling, this study found that the majority of services still use a technician to model the digital scans. Although it has previously been suggested that optimal orthotic design would be achieved if the modelling was undertaken by the clinician responsible for the patients' care (Gatt, Formosa and Chockalingam, 2016), however it is unknown how this aspect of the manufacture process impacts on the clinical effectiveness of the final insole. Further research is required to understand how a hybrid-digital workflow compares with a fully-digital workflow in terms of patient outcomes, overall costs, and long-term sustainability.

4.9.3. Limitations

The main limitation of this study was the inability for some services to provide details on the specific processes used in the manufacture of CAD/CAM insoles due to these processes being undertaken off-site by an external manufacturer. It was therefore not possible to determine the consistency of different processes across Trusts/HBs. Furthermore, the study did not distinguish between different additive or subtractive manufacturing techniques (e.g., milling, direct extrusion, or selective laser sintering), which may each carry distinct operational, cost, and sustainability implications. A potential future development of this study would involve a mixed-methods follow-up study combining quantitative survey data with semi-structured interviews and observational audits of production processes, which should involve not just the NHS service providers, but also external manufacturers. This would provide greater contextual insight into operational variability, CAD/CAM resources, and perceived barriers to adopting fully-digital manufacturing approaches.

Due to the wording of one of the questions (question 3.7 “in your orthotic service, which is the most common method used to capture the shape of the patient's foot, when prescribing CAD/CAM insoles?”) data analysis had to be carried out on the assumption that 51% of the insoles from that service were manufactured using this method, it is therefore likely that the true number of foam-boxes used during the 2021/22 financial year was actually substantially more than stated in this paper, which was reported as “the minimum total number of CAD/CAM insoles produced using foam-box impression casts was 36,316”. Future studies should consider rewording this question to ask for the exact number or percentage of insoles manufactured using each shape capture method, to more accurately demonstrate the volume of each.

Only those Trusts/HBs who did not use CAD/CAM were asked to explain the barriers. This limited the ability to identify the barriers faced by those services who do use CAD/CAM processes, with regard to potential specific barriers relating to hybrid-digital and fully digital workflows.

An important aspect which was not considered in this study is the environmental management or waste disposal practices associated with CAD/CAM insole manufacture. Given the growing emphasis on sustainability within the NHS and the P&O profession’s alignment with NHS Net-Zero commitments, the omission of this line of enquiry represents a missed opportunity to quantify waste-handling practices or recycling strategies in current orthotic workflows. Future surveys could explore this by including targeted questions on how foam-box casts, plaster models, and milling waste are processed or disposed of, as well as whether services employ recycling or material-reduction strategies. Collecting such data would allow for meaningful comparison between hybrid-digital and fully-digital workflows in terms of environmental impact, and would provide evidence to guide policy and procurement decisions toward greener manufacturing pathways.

This study represents a cross-sectional snapshot of UK orthotic service practice during the 2021/22 financial year. As CAD/CAM technologies, materials, and clinical workflows continue to evolve rapidly, the findings may not reflect future practice. Longitudinal follow-up would therefore increase the ability to determine how CAD/CAM adoption, workflow preferences, or barriers change over time as

the evidence-base expands, services gain experience, or as new digital tools become more accessible. A valuable follow-on study would therefore be a repeat national survey undertaken within five years, using the same question framework to enable direct comparison and analysis of change. Such a longitudinal approach would help identify any trends in the transition from hybrid-digital to fully-digital workflows, the use of additive manufacture, and the long-term impact of sustainability initiatives, providing a more complete understanding of technological progression within UK orthotic services.

4.9.4. Conclusion

This study has identified considerable variations in processes currently associated with CAD/CAM insole production in UK orthotic services. A hybrid-digital workflow was found to be the most commonly used in the UK, which has been associated with increased waste products and greater transportation costs compared with a fully-digital workflow. Those services who are not currently utilising CAD/CAM in their insole workflow predominantly highlighted equipment costs and staff training as the main barriers. Services should consider engaging their staff in CAD/CAM training which has previously been identified as a priority for the future of the profession.

4.10. Contribution to knowledge

This study provided new knowledge on the use of CAD/CAM insoles across the UK, confirming that CAD/CAM has been widely adopted by NHS orthotic services, but highlighting the variation in workflow. The study provided information on the volume of CAD/CAM insoles produced in the UK and, importantly, the volume of waste products generated in the production of these insoles in the form of single-use foam-box impression casts; over 36000 of which were used to produce CAD/CAM insoles by NHS UK orthotic services in the 2021/22 financial year. The study also provided new knowledge on the barriers faced by orthotic services who do not currently use CAD/CAM insoles in their services and provides insights for services who may wish to pursue the use of CAD/CAM in the future. This study helped to set the stage for the RCT described in Chapter 5, providing valuable context to the processes used in the

UK which could then be aligned to the patient outcomes associated with these two shape capture methods.

4.11. Recommendations for further research

This cross-sectional survey was used to provide context for an RCT, described in Chapter 5, which explores how the shape capture element of the CAD/CAM workflow affects patient treatment outcomes.

Future research is required to understand how other elements in the CAD/CAM workflow may affect patient outcomes and service costs, for example this cross-sectional survey demonstrated variation in the staff members responsible for digitally modelling the insole, and it is currently unknown if this influences treatment outcomes.

This study considers the waste production by UK orthotic services using hybrid-digital workflows, however aspects such as carbon emissions associated with this workflow were not calculated in this study. In order to fully understand the environmental impact of hybrid-digital and fully digital workflows, future research should be considered to calculate the emissions associated with each stage of the various CAD/CAM processes.

CHAPTER 5. THE EFFECTIVENESS OF CAD/CAM INSOLES MANUFACTURED FROM FOAM-BOX CASTS VERSUS DIRECT SCANS IN TREATING MSK CONDITIONS OF THE FOOT AND ANKLE

5.1. Chapter structure and statement of contribution

This chapter describes part of the live project work that was undertaken during my enrolment at the University of Central Lancashire as a PhD by Portfolio student, from 2022 to 2025. This project aimed to demonstrate the effectiveness of two of the most common shape capture methods in the production of insoles using computer-aided design and computer-aided manufacture (CAD/CAM), in the treatment of patients with musculoskeletal (MSK) conditions. This was achieved by undertaking a double blinded randomised controlled trial (RCT) within a National Health Service (NHS) orthotic service. The protocol for the clinical trial described within this chapter, and the results of the clinical trial, have both been published as original peer-reviewed research articles which are presented as full PDFs in Appendix 44 and 45.

Article publication - RCT protocol: *Comparing the effectiveness of computer-aided design/computer-aided manufacturing (CAD/CAM) of insoles manufactured from foam box cast versus direct scans on patient-reported outcome measures: a protocol for a double-blinded, randomised controlled trial. Barr L, Richards J, Chapman GJ. BMJ Open. 2024 April; 14(4). doi: 10.1136/bmjopen-2023-078240.*

Article publication - RCT: *To scan or not to scan? Comparing the effectiveness and cost differential of insoles manufactured from foam-box casts versus direct scans in treating musculoskeletal conditions of the foot and ankle: A double-blinded, randomised controlled trial. Barr L, Richards J, Dickson C, Tawse J, Munro N, Scott H, Holland A, Chapman GJ. BMC Musculoskeletal Disorders. 2025 March; 26(282). doi: 10.1186/s12891-025-08513-2.*

This chapter presents an extended version of these publications, offering additional detail and context to the project.

The chapter begins with an introduction to the subject area to set the scene for the research, followed by a description of the clinical trial and how this was

developed to fill a gap in the knowledge base. The objectives and hypotheses associated with the clinical trial are described, and the methods and results of the trial are then presented. The chapter concludes with a discussion of the study findings and their relevance to the existing evidence base, along with suggestions for future research to build on the knowledge generated by this project.

5.1.1. Contribution by L Barr

The author developed the concept for the RCT, carried out the literature review, contributed to the methodology for the RCT, contributed to data-collection and analysis for the RCT, led the writing of the publications for the RCT protocol and the RCT, contributed to the review and editing of the final publications, and was first author on the final publications.

5.2. Introduction

5.2.1. Incidence of MSK conditions.

Musculoskeletal disorders are a significant concern for public health services, due to the growing prevalence of MSK conditions and the associated burden placed not just on individuals, but also on healthcare systems, economies, and communities at large (Gill *et al.*, 2023). Globally, MSK conditions include diseases such as osteoarthritis, rheumatoid arthritis, connective tissue disorders and low back pain, among others. The World Health Organization has identified MSK disorders as a leading cause of disability indicating that between 20% to 33% of the world population have pain due to an underlying MSK diagnosis, irrespective of age, gender or ethnicity (Vos *et al.*, 2017). A substantial increase in the incidence of MSK conditions is predicted for the future due to aging populations, which increases the risk of conditions such as osteoarthritis and chronic pain due to age related modification in bone density, muscle mass and protective fat pad atrophy (Sit *et al.*, 2020), in conjunction with concerns over an increasingly sedentary population which is known to negatively impact musculoskeletal health (Liu *et al.*, 2022; Mahdavi *et al.*, 2021). The development of chronic MSK conditions such as osteoarthritis and generalised MSK pain has been attributed not just to sedentary behaviour in elderly populations but is also an increasing concern linked to working conditions and

social habits in adulthood (Dzakpasu *et al.*, 2021), and late adolescence (Heikkala *et al.*, 2019). In the UK specifically, the burden of MSK conditions is apparent throughout the healthcare system, with an estimated 28.9% of the population living with MSK related pain or dysfunction (Keavy, Horton and Al-Dadah, 2023), and approximately 20% of GP consultations dedicated to the management of such conditions (Heron, Hart and Cupples, 2015; Murray, Murray and Murray, 2021).

The consequences of increasingly prevalent MSK conditions extend beyond the impact on the individual, to the financial burden placed on the healthcare system. In the UK, the annual costs associated with the treatment of MSK conditions have been estimated to be £5 billion (Murray, Murray and Murray, 2021). This figure is reflected in the global healthcare system, with MSK conditions considered to be one of the highest health expenditures, exceeding even that of heart disease and cancer combined in some contexts (Dieleman *et al.*, 2020; Wikström *et al.*, 2023).

MSK conditions of the foot and ankle are common, with UK studies indicating approximately 24% to 36% of the population to be affected by foot pain in adulthood (Thomas *et al.*, 2011; Gates *et al.*, 2019), accounting for 8% of all MSK conditions treated in primary care (Menz *et al.*, 2010), and thought to be persistent and long-term in approximately one third of cases (Marshall *et al.*, 2023). MSK conditions affecting the foot and ankle are common, including osteoarthritis (Paterson *et al.*, 2018), plantar heel pain (Rasenberg *et al.*, 2019), lateral ankle injury (Doherty *et al.*, 2014), Achilles tendinopathy (Wang *et al.*, 2022) and hallux valgus (Cai *et al.*, 2023). However MSK foot pathology frequently presents in multiple areas of the foot rather than one specific area, which can be a complication with regard to treatment (Chuter, Searle and Spink, 2016; Hendry *et al.*, 2019; Trotter and Pierrynowski, 2008). This is in keeping with MSK pathology in general which it is increasingly understood to affect more than one area of the body, with a recent cross-sectional study of 62 patients with MSK conditions demonstrating a median of seven areas of pain (Ferreira *et al.*, 2022), and an observational study including 115 podiatry patients in the UK showing that over 60% of patients had more than one area of foot pain prior to treatment (Hendry *et al.*, 2019). This should be a consideration when

interpreting the information from studies which focus only on one specific pathology, as the findings may not be directly transferable to usual clinical practice.

5.2.2. The use of insoles in the treatment of MSK conditions

With consideration to treatment of MSK foot and ankle conditions, insoles are widely used and presented as a viable treatment option within the literature, with prior systematic reviews and meta-analyses linking their effect to mechanisms such as kinematics and plantar pressures (Moisan *et al.*, 2022), loading forces and shock attenuation (Mills *et al.*, 2010), as well as their effect on muscle activity (Murley *et al.*, 2009), and kinetic impact forces (McMillan and Payne, 2008). A Cochrane review in 2008 explored the effectiveness of custom insoles on treating various MSK conditions of the feet, concluding that custom insoles had the potential to reduce the pain associated with hallux valgus, pes cavus, plantar fasciitis, hallux valgus, and rheumatoid arthritis, but did highlight the need for larger, higher quality studies to build on this evidence base (Hawke *et al.*, 2008). A more recent systematic review identified that insoles tend to have a positive effect on pain, function and quality of life when used in the treatment of MSK conditions (Mendes *et al.*, 2020), a conclusion which is supported by meta-analyses exploring the outcome of insole treatment for specific MSK pathologies such as tibialis posterior tendon dysfunction (Adukia *et al.*, 2025), plantar heel pain (Salvioli, Guidi and Marcotulli, 2017; Whittaker *et al.*, 2017) and adult acquired flatfoot (Hoang, Chen and Chou, 2021). The use of insoles as a preventative measure for soft tissue injury however is not well supported, with a meta-analysis in 2017 demonstrating that insoles were not effective in preventing the development of specific MSK conditions such as Achilles tendinopathy (Bonanno *et al.*, 2017), a conclusion which concurred with prior systematic reviews on the topic (Yeung, Yeung and Gillespie, 2011; Landorf and Keenan, 2007) and a subsequent meta-analysis (Paradise *et al.*, 2024) and systematic review (Arslan *et al.*, 2021). But despite their widespread use, there is currently no consensus on the optimal prescription criteria, assessment criteria or workflow in terms of insole production, an issue which has been raised throughout much of the literature (Hawke *et al.*, 2008; Williams *et al.*, 2016; Tedeschi *et al.*, 2024).

Considering the incidence of MSK conditions and the evidence for use of insoles as a treatment option, it is not surprising that 92.7% of UK orthotists report treating adult MSK conditions (Eddison *et al.*, 2023; Leone *et al.*, 2024), with 95.7% of orthotists prescribing insoles for these conditions, confirming this to be the most common condition treated by orthotists in the UK (Nester *et al.*, 2018). This in conjunction with statistics showing that the global medical foot orthotic market is expected to increase upwards of $3.9 billion by 2030, with a compound annual growth of 4.6% (Cheng and Wang, 2024) in tandem with the increase in the incidence of MSK conditions, the importance of minimising costs and optimising treatment outcomes should be of the upmost importance.

5.3. Background to the project

As described in Chapter 4, a cross-sectional study of orthotic services across the UK demonstrated variation in CAD/CAM workflow for the production of insoles, with the majority of services using a hybrid-digital approach whereby shape capture was undertaken with a foam-box impression cast as opposed to a fully digital workflow using a direct scan of the foot. In order to understand how these two methods of shape capture would affect patient outcomes, and to assist orthotists in making evidence-informed choices for their patients, the clinical trial described in this chapter was designed.

In the early design stages of the project, consideration was given to the most appropriate participant group to investigate in terms of the clinical trial. Given the significance of MSK pathology in terms of the burden that it presents to healthcare services, and the widely evidenced use of insoles in the treatment of MSK lower limb pathology, the RCT described in this chapter was designed to recruit MSK patients. With consideration to the prevalence of multi-pathology MSK conditions as described in the literature, the study was designed to investigate participants with any presentation of foot and ankle MSK condition rather than limiting to one specific pathology, thus ensuring the trial was closely representative of standard day-to-day clinical practice.

5.4. Knowledge gap

The literature demonstrated a lack of evidence relating specifically to how foot-shape capture methods affect patient outcomes in the treatment of MSK foot and ankle conditions when prescribing CAD/CAM insoles.

5.5. Objectives

Given the knowledge gap, this project aimed to demonstrate the effect on patient outcomes comparing two different common foot-shape capture methods used in the workflow of CAD/CAM insole production when treating patients with MSK foot and ankle conditions, as well as exploring related concepts which would be of relevance to healthcare services, including a cost analysis of both methods and consideration of the environmental impact of both methods. When considered in combination with the cross-sectional study described in Chapter 4, this would provide clinical services with valuable insights into the most effective methods for shape capture within the CAD/CAM workflow, while additionally demonstrating the breadth of services for which this information is likely to be relevant.

5.6. Hypotheses

In order to meet the objectives, the RCT explored the hypotheses that the shape capture method used to produce custom CAD/CAM insoles, would not affect patient outcomes relating to foot pain, function, foot health and footwear, but that there would be greater cost and waste associated with the use of foam-box casts compared with direct foot scanning.

5.7. Methods

5.7.1. Trial design

A single centre, double blinded, randomised controlled trial comparing the effectiveness of two methods of foot shape capture to manufacture custom made insoles. An interventional, equivalence trial using medical devices commonly known as insoles.

5.7.2. Trial setting

Participant assessment and treatment was provided in a hospital setting, within the NHS Greater Glasgow and Clyde (GGC) orthotic service. There was one trial site, located at Glasgow Royal Infirmary. The trial minimised participant on-site visits by utilising telephone contacts throughout the participation period to collect relevant participant reported outcome measures (PROMs). At the conclusion of the participants' involvement in the trial, they were transitioned back to usual care within the NHS GGC orthotic service. The study protocol was reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan *et al.*, 2013).

5.7.3. Participant Recruitment

Individuals referred to the NHS GGC orthotics service with a musculoskeletal (MSK) medical condition or lower limb biomechanical deficit which would commonly be treated with the use of insoles as a first or second line intervention following the NHS GGC MSK Foot and Ankle Pathway (Munro, 2014) were offered the opportunity to enrol in the trial. In order to provide a realistic representation of day-to-day clinical practice, participants' pathology was not be limited to one specific pathology, this was similar to approaches taken in other studies investigating orthoses for non-specific lower limb MSK pathologies (Chuter, Searle and Spink, 2016; Hendry *et al.*, 2019; Trotter and Pierrynowski, 2008). Table 5.1 provides detail of the inclusion and exclusion criteria.

Table 5.1. Participant eligibility criteria.

Inclusion	Exclusion
• Aged 18 years or above • Referred to the NHS GGC orthotic service requiring a new assessment for insoles • Deemed suitable for CAD/CAM insoles as assessed by the Primary Investigator (PI) or Co-Investigator (Co-I) on clinical assessment • Able to commit to five appointments over a 16-week period (two face-to-face appointments, three telephone appointments) • Have suitable own outdoor footwear that can accommodate a CAD/CAM insole as assessed by the PI or Co-I, and can wear these for 12-weeks in accordance with standard practice • An adequate understanding of written and verbal information in English in order to provide informed consent and answer the study questionnaires	• Scheduled elective surgery or other procedures which is likely to affect mobility during the trial. • Scheduled steroid injections to the foot or ankle up to three months prior to joining or during the trial • Aged <18 years • Adults with incapacity, under The Adults with Incapacity (Scotland) Act • Participant unable or unwilling to consent • Medial longitudinal arch height of the foot exceeds depth of ethylene vinyl acetate (EVA) blank (35mm) • Clinical assessment concludes that the participant requires an insole material other than EVA • Clinical assessment concludes that the participant does not require or will be unlikely to benefit from CAD/CAM insoles, as outlined in the NHS GGC Foot and Ankle Pathway (Munro, 2014) • The participant is unable to commit to the trial conditions. • Peripheral neuropathy present • Active foot ulceration present • Participants with life expectancy of less than 6 months. • Any other significant disease or disorder which, in the opinion of the PI or Co-I, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial. • Participants who have participated in another research trial involving an investigational insole in the past 12-weeks.

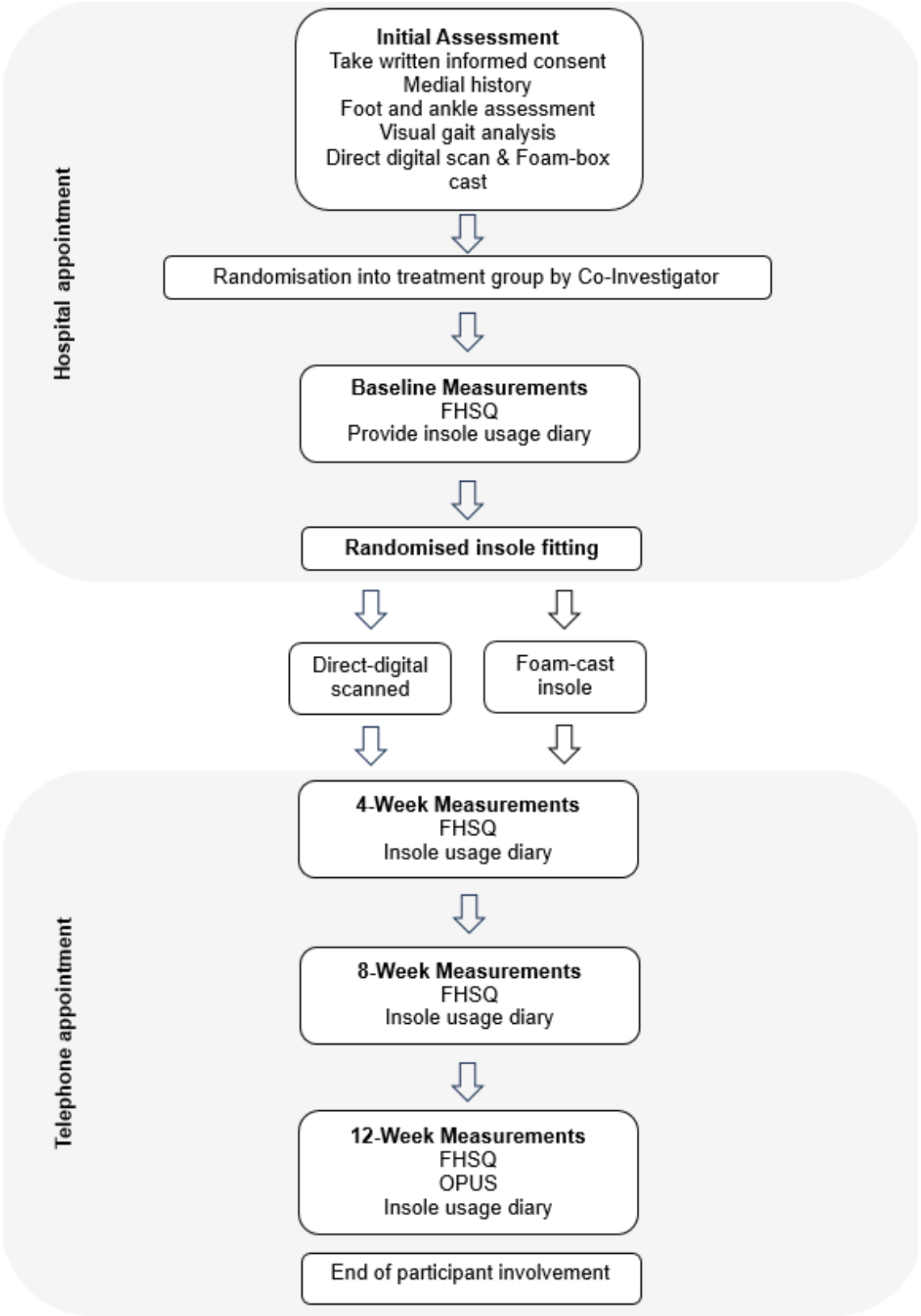
5.7.4. Assessments

Figure 5.1 shows the study flow chart for eligible participants. At the initial visit, participants attended a face-to-face hospital visit and were assessed and

screened according to the inclusion and exclusion criteria. Having read the participant information sheet for the trial and having the opportunity to ask further questions, participants signed a consent form and formally enrolled in the trial. During the baseline assessment, relevant medical history was recorded, as well as any routine medications taken by the participant. Physical examination of the foot and ankle included the Foot Posture Index-6 (FPI) (Redmond, Crosbie and Ouvrier, 2006), Jack's test for functional hallux limitus (Sánchez-Gómez *et al.*, 2020), palpation technique for subtalar joint axis location (De Schepper *et al.*, 2012), passive assessment of ankle dorsiflexion stiffness by position of first detectable resistance (Araújo *et al.*, 2011), supination resistance test (Noakes and Payne, 2003) and a visual gait analysis in the sagittal and coronal planes. Following the clinical assessment, participants underwent both a direct digital scan and foam-box cast of their feet so that the participants were unaware of which manufactured insole group they would be randomly assigned to. Direct digital scans were acquired using the Paromed ParoScan 3Dm mobile 3D scanner, and foam-box casts were taken using 6cm deep "Foot Impression Boxes" (Algeos Ltd, UK). In order to minimise any differences between casting and scanning methods, all foam-box casts and direct digital scans for all participants were taken by the Primary Investigator (PI) who has over 15 years' experience in the assessment, shape capture and design of insoles. All foam-box casts and direct digital scans were taken in a semi weight-bearing position, with the participant seated, and shape capture undertaken one foot at a time, with the contralateral foot positioned on the floor. The foot was manipulated by the clinician into the optimal position as determined by the participant's clinical assessment, the presenting MSK pathology and the FPI, before being placed into the foam-box and the scanner. For example, in instances of pathologies affecting the medial aspect of the foot, ankle or leg, and where FPI values are between 0 and +12, an external rotational force was applied to the participant's leg by the clinician, effectively supinating the foot in the foam-box cast and on the direct digital scanner. Conversely, in instances of pathology affecting the lateral aspect of the foot, ankle or leg, and where FPI values are between 0 and -12, an internal rotational force was applied to the participant's leg by the clinician, effectively pronating the foot in the foam-box cast and on the direct digital scanner. Where the

participant had mobility of the first ray and the insole prescription was to be designed to facilitate first ray plantarflexion, the clinician manipulated the first ray into a plantarflexed position by applying a downward force to the first metatarsal head in the foam-box cast and onto the direct digital scanner. These example techniques described for positioning the leg, foot and first ray, are similar to those described in previous literature regarding the effectiveness and repeatability of casting and scanning techniques (Trotter and Pierrynowski, 2008; Reina-Bueno *et al.*, 2021).

Figure 5.1. Trial flow chart for eligible participants.



5.7.5. Randomisation

At the end of the initial visit, participants were randomised to either the direct digital scan or foam-box cast manufactured insole group. Randomisation was

conducted according to a random number algorithm, contained in pre-sealed envelopes. The envelopes were opened on a 1:1 basis by the Co-Investigator (Co-I). The PI and the participants were blinded to the treatment arm.

In the event of a participant experiencing an adverse event and/or the medical condition of a participant necessitated unblinding, a Co-I (not blinded to the randomised intervention) would access the CAD/CAM insole ordering system to confirm the treatment arm. This process would not unblind the whole trial, nor would it disclose the randomisation schedule.

5.7.6. Interventions

All participants received a pair of custom, CAD/CAM EVA insoles. The insoles were manufactured from the allocated randomised technique; either direct digital scan or foam-box cast which was then scanned into the CAD/CAM system (ParoManager Paro360 v1.99, Paromed, Germany). All scanned CAD/CAM images were then modelled by the PI, who was blinded to the treatment arm, and has over 15 years' experience using the Paro360 CAD/CAM modelling system. The insole prescription and design was conferred by the PI and the Co-I who assessed the participant. It was not possible to design a prescription protocol due to the variety of presentations which would be recruited to the trial. In accordance with standard practice, insole prescription was determined by the physical and biomechanical assessment for each participant, and was conferred by two experienced clinicians at the time of assessment. Prescriptions included a variety of functional design features, for example the use of medial heel wedging for participants presenting with medial foot, ankle or lower limb pathology (Akuzawa *et al.*, 2021; Murley, Landorf and Menz, 2010), and medial heel skives if participants did not present with plantar heel pain (Bonanno *et al.*, 2012). Medial forefoot wedges were considered for participants presenting with medial foot or ankle pathology and a concurrent forefoot varus (Desmyttere *et al.*, 2018). Conversely the use of lateral forefoot wedges were included for participants with a lateral foot or ankle pathology (Palomo-Fernández *et al.*, 2023). Heel raises were considered where there was reduced range of ankle dorsiflexion, posterior or plantar heel pain, or leg length discrepancy (Rabusin *et al.*, 2019). Metatarsal domes were considered in conjunction with other functional design elements for participants with plantar

forefoot pathology (Collings *et al.*, 2021). The EVA Shore hardness was determined by the individual characteristics of the participant assessment. Participants with moderate to high supination resistance score or medially deviated subtalar joint axes were considered for harder EVA insoles (A50 – 70 Shore). Those participants with a low supination resistance score were considered for A30 – 40 Shore. Participants with characteristics such as forefoot plantar fat pad atrophy were considered for mixed A30/50 or A50/70 Shore EVA with the Shore hardness at the forefoot being softer.

5.7.7. Follow-up

Three weeks after the initial assessment, participants returned to the hospital setting for their insoles to be fitted. At this appointment, baseline outcome measures were collected and participants were provided with a diary to record their daily insole use. Outcome measures and insole use were collected via telephone appointments at 4-weeks, 8-weeks and 12-weeks post-baseline. Any issues with the insoles could also be raised by participants at these time points and appropriate action taken by the research team to resolve and record any issues or adverse events that may have arisen. Participants were also provided with contact details for the NHS GGC orthotic service and the research team, to raise any issues outside of these time points, and appropriate resolution was agreed and recorded on a case by case basis.

5.7.8. Outcome measures

Patient reported outcome measures were collected at baseline, week 4, week 8 and week 12 after insole fitting. The FHSQ has validated subdomains for pain, function, foot health and footwear (Bennett *et al.*, 1998; Landorf and Radford, 2008; Palomo-López *et al.*, 2019), which were completed at each time point. The FHSQ comprises 13 questions, with possible scores from 0 (worst outcome) to 100 (best outcome) (Bennett *et al.*, 1998; Landorf and Radford, 2008; Palomo-López *et al.*, 2019). The primary outcome measure was the FHSQ pain subdomain, with the subdomains for function, foot health and footwear being used as secondary outcome measures. The Orthotic and Prosthetic User Survey (OPUS) was also used as a secondary outcome measure, completed after 12-weeks of insole use to evaluate the patient satisfaction (Heinemann, Gershon and Fisher Jr, 2006; Sorrentino *et al.*, 2021).

The OPUS-CSD module is a PROM including nine questions about the overall experience with the orthotic device, producing raw scores from 0 (least satisfaction) to 36 (most satisfaction) which were then converted to Rasch scores 0 (least satisfaction) to 100 (most satisfaction), as this produces a linear internal-level scale which accounts for the importance of the individual survey questions (Fellinghauer, Debelak and Strobl, 2023; Piscitelli and Pellicciari, 2018). A further secondary outcome measure included participant adherence to treatment, whereby participants were be asked to keep a diary of daily wear time, in accordance with prior publications on measuring orthotic adherence (Duong *et al.*, 2021). The minimum threshold for adherence for this trial was considered to be >21 hours per week (Halstead *et al.*, 2016).

5.7.9. Cost analysis

The cost of service use was determined using published national unit costs available from the time of data collection (Jones and Burns, 2021; Scotland, 2023). Staff costs were calculated using mid-point NHS Band 6 pay scales for clinical costs and mid-point Band 4 for technical costs (£52 and £35 per hour respectively), as recommended by Jones and Burns et al (Jones and Burns, 2021) which accounted for overheads, capital overheads and inflated on-costs. Individual item costs for ethylene-vinyl acetate (EVA) blanks and foam-box casts included value added tax (VAT) and delivery charges.

5.7.10. Sample size

A sample size power calculation, based on data from (Landorf, Radford and Hudson, 2010) regarding FHSQ, was used to detect a clinical minimal important difference (MID) between groups of 13 (SD = 26.9) points in FHSQ scores using the pain subdomain as the primary outcome. As such, recruitment of 114 participants (57 per group) was required at a 5% significance level, with 90% power, allowing for 5% drop out.

5.7.11. Data management and auditing

Upon entering the study, participants were given a unique trial number to ensure participant anonymity throughout the trial. The unique trial numbers and participant details were stored securely and separate from the project files. All data and personal information complied with the requirements of the General

Data Protection Regulation 2018. Data handling complied with the standard operating procedures of the trial sponsor (NHS GGC) and the University of Central Lancashire. Trial monitoring was conducted by the sponsor (NHS GGC).

5.7.12. Adverse events

This trial was considered a low-risk trial for adverse events by the sponsor (NHS GGC). Any adverse events were recorded and reported to the trial sponsor.

5.7.13. Withdrawal of participants from study

During the course of the trial a participant could choose to withdraw from the trial at any time. The trial protocol recognised that this could happen for a number of reasons, including but not limited to the occurrence of what the participant perceives as an intolerable adverse event, inability to comply with trial procedures, or participant decision without reason. In addition, the PI could discontinue a participant from the trial treatment at any time if the PI considered it necessary for any reason including, but not limited to ineligibility arising during the trial i.e. development of a medical condition as outlined in the exclusion criteria, or significant non-compliance with treatment regimen or trial requirements i.e. participant had not worn or unable to wear the insoles. The type of withdrawal and reason for withdrawal was recorded in the CRF.

5.7.14. Missing data

Where data was missing for no more than two follow-up appointments, the last observation recorded was carried forward in the primary analysis. Data for participants who do not reach the minimum self-reported adherence threshold of >21 hours per week, calculated as an average across the 4-week, 8-week, and 12-week time points, was still included in the final between-group analysis to establish if adherence differed between groups.

5.7.15. Patient and public involvement

The study protocol and documentation were prepared with input from five patients who attended the NHS GGC orthotic service. Upon reviewing the patients' feedback, the study design was refined to incorporate telephone

follow-up appointments to minimise participant commitment to face-to-face appointments.

5.7.16. Ethics approval, trial registration and consent

Ethical approval was obtained from London Stanmore Research Ethics Committee (22/LO/0579), and the trial is registered on ClinicalTrials.gov. All participants were provided written informed consent to participate in the study prior to data collection. This trial was written and performed according to the Declaration of Helsinki.

5.7.17. Statistical analysis

Statistical analysis was undertaken at the end of the trial by a member of the research team (JR) who was blinded to the intervention allocation using SPSS (version 29). In accordance with the statistical plan outlined in the protocol, where data was missing for no more than two follow-up appointments, the last observation recorded was carried forward in the primary analysis. To assess the potential impact of missing follow-up data, a sensitivity analysis was performed using worst-case and best-case scenarios; in the first scenario all missing data from the direct scan group were assumed to correspond to the least favourable outcome with all missing data from the foam-box cast group corresponding to the most favourable outcome, in the second scenario these assumptions were reversed. The results were compared to the primary analysis to evaluate the robustness of the findings.

The main analysis investigated between-group differences in the primary and secondary outcome measures for the treatment groups at all time points. The distribution of the data was determined using Kolmogorov-Smirnov tests. Normally distributed data with only one time point were analysed using independent sample t-tests, those with more than one time point were assessed using mixed methods ANOVA and post hoc pairwise comparisons where significant main effects were seen. For non-normally distributed data with only one time point Mann Whitney U tests were performed, for data with more than one time point Friedman’s tests were first used to establish any within-group differences with post hoc Wilcoxon signed rank tests for those where significant differences were identified, and Mann Whitney U tests were used to test for

between-group differences with post hoc frequency tests for each time point. Minimal important differences were used at each time interval for the primary outcome measure, as well as the secondary outcomes of function, foot health and footwear.

With regard to the primary aim of the trial we felt it was clinically relevant to include any association between group allocation and the requirement for manual insole adjustment by the clinician during the trial period, and the effect of group allocation on the requirement for manual insole adjustment was assessed using a Chi-square test.

5.8. Results

5.8.1. Participants and attrition

Screening and recruitment was undertaken at the NHS GGC orthotic service between 29 September 2022 and 06 July 2023. During this period 118 adults with an MSK pathology of the foot or ankle were screened. Of these, four either declined to participate or were excluded due to ineligibility. Overall 114 consented to participate in the trial and were randomly assigned to receive an insole manufactured from a foam-box cast (n=57) or a direct scan (n=57) [see Figure 5.2]. For the whole cohort, participants were predominantly female (72%, n=82), with a median age of 50 years, and median body mass index (BMI) of 29.78. The randomised groups were found to be well balanced across baseline characteristics [Table 5.2].

Figure 5.2. Study flow chart.

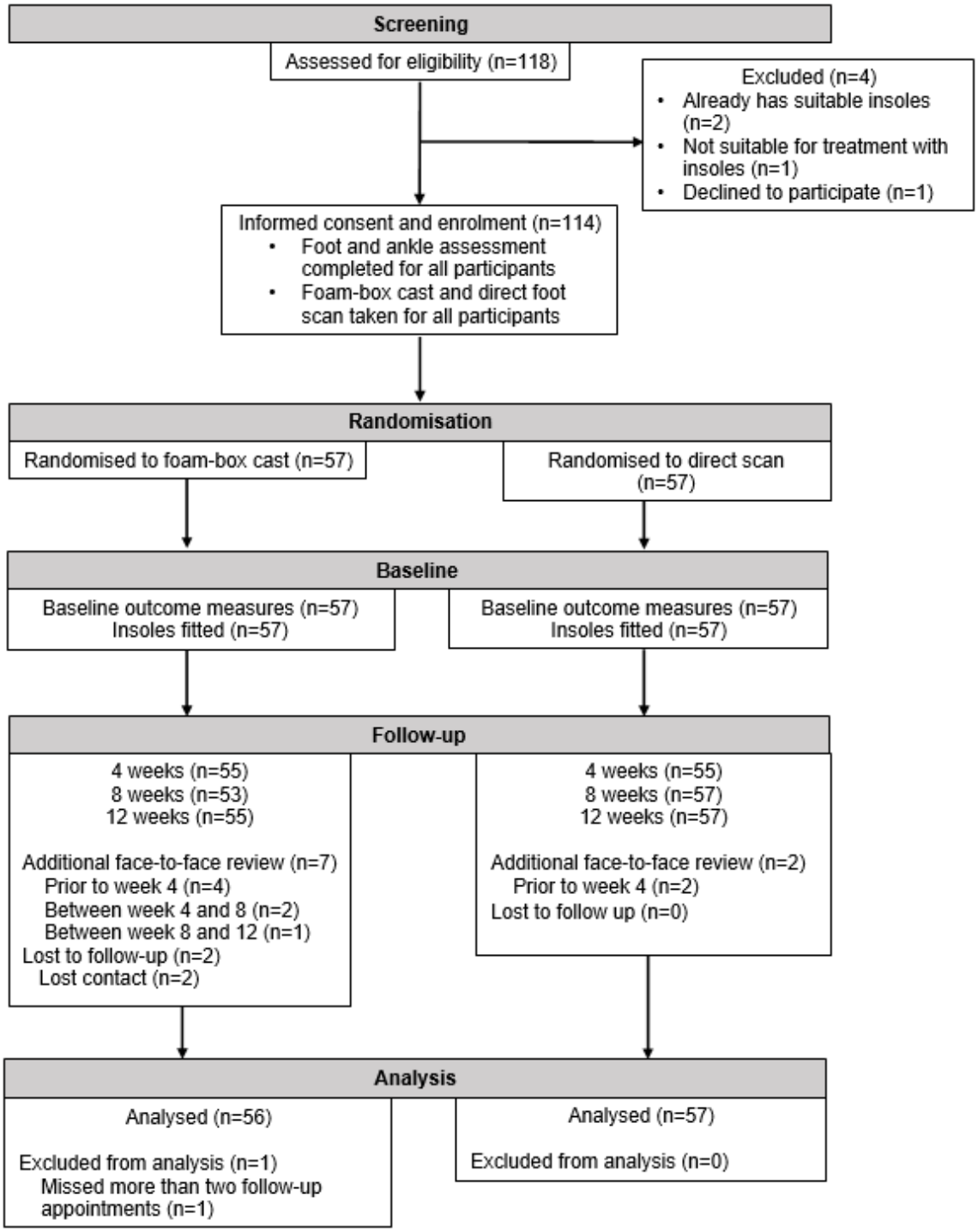


Table 5.2. Baseline demographics and clinical characteristics of participants by allocated treatment group. Number of participants (percentage) unless otherwise stated.

Characteristics	Foam-box cast (n=57)	Direct scan (n=57)	Overall (n=114)
Sex			
Male	16 (28)	16 (28)	32 (28)
Female	41 (72)	41 (72)	82 (72)
Ethnicity			
African	1 (2)	0 (0)	1 (1)
Other (mixed)	0 (0)	1 (2)	1 (1)
White	56 (98)	56 (98)	112 (98)
Age (median (IQR))	50 (32.0, 61.0)	50 (34.0, 59.0)	50 (33.0, 60.0)
BMI (median (IQR))	30.28 (24.91, 35.53))	29.13 (25.86, 35.32)	29.78 (25.70, 35.40)
Primary area of pathology*			
Ankle	21 (37)	24 (42)	45 (39)
First ray	3 (5)	10 (18)	13 (11)
Forefoot	17 (30)	10 (18)	27 (24)
Lower leg	0 (0)	1 (2)	1 (1)
Midfoot	4 (7)	1 (2)	5 (4)
Plantar heel / plantar fascia	12 (21)	11 (19)	23 (20)
Affected side			
Left	28 (49)	26 (46)	54 (47)
Right	29 (51)	31 (54)	60 (53)
Medication			
Biologics	2 (4)	4 (7)	6 (5)
DMARDs	7 (12)	9 (16)	16 (14)
NSAIDs	6 (11)	8 (14)	14 (12)
Oral steroids	3 (5)	2 (4)	5 (4)
Analgesics	23 (40)	15 (26)	38 (33)

*Pathology detail: Ankle pathology including Achilles tendinopathy, lateral ankle ligament pathology, peroneal tendinopathy, peroneal subluxation, ankle joint OA, anterior ankle impingement, sub fibular impingement, talar fracture, deltoid ligament tear, posterior tibial tendon dysfunction. First ray pathology including first metatarsophalangeal (MTP) joint osteoarthritis (OA), symptomatic hallux valgus, symptomatic functional hallux limitus, first tarsometatarsal joint OA, sesamoiditis. Forefoot pathology including intermetatarsal neuroma / plantar digital neuritis, inflammatory arthropathy of the lesser MTP joints, plantar plate dysfunction, migration of plantar fat pad and forefoot overload. Lower leg including medial tibial stress syndrome. Midfoot pathology including dorsal midfoot impingement, talonavicular joint OA, spring ligament tear. Plantar heel / plantar fascia including calcaneal fracture, plantar fasciopathy, plantar fibroma, plantar heel pain associated with inflammatory arthropathy. DMARDs=Disease-modifying antirheumatic drugs. NSAIDs=non-steroidal anti-inflammatory drugs.

All participants in the direct scan group completed the trial and in the foam-box cast group, two participants were lost to follow-up before the trial end point, with an attrition rate of 3.5%, thus keeping the sample size above the 5% allowance for dropout. One of the two participants who were lost to follow-up before the trial end point missed more than two follow-up appointments and their data could therefore not be carried forward in the analysis, as such 56 participants were included in the final analysis of the foam-box cast group and 57 in the direct scan group. With regard to missing data, in the direct scan group the last observation was carried forward for two participants from baseline to week 4 , and in the in the foam-box cast group the last observation was carried forward for two participants from week 4 to week 8, this data was used for the primary analysis.

The worst-case and best-case sensitivity analyses produced results consistent with the primary analysis. While slight variations in the p-values were observed for some secondary outcomes, these changes were minor and did not affect the overall conclusions. No serious adverse events were reported. Nine participants reported adverse events which included discomfort in the arch area of the foot (n=7), the lateral midfoot (n=1) and the forefoot (n=1), and were resolved following review and manual adjustment of the insole; 7 participants in the foam-box cast group (4 within the first 4 weeks, 2 between week 4 and week 8, and 1 between week 8 and week 12), and 2 in the direct scan group (both within the first 4 weeks). Three participants experienced non-related adverse events; fell and sustained a broken toe (n=1), diagnosed with a tibial stress fracture after participating in high impact sport while not wearing insoles (n=1), fell and developed knee pain (n=1). 112 participants completed the final outcome measures at the 12-week follow-up appointment (Figure 1).

5.8.2. Outcomes

The Kolmogorov-Smirnov tests showed that pain, foot function, foot health and footwear were not normally distributed. OPUS-CSD and adherence both showed a normal distribution. For the primary outcome measure of pain, Friedman test demonstrated significant differences between time points for both the foam-box cast group ($p<0.001$) and the direct scan group ($p<0.001$). Post

hoc Wilcoxon test demonstrated that compared to baseline, both the foam-box cast group and the direct scan group reported significant improvements in pain at week 4 ($p<0.001$ and $p<0.001$), week 8 ($p<0.001$ and $p<0.001$), and week 12 ($p<0.001$ and $p<0.001$) respectively, all of which exceeded the minimal importance difference (MID) of 13. No significant change was observed between week 4 and 8 ($p=0.995$ and $p=0.509$), between week 4 and 12 ($p=0.312$ and $p=0.118$), or week 8 and 12 ($p=0.225$, and $p=0.117$) respectively. Mann-Whitney U tests demonstrated no significant between-group differences for pain at any time point (baseline $p=0.683$, week 4 $p=0.906$, week 8 $p=0.418$, week 12 $p=0.557$) [Table 5.3].

Table 5.3. FHSQ Pain, Function, Foot Health and Footwear subdomains. Values are Median (IQR 25, 75) unless otherwise stated.

FHSQ subdomain	Visit	Foam-box cast		Direct scan		Between-group p-value
		n	Median (IQR)	n	Median (IQR)	Mann Whitney U
Pain	Baseline	57	48.13 (29.38, 71.88)	57	53.75 (27.19, 72.5)	0.683
	Week 4	56	72.50 (57.19, 84.38)[a]	57	78.13 (48.13, 84.38) [a]	0.906
	Week 8	56	72.50 (49.53, 84.38) [a]	57	78.13 (54.06, 85.00) [a]	0.418
	Week 12	56	78.13 (53.75, 92.97) [a]	57	78.75 (53.75, 93.75) [a]	0.557
Within group p-values			**<0.001***		**<0.001***	
Function	Baseline	57	68.75 (43.75, 87.50)	57	62.50 (37.50, 90.63)	0.556
	Week 4	56	87.50 (57.81, 93.75) [a]	57	87.50 (62.50, 100.00) [a]	0.818
	Week 8	56	75.00 (51.56. 93.75) [a]	57	93.75 (59.38, 100.00) [a]	0.077
	Week 12	56	87.50 (68.75, 100.00) [a,c]	57	93.75 (65.63, 100.00) [a]	0.322
Within group p-values			**<0.001***		**<0.001***	
Foot Health	Baseline	57	25.00 (0.00, 60.00)	57	42.50 (0.00, 72.50)	0.336
	Week 4	56	42.50 (25.00, 72.50) [a]	57	60.00 (25.00, 85.00) [a]	0.158
	Week 8	56	46.25 (25.00, 69.38) [a]	57	72.50 (25.00, 85.00) [a]	**0.039***
	Week 12	56	60.00 (25.00, 81.88) [a]	57	72.50 (25.00, 85.00) [a,b]	0.080
Within group p-values			**<0.001***		**<0.001***	
Footwear	Baseline	57	33.33 (16.67, 58.33)	57	50.00 (25.00, 75.00)	0.084
	Week 4	56	41.67 (25.00, 64.58)	57	50.00 (25.00, 75.00)	0.365
	Week 8	56	25.00 (16.67, 58.33) [b]	57	50.00 (25.00, 75.00)	**0.047***
	Week 12	56	25.00 (10.42, 56.25) [b]	57	50.00 (25.00, 83.33)	**0.022***
Within group p-values			**0.009***		0.344	

* denotes significance; a denotes significantly different from baseline; b denotes significantly different from 4-weeks; c denotes significantly different from 8-weeks
IQR = Interquartile range
FHSQ = 0 to 100, higher scores indicate less pain

For foot function, Friedman test demonstrated significant differences between time points for both the foam-box cast group ($p<0.001$) and the direct scan group ($p<0.001$). Compared to baseline, post hoc Wilcoxon test demonstrated that the foam-box cast group and the direct scan group reported significant

improvements in function at week 4 ($p<0.001$ and $p<0.001$), week 8 ($p<0.02$ and $p<0.001$), week 12 ($p<0.001$ and $p<0.001$) respectively. For both groups, the MID of 7 was exceeded at all time points with the exception of baseline to week 8 for the foam-box group. A significant improvement in foot function was observed from week 8 to week 12 in the foam-box cast group ($p=0.019$). No significant changes were observed in either the foam-box cast group or the direct scan group from week 4 to week 8 ($p=0.234$ and $p=0.589$), week 4 to week 12 ($p=0.397$ and $p=0.412$) respectively, or week 8 to week 12 in the direct scan group only ($p=0.585$). Mann-Whitney U tests demonstrated no significant between group differences for foot function at any time point (baseline $p=0.556$, week 4 $p=0.818$, week 8 $p=0.077$, week 12 $p=0.322$).

For foot health, Friedman test demonstrated significant differences between time points for both the foam-box cast group ($p<0.001$) and the direct scan group ($p<0.001$). Compared to baseline, post hoc Wilcoxon test demonstrated that both the foam-box cast group and the direct scan group reported significant improvements in foot health at week 4 ($p<0.001$ and $p<0.001$), week 8 ($p<0.001$ and $p<0.001$), and week 12 ($p<0.001$ and $p<0.001$) respectively, all of which exceeded the MID of 0. A significant improvement in foot health was observed from week 4 to week 12 in the direct scan group only ($p=0.026$). No significant change was observed in either the foam-box cast group or the direct scan group from week 4 to week 8 ($p=0.261$ and $p=0.069$), week 8 to week 12 ($p=0.172$ and $p=0.417$) respectively, or week 4 to week 12 in the foam-box cast group only ($p=0.052$). Mann-Whitney U tests demonstrated a significant between-group effect at week 8 ($p=0.039$), with the direct scan group reporting significantly better foot health (median 72.5, IQR 25.00 to 85.00) compared to the foam-box cast group (median 46.25 IQR 25.00 to 69.38) [Table 5.3]. No significant between group differences were observed for the other time points (baseline $p=0.336$, week 4 $p=0.158$, week 12 $p=0.080$).

For footwear, Friedman test demonstrated significant differences between time points for the foam-box cast group ($p=0.009$) but no significant differences were seen for the direct scan group ($p=0.344$). Post hoc Wilcoxon test demonstrated that, compared to week 4 the foam-box cast group reported significant worsening footwear scores at week 8 ($p=0.005$) and week 12 ($p=0.004$)

exceeding the MID of -2. No significant change was observed from baseline to week 4 (p=0.072), baseline to week 8 (p=0.59), baseline to week 12 (p=0.529) or week 8 to week 12 (p=0.682). Mann-Whitney U tests demonstrated a significant between-group effect for footwear at week 8 (p=0.047) and week 12 (p=0.022), with the direct scan group reporting significantly better footwear scores compared to the foam-box cast group [Table 5.3]. No significant between group differences were observed for baseline (p=0.084) or week 4 (p=0.365).

For OPUS-CSD Rasch scores, independent sample t-tests demonstrated a significant between group difference (mean difference 6.88, 95% CI 0.31 to 13.45, p=0.04) with the direct-scan group reporting greater satisfaction with their insoles at week 12 [Table 5.4]. For adherence the Mixed methods ANOVA demonstrated a significant main effect of group (p<0.001), and no significant main effect of time (p=0.515), and no significant interaction effect between time and adherence (p=0.731). Post hoc analysis demonstrated that the direct scan group showed greater adherence, wearing their insoles for a mean of 1.02 hours longer per day (mean 6.09 hours per day, 95% CI 5.68 to 6.51) compared to the foam-box cast group (mean 5.08 hours per day, 95% CI 4.66 to 5.50) [Table 5.4]. A chi-squared test found a significant association between group and requirement for insole adjustment (p=0.006), with the foam-box cast group requiring more adjustments (N=15) than the direct scan group (N=4), with a moderate effect size (Phi 0.26) [Table 5.4].

Table 5.4. Secondary outcome measures: OPUS-CSD Rasch scores, Adherence (hours per day), Manual insole adjustment (number of participants requiring insole adjustment). Results are presented as Mean (95% CI) unless otherwise stated.

Outcome Measure	Foam-box (95% CI)		Direct scan (95% CI)		Mean difference (95% CI)	p-value
	n		n			
OPUS-CSD	55	69.48 (64.59 to 74.36)	57	76.35 (71.84 to 80.86)	6.88 (0.31 to 13.45)	**0.04***
Adherence	56	5.08 (4.66 to 5.50)	57	6.09 (5.68 to 6.51)	1.02 (0.43 to 1.61)	**<0.001***
Total number of manual adjustments (n)	57	n=15	57	n=4		**0.006* (Phi 0.26)**

* denotes significance
OPUS-CSD Rasch scores = 0 to 100, higher scores indicate greater satisfaction

5.8.3. Differential cost analysis

The hybrid-digital process for the foam-box cast group cost an average of £55.46 per participant compared with an average of £44.94 per participant using the fully digital process in the direct scan group, resulting in an 23.41% (£10.52) cost difference per participant between the groups [Table 5.5]. Staff time accounted for most of the variation observed between the groups, with the foam-box cast group requiring an additional 9 hours 4 minutes of staff time throughout the duration of the trial period (total staff time for foam-box cast group hh:mm = 51:03) compared with the fully digital process (total staff time for foam-box cast group hh:mm = 41:59), leading to a difference of £422.85 in total staff time costs.

Table 5.5. Cost (£) and time (hh:mm) associated with different aspects of the hybrid-digital process for the foam-box cast group# and the fully digital process for the direct scan group.

Fully digital process: Direct-scan group								
Item/ Activity	**Item cost per participant**	**Total item cost per group**	**Mean staff time (SD) per participant**	**Total staff time per group**	**Mean staff cost per participant**	**Total staff cost per group**	**Total cost per participant**	**Total cost per group**
Clinical time for foot shape capture	N/A	N/A	00:02 (00:00)	01:36	£1.47	£83.79		
Clinical modelling	N/A	N/A	00:14 (00:02)	12:59	£11.84	£674.97		
Technical manufacture	N/A	N/A	00:28 (00:10)	26:24	£16.21	£923.97		
EVA blank	£14.52	£827.64	N/A	N/A	N/A	N/A		
Service use (additional 30 minute review appointment)	N/A	N/A	00:01	01:00	£0.91	£51.87		
Total	£14.52	£827.64	00:44	41:59	£30.42	£1,734.60	£44.94	£2,562.24
Hybrid-digital process: Foam-box cast group								
Foam-box	£1.97	112.29	N/A	N/A	N/A	N/A		
Clinical time for foot shape capture	N/A	N/A	00:01 (00:00)	00:57	£0.83	£47.31		
Transit per day (foam-box cast from trial site to manufacture site)#	£1.11	£29.97	N/A	N/A	N/A	N/A		

Technician cost for digital upload of foam-box cast	N/A	N/A	00:03 (00:01)	03:07	£1.92	£109.44		
Clinical modelling	N/A	N/A	00:18 (00:03)	17:30	£15.96	£909.72		
Technical manufacture	N/A	N/A	00:27 (00:09)	25:59	£15.95	£909.15		
EVA blank	£14.52	£827.64	N/A	N/A	N/A	N/A		
Service use (additional 30 minute review appointment)	N/A	N/A	00:04	03:30	£3.19	£181.83		
Total	£17.60	£969.90	00:54	51:03	£37.86	£2157.45	£55.46	£3127.35

*Excluding disposal costs #Calculated in miles using RAC Calculator (RAC, 2019) based on NHSGGC Fleet vehicle Ford Transit Connect using unleaded 95 Octane petroleum for city driving, with fuel economy of 24 miles per gallon, for one journey per day for the 27 days of recruitment. Price per litre calculated as an average using AA Fuel Price Reports for Scotland throughout the recruitment period = 149.33 pence per litre (Automobile Association (AA), 2023).

5.9. Discussion

5.9.1. Statement of principle findings

This publication presents a double blinded randomised controlled trial in which participants with MSK conditions were randomly assigned to receive custom CAD/CAM insoles using one of two commonly used foot shape capture methods; direct foot scanning or foam-box impression casting, which represented a fully digital workflow and hybrid digital workflow respectively. Participants completed outcome measures to assess the effect of the insoles on foot pain, function, foot health, footwear and satisfaction over 12 weeks of use, and a cost analysis of both workflows was conducted. 112 participants completed the trial, and both groups reported significant improvements in pain, function and foot health from baseline to 4, 8 and 12-weeks, which all exceeded their respective minimal important differences. As there was no significant difference between the groups in terms of pain, function and foot health at any time point, these results partially confirmed the hypothesis that there was no

difference between the two shape capture methods. However in contrast to the hypothesis, the results showed that foot scanning was superior to foam-box impression casting in terms of participant satisfaction, footwear, and adherence, with the direct scan group reporting greater satisfaction at 12-weeks ($p=0.04$), greater adherence ($p<0.001$), and requiring less insole adaptations ($n=4$) compared to the foam-box cast group ($n=15$) ($p=0.006$). The results also confirmed the hypothesis that insoles produced from foam-box casts would be associated with higher production costs compared with those produced from direct scans.

5.9.2. Interpretation within the wider context of the literature

To the authors' knowledge, this is the first randomised controlled trial comparing the effectiveness of CAD/CAM insoles produced from two different shape capture techniques. Both groups reported significant improvements in pain, function and foot health scores within 4 weeks of wearing their allocated insole, which were sustained at 12 weeks, which supports our hypothesis of equivalence between techniques. Importantly, the direct scan group reported significantly greater satisfaction, better adherence and required significantly less manual adaptations to their allocated insoles compared to the foam-box cast technique. In addition, insoles manufactured from direct scans cost less, and produced less waste products compared with insoles made from single-use, non-recyclable foam-box casts.

Many studies have investigated the effect of insoles on pain reduction in MSK conditions, yet there is no consensus on the timescale for maximum effect. Prior research on custom insoles show pain reductions at 12 weeks (Bishop, Thewlis and Hillier, 2018; Costa *et al.*, 2020; Shim *et al.*, 2021; Rasenberg *et al.*, 2021), while others report reduction between 4 to 8 weeks (Xu *et al.*, 2019; Schuitema *et al.*, 2019; Mayer *et al.*, 2007). Our study provides further evidence that custom CAD/CAM insoles can reduce pain within 4 weeks, sustained up to 12 weeks. These findings provide valuable information to orthotic services regarding timescales around treatment planning, suggesting that future studies could maximise the benefits of insoles within 4 weeks. Importantly, the present findings provide evidence that has the potential to minimise patient waiting times for treatment, in instances where orthotic treatment is unsuccessful,

rather than waiting the NHS standard of 8 to 12 weeks, patients could be offered the opportunity to review their treatment options after 4 weeks.

The direct scan group reported significantly better satisfaction and adherence than the foam-box cast group. Both groups exceeded previously published patient satisfaction scores with insoles (mean OPUS-CSD Rasch score 64.2) (Amer, Jarl and Hermansson, 2014) and lower limb orthoses (mean OPUS-CSD Rasch score 45.4) (Ghoseiri and Bahramian, 2012). Similarly, adherence for both groups was above the predefined threshold of >21 hours per week. Thus, it is plausible to suggest a link between greater satisfaction and better adherence whereby participants in the direct scan group wore their insoles for longer and were more satisfied with insole function while carrying out day-to-day activities compared to the foam-box cast group. This notion is contradicted by previous studies (Amer, Jarl and Hermansson, 2014) (Yamaguchi *et al.*, 2023) potentially due to participants encountering more diverse and/or complex tasks while wearing their orthosis which could result in lower satisfaction. More research is required to determine the relationship between adherence and satisfaction specifically focussing on insole use in heterogenous lower limb musculoskeletal patient groups. The lower satisfaction and adherence scores in the foam-box cast group could be due to greater requirement for manual adjustments (n=15) compared with the direct scan group (n=4) which could potentially be explained by past research showing greater shape variability between foot models obtained from foam-box casts and direct scans (Laughton, Davis and Williams, 2002; Telfer *et al.*, 2012). Sensitivity analysis using worst-case and best-case scenarios confirmed the robustness of the main findings. Although some secondary outcomes exhibited minor changes in p-values, these changes were not clinically meaningful. This suggests that the influence of missing data on the study conclusions is minimal. The results from our study suggest that a more comfortable device was achieved when using direct scans; although our study did not include comfort as a specific outcome measure, this effect could be explained by a previous study which demonstrated superior offloading properties in the midfoot when wearing insoles produced from direct scans compared with insoles from foam-box casts (Ki, Leung and Li, 2008). This, in keeping with another study showing superior offloading performance of CAD/CAM insoles from direct scans in diabetic patients (D'Amico *et al.*, 2021),

suggests a possible reason for the arch discomfort which was most frequently experienced by participants in the foam-box cast group in the current study. Thus, we suggest that the difference in model shape produced by the direct scan in the current study may be more favourable than the foam-box cast in terms of patient comfort and plantar pressure, which is reflected in greater satisfaction and greater adherence.

As a final consideration of the patient reported outcomes we acknowledge the differences between groups observed in foot health at week 8, and footwear at week 8 and 12; all of which were superior in the direct scan group. In terms of foot health, given the non-significant difference at any other time point compared with the direct scan group, and the overall improving trend in the foam-box group from baseline to 12 weeks, the difference at week 8 is not considered to be of clinical significance. The difference in footwear scores between groups at week 8 and 12 may be explained by the significant worsening of footwear scores observed in the foam-box cast group after week 4, whereas footwear scores for the direct scan group remained unchanged throughout the trial period. It is accepted that insoles reduce internal footwear volume by the nature of their physical position within the shoe, it is therefore unsurprising that footwear scores may reduce following the fitting of an insole; worsening of scores is indeed anticipated by the MID of -2 reported in the literature (Landorf, Radford and Hudson, 2010). Therefore the difference may be better viewed from the perspective of the scores in the direct scan group which are better at all time points compared with other publications investigating custom insoles (Tarrade *et al.*, 2019; Oliveira *et al.*, 2015; Whittaker *et al.*, 2020), this may provide another possible explanation for the higher satisfaction and adherence scores seen in the direct scan group.

Direct scanning costs less and required less staff time compared to the foam-box cast group. This in conjunction with the improved satisfaction and adherence also observed in the direct scan group would support the use of direct scanning in orthotic services. The reduced costs associated with direct scanning as demonstrated in this study, may assist those services wishing to explore innovation in terms of adopting a fully digital supply chain for CAD/CAM insoles. While costs are likely to be sensitive to local service and manufacture

arrangements as well as staff experience and training (Parker *et al.*, 2019), costings were based on established orthotic services who already use either fully digital CAD/CAM or hybrid-digital CAD/CAM techniques (Table 4). Costs associated with the scanning equipment are not included, and perceived as a reasonable exclusion as scanning equipment is a requirement for both methods. Services intending to make a case for integrating direct scanning equipment in to their service, need to consider equipment costs. The transportation of foam-box casts in this study are representative of standard practice for services who do not have access to scanners. However we acknowledge that transportation distance varies dependent on the orthotic centre, and the short distance in this study may actually underrepresent this aspect. Further research is required to understand how other orthotic services transport foam-box casts for scanning in order to evaluate cost implications across different geographic regions. While the authors acknowledge the importance of monetary and environmental costs associated with phenolic foam production (Sarika *et al.*, 2021; Tingley *et al.*, 2017), these costs could not be acquired from international manufacturers for this study, similarly transportation cost per item were unknown. Healthcare industries are being widely encouraged to meet net zero carbon emission targets and to achieve this goal, previous research highlights the importance of minimising waste products, unnecessary travel (Torjesen, 2020), and unwarranted treatment variation (van Hove *et al.*, 2024). In the orthotics industry, direct scanning for insoles decreases waste from non-recyclable single-use foam-box casts and reduces the necessity for transportation. The current study provides new insight into the benefits of direct scanning in relation to treatment outcomes and suggest shorter, four-week treatment evaluations, thus providing vital information to support orthotic services aiming to reduce waste, transportation, costs, and treatment variation when prescribing CAD/CAM insoles. Given that the previous study described in Chapter 4 showed that 86.8% of orthotic services in the UK use foam-box casts rather than direct scans, with over 36,000 foam-boxes used annually to produce CAD/CAM insoles (Barr, Richards and Chapman, 2025), it is crucial to consider the environmental impact of this hybrid-digital workflow. Studies show that workflows involving foam-box casts have lower sustainability scores compared to fully digital processes using direct scanners (Cheng and

Wang, 2024). Considering the positive clinical outcomes associated with direct scanning as demonstrated by the current study, along with the less favourable sustainability scores, transportation needs, and waste associated with foam-box casts; services should be encouraged to evaluate the environmental impact of using such waste products in their own service, in relation to net-zero targets (van Hove *et al.*, 2024; Torjesen, 2020).

5.9.3. Limitations

The main limitation of this study was the single centre design, which led to a lack of diversity among participants, and is also known to potentially overestimate intervention effects (Aïda *et al.*, 2012). While demographic characteristics were similar between groups, overall diversity was limited, with the majority of participants being white (98%) and female (72%), with a high BMI (median 29.78). Given that previous studies have shown an association between higher BMI and some MSK foot and ankle pathologies (Butterworth *et al.*, 2012), and that MSK conditions are more prevalent in females (Overstreet *et al.*, 2023), this aligns with the study population. To address this, we recommend future multicentre studies to determine whether the observed effects are consistent in a more diverse population.

This study chose to recruit participants referred to the orthotic service who met the criteria for insoles as outlined by the NHS GGC MSK Foot and Ankle Pathway (Munro, Tougher and Barr, 2024), therefore yielding a heterogeneous MSK pathology cohort which reflects the diversity typically seen in NHS orthotic services and enhances ecological validity. However, this heterogeneity limited the ability to draw condition-specific conclusions about the comparative effects of direct scanning and foam-box casting on clinical outcomes. Future research should therefore focus on larger, adequately powered multicentre studies that recruit homogenous diagnostic groups to allow for stratified analyses. Such studies could identify whether the benefits associated with direct scanning are consistent across pathologies or whether specific patient populations may derive greater advantage from one workflow over another, ultimately enabling more targeted and evidence-based clinical practice.

The decision not to include the capital costs associated with the initial purchase of the 3D scanning equipment was made for three reasons; firstly the use of scanners was required for both workflows and so it was decided that the capital outlay would have been redundant in terms of the cost differential, secondly the main intention of the cost-analysis was to show the cost per patient, thus including the capital outlay for the scanning equipment would have resulted in an over estimation of the individual patient cost, and thirdly the study was designed on the premise of a service which was already using CAD/CAM workflows and therefore the financial outlay for scanning equipment had already been made. This does limit the applicability of this aspect of the study to services who have not yet introduced direct scanning for CAD/CAM insoles, however despite this limitation the outcome of the study should be of use to services in developing capital bids for scanning equipment, as it demonstrates the long-term cost savings which can be achieved using this method, aligned with the clinical effectiveness and waste reduction outcomes. In order to align with the barriers of cost and staff training relating to the use of CAD/CAM, as identified in the prior study (Chapter 4), it would be advisable for future studies to explore the capital costs, cost of staff training requirements, and the potential downstream savings associated with reduced patient review appointments or remanufacture rates, alongside the positive outcomes identified in the current study relating to patient outcomes and workflow costs. Incorporating these variables within future health economic models would provide a more comprehensive understanding of the cost-effectiveness of transitioning to fully-digital workflows and provide valuable insight into implementation and training needs during digital transformation in orthotic services.

Within this study the possibility of including a full environmental impact analysis of both the hybrid-digital and fully-digital workflows was considered. Although initial discussions were held with the Head of Sustainability Services in NHS GGC, it was agreed that the scope required to perform such a comprehensive life cycle assessment exceeded the practical boundaries of this study. A complete life cycle assessment would need to encompass every aspect of the workflows, including the carbon footprint associated with the production of phenolic foam boxes and foot scanners, the international and domestic transportation of these materials and devices, and the subsequent disposal or

recycling streams following their use. Furthermore, to generate meaningful comparative data, the operational lifespan of scanners and associated equipment would need to be determined, allowing services to compare the cumulative carbon cost of long-term digital systems against repeated single-use foam-box casting. The complexity of performing such analyses is compounded by the wide variability in CAD/CAM systems available commercially, each with differing manufacturing origins, material compositions, and energy profiles. Despite these challenges, future research in this area would be of high value, as a comprehensive life cycle assessment could provide robust evidence to inform sustainable procurement decisions and guide the orthotic industry toward alignment with NHS Net-Zero targets (Torjesen, 2020; van Hove *et al.*, 2024).

Finally, although adherence was captured through participant self-report, objective monitoring of insole wear-time was not performed. The inclusion of embedded activity monitoring devices, such as temperature or pressure-based wear-time sensors (Devanand and Kedgley, 2023; Menz and Bonanno, 2021), could provide more accurate quantification of adherence in future studies. Combining such objective measures with patient-reported outcomes would enhance data reliability and allow researchers to explore the relationship between wear duration, comfort, and clinical benefit with greater precision.

5.9.4. Conclusion

This trial showed that shape capture with foam-box casts and direct scans are equally effective in producing CAD/CAM insoles which improve pain, function and foot health in MSK patients, and these effects occur within the first 4 weeks of insole use regardless of shape capture method. However, direct scan insoles showed benefits over those from foam-box casts when considering factors such as satisfaction, adherence, footwear and requirement for manual insole adaptions. In addition, direct scans also reduce the waste products associated with foam-box casts with the latter being more expensive than those produced by direct scan when considering staff time, transport, and foam-box purchase. As such, it is recommended that orthotic services explore the potential to use direct scanning for CAD/CAM insoles when treating MSK foot and ankle conditions, rather than using foam-box casts.

5.10. Contribution to knowledge

The positive results presented in this study relating to direct foot scanning provides orthotic services with new information regarding the potential to improve patient outcomes, while simultaneously reducing cost and waste, by using a fully digital workflow in the production of CAD/CAM insoles when used to treat MSK conditions of the foot and ankle. When these results are considered in tandem with the results from the cross-sectional survey described in Chapter 4, it is possible to appreciate the significance of the findings and the scope for possible improvements in terms of waste production and suitability across the UK which could be achieved by NHS orthotic services moving from foam-box casting to direct foot scanning.

This publication of the trial protocol contributed to the knowledge base by providing a structured framework outlining the objectives, methodology, and procedures of the trial conditions. In doing so, it demonstrated the consistency and reliability of the trial which would follow, while promoting transparency to other services who may wish to replicate the trial in future to validate or expand upon the findings. The protocol ensured ethical compliance, safeguarding the rights and well-being of participants, while also specifying the methods for data collection and analysis, in order to guarantee that the results of the final trial would be accurate, meaningful and replicable

5.11. Recommendations for further research

The results from this clinical trial have provided a foundation to support orthotic services and clinicians with clinical decision making when it comes to the prescription of CAD/CAM insoles; an orthotic intervention which is already being widely used in the UK. Future research is required to understand how other elements in the CAD/CAM workflow may affect patient outcomes and service costs.

A cost analysis was undertaken in this study and presented alongside waste production, sustainability and environmental considerations, however aspects such as carbon emissions associated with each workflow were not calculated in this study. In order to fully understand the environmental impact of these

workflows, future research should be considered to calculate the emissions associated with each stage of the two processes.

The clinical trial described in this chapter recruited patients with MSK foot pathology, but it is unknown if these results would be transferable to other patient cohorts which are routinely treated with custom insoles, such as those with high risk diabetic foot conditions. Future studies should consider investigating the use of direct foot scanning for CAD/CAM insoles for other patient groups in order to determine if the positive outcomes can be replicated in these scenarios.

CHAPTER 6. A VIEW TO THE FUTURE

This thesis has offered an autoethnographic perspective on my project work and research as a clinical member of an NHS orthotic service, and has identified areas of future research which could be considered as a response to the outcomes, and limitations, of the studies undertaken. As discussed within Chapters 3 to 5, a key theme of the research I have undertaken with regard to CAD/CAM insoles has been the effect on patient outcomes, which is central to my research interests as a member of the clinical workforce. As such, my suggestions for future research directions within Chapters 3 to 5 have focused on possible further developments and extensions of the described studies; with the aim of identifying the effectiveness of treatment on specific patient populations, and improving manufacture processes to optimise treatment outcomes. Conversely, this chapter offers wider philosophical consideration as to potential future directions of study, which could act as a driver for embedding research as a routine element of orthotic practice, and where aspects of the projects in this thesis could be translated into other areas of orthotic care.

As highlighted in Chapter 1, research remains the least developed pillar of practice within the orthotic profession. For clinicians and services, research is often perceived as secondary to the immediate demands of clinical care, professional education, and service leadership. Yet this thesis has aimed to offer a narrative that demonstrates research, far from existing in isolation, has the power to act as a driver and unifier of all four pillars of practice. Over the course of ten years, this project work has evolved from an interest in literature appraisal and clinical evaluation, to clinical trials and national studies, with the power to inform clinical innovation, underpin educational development, and strengthen professional leadership by promoting evidence-based decision-making.

One of the themes in this thesis has been the constraints often encountered within NHS practice. Within the orthotic profession, this may be seen in the use of legacy materials and systems, and the challenges faced by services who may wish to invest in new technologies without robust supporting evidence. Prior studies have raised the philosophical question "*is research a barrier to service delivery, or is service delivery a barrier to research*" (Frost and Britten,

2020), however it may be relevant to consider the alternative view that research can play a transformative role, offering a pathway through which clinicians can explore new practices, trial emerging technologies, and gather evidence that can, in turn, support more effective clinical pathways. An example of this was the integration of 3D printing into an NHS clinical pathway, explored in Project 2 (Chapter 3), which stemmed from clinical appraisal, and integration of new technology with systems which were already present in the orthotic service. While the focus of this project was based on insole manufacture, the principles and benefits explored within could have broader applications in areas such as Ankle Foot Orthosis (AFO) production. Although not a core focus of the research presented here, 3D-printed AFOs represent a logical extension of the themes explored, offering avenues for future research investigating the clinical outcomes and environmental sustainability of these innovations.

Sustainability, as discussed predominantly in relation to foam-box waste within Project 3 (Chapters 4 and 5), is particular area where further research is both necessary and expected in terms of international healthcare priorities (Sherman *et al.*, 2020; Lennox, Maher and Reed, 2018). Project 3 provided a foundation for exploring how the shape capture stage of digital manufacture for insoles could reduce material usage and waste production. Project 2 explored the use of 3D printing but did not quantify the impact of this method on waste production. As such, these two studies could be expanded upon and combined to better understand the cumulative environmental benefits of shifting away from a reduction milling process to 3D printing for CAD/CAM insole manufacture. As environmental awareness increases across the NHS and society more broadly, the orthotic profession must also critically evaluate its own carbon footprint and waste output. Future studies could therefore use these methods to examine full CAD/CAM manufacture analyses of different orthoses such as AFOs, where the volume of materials used and manufacturing waste tend to be greater due to the larger limb segment involved.

Another area that warrants exploration is the impact of research engagement on clinicians themselves. My initial journey into research was, in some respects, unintentional and undirected. What began as project work, largely driven by curiosity and a desire to improve service delivery, gradually evolved into a

structured research process. This evolution introduced me to new educational spaces, improved my confidence as a clinical leader, and facilitated national and international learning opportunities. This experience raises an important consideration: research does not need to be the exclusive domain of academic orthotists or those working in research posts. Prior studies have shown that healthcare providers seek to engage in research in which they have a personal interest (Marjanovic *et al.*, 2019), and this has certainly been my own experience. In the case of orthotic research, this could be considered as professionally advantageous, as the current lack of orthotic researchers means there is a significant opportunity for clinicians and services to explore any research area which is of professional interest to them and their service users. With appropriate support and mentorship, practicing clinicians can and should be empowered to engage in research activity; doing so not only benefits the individual, enhancing their understanding, reflective practice, and confidence, but also brings new, practice-based perspectives to the evidence base of the profession (Daniels, Gillen and Casson, 2021; D'Arrietta *et al.*, 2025). To embed research into routine NHS orthotic practice, a culture shift is required: one which sees research not as an optional aspect of practice, but as a core part of everyday professional activity.

A cultural shift towards a more research active profession is likely to be supported not only by research training provided in undergraduate and postgraduate orthotic education (McDonald, Kartin and Morgan, 2020; Al Qaroot and Sobuh, 2016), but additionally, by the creation of local research champions or clinical-academic roles within orthotic services, which could provide a visible and accessible route for colleagues to begin their own research journeys. As I approach the end of what I consider to be the first "research chapter" of my own career, I find myself looking ahead to where I might position myself in this wider research sphere of the orthotic profession. By stepping into new roles on national research committees such as the Community for Allied Health Professions Research Strategy Committee and the British Association of Prosthetics and Orthotics Research Committee, nurturing the new passion for research within my own orthotic service in NHS Greater Glasgow and Clyde, and expanding on my delivery of orthotic education with

new outcomes to share from the studies in this thesis, I hope to position myself as a resource for other clinicians starting on their own research journeys.

By exploring the ideas that emerged organically from clinical practice, this thesis has demonstrated how research can positively impact on treatment pathways, professional growth, patient outcomes, and the on the wider orthotic profession in terms of evidence-based practice. The future of orthotic practice lies in embracing research not as a separate activity, but as an integral part of daily practice, with the aim of fostering innovation, improving sustainability, and strengthening our profession for the challenges and opportunities ahead.

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APPENDICES

Appendix 1 - MSK and Orthopaedic Quality Drive: Spread and Sustainability of Five High Impact Workstrands Summary

Directorate for Health Workforce and Performance
Access Support Team

The Scottish Government

DELIVERING A GAMES LEGACY FOR SCOTLAND

Dear Colleague

MSK & Orthopaedic Quality Drive: Spread and Sustainability of Five High Impact Workstrands

CEL (2014) 2

24th February 2014

Addresses

For action
NHS Board Chairs
NHS Board Chief Executives
NHS Board Executive Leads

For information
Scottish Committee of Orthopaedics & Trauma,
Scottish Orthopaedics Services Development Group,
NHS Board Medical Directors, Nurse Directors and AHP Directors
HIS

Summary

This letter provides you with a practical framework to underpin spread and sustainability of five MSK & Orthopaedic high impact workstrands in your Board, at pace, for maximum benefit.

The national aspiration is that by generating momentum through a co-ordinated 'national effort', all five workstrands will be fully embedded in all territorial Boards. This will focus work to address current challenges in this specialty and support geographical service-equality for all patients across Scotland. There is a national lead for each workstrand to support you locally.

Each workstrand already has a clinical evidence / best practice base:

A. AHP MSK Redesign – Getting patients on the right pathway, starting in the community: By 31st March 2016, for people with MSK problems across Scotland to have easy access to a self-management resource and early appropriate advice and, if necessary, assessment by an efficient AHP service to get them started on the right pathway for their treatment first time.

B. Fracture Pathway Redesign – Patients only attend fracture clinics if there is a clinical need: By 31st March 2015, patients across Scotland with non-operative fractures to be either discharged directly by Emergency Departments or referred to virtual Orthopaedic clinics by using consensus protocols. Subsequently, for those reviewed virtually, only those patients with a clinical need to be brought back for an outpatient appointment.

C. Optimising patient recovery after joint replacement – Enhanced Recovery Pathway: By 31st March 2015, Arthroplasty patients across Scotland to have the best practice interventions along their care pathway that enhance their experience and optimise their recovery so that they reach their discharge criteria as soon as possible.

D. Hip Fracture Care Pathway – Optimising care of the frail elderly: By 31st March 2015, the care for hip fracture patients across Scotland to follow the '*Scottish Standard of Care for Hip Fracture Patients*' (to be distributed shortly). This is a pathway of evidence based/best practice clinical interventions to support patients' early recovery and optimise their ability to retain their independence.

E. Demand and Capacity Planning and Management – Supporting strategic and operational decisions: By 31st March 2015, all MSK and Orthopaedic Services to have the expertise and tools to drive strategic and operational capacity planning and management decisions to optimise capacity and ensure demand can be sustainably met.

Enquiries to:
Kate James
Access Support Team
St Andrew's House
Regent Road
Edinburgh EH1 3DG

Tel: 0131-244 5211
kate.james@scotland.gsi.gov.uk
http://www.scotland.gov.uk

Appendix 2 - Article published In BAPO Mag, 2016, issue 3, pp.22-23

Laura Barr

Orthotist, NHS Greater Glasgow and Clyde

"I still get nervous before (and during) every MSK course. I still don't sleep the night before. I still spend far too much time reading things I already know. I still take every opportunity to learn more. The course content has grown with the evidence, I think the handouts are currently 30% larger than they were on the first course – the poor BAPO Secretariat need an industrial stapler. And I still absolutely love it."

OVER THE PAST 2 years, one of the most common phrases used by the team who deliver the Assessment, Diagnosis and Treatment of Muskuloskeletal Foot and Ankle Problems for Orthotists course has been - 'the biggest challenge is standing up and presenting to your peers.' I'd like to suggest an addendum to that, being; 'with the exception of writing in the first-person about your experience of standing up and presenting to your peers.'

Bottle of wine on stand by. Let's get started.

I've been a trainer on nine of the affectionately termed 'MSK courses' and although I've never quite managed to shake the pre-course nerves (I'm talking 'sleep deprivation to the point of nausea' nerves, nothing serious), I've loved every single one of them. It's been fantastic to meet so many talented people in our profession, and to work with such a truly inspirational team. From a personal point of view, starting this program has ultimately changed the course of my career, provided the opportunity to speak on national and international platforms and helped me find the direction for my final year MSc project. It really has become a part of my life - this became abundantly clear when I realised that my parents were using the term 'MSK' in day-to-day conversation. And yes they do know what it stands for, I checked. But perhaps I should start this little reminiscence at the beginning.

I first spoke with Chris Rowley about enrolling in the Train the Trainers program on 30th October 2014. I remember the date because the discussion took place after a 10-hour stint on the NHS stand at the SECC careers symposium ('stand' being the operative word, no chairs to be seen. And working with teenagers all day. Exhausting). Consequently, the conversation was a bit of a haze, but I did know this was something I very much wanted to be a part of. I was somewhat aware of what my colleagues were developing with DEBOP, and the idea of a specific education program for Orthotists based on a robust evidence-database had me searching for the dotted line with my pen in hand. Admittedly at that point I was more focused on developing my own knowledge rather than the teaching aspects (that would soon change), but it still wasn't going to be an easy process.

The pre-course reading, all 27 journal articles, arrived in nice time for Christmas and also happily coincided with the conclusion of my 2nd year exams, so as you can imagine it was a very welcome email. I definitely didn't file it in the 'maybe later' folder and ignore it for a month (the 'maybe later' folder has another name by the way, but I don't think BAPO would publish it). In all honesty though, I didn't find the studying and critical appraisal too much of an issue, it was the volume and intensity of work that I found the biggest challenge. With the addition of commencing another two Masters modules in January I found myself studying every evening and weekend, an unfortunate trend which I still haven't quite managed to shake. My friends have threatened to disown me.

The 4-day Train the Trainers course was a professional turning point.

As we discussed scenarios and radiological imaging and diagnoses: patient after patient ran through my head: 'I could have treated them differently if I'd known that test', 'I could have treated them differently if I'd had that x-ray', 'I could have treated them differently if I'd known how to treat them differently'.

Those patients who never quite responded to treatment the way I hoped they would, suddenly made sense, I'd missed the answers because I didn't know what I was looking for (of course I didn't think of all the positive treatments I'd undertaken over the years, what would be the point of that). It was like being handed clinical ammunition.

When I returned to clinic, my practice changed, subtly in some areas and more dramatically in others. Simon and all the trainers kept in regular contact, sharing experiences and case studies and generally keeping the momentum going. For the first few weeks my assessments were taking double the time and my notes, already substantial by any standards (apologies to my colleagues who regularly have to trawl through these) somehow quadrupled. I felt more empowered when speaking to staff in the wider healthcare team, more assured and specific with regard to treatments and diagnoses, but most disturbingly of all I felt excited, genuinely excited, about going to work every day. Please don't judge me.

"So my happy little work bubble would have been a very comfortable place, had there not been an elephant sitting in the middle of it. In a few weeks I would be expected to stand up and actually teach all of this. I've always enjoyed teaching students during clinical placements, but standing in front of a group of senior colleagues, two clinical service managers – including my own, and four other MSK trainers somehow didn't quite compare. I did the only thing I could to get through it: I went on sleep-strike."

So my happy little work bubble would have been a very comfortable place, had there not been an elephant sitting in the middle of it. In a few weeks I would be expected to stand up and actually teach all of this. I've always enjoyed teaching students during clinical placements, but standing in front of a group of senior colleagues, two clinical service managers – including my own, and four other MSK trainers somehow didn't quite compare. I did the only thing I could to get through it: I went on sleep-strike. Oh no wait, that's the worst possible thing I could have done. Funnily enough, to this day I don't think I've ever slept more than 4 hours the night before an MSK course. It's a distinct possibility that the other trainers wouldn't recognise me if I wasn't horribly sleep deprived.

I'd like to be really cool and say that I sat there on the first day of the first course feeling calm and confident, but instead I sat on my hands to stop myself nervously turning through my notes again and again and hoping that my face wasn't tinged as green as I felt. Interestingly though, when it was finally my turn to stand up, something just fell into place. The nerves were still playing havoc, but it didn't matter because I finally realised - I knew what I was talking about. The studying and enthusiasm and years of clinical practice and help from indescribably inspirational colleagues had paid off. I absolutely loved it. I loved the questions and watching people taking notes, I loved seeing the interest from all levels of our profession, I loved listening to peoples language change as they spoke to each other, I loved the fact that we all kept talking about it through the coffee breaks and lunch breaks, because everyone else was loving it too.

I still get nervous before (and during) every MSK course. I still don't sleep the night before. I still spend far too much time reading things I already know. I still take every opportunity to learn more. The course content has grown with the evidence, I think the handouts are currently 30% larger than they were on the first course – the poor BAPO Secretariat need an industrial stapler. And I still absolutely love it.

Beyond the MSK courses, there have been some interesting new developments in my working life. I've presented at various national and international conferences, been asked to speak at orthopaedic study days and meetings, been commissioned to write about biomechanical foot function, participated in steering groups for national MSK projects, and been awarded my MSc. I'm also considering putting out a 'missing in action' notice for my comfort zone, it seems to be absent these days (last seen in the company of my social life).

Probably the biggest change for me is my new role as an Extended Scope Practitioner in Orthopaedics, specialising in foot and ankle. I've worked in Orthopaedic departments before, but being in a position to be on this side of it is a career goal that I always considered to be fairly unrealistic. There is so much to be said for being in the right place at the right time and I am immeasurably fortunate and grateful to have such a supportive management duo and consultant in my health board, but even my self-deprecating nature won't let me deny the immense amount of work that I undertook to get here.

I'm not going to bore you too much with the details of my clinical duties, feel free to contact me if you want more information, I'm not opposed to boring you senseless if you volunteer for it. Essentially I assess, refer for radiological investigation, raise biochemistry/ haematology requests, diagnose, refer for treatment, list for surgeries, attend trauma meetings when I can, attend theatre when I can. Sometimes I'm allowed to assist a little bit. Sometimes I lie on the prep-room floor with one of the nurses holding my legs (don't contact me about that). Under consultant supervision I can administer certain injections. I'm currently in the process of developing PGD's for steroid and local anaesthetic for my orthopaedic clinics, and later this year I will be training to administer Botox for spasticity. It's been an exhilarating eight months so far and I'm excited to see how the service might develop with time.

So, I've reached the bottom of the wine bottle and the end of this particular BAPO challenge. I hope this has been useful in some way to whoever is still reading, even if it's just knowing that all of us struggle with aspects of career development, even if it looks easy from the outside. If I were to suggest only two pieces of advice from my own journey they would be:

- if you want to learn something in a huge amount of depth then try teaching it to someone else.
- if you want to learn anatomy then find an opportunity to get scrubbed into surgery. It's particularly useful if you can stay conscious through the whole procedure. So I've heard.

Appendix 3 - Search strategies for healthcare databases DEBOP 2017 to 2023

DEBOP drop-foot
S11 S7 AND S8 AND S10
S10 S4 OR S9
S9 fes OR functional electrical stimulation OR boxia ankle brace OR foot up
S8 weak dorsiflexors OR achilles tendon contracture OR ankle muscle weakness OR floppy foot OR tripping OR foot slap OR flaccid foot OR foot drop OR dorsiflexor weakness OR peroneal nerve palsy OR peroneal nerve injury
S7 S5 OR S6
S6 proprioception OR kinetics OR kinematics OR energy expenditure
S5 reduce pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress
S4 S1 OR S2 OR S3
S3 supra malleolar orthos*s OR calliper OR walker boot OR silicone insole OR night splint OR heel elevator OR heel lift OR afo OR ucbl
S2 orthotics OR total contact insole OR tci OR footwear OR footwear adapts OR footwear adaptations OR footwear modifications OR footwear modification OR functional foot orthos*s OR function foot orthos*s OR ffo OR smo
S1 orthos*s OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthos*s OR rocker sole OR rocker OR foot orthos*s OR orthotic

DEBOP forefoot
S12 S4 AND S7 AND S11
S11 S8 OR S9 OR S10
S10 hallux limitus OR foot pain OR fat pad atrophy OR fat pad atrophy OR forefoot pain OR gout OR stress fracture OR mortons neuroma OR neuroma OR forefoot callus OR forefoot pain OR toe pain
S9 sesamoiditis OR forefoot pathology OR painful forefoot OR 1st MTP OA OR 1st metatarsophalangeal joint osteoarthritis OR hallux abducto valgus
S8 HAV OR HALLUX VALGUS OR hallux rigidus OR functional hallux limitus OR toe deformities OR hammer toe OR claw toe OR mallet toe OR metatarsalgia OR atrophy of fatty pad OR freiberg* OR tailors bunion
S7 S5 OR S6
S6 proprioception OR kinetics OR kinematics OR energy expenditure
S5 reduce pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress
S4 S1 OR S2 OR S3
S3 supra malleolar orthos*s OR calliper OR walker boot OR silicone insole OR night splint OR heel elevator OR heel lift OR afo OR ucbl
S2 orthotics OR total contact insole OR tci OR footwear OR footwear adapts OR footwear adaptations OR footwear modifications OR footwear modification OR functional foot orthos*s OR function foot orthos*s OR ffo OR smo
S1 orthos*s OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthos*s OR rocker sole OR rocker OR foot orthos*s OR orthotic

DEBOP hindfoot
S12 S4 AND S8 AND S11
S11 S9 OR S10
S10 stability OR strain OR stress OR proprioception OR kinetics OR kinematics OR energy expenditure
S9 reduce pain OR improve mobility OR adl OR activities of daily living OR qol OR quality of life OR increase rom OR reduce healing time OR increase range of motion OR strength OR repair OR independence
S8 S5 OR S6 OR S7
S7 ischemic bone necrosis of talus OR osteonecrosis of talus OR tarsal coalition OR post ankle surgery
S6 stj oa OR ankle osteoarthritis OR ankle pain OR osteochondral lesion OR osteochondral lesion OR avn talus OR avascular necrosis talus OR avn navicular OR avascular navicular OR calcaneal fracture OR avascular necrosis of talus OR aseptic necrosis of talus
S5 ankle arthritis OR osteochondral defect OR anterior tibial beak OR talar tilt OR subtalar arthritis OR ankle impingement OR talus OR calcaneum OR calcaneal OR talo crural OR ankle OR std oa
S4 S1 OR S2 OR S3
S3 supra malleolar orthos*s OR calliper OR walker boot OR silicone insole OR night splint OR heel elevator OR heel lift OR afo OR ucbl
S2 orthotics OR total contact insole OR tci OR footwear OR footwear adapts OR footwear adaptations OR footwear modifications OR footwear modification OR functional foot orthos*s OR function foot orthos*s OR ffo OR smo
S1 orthos*s OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthos*s OR rocker sole OR rocker OR foot orthos*s OR orthotic

DEBOP hip
S11 S3 AND S7 AND S10
S10 S8 OR S9
S9 footwear OR footwear adapts OR wedge OR heel raise OR elevator
S8 brace OR splint OR orthotic devices OR lycra OR night splint OR raise OR immobilisation OR insole OR orthos*s OR biomechanical OR hip abduction orthos*s OR hip spica
S7 S4 OR S5 OR S6
S6 knee contracture
S5 total hip replacement OR groin strain OR trochanteric bursitis OR hip pain OR groin pain OR leg length discrepancy OR lld OR pelvis pain OR hip tendinitis OR weak quadriceps OR knee extensor weakness OR hip contracture
S4 iliotibial band syndrome OR trochanter OR bursitis OR perthes OR cdh OR slipped capital femoral epiphysis OR hip avn OR hip avascular necrosis OR hip instability OR girdlestone OR hip impingement OR hip osteoarthritis OR pelvis osteoarthritis
S3 S1 OR S2
S2 proprioception OR kinetics OR kinematics OR energy expenditure
S1 reduce pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress

DEBOP knee
S14 S3 AND S10 AND S13
S13 S6 OR S11 OR S12
S12 footwear modifications OR rockersole OR rocker sole OR ucbl
S11 spring OR insert OR orthos*s OR biomechanical OR ko OR kafo OR knee orthosis OR knee ankle foot orthos*s OR heel cup OR footwear adaptation OR footwear adaptations OR footwear modifications
S10 S7 OR S8 OR S9
S9 epiphyseal dysphasia knee OR femoral nerve palsy OR rickets OR ligament knee OR medial compartment knee OR patellofemoral OR anterior knee pain OR chondromalacia OR chondromalacia patella OR osgood-schlatters OR tendonitis knee
S8 posterior cruciate ligament OR medial collateral ligament OR mcl OR lcl OR lateral collateral ligament OR ligamentous injury knee OR varus knee OR valgus knee OR osteoarthritis knee OR oa knee OR hypermobility knee OR blounts
S7 patella OR knee instability OR knee dysfunction OR loss of function knee OR knee post lateral corner OR anserine bursitis OR unicompartmental knee OR degenerate knee OR knee instability OR acl OR anterior cruciate ligament OR pcl
S6 S4 OR S5
S5 footwear OR footwear adapts OR wedge OR heel raise OR elevator
S4 brace OR splint OR orthotic devices OR lycra OR night splint OR raise OR immobilisation OR insole OR orthos*s OR biomechanical OR hip abduction orthos*s OR hip spica
S3 S1 OR S2
S2 proprioception OR kinetics OR kinematics OR energy expenditure
S1 reduce pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress

DEBOP Lateral ankle
S11 S3 AND S7 AND S10
S10 S8 OR S9
S9 proprioception OR kinetics OR kinematics OR energy expenditure
S8 reduce pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress
S7 S4 OR S5 OR S6
S6 supra malleolar orthos*s OR calliper OR walker boot OR silicone insole OR night splint OR heel elevator OR heel lift OR afo OR ucbl
S5 orthotics OR total contact insole OR tci OR footwear OR footwear adapts OR footwear adaptations OR footwear modifications OR footwear modification OR functional foot orthos*s OR function foot orthos*s OR ffo OR smo
S4 orthos*s OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthos*s OR rocker sole OR rocker OR foot orthos*s OR orthotic
S3 S1 OR S2
S2 peroneal injury OR ankle sprain
S1 lateral ankle instability OR unstable ankle OR lateral ankle instability functional OR lateral ankle instability structural OR lateral ankle instability

neurological OR anterior talofibular ligament injury OR anterior talofibular ligament rupture OR calcaneo-fibular ligament injury OR calcaneo-fibular ligament rupture OR lateral ligament laxity OR ankle weakness OR peroneal weakness

DEBOP Midfoot
S17 S8 AND S13 AND S16
S16 S14 OR S15
S15 proprioception OR kinetics OR kinematics OR energy expenditure
S14 reduce pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress
S13 S9 OR S10 OR S11 OR S12
S12 smo OR supra malleolar orthosis OR calliper OR walker boot OR silicone insole OR night splint OR heel elevator OR heel lift OR afo
S11 orthotic OR orthotics OR total contact insole OR tci OR footwear OR footwear adapts OR footwear adaptations OR footwear modification OR footwear modifications OR functional foot orthosis OR function foot orthosis OR ffo
S10 orthosis OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthosis OR rocker sole OR rocker OR foot orthos*s
S9 orthosis OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthosis OR rocker sole OR rocker OR foot orthos*s
S8 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7
S7 midfoot pain
S6 pes cavus OR peroneal tendonitis OR peroneal tendinopathy OR tib post tendonitis OR medial shin splint OR anterior shin splint OR tibialis posterior dysfunction OR tibialis posterior tendonitis OR sprint ligament OR spring ligament rupture OR dorsal midfoot interosseous compression syndrome OR cuboid syndrome
S5 S1 OR S2 OR S3 OR S4
S4 midfoot arthritis OR midfoot arthitis OR midfoot osteoarthritis OR planovalgus OR cavo varus
S3 shin splints OR medial tibial stress syndrome OR stress fracture OR pttd OR tib post dysfunction OR tibialis posterior OR accessory navicular OR lisfranc OR chopart OR pronation OR supination
S2 arch pain OR plantar arch pain OR plantar fibromatosis OR calcaneo cuboid impingement OR mid tarsal pain OR midfoot osteoarthritis OR talo navicular OR shin splints treatment
S1 midfoot instability OR flat foot OR pes planus OR midfoot hypermobility OR DMICS OR DCIMS

DEBOP plantar heel
S10 S1 AND S5 AND S8
S8 S6 OR S7
S7 proprioception OR kenetics OR kinematics OR energy expenditure
S6 reduce pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress
S5 S2 OR S3 OR S4

S4 supra malleolar orthos*s OR calliper OR walker boot OR silicone insole OR night splint OR heel elevator OR heel lift OR afo
S3 orthotics OR total contact insole OR tci OR footwear OR footwear adapts OR footwear adaptations OR footwear modification OR footwear modifications OR functional foot orthos*s OR function foot orthos*s OR ffo OR smo
S2 orthosis OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthosis OR rocker sole OR rocker OR foot orthos*s OR orthotic
S1 plantar fasciitis OR heel spur OR heel pain OR tarsal tunnel OR heel pad atrophy OR tarsal tunnel syndrome OR plantar heel pain

DEBOP posterior heel
S11 S4 AND S7 AND S10
S10 S8 OR S9
S9 heel bursitis OR retrocalcaneal bursitis OR osteo trigonum OR os trigonum OR accessory trigonum
S8 achilles OR tendo achilles OR achilles tendon OR achilles tendon rupture OR tendo achilles rupture OR ta rupture OR haglunds OR achilles tendonitis OR achilles tendonopathy OR calf pain OR achilles tendonitis OR achilles tendinopathy
S7 S5 OR S6
S6 proprioception OR kinetics OR kinematics OR energy expenditure
S5 reduce pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress
S4 S1 OR S2 OR S3
S3 supra malleolar orthos*s OR calliper OR walker boot OR silicone insole OR night splint OR heel elevator OR heel lift OR afo OR ucbl
S2 orthotics OR total contact insole OR tci OR footwear OR footwear adapts OR footwear adaptations OR footwear modifications OR footwear modification OR functional foot orthos*s OR function foot orthos*s OR ffo OR smo
S1 orthos*s OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthos*s OR rocker sole OR rocker OR foot orthos*s OR orthotic

DEBOP upper limb
S9 S6 AND S7 AND S8
S8 pain OR time OR grip strength OR adl OR independence OR increased range of motion OR stability OR force measure OR stress OR strain
S7 brace OR splint OR orthotic OR lycra OR orthos*s OR night splint OR spring OR immobilisation OR support
S6 S1 AND S5
S5 S2 OR S3 OR S4
S4 trigger thumb OR mallet finger OR de quervain OR osteoarthritis OR tenosynovitis OR repetitive strain OR tennis elbow OR golfers elbow OR epicondylitis
S3 bursitis OR phalange OR thumb pain OR cmcj OR carpometacarpal OR carpometacarpal joint pain OR carpometacarpal joint arthritis OR wrist pain OR hand pain OR carpal tunnel OR tendonitis OR trigger finger

S2 humeral OR epicondylitis OR ulnar OR median OR radial OR pollux OR dupytrens OR contracture OR reduced function OR brachial plexus OR non union OR carpal
S1 hand OR upper limb OR elbow OR shoulder OR finger OR thumb OR forearm OR upper arm

DEBOP Diabetes
S9 S4 AND S7 AND S8
S8 Diabetes OR diabetic
S7 S5 OR S6
S6 proprioception OR kinetics OR kinematics OR energy expenditure
S5 ulcer OR charcot OR neuroarthropathy OR pressure reduc* OR reduc* pain OR improve mobility OR adl OR qol OR increase rom OR reduce healing time OR strength OR repair OR independence OR stability OR strain OR stress
S4 S1 OR S2 OR S3
S3 supra malleolar orthos*s OR calliper OR walker boot OR silicone insole OR night splint OR heel elevator OR heel lift OR afo OR ucbl OR TCC OR total contact cast OR crow OR Charcot Restraint Orthotic Walker
S2 orthotics OR total contact insole OR offload* OR tci OR footwear OR footwear adapts OR footwear adaptations OR footwear modifications OR footwear modification OR functional foot orthos*s OR function foot orthos*s OR ffo OR smo
S1 orthos*s OR splint OR insole OR insert OR footbed OR brace OR ankle brace OR ankle foot orthos*s OR rocker sole OR rocker OR foot orthos*s OR orthotic

Appendix 4 - Guide 1. Does this paper belong on the Orthotics Evidence Portal

Does this paper belong on the Orthotics Evidence Portal: A guide

If you can answer YES to all three of these questions, then the paper should be included in the Orthotics Evidence Portal

Does the paper relate to an orthotic treatment?

Notes:

- Papers should still be included if the orthotic treatment is provided alongside another treatment, for example exercise therapy which also includes the use of an orthosis.
- Be aware of papers which study the use of “wearables”, i.e. electronic insoles that are designed only to measure the pressure or temperature or step parameters of a patient’s foot, these are not “orthotic treatment”.

Does the paper explore a specific diagnosis which relates to a musculoskeletal or a diabetic issue?

Notes:

- Some studies will explore the effect of orthoses on healthy subjects, these should not be included in the Orthotics Evidence Portal.
- Papers may explore the use of orthoses to see how they influence things like joint position and posture, but not a specific diagnosis – some common examples of these are “Flatfoot” or “knee valgus”. You should read these papers carefully to check if they disclose a diagnosis later on, for example “flat foot with midfoot with posterior tibial tendon dysfunction” or “knee valgus with compartmental osteoarthritis”. If a specific diagnosis is not included then the paper should not be included in the Orthotics Evidence Portal.

Does the paper include adult subjects aged ≥16 years old?

Notes:

- Papers studying mixed cohorts of adult and paediatric patients should be included.

Appendix 5 - Guide 2. Identifying study types for the Orthotics Evidence Portal

Identifying study types for the Orthotics Evidence Portal

Meta-analyses

A thorough examination of a number of valid studies on a topic with mathematical combining of the results, using accepted statistical methodology, and report the results as if it were one large study.

Systematic reviews

Focus on a clinical topic and answer a specific question. An extensive literature search is conducted to identify studies with sound methodology. The studies are reviewed, assessed for quality, and the results summarised according to the predetermined protocol of the review question.

Interventional studies

A type of study where researchers actively introduce an intervention or treatment to the participants and measure a health related effect against a control group or an alternative treatment group.

Main examples include:

- Randomised controlled trials
- Randomised cross-over trials
- Non-randomised controlled trials
- Equivalence trials
- Non-inferiority trials
- Phase trials

Observational studies

A type of study where investigators observe the effect of an intervention or risk factor to which a population is already exposed, but do not perform any active intervention. For example patients may already be using insoles, or insoles may be provided as part of a standard treatment, and researchers then observe or measure the effect.

Main examples include:

- Cohort studies
- Case control studies
- Cross-sectional studies
- Retrospective studies
- Longitudinal studies
- Laboratory gait analysis studies

Narrative literature reviews

Rather than answering a specific clinical question, they provide an overview of the research landscape on a given topic and so maybe useful for background information. Narrative reviews usually lack systematic search protocols.

Case series / case studies

Single case studies or series of case studies.

Expert opinion

Opinion pieces written by clinicians disclosing their clinical preferences which have been influenced by their own experience in clinical practice.

Study protocols

Published protocols for clinical trials

Appendix 6 - Proposal for BAPO Short Course: Diabetes

Proposal page 1 only. Full 10 page proposal available from BAPO on request.

Proposal for BAPO short course

Title	Orthotic Diabetic Foot Care
Aims	This event aims to provide participants with the screening, wound management, biomechanical knowledge and image interpretation skills to enable them to identify and treat a range of diabetic foot conditions.
Learning Outcomes	By the end of this event the participant will be able to: 1. Describe the basic pathophysiology, disease progression and diagnosis of diabetes mellitus. 2. Describe a range of diabetic foot pathologies. 3. Perform diabetic foot screening and identify foot risk stratification. 4. Demonstrate clinical ability to recognise wound infection. 5. Describe the basic action and use of dressings. 6. Utilise imaging as part of the foot assessment and treatment planning. 7. Establish an evidence-based orthotic treatment objective and prescription to address prevention and healing of diabetic foot disease. 8. Identify when to escalate treatment within a multidisciplinary setting.
Learning and	

BAPO Unit 64, Sir James Clark Building, Abbey Mill Business Centre, Paisley, PA1 1TJ
Tel: 0141 561 7217 Fax: 0141 561 7218
enquiries@bapo.com www.bapo.com

Appendix 7 - Review of BAPO Orthotic Diabetic Foot Care Course.

Published in BAPO Connect, 2017, issue 1, page 21

A REVIEW

Orthotic Diabetic Foot Care course

Glasgow, December 2016

On attending the 'Orthotic Diabetic Foot Care Working Within a Competency Framework' course, I was hoping to enhance my knowledge on treating the acute diabetic foot and improve my understanding of alterations within wound conditions to improve practice in our own Diabetic Foot Rehab and Multi-disciplinary clinics. I was not left disappointed in this respect. It was evident the speakers had a vast knowledge surrounding diabetes in general, and orthotic/podiatric treatment of at risk feet.

Firstly, it was interesting to get a detailed insight into the creation of the Competency Framework and how in Glasgow, and surrounding areas, this is implemented effectively. A very detailed aetiology and pathophysiology of diabetes followed which refreshed/improved my knowledge regarding the formation and progression of diabetes. From a personal point of view, I felt the presentations on pharmacology, wound management and care were very interesting, with case studies to back up their treatment. Although it's not something all Orthotists involved in diabetic foot care will have direct influence on, I feel it has improved my understanding of the different stages of the healing ulcer, and will improve my documentation and feedback to the patient's, Podiatrists and the MDT. Furthermore, more in-depth information regarding the different medications involved and the indications/contra-indications for these, allows us to better understand how each individual's diabetes is affecting them.

The importance of foot screening and documentation of such screening was discussed, and formed the basis of the practical session in which we practiced using a variety of screening tools – some commonly used, others not so routinely – on each other. The hands on approach allowed us to better appreciate and get to grips with the different tools involved in neurological and vascular assessment. Personally, I only use a few of the screening tools routinely in clinic, as often the screening assessments are carried out prior to seeing the patient, due to a strong MDT set up where I work. It made me realise the importance of having this skill set in case someone appears in a general clinic presenting with such complications.

The section based around chronic complications of the high risk diabetic foot and Charcot arthropathy, allowed for group discussion... and a little bit of healthy debate. It was interesting to see how professionals working in different regions, and Trusts, have different treatment protocols for the same presenting issue/condition and their reasons for such. Obviously, no treatment method discussed was inappropriate, but I think discussion like this allows you to better appreciate the variety of options – and emphasises that treatment purely depends on the presenting patient, and their condition/lifestyle.

> "The section based around chronic complications of the high risk diabetic foot and Charcot arthropathy, allowed for group discussion... and a little bit of a healthy debate."

The course was rounded off with a short section on biomechanics and orthotic intervention, highlighting the importance of setting out aims for treatment pathway and the importance of patient education. An informative graph taken from Cavanagh et al.'s (2010) paper directly compared variety of orthotic interventions effectiveness on healing and maintaining healed ulcer rates – which forms a good baseline for educating patients, and involving them in the decision-making process.

Overall I feel the course has improved my knowledge to better inform and educate our diabetic population and improve treatment from the MDT stance. I thoroughly enjoyed the course, and would recommend other Orthotists working within diabetic clinics to attend if the course runs in future.

Mark Scott
Orthotist, Trulife

Appendix 8 - Proposal for BAPO Short Course: MSK Foot and Ankle 2019

Proposal page 1 only. Full 11 page proposal available from BAPO on request.

Proposal for BAPO short course

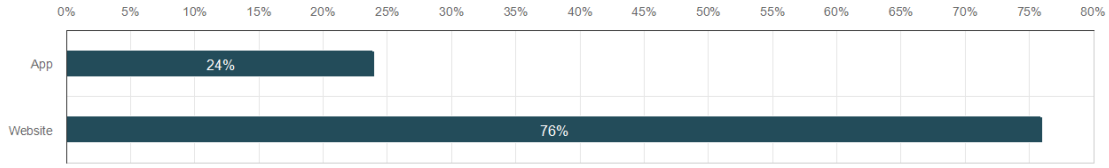
Title	MSK Foot & Ankle: Holistic Management and treatment strategies
Aims	This event aims to: equip Orthotists with the assessment, diagnostic and image interpretation skills to enable them to differentially diagnose and manage Musculoskeletal foot and ankle conditions, in line with the most recent evidence base.
Learning Outcomes	By the end of this event the participant will be able to: 1. Describe normal Foot and Ankle function. 2. Describe a range of Musculoskeletal Foot and Ankle pathologies. 3. Define the tests required for differential diagnosis of a range of Musculoskeletal Foot and Ankle pathologies. 4. Demonstrate competence in interpreting the outcomes of a range of diagnostic tests. 5. Utilise imaging as part of the MSK patient assessment. 6. Demonstrate the ability to differentially diagnose a range of Musculoskeletal Foot and Ankle conditions. 7. Perform a thorough biomechanical examination to determine the biomechanical deficit. 8. Establish an evidence-based orthotic treatment objective to address the biomechanical deficit.

BAPO Unit 64, Sir James Clark Building, Abbey Mill Business Centre, Paisley, PA1 1TJ
Tel: 0141 561 7217 Fax: 0141 561 7218
enquiries@bapo.com www.bapo.com

Appendix 9 - RDS Orthotic Evidence Portal Toolkit User Testing 2024 Report - Mobile App and Website

Please tell us which version you will be testing: App or Website

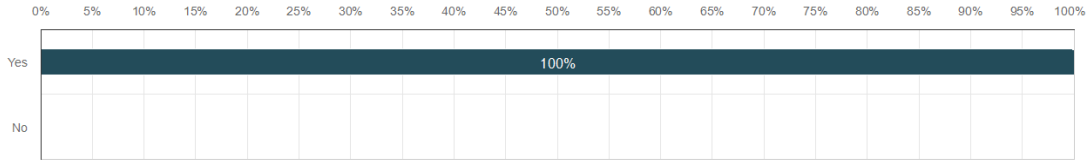
Number of respondents: 17



	n	Percent
App	4	23,5%
Website	13	76,5%

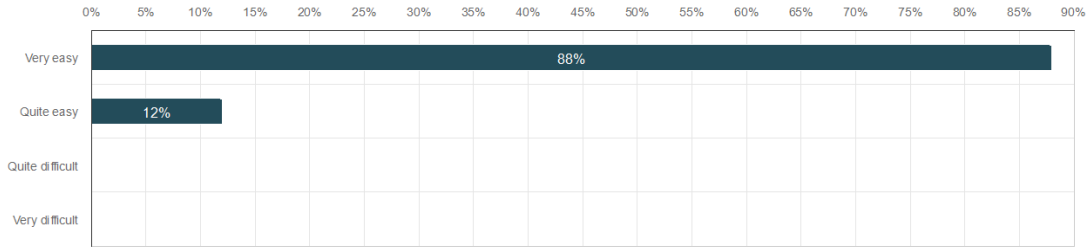
1.1 Can you find the information for "first line intervention" of musculoskeletal conditions?

Did you find this information successfully? Number of respondents: 17



	n	Percent
Yes	17	100,0%
No	0	0,0%

How easy was it to find? Number of respondents: 17



	n	Percent
Very easy	15	88,2%
Quite easy	2	11,8%
Quite difficult	0	0,0%
Very difficult	0	0,0%

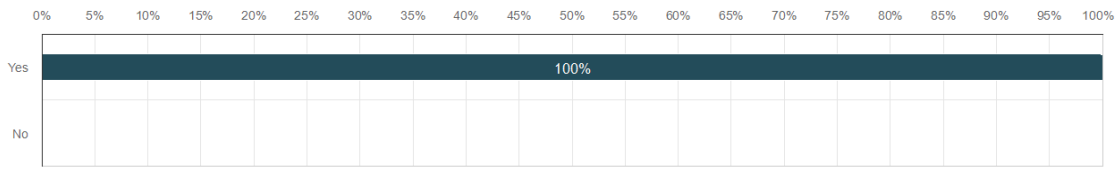
Briefly outline the steps you took to answer this question. Number of respondents: 12

Free Text Responses
I simply clicked on the corresponding icons on the webpage until I reached the required page re the 'first line interventions'
went to the home page, clicked adult MSK then clicked the first line intervention link
evidence portal - adult msk - first line intervention
Access website click on two links
Clicked on the links
Clicked on adult musculoskeletal and then First line and additional interventions then first line interventions.
adult MSK condtions - first line and additional interventions - first line interventions
From the front page of the portal:

1. selected Adult Musculoskeletal 2. selected First line and additional interventions
clicked MSK, then first line interventions
'Adult musculoskeletal' then 'first line and additional interventions' then expanded 'first line interventions'
adult MSK - first line interventions
layout and navigation is much simpler than original version

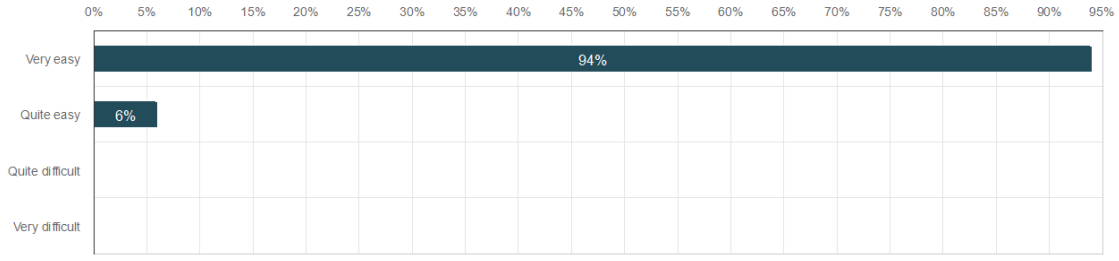
1.2 Can you find the evidence (journal articles) for musculoskeletal "biomechanical assessment"?

Did you find this information successfully? Number of respondents: 17



	n	Percent
Yes	17	100,0%
No	0	0,0%

How easy was it to find? Number of respondents: 17



	n	Percent
Very easy	16	94,1%

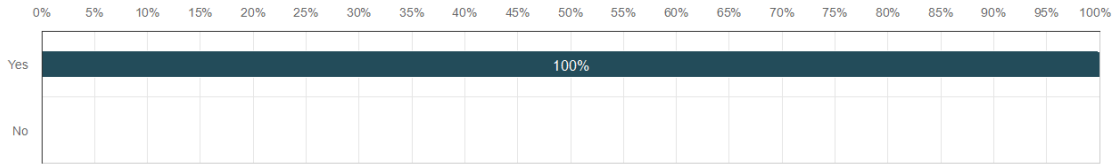
Quite easy	1	5,9%
Quite difficult	0	0,0%
Very difficult	0	0,0%

Briefly outline the steps you took to answer this question. Number of respondents: 11

Free Text Responses
As above.
same as above but biomechanical link
evidence portal - adult msk - biomech assessment
Access website homepage click on one link
Followed the links
Click Adult Musculoskeletal Then Biomechanical assessment
adult MSK conditions - biomechanical assessment
Same as previous - started from the front page of the website, and selected Adult Musculoskeletal, and then Biomechanical Assessment.
clicked on biomechanical ax button
Went back to the main page by clicking 'the orthotics evidence portal' at the top, then adult musculoskeletal, then biomechanical assessment.
adult MSK - biomechanical assessment

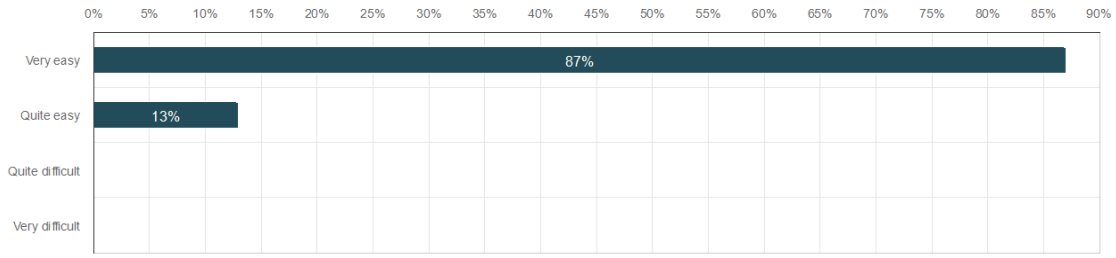
1.3 Can you find the evidence (journal articles) for orthotic treatment of the upper limb?

Did you find this information successfully? Number of respondents: 17



	n	Percent
Yes	17	100,0%
No	0	0,0%

How easy was it to find? Number of respondents: 16



	n	Percent
Very easy	14	87,5%
Quite easy	2	12,5%
Quite difficult	0	0,0%
Very difficult	0	0,0%

Briefly outline the steps you took to answer this question. Number of respondents: 11

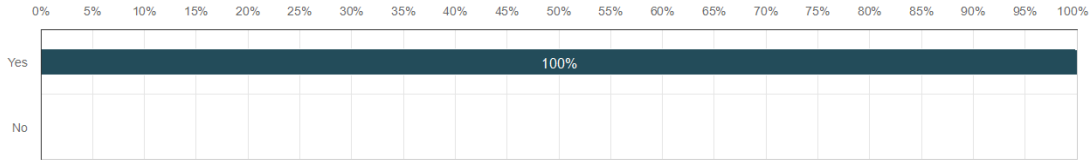
Free Text Responses
Same again
As above but clicked areas of the body > upper limb
portal - adult msk - areas of the body - upper limb - evidence

From the homepage click on Adult MSK then areas of the body and upper limb
Click Adult Musculoskeletal Area of the body Then Upper limb All evidence is with in the specific conditions.
adult MSK - areas of body - upper limb - patient history and differential diagnosis - select condition
1. started at the front page of the portal 2. Clicked on Adult Musculoskeletal 3. Clicked on Areas of the Body 4. Clicked on Upper Limb 5. Clicked on First line and additional interventions - this was interesting but did not contain journal articles (unless I missed them), so... 6. clicked back to the Upper Limb main page 7. Clicked on Patient history and differential diagnosis From there I was able to see the journal articles associated with each condition.
Clicked - MSK, Areas of the body, UL
Back to 'adult musculoskeletal', then 'areas of the body', then 'upper limb' and expanded the sections.
Adult MSK - areas of the body - UL - patient history and differential diagnosis and when you click in each one, it has the articles for each category i.e. OA, CTS

The only thing I would comment on, is that the upper limb section has a 'first line and additional interventions' section, whereas the other body parts don't have this drop-down option.

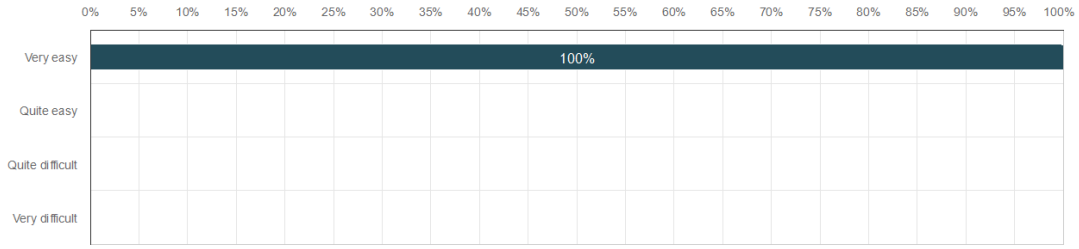
1.4 Can you find the Diabetic foot risk stratification systems?

Did you find this information successfully? Number of respondents: 17



	n	Percent
Yes	17	100,0%
No	0	0,0%

How easy was it to find? Number of respondents: 16



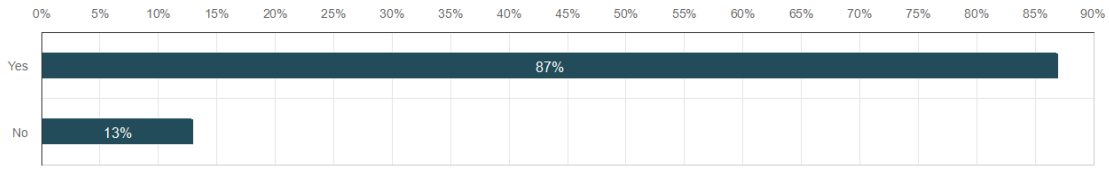
	n	Percent
Very easy	16	100,0%
Quite easy	0	0,0%
Quite difficult	0	0,0%
Very difficult	0	0,0%

Briefly outline the steps you took to answer this question. Number of respondents: 10

Free Text Responses
Same again
as previous but diabetes link
portal - diabetes - foot risk stratification
Homepage diabetes link then the top link
Click Diabetes- Then click Diabetic foot risk stratification system
diabetes - Diabetic foot risk stratification systems
1. Started at the portal front page 2. Clicked on Diabetes 3. Clicked on Diabetic foot risk stratification systems.
Clicked, Diabetes then risk
Back to the 'orthotics evidence portal' by clicking on the top grey bar, then 'diabetes', then 'diabetic foot risk stratification systems'.
evidence portal - diabetes - diabetic foot risk stratification systems

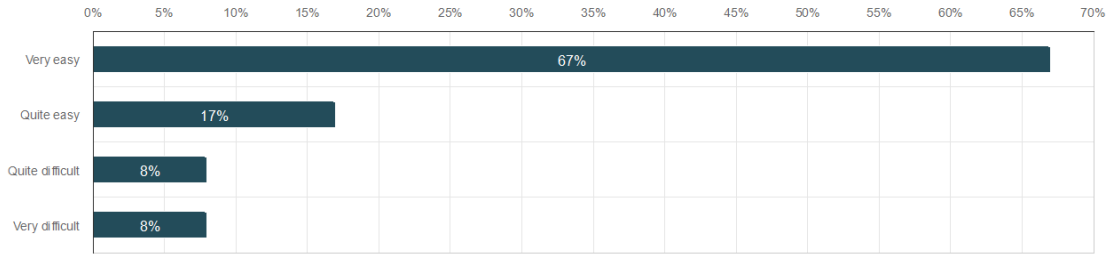
1.5 Can you find the information on the knowledge network?

Did you find this information successfully? Number of respondents: 15



	n	Percent
Yes	13	86,7%
No	2	13,3%

How easy was it to find? Number of respondents: 12



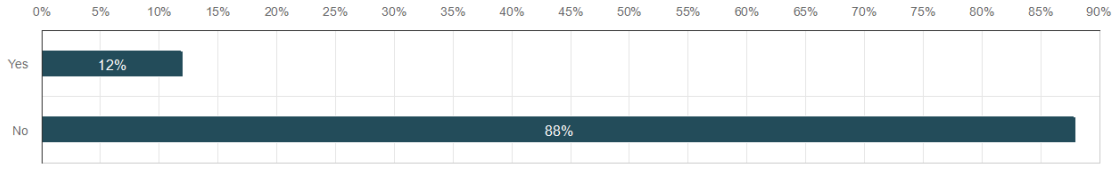
	n	Percent
Very easy	8	66,7%
Quite easy	2	16,7%
Quite difficult	1	8,3%
Very difficult	1	8,3%

Briefly outline the steps you took to answer this question. Number of respondents: 10

Free Text Responses
Less obvious but after eliminating what 'not to click' this was simple also.
I'm not sure how to do this sorry I always just use the hyperlink
portal - about the portal - knowledge network. Went backward and forwards a bit
Follow link orthotics evidence portal
Click About the orthotic evidence portal then the knowledge network
about the portal - knowledge network
1. Started at the portal front page 2. Clicked on About the orthotics evidence portal 3. Clicked on the subheading titled The Knowledge Network.

Clicked about and then the knowledge network
Back to the 'orthotics evidence portal' by clicking on the top grey bar, then 'about the orthotics evidence portal', then expanded 'the knowledge network'
evidence portal - about the orthotics evidence portal - the knowledge network

2.1 Functionality. **Did you experience any problem with the website / app features and functions: e.g. search, navigation, menus, buttons, hyperlinks?** Number of respondents: 17



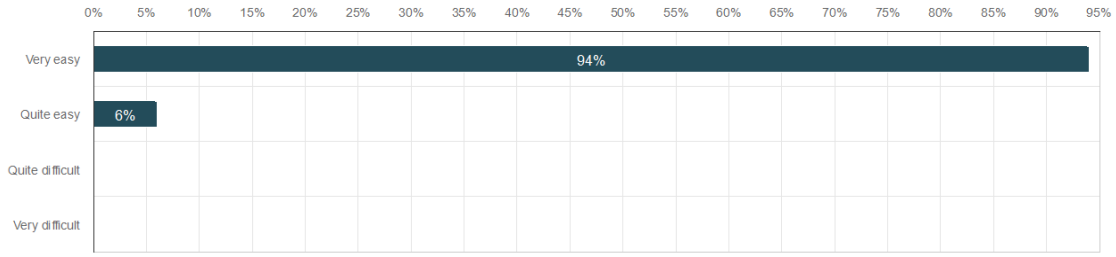
	n	Percent
Yes	2	11,8%
No	15	88,2%

If you answered yes, please provide details of any problems you experienced with the functionality

Number of respondents: 0

Responses

2.2 Ease of use. **How easy is it to learn how to use this website / app?** Number of respondents: 17



	n	Percent
Very easy	16	94,1%
Quite easy	1	5,9%
Quite difficult	0	0,0%
Very difficult	0	0,0%

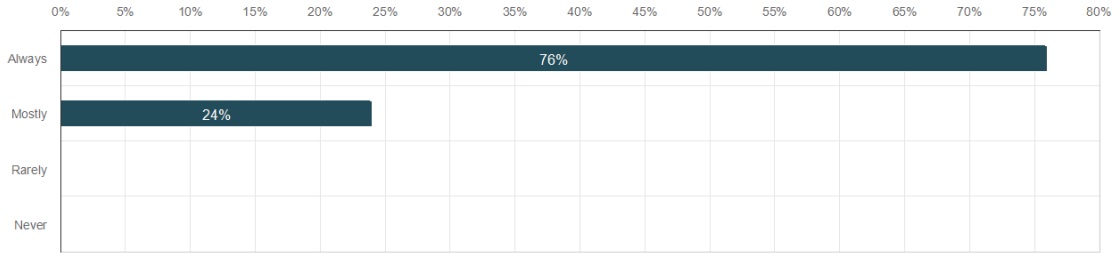
Please provide details of any problems you experienced with ease of use.

Number of respondents: 3

Free Text Responses
When on upper limb I would have a separate drop down for evidence instead of having to go into all conditions/differential diagnosis.
easy to find what i was looking for and going back was easy
None - all really self explanatory - everything seems in a logical place!

2.3 Navigation. **Is moving between screens logical and appropriate?**

Number of respondents: 17



	n	Percent

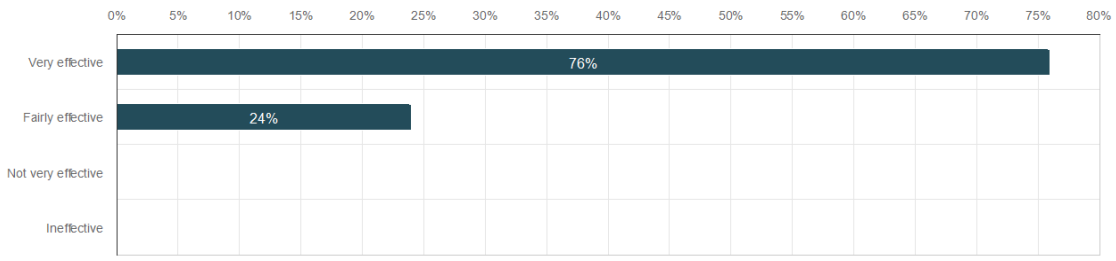
Always	13	76,5%
Mostly	4	23,5%
Rarely	0	0,0%
Never	0	0,0%

Please provide details of any problems you experienced with the navigation. Number of respondents: 2

Free Text Responses
Generally, navigation seems really intuitive. There's a logical pathway to get to each topic. The only time I had to backtrack was when I picked the wrong topic whilst looking for upper limb orthotic intervention evidence - I wonder whether the "First line and additional interventions" section might also want a link to take the user straight to the orthotic evidence, after reviewing that section? (not sure if this is actually useful or just a 'me' thing though!)
Would have been nice to have a back button or tree to take you back up levels as using the browser back button is not always easy on the NHS computers and the 'the orthotics evidence portal button' takes you back to the very start

2.4 Visuals

How effective is the visual design of the website / app? Number of respondents: 17



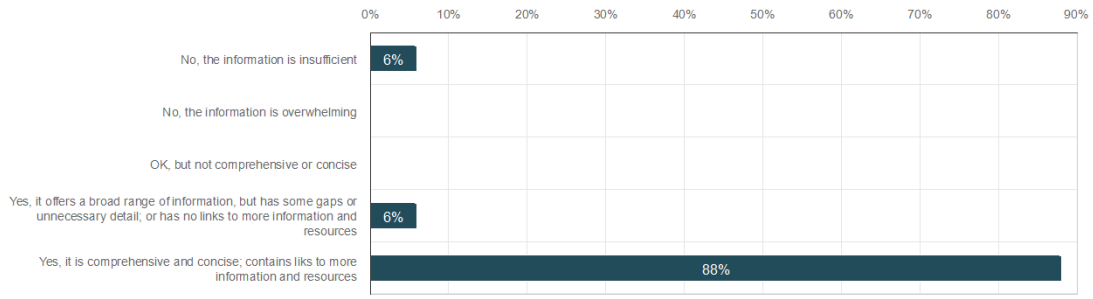
	n	Percent
Very effective	13	76,5%
Fairly effective	4	23,5%
Not very effective	0	0,0%
Ineffective	0	0,0%

Please highlight any issues you identified with the visual design. Number of respondents: 3

Free Text Responses
Easy to read, minimal and bold separation easy reading for a dyslexic.
When searching the results come up as white writing on a black background, this can be difficult to see/read, i couldn't spot an accessibility tool to change this but am aware this is the HIS site choice not the orthotics tool as it is present throughout
Diagrams are straight forward

3.1 Quantity of information. Is the extent of the information provided in the website / app suitable?

Number of respondents: 17



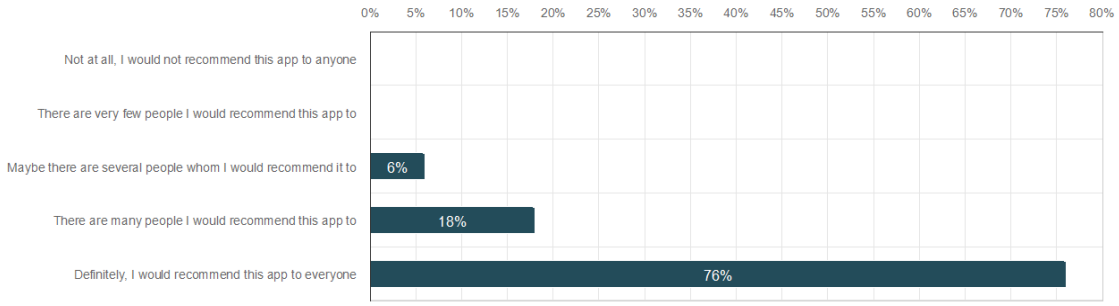
	n	Percent

No, the information is insufficient	1	5,9%
No, the information is overwhelming	0	0,0%
OK, but not comprehensive or concise	0	0,0%
Yes, it offers a broad range of information, but has some gaps or unnecessary detail; or has no links to more information and resources	1	5,9%
Yes, it is comprehensive and concise; contains links to more information and resources	15	88,2%

Please provide more detail on any issues you identified. Number of respondents: 1

Free Text Responses
I think its a really good resource to be able to go onto if necessary

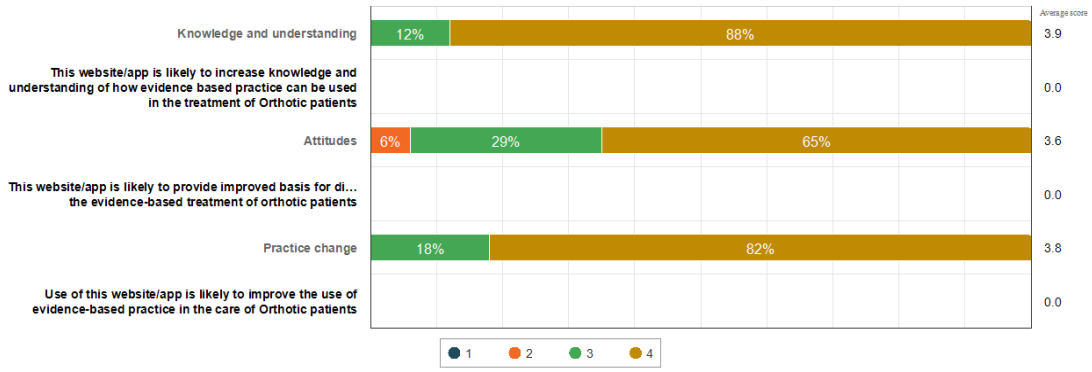
3.2 Would you recommend this website / app to clinicians who might benefit from it? Number of respondents: 17



	n	Percent
Not at all, I would not recommend this app to anyone	0	0,0%
There are very few people I would recommend this app to	0	0,0%
Maybe there are several people whom I would recommend it to	1	5,9%

There are many people I would recommend this app to	3	17,6%
Definitely, I would recommend this app to everyone	13	76,5%

3.3 Impact: please select the score that most accurately represents your view of the likely impact of the website / app. Strongly Disagree = 1, Strongly Agree = 4. Number of respondents: 17



	1	2	3	4	Average	Median
Knowledge and understanding	0,0%	0,0%	11,8%	88,2%	3,9	4,0
This website/app is likely to increase knowledge and understanding of how evidence-based practice can be used in the treatment of orthotic patients						
Attitudes	0,0%	5,9%	29,4%	64,7%	3,6	4,0
This website/app is likely to provide improved basis for discussion within the allied health						

professionals community as well as between AHP's and medics in the evidence-based treatment of orthotic patients						
Practice change	0,0%	0,0%	17,6%	82,4%	3,8	4,0
Use of this website/app is likely to improve the use of evidence-based practice in the care of orthotic patients						
Total	**0,0%**	**2,0%**	**19,6%**	**78,4%**	**3,8**	**4,0**

4.1 What is your job title? Number of respondents: 17

Free text Responses
Senior Orthotist
orthotist
Orthotist
Orthotist
Orthotist
Senior orthotist
Orthotist
senior orthotist
Podiatrist

Clinical Skills Tutor
Orthotist
Senior Orthotist
Doctoral Clinical Academic Fellow
Consultant Orthotist
Senior orthotist
AHP Service Lead
Medical Director & Consultant Orthotist

4.2 Where is your place of work? Number of respondents: 17

Free Text Responses
Talarmade/Lincolnshire
Fife/buchanan orthotics
NHS
Blackpool Victoria Hospital
NHS Grampian
Nhs ggc
NHS Greater Glasgow and Clyde
nhs GG&C
private and NHS
University of Salford
Scotland
Rotherham

University of Oxford
The Royal Wolverhampton NHS Trust
NHS GGC
NHS Borders
Chesterfield

4.3 Which orthotic or Health Service do you work in? Number of respondents: 17

	n	Percent
NHS Scotland	9	52,9%
NHS24	0	0,0%
NHS England	6	35,3%
NHS Wales	0	0,0%
Health and Social care (HSC) Ireland	0	0,0%
Non-NHS/HSC Orthotic service	0	0,0%
Higher Education Institute	1	5,9%
Other	1	5,9%

Appendix 10 - Funding approval for the development of animation assets for the Orthotics Evidence Portal

From: Enquiries <Enquiries@bapo.com>
Date: 3 December 2024 at 11:12:28 GMT
Subject: RE: OETT Application - LT0124 Laura Barr

Hi Laura

My apologies for the delay but this had to be reviewed by all of the Trustees.

I am pleased to inform you that your application for funding has been approved by OETT *for **full funding - on behalf of the Orthotics Evidence Portal (previously the Directory of Evidence Based Orthotic Practice) to produce an engaging animation in the form of an "explainer animated video"**

AFTER completing the animation, could I kindly ask you to forward me your receipts, as below, at your earliest convenience please and within 3 months*:

= Animation fees payment receipt

Can you also please advise which company you will be using to do the work and what the completion date might be?

With regards to funding payment, can you advise once you know, who you would like payment to go to please.

OETT funding has previously been paid by cheque and required 2 signatories, taking up to 10 days to process. We are pleased to advise that OETT have now successfully set up online banking payments with the CAF (Charities Aid Foundation) bank and once processed payments should be in the specified bank account within 3-5 working days.

Can I therefore ask for the below information, in order to process the funding payment. Please ensure that the details provided are correct:

Full name on Bank Account
Sort Code
Account Number
Name of Bank

As per the OETT website, please read the attached Important Points for funding applications

Please use your application reference **LT0124** from the subject line in all correspondence.

Thank you for your patience in this matter.

Sharon Parker
Events & Membership Administrator / OETT Administrator
Working hours: Monday to Friday 10:00 – 14:00
BAPO
British Association of Prosthetists and Orthotists
0141 561 7217
enquiries@bapo.com
www.bapo.com
Clyde Offices, 2nd Floor, 48 West George Street, Glasgow G2 1BP

Appendix 11 - Article published in BAPO Connect, March 2025, issue 1, pp.40-41

Introducing the Orthotics Evidence Portal!

A revitalised resource for evidence-based orthotic practice

By LAURA BARR, Project lead for the Orthotics Evidence Portal

Formerly known as the Directory of Evidence-Based Orthotic Practice (DEBOP), the Orthotics Evidence Portal has been completely rebuilt and relaunched for 2025. With a fresh new look and an intuitive interface, this essential resource is now more accessible than ever.

WHAT IS THE ORTHOTICS EVIDENCE PORTAL?

The Orthotics Evidence Portal is a unique, dedicated resource designed to improve access to evidence-based research on orthotic treatment for musculoskeletal (MSK) conditions and diabetic foot care. Developed over the past decade by a committed group of UK Orthotists, the Portal aims to support evidence-based practice within the profession, ensuring clinicians have the latest research at their fingertips.

The Portal serves as a gateway to a vast collection of categorised literature, organised by orthosis type, pathology, and anatomical region. Research is presented according to the hierarchy of evidence, making it easier for Orthotists to evaluate and apply findings in clinical practice. Since 2017, the Portal has been consistently updated through monthly literature reviews, ensuring it remains current and relevant. Today, it remains a critical resource for UK Orthotists working in MSK and diabetic foot care – two primary areas of orthotic practice.

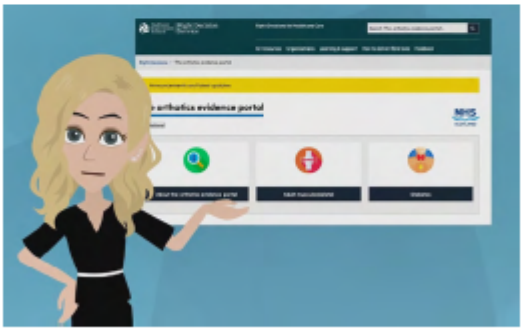
THE JOURNEY SO FAR

The Orthotics Evidence Portal was first launched as DEBOP in 2014 as part of the MSK & Orthopaedic Quality Drive, funded by the Scottish Government. Initially, its primary goal was to re-position orthotic services within the MSK treatment pathway in NHS Scotland. By 2017, DEBOP had been redesigned with a specific focus on improving accessibility to orthotic research, ensuring practitioners could easily find relevant evidence for their work.

Since 2017, it has been maintained and further developed by UK Orthotists with oversight from the British Association of Prosthetists and Orthotists (BAPO) and support from the Orthotic Education and Training Trust (OETT). From 2014 to 2024, DEBOP was hosted on the Clinical Knowledge Publisher platform. However, as technology advanced, the platform became outdated and was not optimised for mobile access – one of the primary ways clinicians seek information today.

KEY INSIGHTS FROM THE 2023 USER SURVEY

In 2023, a cross-sectional survey of 108 UK Orthotists was conducted to assess DEBOP's functionality and impact. The results highlighted the clinical value:



- 82.9% of users stated that DEBOP made them more likely to engage with published research.
- 87.1% said that using DEBOP made accessing research easier and less time-consuming.
- 85.7% reported that DEBOP helped them identify research relevant to their clinical practice.
- 71.4% preferred using DEBOP over conducting literature searches in scientific databases.
- 68.6% said this resource had directly changed their clinical practice.

A NEW ERA: THE 2025 RELAUNCH

Recognising the need for an upgraded platform, feedback from the 2023 survey played a key role in shaping the next phase of development. Users requested better mobile compatibility, an improved interface, and enhanced visibility in search engines.

In 2024, in collaboration with NHS Knowledge Services, an application was submitted to migrate DEBOP to the Right Decisions Service platform. This modern platform is fully optimised for both desktop and mobile use and offers a dedicated mobile app for even greater accessibility.

Over six months, the resource underwent a complete transformation, including a full restructuring and two rounds of user testing involving Orthotists from across the UK. The result is a seamless, user-friendly experience that makes accessing orthotic research more convenient than ever. Officially relaunched in January 2025, the Orthotics Evidence Portal is now live and ready for use. Follow the links or scan the QR codes below to explore the new platform.

GET INVOLVED!

Are you passionate about evidence-based orthotic practice? We want to hear from you! The continued growth and success of the Orthotics Evidence Portal rely on dedicated Orthotists like you. Whether you're interested in honing your critical appraisal skills by contributing to monthly literature reviews or have ideas for expanding the Portal into new specialist areas, your involvement is invaluable.

Join us in shaping the future of evidence-based orthotic practice. To get involved, contact us at: **evidence@bapo.com**.

The Orthotics Evidence Portal has come a long way from its early days as DEBOP. With its 2025 relaunch, it is now more accessible, efficient, and valuable than ever before. This is not just a relaunch—it's a reinvigoration of evidence-based practice in orthotics. Explore the Portal today and see how it can enhance your clinical decision-making.

WANT TO FIND OUT MORE?

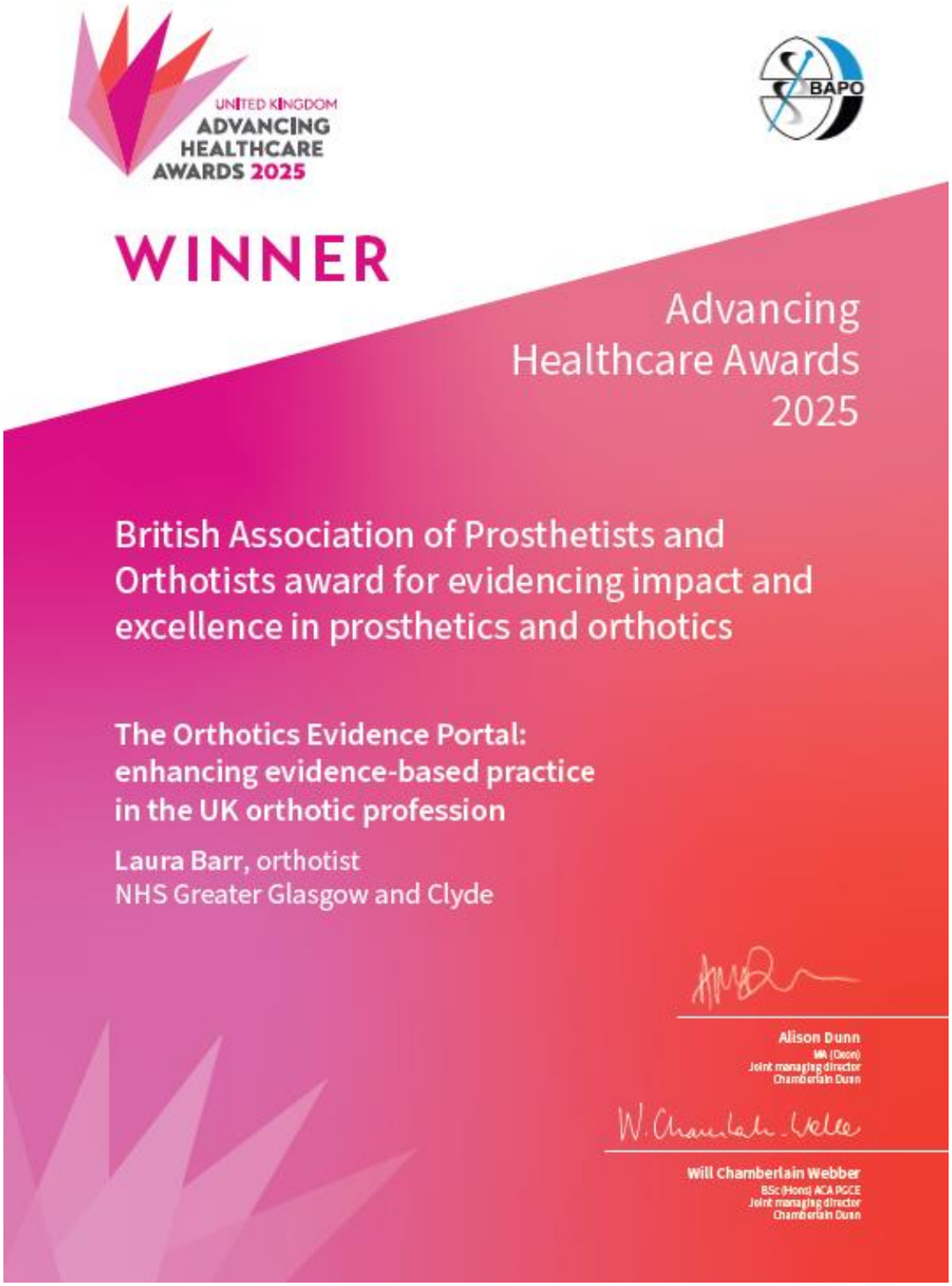
Access the Orthotics Evidence Portal here:

https://rightdecisions.scot.nhs.uk/the-orthotics-evidence-portal/

Watch an animated overview of the Portal for more information on the history and function of this one-of-a-kind resource:

https://youtu.be/ogfya0SlWa8?feature=shared

Appendix 12 - Advancing Health Care Awards 2025 - "British Association of Prosthetists and Orthotists award for evidencing impact and excellence in Prosthetics and Orthotics"



Appendix 13 - Letter from Orthotic Professional Lead for NHS GGC confirming contribution of L Barr to the CAD/CAM training programme within the NHS GGC orthotic service

Orthotic Department
Gartnavel General Hospital
Lower Ground Floor
1053 Great Western Road
Glasgow
G12 0YN

01/05/2025

To whom it may concern,

I am writing to confirm Laura's development of a CAD/CAM staff training programme within the NHS Greater Glasgow and Clyde (NHS GGC) orthotic service. Laura has been the project lead since 2013 for the Paromed, Paromanager and Paro360 CAD/CAM modelling systems used in NHS GGC orthotic service for the production of foot orthoses. The initial aim of this role was to standardise the CAD/CAM scanning, modelling, and manufacturing processes across the department, an objective which has been achieved, monitored, and sustained for many years.

Since 2013, Laura has developed multiple resources for the department, in both written and video formats. These resources include modelling, training and competency assessment processes, as well as standard operating procedures for clinical and technical staff, to assure the quality and replicability of CAD/CAM foot orthoses. I have included a list of the key resources that Laura has developed over the past 12 years at the end of this letter.

Laura has delivered CAD/CAM training to all clinical staff and students within the department since 2013 and has also provided training to external commercial manufacturing partners and to orthotic services in other Health Boards and Trusts across the UK. Laura provides continuous support to all staff members in the NHS GGC orthotic service regarding the use of Paromed CAD/CAM systems in the department, with weekly one-on-one drop-in sessions as well as group CPD sessions.

CAD/CAM Resources developed by Laura Barr on behalf of the NHS GGC orthotic service:

<u>Written clinical and technical guides</u>
Paromanager / Paro360 modelling manual
Paromanager / Paro360 milling manual
Paromanager / Paro360 Guide to common errors, hints and tips
Paromanager / Paro360 Guide to importing and exporting files
Paromanager / Paro360 Converting Paro V6 models to Paro360

Video tutorials
Paromanager / Paro360 modelling tutorial
Creating differential files for double milling
Complex modelling examples

Competency assessment
Individual competency framework Paromanager / Paro360
Competency assessment process

Advanced modelling tutorials
Guide to using Skives in Paromanager
Paromanager Challenge Number 1
Paromanager Challenge Number 2
Paromanager Challenge Number 3

Standard operating procedures
Storage of patient information in Paromanager
Exporting scans and order details for external manufacture
Ordering CAD/CAM insoles from GGH workshop
Technical CAD/CAM insole production
Postal procedure for CAD/CAM insoles

NHS GGC IT packaging guides
IT packaging instructions for Paro360

Yours sincerely

Nikki Munro
Orthotic Clinical Lead / Manager NHSGGC
Contact:
0141 211(5)8567
07972731945

Orthotic Professional Lead NHSGGC
NHSGGC AHP Quality Improvement Lead
Chair of Scottish Clinical Orthotic Leads Group
Scottish Improvement Leader
Professional Member of the Institute for Continuous Improvement in Public Services

Appendix 14 - Scottish Improvement Foundation Skills project report 2021/2022

Background

Throughout the past few years an increasing number of issues have been raised from both clinical and technical staff in the NHS GGC orthotic service regarding variability of CAD/CAM insole production. Various steps had been put in place prior to the commencement of this project to measure and minimise the issues. These included:

1. The development of a Standard Operating Procedure for technical process of milling, including management of the milling machine at Gartnavel General Hospital
2. Clinical meetings to reinforce Clinical Process for modelling and ordering CAD/CAM insoles
3. Standardisation of measuring completed insoles using Vernier Gauge
4. Introduction of recording issues with insoles to be completed by clinical and technical staff in the department Common Folder

Despite these steps, there was still uncertainty about the variance in finished insole production, and no definitive measurement data to demonstrate the consistency of production, or resulting issues.

This project was developed as a means to measure the scope of the issues, to identify areas for improvement, and to implement positive change within the process of CAD/CAM insole production.

Project Aim

"By January 2022, 90% of CAD/CAM insoles in the orthotic service will have a milled thickness within a 1mm margin of error of the modelled specification, as per Paromed PCS Milling Guidance"

Of note, the standard calibration of the millers includes a spindle height of 0.7mm above the vacuum table of the milling machine, therefore a 1mm variance would allow for an acceptable range from -0.3mm to +1.7mm difference between the modelled and milled thicknesses. This is not allowing for any standard deviation relating to physical measurement.

Primary Drivers:

- Reducing error with clinical processes
- Reducing error with technical processes
- Financial impact - maximising the cost / time efficiency

Secondary Drivers – Clinical Processes:

- Achieving consistent and accurate documentation of insole thickness on the calloff
- Achieving a consistent modelling process

Secondary Drivers – Technical Processes:

- Reducing issues at the point of manufacture

Secondary Drivers – Financial impact:

- Identifying the most cost effective suppliers
- Maximising on technical manufacture time via time in motion study comparing Plate and Trapez blanks

Early planning

With consultation from technical staff, clinical staff, and review of the "*reporting a problem with insoles*" and "*reporting a problem with goods*" spreadsheets, the following possible elements contributing to variable output were identified:

- Interchanging between Blank types: The use of 2 type types had been standard milling practice in the NHS GGC orthotic service, Plate blanks and Trapez blanks. However, technicians had identified the comparable differences of mounting frames and plates, resulting in different output when milling the same insole file.
- Variance in the starting thickness of the same blank types: Plate blank thickness from preferred supplier was found to vary.
- Variance between persons undertaking final measurement: Concerns were raised over inter-rater reliability with use of the Vernier gauge.
- Clinical expectation issues: Inconsistencies between the documented insole thickness on the calloff, and the modelled thickness on Paromanager.
- Vibration within the milling machine: correct set up, install, and maintenance of the milling machines minimise this but cannot fully eliminate it
- Dust within the machine: This can affect the vacuum and blank position

Change ideas

In order to limit the project variables in accordance with the above, the following change ideas were agreed prior to commencing data capture:

- Agreement to use only plate blanks for the duration of the project
- Calibration of both millers to produce an output difference of <0.5mm when milling the same file, completed on 20/10/2021
- Agreement that all measures would be taken and documented by the same staff member
- A standard operating procedure would be followed regarding use of the milling machines
- The CAD insole ordering process for orthotists was reviewed, and a training session provided to the clinical team on 15/09/2021
- Consistency of blank thickness and pricing to be reviewed and financial impact measured with time-in-motion study

Commencing data collection

Data was collected for all CAD insoles manufactured between 26/10/2021 - 10/12/2021, including the following:

- Blank thickness – collected for the first 4 weeks only
- Requested thickness – as specified on the calloff
- Modelled thickness – measured on screen at the central forefoot or the narrowest side if wedging in situ
- Milled thickness – measured at the central forefoot or the narrowest side if wedging was in situ

Data collected

Throughout the project the following data was collected:

- 1020 insoles manufactured and recorded
- 611 useable data sets
- Various clinical input issues identified:
  - 23.8% inaccuracies between models and documentation
  - 29.4% of orders had missing information

The following data relating to original blank thickness was collected:

- Over 2 weeks 146 blanks were measured

- Measures were taken from all 4 corners
- Range from 31.2mm – 34.96mm

PDSA cycles

Two changes were made relating to miller recalibration and change of drill bit throughout the project. These two changes points (01/11/2021 and 01/12/2021) are noted in the chart below [***Figure 1***].

- Predicted change: Calibration of both milling machines and the change of drill bit on the
  2nd miller would improve overall output
- Measured change: At no point did the average disparity in thickness exceed 1mm (**all points were within the expected range of -0.3mm to +1.7mm**). There was a decreasing trend of insole thickness prior to the first change. Following the first change, there was an improving trend. Following the second change there was a reduction again. Analysing the whole dataset, showed a median of 0.5mm disparity, which is just below the anticipated median of 0.7mm [***Figure 2***].

One change was made to the standardisation of blank thickness as assured by the manufacturer following the inconsistencies found after the 1st 4 weeks. This change was note measurable due to the slow introduction on newly ordered blanks and usage of the bulk stock of blanks held in Gartnavel General Hospital.

- Predicted change: The variance in blank thickness affects the variance in milled insole
  output.
- Measured change: Variance in blank thickness was not found to significantly affect the outcome of the finished insole thickness. In the chart below, the blank thicknesses were ordered from thinnest to thickest on the X-axis, with the difference in milled thickness vs Modelled thickness (mm) on the y-axis [***Figure 3***].

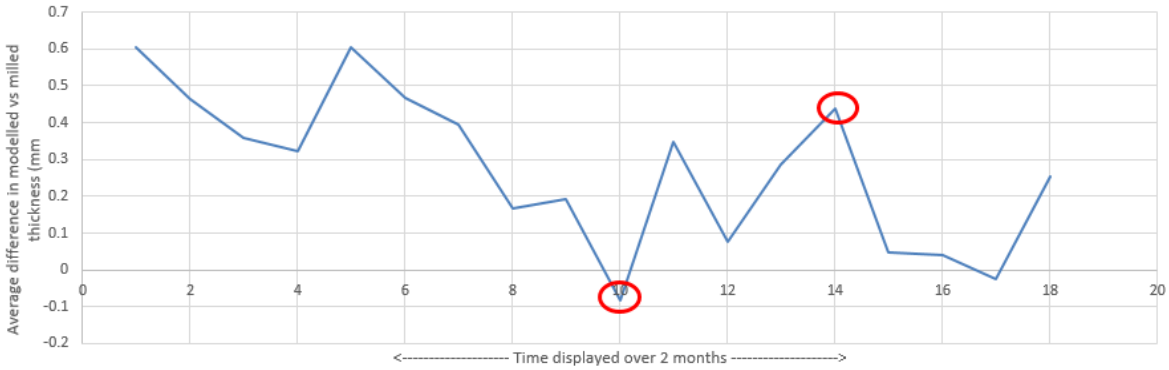


Figure 1. *Average difference in modelled vs milled thickness (mm) displayed over the duration of the trial, with change points (miller calibration and new drill bit) marked in red.*

Figure 2. *Run chart of full dataset showing average differnece in modelled thickness vs milled thickness.*

Figure 3. *Blank thicknesses were ordered from thinnest to thickest on the X-axis, with the difference in milled thickness vs Modelled thickness (mm) on the y-axis. Red line indicating the expected median value of 0.7mm*

Outcomes

Prior to project beginning, from January 2021 – September 2021 there were 96 complaints relating to inconsistent insole thickness resulting in **10.7 reported issues per month**

From commencement of the project October 2021 – February 2022 there were 3 complaints relating to inconsistent insole thickness resulting in **0.6 reported issues per month**

Insoles manufactured within 1mm margin of error, where error is counted from the 0.7mm drill-bit allowance, within a range of **1.7mm to -0.3mm**

- **84.2%** before the 1st PDSA
- **90.3%** after the 1st PDSA cycle
- **89%** after the 2nd PDSA cycle

Appendix 15 - Freedom of Information Response NHS Greater Glasgow and Clyde 2021/2022

Two page excerpt of FOI response received from NHS GGC demonstrating the volume of CAD/CAM insoles produced in the 2021/2022 financial year.

Section 1

1. Does your Trust/Health Board have an orthotics department?

   ☐ Yes

If the answer is "Yes" please answer section 2. If the answer is "No" no further information is required

---

Section 2

2.1 Which of the following best describe your Orthotic Service?
(select **all that apply** option by entering "X" in the left-hand column)

X	NHS In-house service (This means the orthotists are directly employed by your Trust/Health Board)
	NHS Contracted service (This means an external contractor employs the orthotists)

2.2 Does your Orthotic Service provide bespoke insoles to patients?
(select **only one** option by entering "X" in the left-hand column)

X	Yes *(continue to question 2.3)*
	No ***(end of questionnaire)***

2.3 How many bespoke insole orders did your Orthotic service place in the 2021/22 financial year?
(In this context we assume that a "bespoke insole order" is likely to be either a pair of insoles for one patient, or a single insole for one patient)

3058

2.7 In your Orthotic service, what **percentage** of insoles were made using **In-house Traditional Manufacture** in the 2021/22 financial year?

0 %

2.8 In your Orthotic service, what **percentage** of insoles were made using **In-house Computer Aided Manufacture with Reduction Manufacture** in the 2021/22 financial year?

99.9 %

2.9 In your Orthotic service, what **percentage** of insoles were made **using In-house Computer Aided Manufacture with Additive Manufacture (3D printed)** in the 2021/22 financial year?

0 %

2.10 In your Orthotic service, what **percentage** of insoles were made using **Outsourced Traditional Manufacture** in the 2021/22 financial year?

0 %

2.11 In your Orthotic service, what **percentage** of insoles were made using **Outsourced Computer Aided Manufacture with Reduction Manufacture** in the 2021/22 financial year?

0.008 %

2.12 In your Orthotic service, what **percentage** of insoles were made using **Outsourced Computer Aided Manufacture with Additive Manufacture (3D printed)** in the 2021/22 financial year?

0.00098 %

Appendix 16 - Standard clinical processes for assessing, ordering and exporting files for Podfo insoles

Clinical process: 3D-printed hard-shell PODFO insoles

Identifying patients who may be suitable to try 3D-printed Podfo insoles

To determine possible suitability to try 3D-printed Podfo insoles you must be able to answer yes to these questions:

1. Has the patient has been assessed for, fitted with, and worn custom CAD/CAM insoles for a minimum of 12 weeks and has not experienced relief from the symptoms for which they initially attended?
2. Is the patient suitable for 3/4 length insoles?
3. Is the patient suitable for insoles without a top cover?
4. Have you discussed the escalation options with the patient as per the MSK Foot and Ankle Treatment Pathway, and are they happy to try hard-shell 3D-printed insoles as the next step in their treatment plan?
5. Is the patient happy to attend for an additional assessment appointment at Gartnavel General Hospital, Glasgow Royal Informary, or the Royal Alexandra Hospital to see Laura Barr, Ross McCaig or Kirsty Watters?

If the answers are yes to all of the above then please contact Laura, Ross or Kirsty to book the patient an appointment.

Ordering process: Order details required when ordering PODFO insoles

When raising call offs for Podfo insoles, please include the following information on your order form:

- Make a very clear statement about what your modelling already includes, i.e.

"I have modelled the insoles with a 2mm skive, 5 degree medial heel wedge, 10mm heel raise etc etc"

- Ensure the correct Paromanager model numbers / Paro360 time and dates are stated clearly on your order.

PODFO offer 3/4 length insoles, the suitability for 3/4 insoles must have been agreed prior to ordering. Ensure the following insoles is included on your GL calloff.

1. Podfo 3D addition printed insoles
2. Colour (pink, red, yellow, green, blue, purple, black)
3. If you want a specific area stiffened or flexible - they offer

- reinforced or flexible medial arch
- flexible lateral side
- flexible first ray

File transfer process: Exporting files from Paromanager and Paro360 to send to PODFO

- There is no direct email option within the Paromanager and Paro30 systems, follow this guide to send modelled scans
- Before sending the files, you MUST delete the community health index number and the date of birth from the patients Paro360 file. It is important that you do not send the community health index number with the scans as this is considered patient identifiable information and is in breach of general data protection regulations.
- After you have sent the files you should re-enter the community health index number into the Paro360 file so that we can continue to correctly identify the patient on our own system.

1. Find the correct patient file on Paro360, expand the folders to show the modelled scans for that patient, and click on the insole that you want to send. To select a pair of insoles, or a set of insoles with differential files, hold down “Ctrl” and “left click” each of the files you want to send, this will highlight the files as shown below:
2. Right click and select ‘Export Projects’
3. Select “Export to File”
4. Save into General > Orthotic Department > Databases > #PARO SCANS

5. Create the GL order as outlined above and press “email”. When the email opens, go to “insert”, “attach file”, and attach the modelled scans that you saved in the last step. Send orders to: Paul.Scott@podfo.com; sales@podfo.com; glasgoworthotics@peacocks.net put call off number in the subject line.

Appendix 17 - Confirmation of successful application to the NHS Education Scotland AHP Careers Fellowship

Westport 102
West Port
Edinburgh EH3 9DN

Telephone: 0131 656 3200
Fax: 0131 656 3201
www.nes.scot.nhs.uk

NHS Education for Scotland

Date: 13 January 2022
Our Ref: E42002/ENES7705
Email: AHP.Fellowships@nes.scot.nhs

Laura Barr
NHS Greater Glasgow & Clyde

Dear Laura

AHP Careers Fellowship

The AHP Careers Fellowship Review Panel met on 24 November 2021 and I am delighted to let you know that your application was well received, and we are keen to offer you a Fellowship.

There are a few details I would like to discuss further with you just to ensure clarity and expectations so I would appreciate it if we could arrange a time to speak to both you and your line manager (approximately 30 minutes phone/Teams call in early 2022 will be fine). Following our discussion, we would hope to organise a service level agreement - which will outline your commitment and reporting requirements - as well as a purchase order for your finance department.

Could you kindly also:

1. Confirm your commitment to attending the Fellowship Sessions. We anticipate that they will be delivered via MS Teams and I would appreciate it if you could hold the dates below for these sessions
   19 April 2022, 10:00 – 12:00
   16 May 2022, 10-00 - 12.00
   15 June 2022, 2:00 – 4:00
   29 August 2022, 10:00 – 12:00
   27 September 2022, 2:00 – 4:00
   31 October 2022, 10:00 – 12:00
   01 December 2022, 2:00 – 4:00
   11 January 2023, 2:00 – 4:00
   23 February 2023, 10:00 – 12:00
   DATE TBC – Celebration and sharing event in early 2023

   Depending on Covid restrictions we may consider combining some of the sessions and deliver them as face-to-face workshops. We will negotiate this with your cohort ahead of time to ensure we agree something that works for everyone.

Appendix 18 - Confirmation of successful application to the NHS Research Scotland AHP Career Fellowship

Chief Medical Officer Directorate
Chief Scientist Office Division

T: 0131 244 2358
E: julie.simpson@gov.scot

Scottish Government
Riaghaltas na h-Alba
gov.scot

Ms Laura Barr
By e-mail only to: laura.barr@ggc.scot.nhs.uk

Our ref: NRS/23/NM03

23 February 2023

Dear Ms Barr

NRS Career Researcher Fellowship Application Reference: NRS/23/NM03

I'd like to thank you for attending for interview on Tuesday. I am delighted to inform you that the Panel were happy to recommend you for an NRS Career Researcher Fellowship.

The Panel thought it might be helpful for to you consider seeking an additional mentor with more clinical trials experience and / or seek to link in with a clinical trials unit as part of your proposed research programme.

The Fellowship will run for 3 years from 1 April 2023 to 31 March 2026.

We pay the funding for all NRS Fellowship via allocation to the board so I am copying Chloe Cowan from the Research Office into this award letter and they will take over the administration of this Fellowship from this point.

Yours sincerely

Julie Simpson

Dr Julie Simpson
Research Manager – Information and Capacity

Appendix 19 - Feedback from the BAPO MSK Foot & Ankle Holistic Management and treatment strategies course

Mean scores from attendees 2021 to 2024 collected from the BAPO secretariat, with written feedback below

I felt familiar with the content of the course before attendance	The aims and objectives were outlined at the start of the course	The course achieved the outlined aims and objectives	The course was organised well	I was happy with the course content	I was happy with the venue (and catering provided)	I was happy with the faculty/ presenters	I was happy with the relevance of the course	I was happy with the timing	I was happy with the handouts
3.68	4.71	4.82	4.84	4.89	4	4.92	4.97	4.84	4.82
1 = strongly disagree, 5=strongly agree									

Experts of written feedback from the MSK course from 2021 to 2024

Excellent course, one of the best I have been on in years. Instantly useful and the presenters were clearly very knowledgeable in this subject.

Hi, thank you so much for this course and the opportunity for me to partake in it. The course content is superb and covered almost every day to day clinical issues that we see at our different workstations.

Fantastic course, very advanced MSK for foot and ankle.

I found the course really beneficial. It built upon teachings from University and beyond and gave reasoning and answers to questions I have found through practicing as an Orthotist.

I am very happy with the content covered in the course and the depth of detail that was explored with each topic. The presenters were great at covering the topics in a way that was both informative and memorable.

This was just such a great course, especially being a COVID uni kid it was great to have lots of information in one and really helped tie a few concepts together that might have got missed over that time and linking things together that i never thought about affecting the other before Example: FnHL and knee hyperextension!

Excellent course - really useful and relevant information provided. Speakers were all excellent too, Laura in particular. Will be recommending the course to my colleagues.

Was also great having a few different presenters, saved feeling like you got used to one persons voice and zoning out. The constant changing presenters and different styles of teaching was really great and engaging

It was an excellent course - evidence based and will help me to confidently explain to patients how the orthoses work. The whole course was fantastic, the presenters were very inspiring and their passion for orthotics was clear to see.

I found it a really beneficial course, allowing continued development on Foot and Ankle MSK. A lovely group of presenters who were all extremely supportive.

Appendix 20 - Feedback from the BAPO Orthotic Diabetic Foot Care Course

Mean scores from attendees 2016 to 2017 collected from the BAPO secretariat

I felt familiar with the content of the course before attendance	The aims and objectives were outlined at the start of the course	The course achieved the outlined aims and objectives	The course was organised well	I was happy with the course content	I was happy with the venue (and catering provided)	I was happy with the faculty/ presenters	I was happy with the relevance of the course	I was happy with the timing	I was happy with the handouts
3.70	4.82	4.82	4.86	4.91	4.10	4.98	4.98	4.91	4.82
1 = strongly disagree, 5=strongly agree									

Appendix 21 - NHS Education Scotland Careers Fellowship poster

Computer-aided insole manufacture: Stepping towards best practice

Laura Barr, NHS Greater Glasgow & Clyde

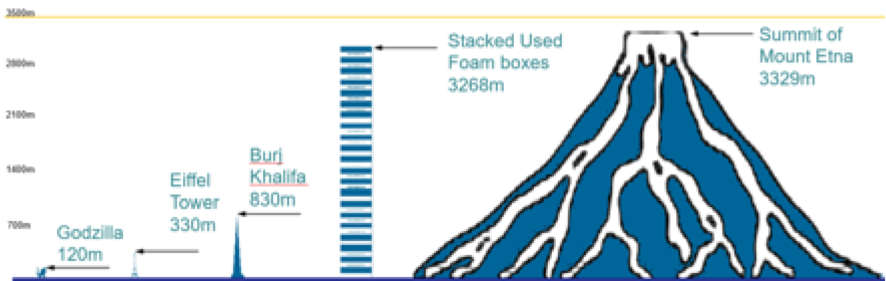
NHS Education for Scotland

Rationale and Background

Insole provision is one of the largest single areas of orthotic intervention in the UK. In NHS GG&C, custom insoles produced by computer-aided-design and manufacture processes (CAD/CAM) represent 14% (n=2739, per annum 2020) of all orthotic provision. In NHS GG&C, service users receive their insoles through a fully digital design and manufacture process, utilising direct foot scanning. Other orthotic services across the UK have adopted a partially digitised approach, whereby shape-capture is achieved with a traditional foam-box casting method. To date, no work has been undertaken to determine the clinical outcomes and economic impact relating to these different treatment approaches. Digitisation in the orthotic industry conceptualised gains in production speed and reduction in waste materials when compared to traditional manufacture utilising physical shape capture[1]. Yet the continued interim stages of foam impression casts and physical transportation sacrifices these benefits, despite the increased accessibility to mobile direct scanners over the past 10 years[2].

Aim and methods

In order to understand the true variability in orthotic practice across the UK, freedom of information requests were sent to 222 Health Boards and Trusts across Scotland, England, Northern Ireland and Wales. Detail about the number of insoles delivered per year using any CAD/CAM process was requested, as well as specifics relating to the full manufacture process from foot-shape-capture, to final insole production. Further questions including barriers and motivators to the use of CAD/CAM were included. The purpose of this scoping service review was to understand the potential impact of any further work in this area, with an overarching goal of identifying best practice in relation to patient care. Discover more about how the freedom of information process was used in this project by scanning this QR code.



Responses and Results

186 responses were received from the 214 Freedom of Information Requests sent to Health Boards and Trusts across the UK. Of those respondents, 131 were able to provide full data in relation to the manufacture processes for CAD/CAM insoles used within their Orthotic services. 76 services reported that they did use CAD/CAM in the manufacture of their bespoke insoles in the 2021/22 financial year, and on average 76.44% of all their bespoke insoles were manufactured using CAD/CAM processes. Therefore a total 90222.74 pairs of CAD/CAM insoles were produced by 76 orthotic services in the UK in 2021/22.

A comparison was then made between services who used direct foot scanning as their primary shape capture method vs those who used foam impression boxes; which are then scanned into the CAD system at a later date. 70 services reported using foam impression boxes as their **primary method** of shape capture, meaning that **36,316** foam impression boxes were used in the 2021/22 financial year to produce CAD/CAM insoles. The true number is likely to differ due to repeat / duplicate insoles not requiring new shape-capture, and the possibility that not all insoles were produced by foam box within services who used this as their primary shape capture method. The graphic above provides a visual representation of these foam impression boxes.

Sustainability?

The manufacture of phenolic foam alone, without even considering the environmental impact of international and trans-UK shipping, is significant[3]. Particularly given the single-use status of these boxes within the Orthotic industry, and the high likelihood of being sent to landfill following one-time use. If direct digital scanning can be shown as an equitable or superior method of shape-capture, with regard to treatment outcomes, then this could be considered as an area of potential change for orthotic services to meet NHS Net Zero targets in the coming years[4].

Conclusions and Next Steps

Mapping the current landscape of clinical practice across the UK is one of two aspects combined to form a larger project. A parallel project area is currently being undertaken in the form of a double blinded randomised controlled trial, investigating the effectiveness of both shape capture methods relating to service-user outcomes. The combination of these two project areas is ultimately intended to form the basis of a best practice guideline for Orthotists prescribing CAD/CAM insoles.

Laura.Barr@ggc.scot.nhs.uk
14\04\2023

References

NES AHP Careers Fellowship Scheme
April 2022 – March 2023

Appendix 22 - Article published by the Institute of Health and Social Care Management, February 2023, and BAPO Connect, 2023, issue 1, pp. 22-23

Available from the Institute of Health and Social Care website at: https://ihm.org.uk/2023/02/08/freedom-of-information-the-what-why-when-and-how/

FREEDOM OF INFORMATION

The what, why, when and how

I must confess being largely unaware of the Freedom of Information (FOI) Act, until last year when I found myself faced with a project intended to identify current practices in NHS Orthotic services across the UK. I won't bore you with the project details here, but to provide some context; building a platform for best practice involves understanding the current clinical landscape. Wholesome blue-sky thinking. But how do you actually get that information? I mean, short of door-stepping every NHS Trust and Health Board in the UK and hoping they will trade information for cupcakes. Did you know there are over 200 Trusts and Boards? That's a lot of cupcakes.

Having been reliably informed that questionnaires may have a slightly disappointing return rate, regardless of the quality of your incentives, I turned to the authors of prior publications and projects which had a similar scoping remit to my own. Enter the wonderful Dr Nicky Eddison, who introduced me to the UK FOI Acts.

WHAT IS THE FREEDOM OF INFORMATION ACT?

The FOI Act 2000 and the FOI (Scotland) Act 2002, provide public access to the information held by public authorities, such as the NHS. Under these acts, public authorities within the UK are required to publish information about certain aspects of their activities and spending, and any member of the public is entitled to request certain types of information directly from that authority.

The Act covers all pieces of information that are recorded and held by a public authority. This includes the usual things that may spring to mind such as official documents and policies, but it also includes recorded information such as emails, notes, document drafts and even CCTV and telephone recordings. While taking the time to ponder the implications of that, you might want to read some of the many news articles disclosing ministerial email communications, or perhaps the cost of the Health and Care Professions Council's Christmas lunch.

WHY WAS THE ACT DEVELOPED?

The purpose of the Act is to provide greater transparency and accountability of public services that can significantly impact the lives of UK residents, and are partly funded by UK taxpayers. In the 1997 "White Paper", the UK government discussed the development of the Act, explaining: "Openness is fundamental to the political health of a modern state. This White Paper marks a watershed in the relationship between the government and people of the United Kingdom. At last there is a government ready to trust the people with a legal right to information."

"The Act covers all pieces of information that are recorded and held by a public authority. This includes the usual things that may spring to mind such as official documents and policies, but it also includes recorded information such as emails, notes, document drafts and even CCTV and telephone recordings."

In evidence of this, the Information Commissioner's office published findings in 2011 demonstrating that 81% of public bodies included in their survey agreed that the Act had increased public trust in their organisation.

There are of course exemptions to the information that public authorities are required to provide. The Act itself is understandably complex in places and there is a degree of "grey area", but fundamentally the main exemptions relate to requests for non-fact based information such as personal opinion, or information that would prove excessively time consuming or costly for the public authority to obtain. There are also limitations on information around personal data that may breach data protection.

WHEN CAN INFORMATION BE REQUESTED FROM NHS SERVICES?

Any member of the public can request information via the FOI Act at any time, as long as this is done in the correct way and through the correct channels. FOI requests made to an NHS Trust or Health Board should be directed to the relevant FOI team within that area. This team will usually sit within the Information Governance department, the contact details for whom will be available on the Trust or Health Board website.

To comply with the Act, FOI requests must be written, state clearly the information that is being sought, contain a contact address or email address, and must contain the requestors real name. Requestors do not need to provide a reason for requesting the information.

The NHS Trust or Health Board has 20 days to reply to a FOI request, to comply with the Act. In some instances, they may request an extension depending on the circumstances surrounding the request.

HOW DOES THE ACT AFFECT ORTHOTIC AND PROSTHETIC SERVICES?

If you manage an NHS orthotic or prosthetic service, or you manage a company that provides orthotic or prosthetic services to the NHS, then you have likely been approached for information requested via the FOI Act at some stage. One of those requests was probably mine. That was the one with the cupcake. If you didn't receive a cupcake then it must have been stolen by the Information Governance team. Speaking of which...

Requests should be routed to you from the relevant Information Governance team in your Trust or Health Board. The Information Governance team will generally screen the request for appropriateness and compliance with the Act before sending this to you, and they will provide guidance on the submission deadline for each request.

The Information Commissioner's Office state that: "Disclosure of information should be the default – in other words, information should be kept private only when there is a good reason and it is permitted by the Act"

IN CONCLUSION

The FOI Act provides a framework for the transparency of information relating to public authorities including the NHS, for the general public who use and contribute to those services.

Further information for public sector organisations can be found at the Information Commissioner's website: **www.bit.ly/BAPO-ico-what-is-the-foi-act**

Further information for the general public can be found at: **www.gov.uk/make-a-freedom-of-information-request**

Laura Barr
Advanced Orthotic Practitioner,
NHS Greater Glasgow and Clyde

Appendix 23 - Confirmation of endorsement from the BAPO Research Committee regarding dissemination of the questionnaire for project 1

7th October 2022

Dear Sir/Madam,

RE: Evidence Based Practice in the UK Orthotics Industry - Laura Barr

The British Association of Prosthetists and Orthotists (BAPO) Research Committee will review the contents of the above survey and assist with its distribution to BAPO members subject to favourable ethical approval. On behalf of the Chair of the BAPO Research Committee I will oversee this process and liaise on behalf of the survey author with our Executive Committee.

Subject to approval, BAPO will distribute an electronic survey link to our membership via email. The link can also be distributed via social media platforms on Facebook and Twitter should the survey author request it.

BAPO will not be responsible for the collation or analysis of any survey data and require that all individual responses from our membership are kept anonymous and confidential.

Please do not hesitate to contact me if you have any further queries regarding this matter.

Yours sincerely,

M. Golding-Day

Miriam Golding-Day

BAPO Research Committee member

Appendix 24 - Case study published in the BAPO Research Training and Career Guide

LAURA BARR

Role: Advanced Orthotic Practitioner and NRS Career Research Fellow

Institution: NHS Glasgow and Clyde

RESEARCH STORY

My interest in research began with my enthusiasm for evidence-based clinical practice. As an orthotist working both in NHS health care and as an educator, I strongly encourage using the evidence base to support and improve the treatment of patients. There is no doubt that there are many areas of Orthotic practice where the evidence underpinning our treatments is limited, and it was from this stance that I started looking at how I could contribute to filling some of these research gaps.

I was fortunate to have some prior exposure to research while working in the diabetes multidisciplinary clinics in Glasgow, where the team were involved in clinical trials. I also conducted some clinical evaluations and a small cohort study as part of my ongoing CPD and MSc studies, but for the first 14 years of my career that was the extent of my involvement in research.

I was keen to become more research-active, but I didn't want to step away from my clinical position. It was during one of our department service evaluations that I met some of the research team at the University of Central Lancashire. We discussed the new part-time PhD programme offered at the university, which would allow me to evaluate previous projects I had worked on, as well as undertaking new research. This would provide me with the research supervision and support that I badly needed, but there was still one issue – where to find the time.

I began applying for Fellowship programmes which were open to NHS staff,

For more stories, visit www.bapo.com/resources/research-resources

and was delighted to be accepted as a NES AHP Careers Fellow, starting in April 2022, which was 3 months after my enrolment at the University. This provided a "salary buyout" two days per week for a year, to ring-fence my project time. The following year I was successful in gaining a second Fellowship, this time as a NRS Career Research Fellow, allowing me to continue my research until 2026.

Being able to undertake research within my own clinical area, on a subject which I am truly passionate about, has made this journey a very enjoyable one, and an experience which I wouldn't hesitate to recommend to others.

RESEARCH TIPS

- You don't need to start research early in your career. If you have a solid foundation of clinical experience you can use this to your advantage when entering the world of research.
- Don't worry if your research journey isn't "linear", not all research positions require you to follow a standard set of steps.
- Chose a research area that you are genuinely interested in. The process can be a long one and if you don't have passion for your subject then you're more likely to lose momentum.

For more stories, visit www.bapo.com/resources/research-resources

Appendix 25 - Excerpt from the NHS GGC Orthotic Musculoskeletal Speciality Professional Development Framework for Orthotists

Orthotic Musculoskeletal Speciality

Professional Development Framework for Orthotists

Purpose of the Framework:

This Framework aims to guide Orthotists working in the Musculoskeletal (MSK) service during their career development. At times the Orthotist may be actively engaged in periods of learning and supported practice within the Orthotic MSK Team. At other times, the Orthotist will be able to continue using this tool to measure, maintain and progress their own level of practice, by identifying key areas for their own development.

Individuals must utilise their professional reasoning and judgement skills to assess their own knowledge and skills and competence in line with the HCPC requirements. HCPC requires all registrants to confirm that they have maintained and can evidence appropriate and current knowledge and practice in their role.

How this Framework compliments the Personal Development Plan & Review (PDP&R):

The necessary knowledge, skills and behaviours relating to levels of practice (Banding) within the Orthotic service are outlined and evidenced as part of your PDP&R. This Framework is a supplementary tool, outlining the specific requirements of clinical staff working at different levels of practice within the NHSGGC Orthotic MSK Service.

The grading points on this framework do not reflect the pay grade of the individual, they reflect the level of knowledge, skills and behaviours within each of the areas. The individual is expected to manage and identify their own development throughout the framework. Development opportunities should be discussed and agreed with the Clinical Team Lead as part of the PDP&R process. The individual may use this Framework to guide their CPD plan during the PDP&R process. The individual may seek confirmation of their level of practice on the framework through production of evidence and discussion with the MSK team lead.

Using the Framework

It is important to remember that level of practice can change (both up and down) throughout an individual's career. CPD is vital to maintain and improve level of practice. It is recommended that all individuals specialising in MSK practice re-assess their own level of practice for each area on the framework annually.

These areas reflect the specific nature of work within the NHSGGC Orthotic service, and although these skills will be transferable throughout all NHS Health Boards and Trusts, they will not necessarily reflect the specific requirements of those services.

Self-Assessment tool:

The individual should rate their level of knowledge, skills, behaviour and confidence in various areas using a 6 point scale. A rough definition has been provided on the next page to guide the process of grading, **however**, you will find a more detailed descriptor within each defined area of the Framework. Individuals should refer to the definition and select the number that best reflects their current level of knowledge and skills. Your skills and knowledge should match your level of confidence in order to score at the levels outlined below. Guidance on the type of activity recommended after the rating has been completed is also detailed on the next page.

Appendix 26 - Article published in O&P Edge Magazine, October 2021, pp. 30-35

MY JOURNEY TO ADVANCED ORTHOTIC PRACTICE IN THE UK

By Laura Barr, MSc, BSc (hons), PGCert, Advanced Orthotic Practitioner

I am a registered orthotist working in Glasgow, Scotland. Right now, I am taking advantage of a rare gap in my clinic schedule to compose this introduction about how orthotists in the United Kingdom (UK) are taking up roles as advanced practitioners in our National Health Service (NHS).

I probably have about ten minutes before my first two patients return from x-ray and I guide one of them through the process of surgical planning and provide the other with a therapeutic corticosteroid joint injection. Those ten minutes will also be sufficient cooling time for my hot chocolate. You may be thinking this doesn't sound like a normal clinical scenario for an orthotist, and yes, a quick consultation with my colleagues confirms that caffeine is the usual choice of fuel, but for me sugar will win out every time.

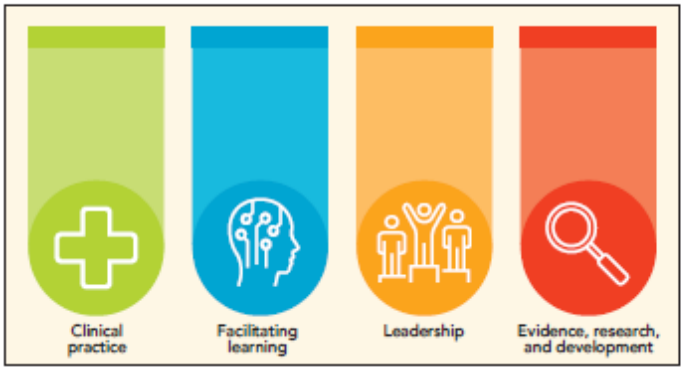
As for the clinical case load, I suppose that is slightly unusual too. So, if you're interested, and have a few spare minutes of your own, why not grab your favorite beverage and I'll tell you about how I got here.

INTRODUCTION TO ADVANCED PRACTICE

Advanced practice is not a new concept in healthcare, our nursing colleagues have been leading the way for over 50 years, developing the first roles of advanced nurse practitioner and nurse physician in response to a shortage of junior physicians, in the United States in the 1960s and the UK in the 1980s.[1] Since then, the concept of these roles remains true to their origins, but the education programs, registration, and certification have progressed significantly. Often emerging from identifiable gaps or congestion in medical services, advanced practice roles now exist in almost every area of healthcare, from pediatrics to surgical specialities, research to education, and all of the space in between. In the UK, working at an advanced practice level means that a clinician meets a measurable and defined level of practice within four areas: clinical practice, facilitation of learning, leadership, and research and development, known collectively as the Four Pillars of Practice. Although the exact definition of advanced practice differs around the world, there is a ubiquitous understanding led by the International Council of Nurses that the term defines a level of practice, rather than role specifics[2]—meaning that in certain areas, it is inevitable that the skills and experience of a particular professional group may lend itself more readily to a particular role. As such, the foundation built by nursing has helped to support the development of advanced practice roles for allied health practitioners (AHPs) such as physiotherapists, podiatrists, radiographers and, of course, orthotists.

THE FOUR PILLARS OF PRACTICE

In line with the Scottish government's guidance on transforming roles within the NHS, AHP advanced practice frameworks are being developed to assist with standardizing the level of skills, knowledge, behaviors, and education required to be considered an advanced practitioner, in much the same way as had previously been done for nursing. NHS Education for Scotland provides a variety of toolkits and support for clinicians working at various levels within



The Four Pillars of Practice

these four pillars,[3] which form the basis of advanced practice roles, regardless of specialty.

ADVANCED CLINICAL PRACTICE

In terms of AHPs, and in particular, orthotists, our underpinning biomechanical and anatomical skill set means that we often provide expertise to services such as neurology, orthopedics, and diabetes. Therefore, it was natural that some of the first advanced orthotic practitioner roles were born from these areas. The clinical aspect of my own advanced practice role lies fundamentally in my work with orthopedics, where I have my own caseload working alongside consultant orthopedic surgeons. The patients within my clinics are most often referred for a surgical opinion or for further investigation to assist with diagnosis and treatment planning. Most of my time in these clinics is spent coordinating care from diagnosis to surgical or non-surgical treatment. I am responsible for clinical assessment, organization, and interpretation of relevant bloodwork, imaging—including x-ray, MRI, and ultrasound—the supply and administration of appropriate medications such as therapeutic and diagnostic injections, pre-listing and listing for surgery, and final post-operative review and discharge. Although it is not strictly part of my job role, where possible I also find it beneficial to observe and assist in surgery, under the mentorship of my surgical colleagues.

In 2015 when I first started in this role, there was no precedent for an orthotist to be working within orthopedics in my Health Board. Indeed, it is testament to the foresight of my consultant surgical colleague and orthopedic clinical services manager that I was even given the opportunity to apply. I like to think that in the time before and since starting the job, I have proven the worth and benefit of having an orthotist in the role, helping pave the way for other similar positions that have been created across the country since. With that said, there have been quite a few challenges to overcome in the intervening six years.

Medical Imaging

One of the fundamental elements of my role is the ability to refer for and interpret relevant clinical imaging such as plain film radiographs, diagnostic ultrasounds, and MRIs. Each aspect of medical imaging usually requires specialist permissions from the Radiology department in which the non-medical referrer works, as well as specialist post-graduate training to a defined level, which can differ depending on the area of practice and referring profession. A recognized certificate in ionizing radiation and medical exposure regulations are requirements for the Health Board in which I work, but the specific qualification for orthotists had never been defined as we had no prior history of requiring access to imaging referral. In collaboration with the Orthopedic, Orthotic and Radiology departments, we agreed on similar standards to those of other AHP professionals, and I undertook recognized post-graduate training at the master's level as part of a larger PGCert in the theory of podiatric surgery.

Biochemistry, Hematology, Virology, and Pathology

Similarly, the requirement to refer for relevant bloodwork and biopsy is a vital element of the diagnostic process for the orthopedic service. In this instance, the ability to interpret the results in conjunction with the physical clinical assessment is necessary to assure the best outcomes and reduce clinical appointments. There was very little existing guidance in this regard when I started, and so I undertook both a post-graduate university validated qualification on clinical investigations, as well as continuing professional development courses on interpretation of blood results.

Supply and Administration of Medication

As I mentioned earlier, one of the aspects of my role is to provide therapeutic and diagnostic injections for a variety of clinical conditions. In the UK, the supply, administration, and prescription of medication is strictly controlled by government regulation and overseen by our registering body, The Health & Care Professions Council.[4] Although orthotists do not have the authority to independently prescribe medication, we are able to supply and administer medication under a tightly controlled legal framework, using Patient Group

Directions (PGD) and Patient Specific Directions (PSD). Although this legislation had been in place since 2008, there were no prior instances of orthotists having developed or worked under a PGD until 2015. In partnership with orthotic management, pharmacy, orthopedic, and spasticity services, I was involved in the development of the first orthotist-specific PGDs for corticosteroid, local anaesthetic, and botulinum toxin injections. To date we have six PGDs in regular use within our department in NHS Greater Glasgow and Clyde, as well as collaborating on various others. The legal documentation aside, specialist training and qualification was once again required to underpin the clinical skills and knowledge required to use the PGDs. Of interest, the authorization to use PGDs meant that during the COVID-19 pandemic, I and six other orthotists from our department were able to volunteer our services as vaccinators for the various vaccination clinics running in our Health Board.

Surgical Listing

Listing directly for surgery is, in my opinion, one of the greatest responsibilities that I hold as an advanced orthotic practitioner. It is also probably the area with the least formal guidance. Listing patients from my clinic for surgical procedures means that I undertake the assessment, explanation of treatment options, pre-listing for suitability, and addition to the surgical waiting list; all in the absence of the orthopedic surgeon who will be performing the procedure. As such, the authority to do so lies firmly with the surgeon for whom I am listing. I work with and list for three orthopedic surgeons, all of whom I have shadowed closely, liaised with clinically, and assisted surgically over the years, to gain the trust and autonomy for listing. To compound my own knowledge, I also completed the aforementioned PGCert in theory of podiatric surgery and undertook a Basic Surgical Skills certificate from the Royal College of Surgeons and Physicians in Glasgow.

These are just some of the clinical areas in which I personally required the addition of specific knowledge, skills, training, and forging of relationships between other specializations and departments to successfully undertake the role of advanced orthotic practitioner. However, each role is individual to the needs of the department and the distinct circumstances they face. The clinical aspects will vary, as will the weighting of the other three pillars of practice, all of which are vital for advanced practice.

FACILITATION OF LEARNING

For some advanced practitioners, the role may be less clinical and focused more acutely on education, research, or leadership. Regardless of the weighting toward one of the four pillars, there should be an element of each within the individual practice. In addition to my clinical role, I have a responsibility for the delivery of education to orthotists throughout the UK and internationally, as well as facilitating learning for

other healthcare practitioners. I am proud to have been involved in the development and delivery of a large-scale education program on behalf of our professional association in the UK, the British Association of Prosthetists and Orthotists (BAPO), where alongside my colleagues we have delivered more than 30 courses on the holistic management of musculoskeletal (MSK) foot and ankle conditions.

LEADERSHIP

Leadership has become an important focus within many industries over the past ten years, including the NHS, and understandably so, as leading others in a supported way is vital to the progression of any healthcare system. Over my current 15 years of clinical practice, I have become acutely aware that my own successes are a result of the fantastic leadership that I have observed and received from the team with whom I work. I can only hope that in my role as MSK Team Lead for Orthotics NHS GGC that I can provide similar support, mentorship, and inspiration to the members of my team. I cannot overstate the importance of leadership to ensure the development of future advanced practitioner posts.

RESEARCH AND DEVELOPMENT

It goes without saying that the future of any healthcare profession relies on research and development to ensure continued evidence-based practice. For this reason, some advanced practitioner roles are based almost exclusively within this pillar. Job roles can be affiliated with universities and rolling research grants, or time simply set aside for interdepartmental service reviews to demonstrate effective clinical practice. I work with BAPO not only to support the continued education of our profession, but I am also responsible for the maintenance and development of our internationally accessible Directory of Evidence-Based Orthotic Practice (DEBOP), a directory which was developed by orthotists for orthotists and is used by clinicians across the world to support patient treatment and clinical development.[5]

CONCLUSION

As the development of advanced practice roles continue, so do the opportunities for orthotists to expand and specialize in a variety of different areas. The non-specificity of advanced practice gives rise to endless possibilities for our small but powerful profession. I would encourage you to seek opportunities within your current service to identify areas which could lend themselves to advanced roles, and don't be discouraged if it hasn't been done before. After all, much like our chosen sources of midday drinks, we all have different preferences to pique our interests, attention, and focus. OAP EDGE

Author's note: If you are interested in accessing or contributing to the Directory of Evidence-Based Orthotic Practice, visit dcp.scot.nhs.uk/pathways/nhs-greater-glasgow-and-clyde-&/orthotics-directory-for-evidence-based-orthotic-practice.

Laura Barr, MSc, BSc (hons), PGCert, is an advanced orthotic practitioner and specialist team lead, based in Glasgow, Scotland.

References are available at opedge.com.

Appendix 27 - Case study published in Advanced Practice in Prosthetics and Orthotics. British Association of Prosthetics and Orthotics. 2024. Version 2, pp.19-20

Advanced level practice

Laura Barr, Advanced Specialist Orthotist and MSK Team Lead for Orthotics

Laura Barr is Advanced Specialist Orthotist and MSK Team Lead for Orthotics at NHS Greater Glasgow and Clyde.

Career Journey

- 2007-2015: General orthotic practice with a focus on diabetes.
- 2013-2016: Completed an MSc.
- 2015-2019: Transitioned into an Extended Scope Practitioner (ESP) role in Orthopaedics.
- 2017 – to date: Leads the MSK team for NHS Greater Glasgow and Clyde (GGC) Orthotic Service.
- 2019: ESP role converted to Advanced Orthotic Practitioner.
- 2022: Pursuing a PhD.
- 2022-2023: Completed NHS Education for Scotland Fellowship.
- 2023 – to date: Undertaking NHS Research Scotland Fellowship.

Key moments in career journey

Laura worked in various aspects of general orthotic practice for a number of years, before pursuing her interest in MSK and orthopaedics. This included undertaking formal education and training, as well as making the most of the clinical opportunities where she worked.

Laura undertook training in image interpretation. This, together with her clinical experience, allowed her to take on an extended scope role. Her role and other similar roles within the NHS Board she works in were later changed to advanced practice, with her role now encompassing all four pillars of practice.

Job role

Laura manages complex clinical caseloads, with responsibilities including triage, assessment, diagnosis, and post-operative discharge planning for foot and ankle service patients.

Laura is responsible for education in the orthotic department relating to MSK conditions. She organises and provides training, as well as managing training plans for staff. She also undertakes a variety of other education roles including as an external examiner on an undergraduate prosthetics and orthotics programme and as a trainer on professional body courses.

Laura is the specialist team lead for MSK in her Health Board's orthotic service and is the national MSK lead for Orthotics in Scotland. She is active in research, leading research initiatives within the orthotic service.

Advanced level practice

Benefits of role
Laura's advanced practice role enhances the orthotic treatment of patients with complex presentations, reducing waiting times, improving access to care and alleviating pressure on other clinical services.

Laura did not want to pursue an office-based ca eer and advanced practice has allowed her to find the right balance between clinical and non-clinical work She enjoys using her advanced skills to manage the care of patients with more complex needs. Working across all four pillars of practice has made her role fulfilling by giving her the f eedom to pursue her own interests.

Challenges
During her training journey, the absence at the time of an established framework for AHP advanced practice posed challenges.

Advice for practitioners considering an advanced practice role
Laura advises aspiring advanced practitioners to start their development early, gain broad experience, use available frameworks, share resources, and seek support from other advanced practitioners.

Future opportunities for advanced practice in prosthetics and orthotics
Laura thinks there is the potential for orthotists to work as first contac practitioners in primary care.

Drawing on her experience, she thinks that advanced practice roles could be created in other clinical areas. Laura thinks lack of access to non-medical prescribing could be a barrier in some clinical areas, such as diabetes care.

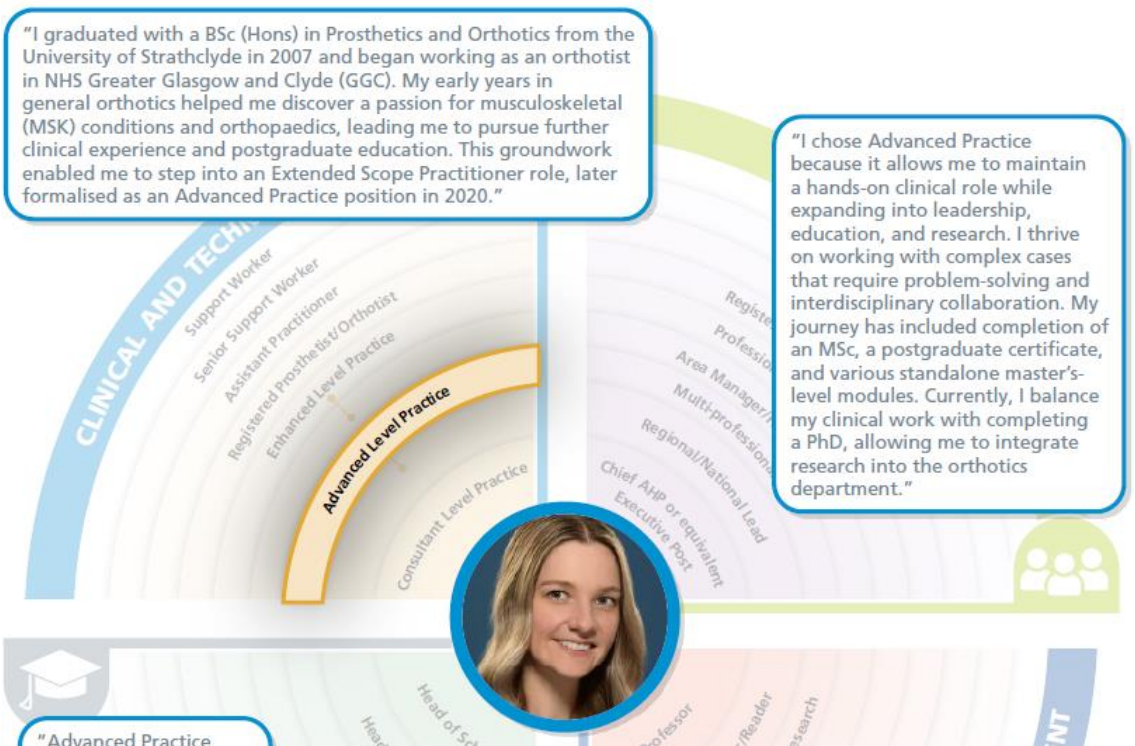
Appendix 28 - Case Study published in Exploring a Career in Prosthetics and Orthotics. British Association of Prosthetics and Orthotics. 2025. Version 1, pp.19

Laura Barr

Advanced Orthotic Practitioner

"I graduated with a BSc (Hons) in Prosthetics and Orthotics from the University of Strathclyde in 2007 and began working as an orthotist in NHS Greater Glasgow and Clyde (GGC). My early years in general orthotics helped me discover a passion for musculoskeletal (MSK) conditions and orthopaedics, leading me to pursue further clinical experience and postgraduate education. This groundwork enabled me to step into an Extended Scope Practitioner role, later formalised as an Advanced Practice position in 2020."

"I chose Advanced Practice because it allows me to maintain a hands-on clinical role while expanding into leadership, education, and research. I thrive on working with complex cases that require problem-solving and interdisciplinary collaboration. My journey has included completion of an MSc, a postgraduate certificate, and various standalone master's-level modules. Currently, I balance my clinical work with completing a PhD, allowing me to integrate research into the orthotics department."



"Advanced Practice offers a dynamic and flexible career path, allowing me to shape my role around my interests, continuously evolve, and contribute to the profession beyond direct patient care."

"I work across both the Orthopaedics and Orthotics services in NHS GGC, covering the four pillars of practice:
Clinical: I assess, diagnose, and manage patients in the Orthopaedic Foot and Ankle service and lead escalation clinics for complex orthotic cases. These clinics also serve as training opportunities for colleagues and external healthcare providers.
Education: I oversee MSK education within the NHS GGC Orthotic department, developing training programs and a Professional Development Framework. I also contribute to university teaching, act as an external examiner, and train clinicians nationally through BAPO courses.
Research: As an NRS Research Fellow, I lead research initiatives to integrate evidence-based practice into the Orthotic service. I co-manage the MSK foot and ankle pathway and lead the national Orthotics Evidence Portal project for BAPO.
Leadership: I serve as the MSK specialist team lead in NHS GGC and the national MSK Lead for orthotics in Scotland. This dual role allows me to combine patient care with strategic service development, education, and research—keeping my career both rewarding and impactful."

Appendix 29 - Review of BAPO MSK Foot & Ankle Holistic Management and treatment strategies Course.

Published in BAPO Connect, 2020, issue 1, page 31

Course Review

MSK Course

Chris Cody explains

This two day course took place at the picturesque Elm Grove Conference Centre, part of the University of Roehampton campus. The course content and presentations was split nicely between the presenters: Simon Dickinson, Laura Barr and Chris Cox (@orthotistUK, @MissBarr, @chrisc0x90 respectively on Twitter) who have a wealth of experience and knowledge. This is the 28th iteration of the course and has been updated and adapted (as it should) with the latest research, processes and advice.

Simon, for those who know him or of him, is like Marmite - love him or hate him he is definitely a clinician who is up to date and not afraid to push the boundaries and agitate the status quo - a skill I believe all of us and not just graduates should realise is in our remit of providing the best for the service user - to query our fellow Orthotists, departments, teams and Trusts. The deliveries of his sections were intermingled with relevant humour, open questions and his sage advice of "Do. Or do not. There is no try" (Empire Strikes Back, 1980).

Laura has an interesting role with her performing Botox injections as part of a holistic treatment - it's definitely extended scope and an opportunity north of the border, however in the session we learnt that one clinician will be taking it on in the UK as well; needless to say it may be an opportunity for others as well, so do check if the pathway exists in your clinics. Also her anatomy knowledge is on another level, think Orthotist going on to Orthopaedic Consult - a definite refresh in her sessions and something we should all know like the back of our hand, especially if you want to extend your skills beyond a traditional Orthotist role.

Chris is a lecturer at Strathclyde (among his various roles) and the biomechanics flow from him like a finely honed martial arts kata - his private practice and case studies are interesting and his medial wedges will definitely raise an eyebrow or two. His sessions also talked about extrinsic and the compensatory (or lack of) intrinsic forces and emphasised the fact that foot orthoses benefit individuals by modifying kinetic parameters, namely the forces and relative moments.

Each presenter had an intimate knowledge and detail on the whole course. The clinical imaging section was extremely interesting - it takes experience and practice to "read" the images and then put that knowledge into the design of an orthoses. We learnt the process and steps of how to look at the image, and then some comparison of "normal" vs "affected" ankle/foot x-ray's. Clinical examination, although a revision of some of what you learn at university, was a good session as we broke out into 3 groups to manipulate and assess each other's feet with one of the presenters - time is a constraint and it would be great to have an extended session on this as there is a real skill in isolating areas and being able to really feel and assess irregularities in structure and form.

Another interesting section was about first line and interventions such as weight management, and strengthening, especially of the intrinsic muscles of the feet. The end of day one started on going through the MSK section of DEBOP (Directory for Evidence Based Orthotic Practice - an online resource, just Google the phrase), with Chris talking to us about Medial Tibial Stress Syndrome and the associated biomechanics - a subject close to my heart since I personally have this issue - and day two carried on this theme of going through DEBOP intermingled with real life examples, and interesting stories and experiences.

As graduates the tendency, without a solid mentor and/or coach, is to fall into the practice of more senior colleagues and age old department practices, and if we are lone workers then we improvise, adapt and overcome. Given the base information we are given at university, we have to keep the motivation to learn alive by reading up on the latest research and applying it to our clinics. Yes we are all limited in our time and have a hundred things to do, but if we adapt good practice from the beginning we are only setting up ourselves to have a strong foundation. For those who are a bit later on in life, remember change is good as it makes you more flexible, adaptable, and if embraced can be really good fun.

I had to leave early so missed the last half hour, and was really gutted as all conversations during the breaks and post presentation were relevant and interesting - it's also great fun to go along and meet others from other Trusts and learn about their processes and practices and you most likely will bump into someone you already know (shout out to Flic, the GSTT crew, Laura and Natasha!)

Key things that I personally took home were: know your anatomy, reach out to MDT (but know your stuff especially if going to chat with consultants and surgeons), insoles change the moments and forces, key names: Richard Blake (drblakeshealingsole.com), Luke Kelly (intrinsic foot muscle exercises), Kevin Kirby and Eric Fuller (multiple papers and active bloggers on Podiatry Arena) and finally DEBOP!

I'd definitely recommend this course both for those who have not been on it and those who may have been through the first iteration. I'd do it each year just for a refresher if it were possible!

Munawar Osman
St Helens, North West Boroughs Trust

Appendix 30 - Reviews of BAPO conference presentation on MSK Differential Diagnosis of Foot and Ankle Conditions

Published in BAPO Connect, 2018, issue 2, pages 29 to 30

MSK UPDATE

Friday morning saw a packed house for the first session which provided an update on differential diagnosis of foot and ankle conditions, fondly referred to as the 'MSK' course. The course was developed in 2015 and to date has provided high quality education and training to over 200 Orthotists nationally and internationally. The course has been constantly updated and changed to incorporate the latest knowledge and research around foot and ankle MSK conditions. The result is the course is now significantly different to the initial one presented in 2015.

The team led by Simon Dickinson presented new and updated data about the most commonly seen conditions in our clinics to over 80 people, while Laura Barr and Chris Cox gave practical sessions demonstrating new diagnostic tests with up to date research findings. This made for an enjoyable and challenging session.

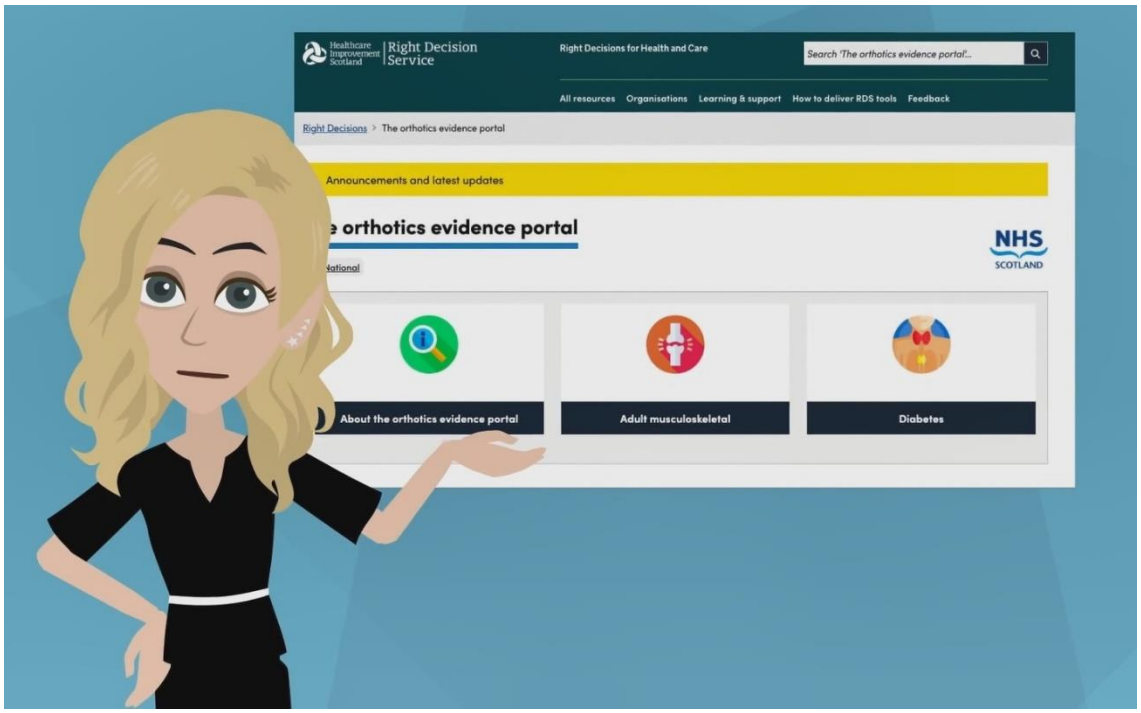
Lynne Rowley

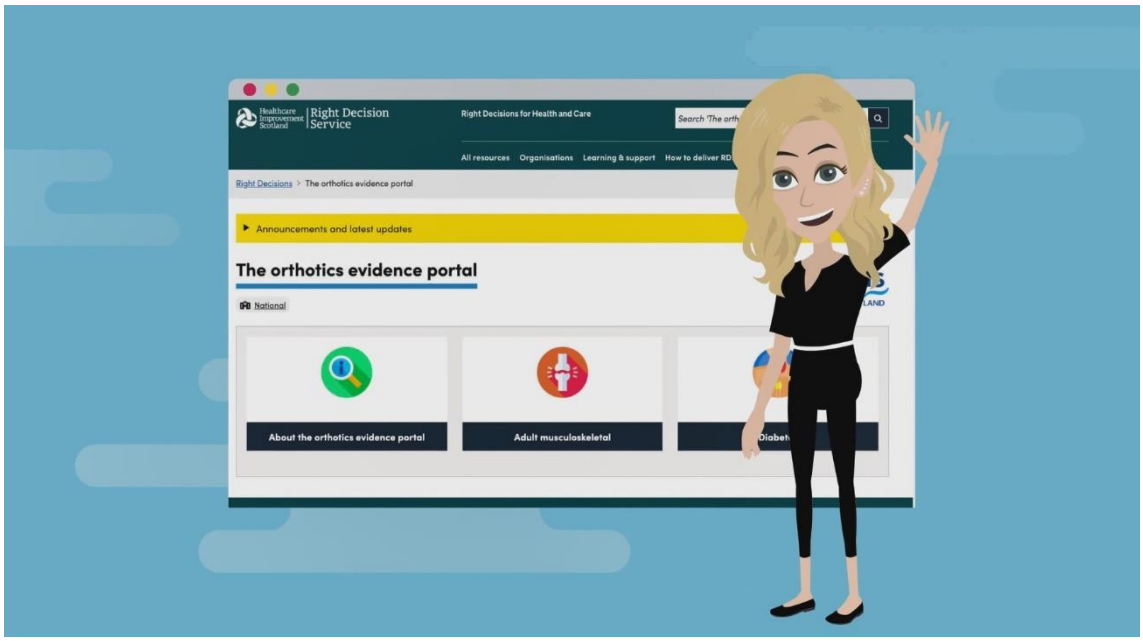
The main presentation I was interested to attend at BAPO was the update from the MSK team. This was mostly because half of my current work load is focused on specialist foot and ankle orthopaedic clinics which I do both alone, and with consultants during their elective clinic lists. As always, the team managed to pack a great deal of anatomical, biomechanical and orthotic knowledge into their three-hour presentation. Simon opened the presentation (and conference) with some anatomical revision as well as setting the seed for Laura's presentation by reviewing the literature on how orthoses can potentially cause intrinsic muscle weakness. He also covered other load management strategies apart from orthotics to assist with the holistic management of foot pain; this for example can include weight loss and providing strengthening exercises. What I found particularly encouraging, as I do the same in my practise, was the recommendation of reviewing the patient several months or even a year down the line after provision of foot orthoses to see if patients still require them. After all, we do this routinely

for patients with a neurological deficit, so why would we not apply a similar practise of reviewing prescriptions for the musculoskeletal patient population. I have certainly expanded my knowledge on a variety of topics from this MSK update and would like to thank Simon, Laura, Chris and all the other MSK gurus (!) for sharing their joy of the subject as well as making it really relevant and informative to improve orthotic practise.

Jessica Makwana, Orthotist

Appendix 31 - Screenshots and link to the animated guide for the Orthotics Evidence Portal





Full animation link: https://www.youtube.com/watch?v=ogfya0SIWa8

Appendix 32 - Full script for the animated guide to the Orthotics Evidence Portal

Welcome to the Orthotics Evidence Portal. This resource has been developed to help orthotists, and those working with orthotic patients, to quickly and easily access evidence to help them with their clinical practice.

The Orthotics Evidence Portal can be accessed from any PC, by visiting the Right Decision Service website. It has also been optimised for use on mobile devices by downloading the Right Decision Health and Care App to your phone or tablet.

Once you have accessed the portal, you can easily navigate around the site using the tiles on the front page and the associated drop-down menus.

NAVIGATION

On the front page of the portal you will see tiles relating to specific areas of orthotic practice. Selecting the area you are interested in will open that section of the portal. from there you can decide what type of evidence you wish to access, for example in the adult musculoskeletal page you can find information on the orthotic treatment associated with specific areas of the body, or you can access more general information on biomechanical assessment and first line interventions.

You can also search for information by typing into the search box.

ACCESSING THE EVIDENCE

The evidence relating to orthotic treatment is displayed under headings for the type of publication, according to the hierarchy of evidence. This means that the highest quality evidence such as meta-analyses and systematic reviews are shown first, and less robust publications such as individual case studies are shown last.

Under these headings, the individual publications are displayed using Harvard referencing format which means they are displayed alphabetically by first author name. Harvard referencing is internationally recognised and should be familiar to the majority of clinicians using the Orthotics Evidence Portal, however it is

important to remember that within this system the most recent publications will not necessarily be displayed first.

You can navigate to any article, using the link below the individual reference. This will open a new page to the host site for that article. You may have access to read part of, or the whole journal article depending on your access rights to the associated journal. This will depend on where you work, and what access your institution has paid for. For users in the UK, information on registering for library services can be found on the “about” page of the Orthotics Evidence Portal.

HISTORY

The Orthotics Evidence Portal is an evolution of the Directory of Evidence-Based Orthotic Practice. Let’s take a look at the development of this resource over the years, and how user feedback has influenced the portal that we see today.

The Directory of Evidence-Based Orthotic Practice was first published in 2015, it was initially developed with funding from the Scottish government with the aim of evidencing the position of orthotic services in the treatment pathway for patients with MSK conditions.

Having fulfilled its original aim, a small group of orthotists from across the UK took on the development and maintenance of the directory. With support from the British Association of Prosthetists and Orthotists, and the Orthotic Education and Training Trust, the directory was rebuilt and transformed into a resource designed to provide orthotists with easy access to the evidence base.

STATISTICS

Over the years the directory has been accessed consistently and in 2023 a survey completed by over 100 orthotists in the UK showed the positive experience of those using the directory. The vast majority of respondents stated that having access to the directory made it easier and less time consuming for them to locate and access published research.

Over 80% agreed that having access to the directory made them more likely to access published research and to identify meaningful publications that were relevant to their clinical practice.

Over 70% of respondents said that they would choose to access published research through the directory rather than using other sources.

Those who use the directory overwhelmingly stated that they would recommend it to other clinicians and felt it to be a useful research resource for the orthotic profession.

One area of improvement requested by respondents was related to the usability of the website on PCs and mobile devices.

These concerns were addressed in 2025 when the new Orthotics Evidence Portal was launched on the Right Decision service.

CLOSING

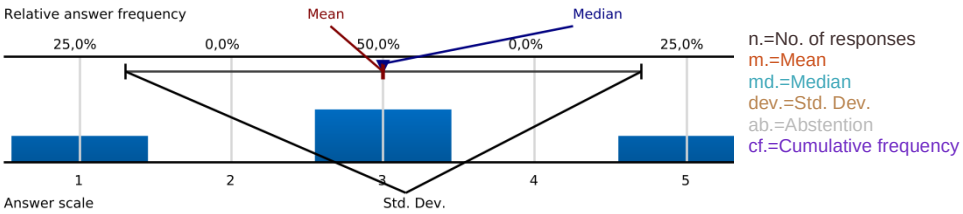
The portal is maintained by orthotists in the UK with support from the British Association of prosthetists and orthotists and the orthotic education and training trust. We are passionate about supporting evidence-based practice in the orthotic profession, and we warmly invite any orthotic practitioners or those working with orthotic patients to contribute to the portal. For more information on how you can contribute, please visit the “about” page.

Appendix 33 - Module evaluation survey for Orthotic Practice 1, University of Derby, Prosthetics and Orthotics Degree Apprenticeship, August 2024

Orthotic Practice 1 (4OR503_6192_OA_2022)

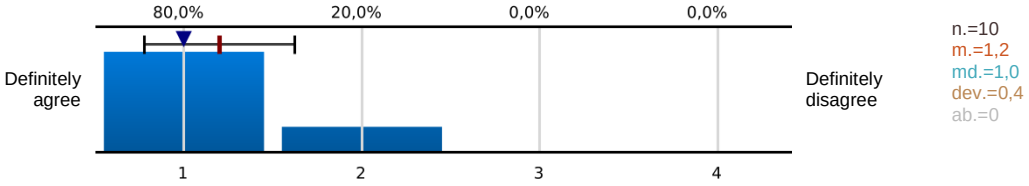
No. of participants = 10 **No. of respondents = 10** **Response rate = 100,0%**

Example question text

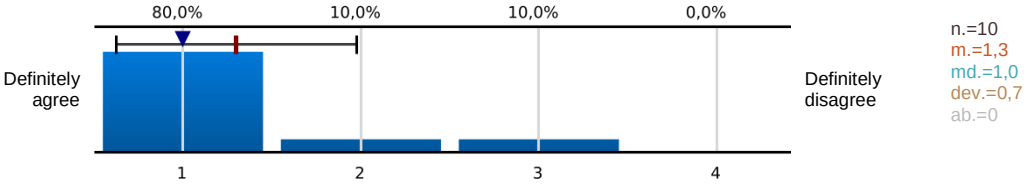


1. Feedback on this Module

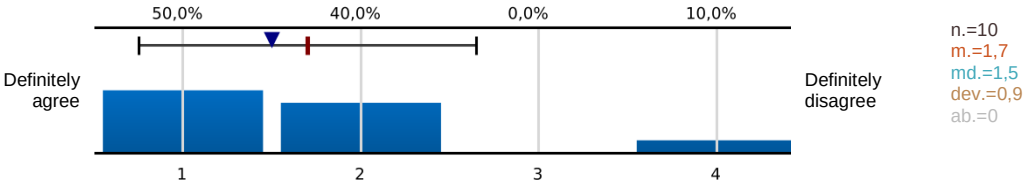
1.1 I found this module interesting and challenging



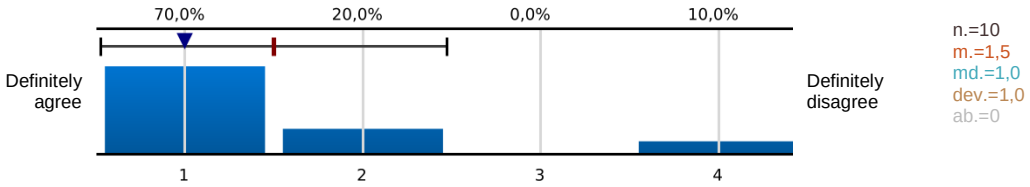
1.2 I believe I will be able to apply what I have learnt in this module



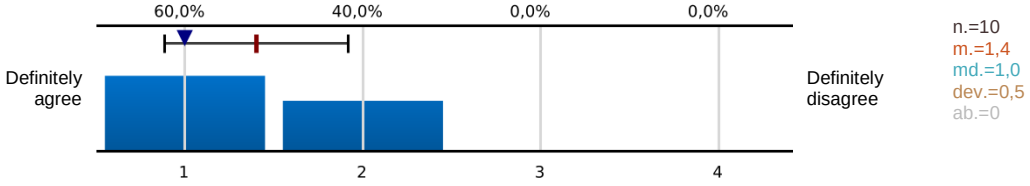
1.3 The assessment tasks were explained clearly



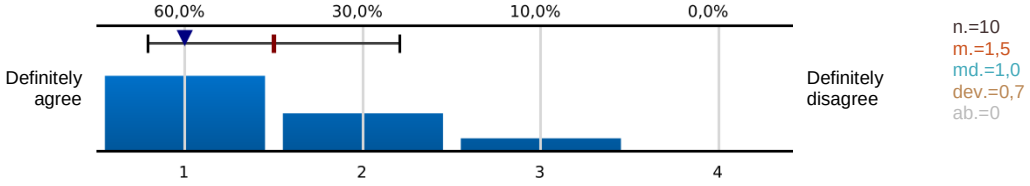
1.4 Through questions, tasks, peer and tutor feedback, I have been supported to reflect upon my learning in this module



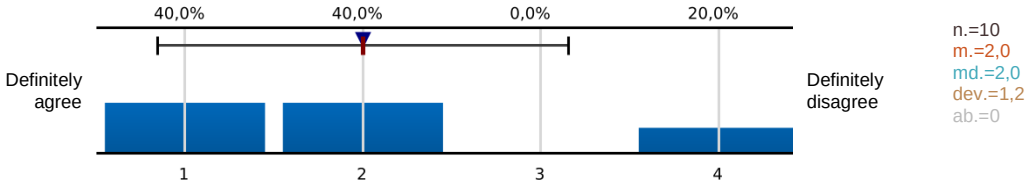
1.5 Module staff have responded helpfully when I have contacted them



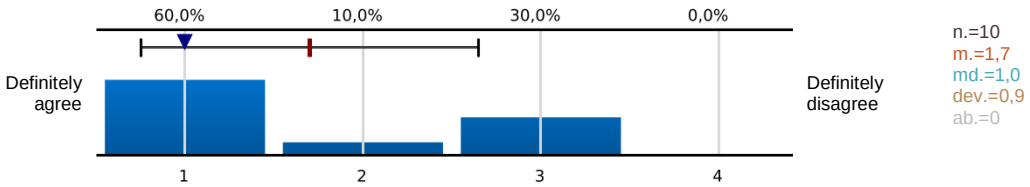
1.6 The module ran according to the plan set out in the module handbook



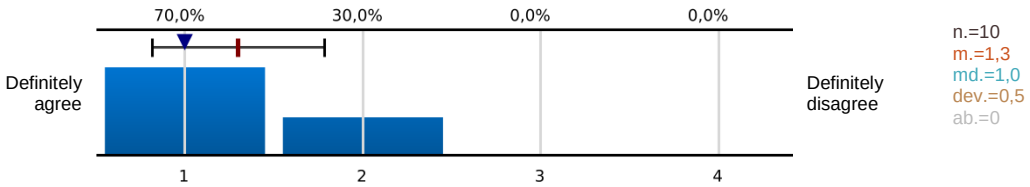
1.7 I am satisfied that I have been able to access the right resources in this module e.g. reading materials, digital, specialist equipment etc.



1.8 In this module, I have felt that my identity, culture and values have been respected



1.9 I felt that in this module staff valued students' views and opinions

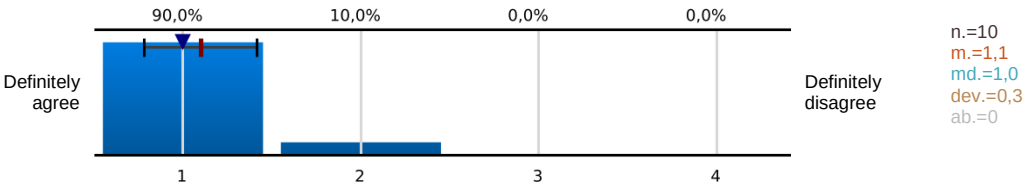


2. Apprenticeships / Distance Learning

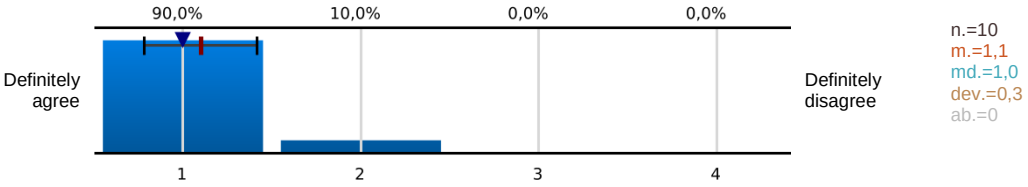
2.1 Have you studied this module as part of an Apprenticeship or as a Distance Learner?

The results for this question cannot be displayed due to the insufficient number of responses.

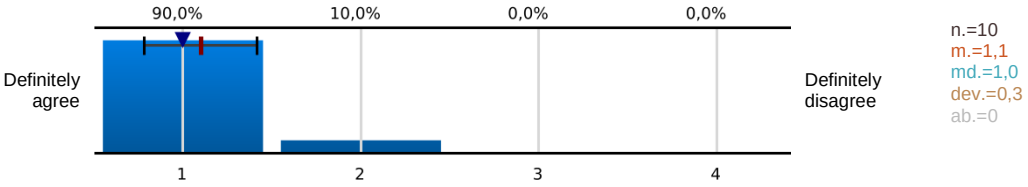
2.2 The module is relevant to my job



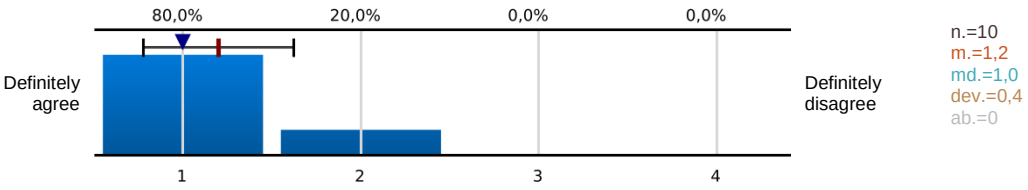
2.3 This module has helped improve my performance in the workplace



2.4 I have been able to apply my learning to the workplace

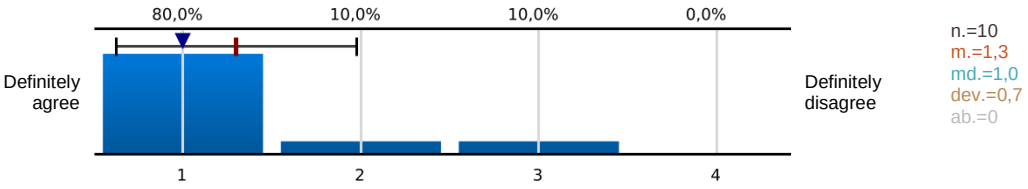


2.5 The knowledge and skills from my workplace have complemented the theory in the classroom



3. Overall Satisfaction

3.1 Overall, I am satisfied with the quality of this module



Appendix 34 - Excerpt from "Keeping up to date with evidence-based practice: A guide to searching research databases", British Association of Prosthetics and Orthotics, published 2024

Full document available to BAPO members at: https://my.bapo.com/Framework/ResourceManagement/GetResourceObject.aspx?ResourceID=a62a4d86-6a55-4f09-9be2-dbc19f0580db

Keeping up to date with evidence-based practice

A guide to searching research databases

Contents

Foreword

This guide has been developed to support the prosthetic and orthotic workforce to engage with research. This guide will provide the reader with information on how to search a research database in a structured and effective way.

We encourage staff and learners at all levels to get involved with research, quality improvement, and work-based projects; this includes prosthetists, orthotists, technicians, support workers, students, and apprentices. BAPO is committed to providing resources that empower and support the prosthetic and orthotic profession to engage with research.

September 2024

Authors

Dr Nicky Eddison
Dr Nicky Eddison is an Associate Professor of Orthotics, a Consultant Orthotist, and the Chair of BAPO.

Eileen Morrow
Eileen Morrow is a Doctoral Clinical Academic Fellow at the University of Oxford, and the Research Committee Chair for BAPO.

Laura Barr
Laura Barr is an advanced practitioner within the orthotic and orthopaedic services at NHS Greater Glasgow and Clyde. Laura also holds a NRS Careers Research Fellowship position

Pam Coulton
Pam Coulton is the Director of Locum Notion and Vice-Chair of BAPO

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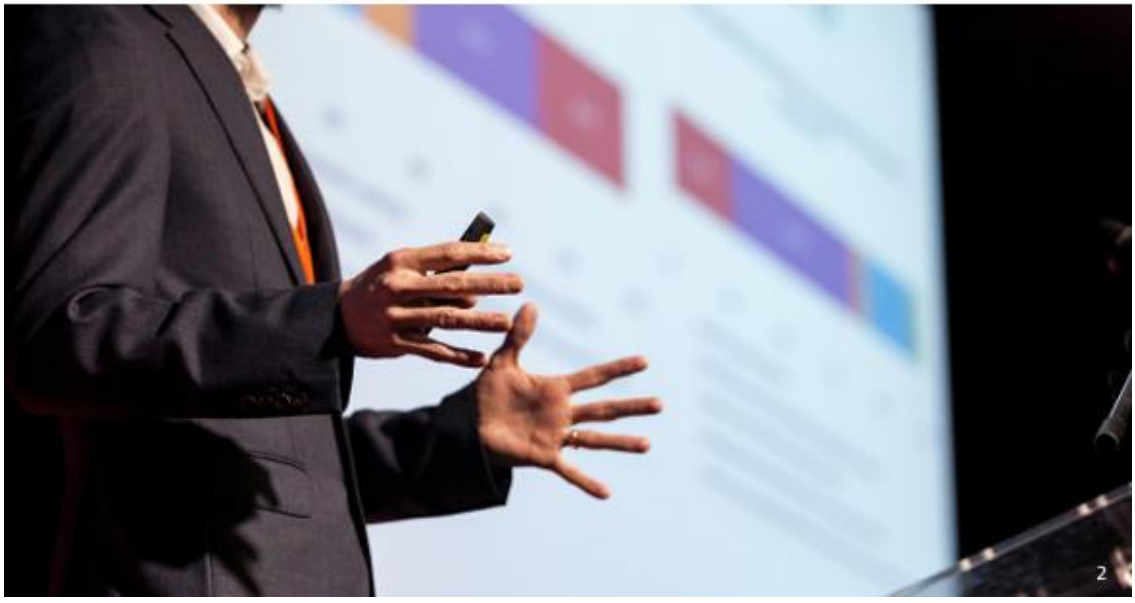
Appendix 35 - Excerpt from "A Guide For Preparing and Presenting Posters at Conferences", British Association of Prosthetics and Orthotics, published 2024

Full document available to BAPO members at: https://my.bapo.com/Framework/ResourceManagement/GetResourceObject.aspx?ResourceID=33027fdb-76b7-4d28-b6be-2dafc3d6813e

A Guide For Preparing and Presenting Posters at Conferences

Contents



Foreword

This guide has been developed to support the prosthetic and orthotic workforce to engage with research. This guide will provide the reader with general information and advice about poster presentations. It is not specific to BAPO conference guidelines, it will serve you well for preparing posters for all kinds of conferences.

We encourage staff and learners at all levels to get involved with research, quality improvement, and work-based projects; this includes prosthetists, orthotists, technicians, support workers, students, and apprentices. BAPO is committed to providing an equitable platform for everybody to submit abstracts and present at BAPO's conferences. We are passionate about enabling our educators to present their work at our conferences. We know how important it is to help to grow the educator workforce within the prosthetic and orthotic profession. We have therefore, committed to ensuring every BAPO conference has the space for an educator presentation.

Authors

Dr Nicky Eddison
Dr Nicky Eddison is an Associate Professor of Orthotics, a Consultant Orthotist, and the Chair of BAPO.

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Eileen Morrow is a Doctoral Clinical Academic Fellow at the University of Oxford, and the Research Committee Chair for BAPO.

Laura Barr
Laura Barr is an advanced practitioner within the orthotic and orthopaedic services at NHS Greater Glasgow and Clyde. Laura also holds a NRS Careers Research Fellowship position

Dr Beverley Durrant
Dr Beverley Durrant is an HCPC registered podiatrist and is Director and Consultant at Vectis Healthcare Solutions, and co-director at The Creative Health Alliance.

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Appendix 36 - Article published in BAPO Connect, March 2019, issue 1, pp. 40-41

The 5 Stages of Grief

Writing a Patient Group Direction

In 2017 we brought you a series of articles by Chris Rowley, discussing the historical development of legislation allowing Orthotists and Prosthetists to supply and administer medications to patients, using "Patient Group Directions" (PGDs).

Interest in the use of PGDs has grown within the orthotic profession over the past few years and BAPO has been contacted by several members seeking further advice and support on implementing this within their local services.

If your department has not worked with medications before, then navigating the legal framework and engaging with the right services at the right time, can seem like a daunting process.

In light of this, we thought it would be useful to offer some guidance and insight into the processes of developing a PGD from someone who has experienced the various challenges first hand.

As an Orthotist working within NHS Greater Glasgow and Clyde, I am fortunate enough to have been involved in several clinics using PGDs over the past 3 years. In doing so I have had the opportunity to be part of a "PGD working group", which is formed when new PGDs are being developed for the service.

Obviously there are many factors that will be taken into account before considering development of a PGD, but for the sake of this article we will begin our journey assuming the service need and working group have already been identified.

QUICK REMINDER

What is a PGD? - "Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment." (HSC 2000/026)

STAGE 1

Denial (Access denied, you do not have permission to sign this PGD)

PGDs are written for a specific medication and usually for a named profession. Don't reinvent the wheel; Firstly you should identify if the required PGD already exists for Orthotists in your area. Information on existing PGDs can be accessed from the PGD Administrator in your local Pharmacy Department. In the (highly unlikely) event that an orthotic PGD is already in use, then congratulations to you! You can skip straight to stage 5. In the (much more likely) event that it isn't, the next step is to identify if a PGD for your required medication has ever been used for another profession; such as physiotherapy or podiatry. It would seem logical at this time to ask if they would consider adding Orthotists to their pre-existing PGD, but be prepared for denial of this request. Although PGDs can be developed for more than one profession, there are various reasons that may prevent this.

STAGE 2

Anger (or more accurately, "frustration")

Yes this stage can be frustrating as this is where the process becomes time consuming. If you have access to the PGD for another professional group, then this can be used as a template which will save the working group time when adjusting this for Orthotists. Otherwise, it would be worthwhile speaking to neighbouring Health Boards or Trusts to find a suitable template. If you do have to construct the PGD from scratch, then this will be done collaboratively with the working group, but of course it will be the most time consuming method. However the PGD is written, all members of the working group must agree to the content of the final document and ensure that this adheres to all legal requirements as outlined in the Human Medicines Regulations.

STAGE 3

Bargaining (can you not just do it now...)

When the content has been approved by all members of the working group, it is time to send the document for Authorisation. This process can differ depending on your specific area and your PGD administrator should be able to familiarise you with the local pathway for your service. Broadly speaking, in Scotland, Authorisation is usually assigned to the local Area Drug and Therapeutics Committee (ADTC) or one of its sub-committees, and in England several organisations including the Clinical Commissioning Groups (CCGs) and local authorities can be assigned to Authorise. These groups will meet at defined times throughout the year, so once your PGD is submitted no amount of bargaining is going to get it approved any faster. So you wait...

STAGE 4

Depression (here we go again)

The Authorising organisation has considered your PGD and the result is... Rejected. If your PGD is rejected at this stage then guidance will be provided on the amendments that are required. There are many reasons why a PGD may require review and it is likely that you will be working closely with Pharmacy at this stage to amend this appropriately. Once again, when all authors are happy with the amendments the PGD can be resubmitted for Authorisation. Be aware that your PGD can be returned more than once for amendments.

STAGE 5

Acceptance (the day has finally arrived!)

Time to crack open the Champagne - the Authorising Organisation has accepted your PGD! All authors will be notified when the PGD is authorised and will be invited to sign the final document. An expiry date and auditor will also be agreed upon, usually this will be a maximum of 3 years, at which time the PGD content will be reviewed again. The PGD is usually electronically stored and hard copies kept in the local department. Health care professionals who are entitled to use the PGD are individually named and should also be provided with a copy of the PGD for their records.

This has been a very general outline of what you may encounter during the PGD process, which I hope will be some use, or at least provide solace, to a few of you! If you have any questions relating to supply and administration of medications please get in touch via BAPO and I will be happy to provide any assistance that I can. For more information on the use of Patient Group Directions, please visit:

- *www.gov.uk/government/publications/patient-group-directions-pgds/*
- *www.hcpc-uk.org/*
- *www.nice.org.uk/guidance/mpg2*
- *www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/prescribing-and-patient-group-direction/*

Laura Barr
Orthotist

QUICK REMINDER

What is a PGD working group? This is the multidisciplinary team who write the PGD. The group must consist of a Doctor, a Pharmacist and a representative of the professional group who will be supplying or administering the medication.

Appendix 37 - Article published in BAPO Connect, November 2023, issue 3, pp. 25

My Career Fellowship journey

The NHS Education Scotland (NES) AHP Careers Fellowship Scheme is designed to support development of the AHP workforce in Scotland. The scheme has three main aspects; the first two happen concurrently over the 10-12 month term of the Fellowship, where current Fellows are provided with an education programme delivered by NES, and funded to undertake a work based project. The final aspect occurs on completion of the Fellowship when Fellows are provided with the opportunity to join the Alumni, which provides ongoing access to a peer support network.

I completed the NES AHP Careers Fellowship in March 2023, having been awarded the maximum funding for 0.2WTE (2 days per week) over a 12 month period. Having ring-fenced time to undertake a project, designed by myself, in an area of practice for which I am incredibly passionate, has truly been a career highlight, and has provided a stepping stone to ongoing project work that I am continuing to pursue.

PROJECT OVERVIEW

The primary aim of my project was to construct a framework for best practice relating to the manufacture of computer aided designed foot orthoses. In order to achieve this, the project consisted of two main areas: Firstly understanding the picture of current practice across the UK, and secondly analysing and synthesising the evidence in this area to support a guide for best practice.

Both areas of the project ran in parallel, changing and expanding over the past 12 months as the work progressed.

AREA 1: CURRENT PRACTICE IN THE UK

Using freedom of information (FOI) I contacted 222 Trusts and Health Boards in the UK regarding the use of computer-aided-design and manufacture of insoles, and received responses from 186 orthotic services. With this 84% return rate I was able to start constructing a picture of current practice across the UK and understand the scope of any future work.

AREA 2: THE EVIDENCE BASE TO SUPPORT BEST PRACTICE

The primary goal with this area of the project was to measure patient outcomes in relation to different computer aided design and manufacture processes. Having conceptualised and constructed a proposal for a clinical trial, and presented this to the Ethics committee in London Stanmore, the project was granted approval for a full randomised controlled (RCT) trial. At the time of my Fellowship conclusion 67 patients had been enrolled in the trial, with the aim of continuing to completions at 114 participants.

CONCLUSION

Undertaking the NES AHP Careers Fellowship has given me the opportunity to immerse myself in a project that has the scope to improve patient experience throughout the UK, has provided me with a network of likeminded peers, and given me the opportunity to present my work at a national celebration event. I would highly recommend the Fellowship scheme to any AHP looking to undertake a work-based project.

Laura Barr, Advanced Practice Orthotist, NHS Greater Glasgow and Clyde

"I was delighted to support Laura on her NES Career Fellowship journey and watched with interest to see what she gained from this. From a managers perspective having funded backfill to allow a member of staff to carry out a project and gain learning to build their career was fantastic and something I wish we had more access to.

"I attended the celebration event at the end of Laura's Fellowship along with her and the other career Fellows and a number of AHP directors and other Leaders in Scotland and was really impressed by the variety and quality of projects presented and the clear leadership training given and skills gained as part of the program.

"For Laura personally I was so impressed with what she presented, particularly around the sustainability aspect of what her project uncovered - which is becoming a real priority for all service managers as we will all be held responsible for improving our sustainability performance very soon. Her poster beautifully highlights the scary amount of waste which goes on in our industry around the use of foam boxes which scanning technology can eliminate along with substantial recurring cost savings."

Nikki Munro, Orthotic Clinical lead/manager, NHS Greater Glasgow and Clyde

Appendix 38 - Questionnaire: Evidence-Based Practice in the UK orthotics Industry

University of Central Lancashire
UCLan

Evidence Based Practice in the UK Orthotics Industry

Participant Information
You are being invited to take part in an anonymous nationwide research study. This research aims to examine the current use of evidence-based practice in UK Orthotic clinics, and the impact that the Directory of Evidence Based Practice (DEBOP) has had on Orthotists in their day-to-day clinical practice.

We are looking for registered Orthotists, and student Orthotists who have finished their Orthotic placement, to complete this survey. Completion of this survey will provide insight into the clinical activities of Orthotists practicing in the UK, and may help to guide future practices and the future development of DEBOP. The results and analysis of this study will form part of a PhD thesis.

The survey takes less than 10 minutes to complete.

Important Information

- Your participation is completely voluntary. There is no reimbursement or payment for completion of this survey.
- You can withdraw at any time, and without reason, simply by closing this browser window.
- All information you provide during this survey will be treated in strict confidence and will not be shared beyond the direct research team. We will not identify any institution or individual within our reporting.
- This study has received ethical approval from the Health Ethics Panel committee of the University of Central Lancashire (Reference number: HEALTH 0365).

Data security

- We will not be asking for your name or contact details for this survey. This means that once your responses have been submitted, it will not be possible to withdraw this data as your individual submission cannot be identified.
- The anonymous data will be stored on a secure server at the University of Central Lancashire.
- The anonymous data will be processed only for the purpose of scientific analysis and as part of a PhD thesis. Summaries of the data may be presented at conferences and included in scientific publications. Data will be reviewed on completion of the research, in line with the University of Central Lancashire's data retention policy https://www.uclan.ac.uk/legal/privacy-notices/research-participants. Your data may be used in follow-up analyses, publications and projects which emerge as a result of this research.
- If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: Officerforethics@uclan.ac.uk
- If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioners Office (ICO).

For further information, please contact:

Laura Barr
Lbarr5@uclan.ac.uk

Or

Dr Graham Chapman
GChapman2@uclan.ac.uk

Consent to participate:
- I confirm that I have read and understood the Participant Information (above) for the study and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

1. To progress to the survey please confirm your consent by selecting the consent box below. *

◯ I have read and agree with the above information and I consent to take part in this study

Section 1 - Demographics

2. Which of the following describes your current work status *

- ◯ Orthotist - HCPC registered and currently working in the UK
- ◯ Dual practice Prosthetist / Orthotist - HCPC registered and currently working in the UK
- ◯ Student Orthotist who has completed their Orthotics placement
- ◯ None of the above

3. Which of the following best describe the Orthotic service in which you work.
If you are currently a student, which of these best describe the service in which you completed your Orthotics placement. *

- ◯ NHS in-house service
- ◯ NHS contracted service
- ◯ Private Practice – Commercial Company
- ◯ Private Practice – Own practice / Jointly owned practice

4. In which UK country is your service located? *

- ◯ England
- ◯ Northern Ireland
- ◯ Scotland
- ◯ Wales
- ◯ Not UK based

Section 2 - Evidence Based Practice

The Sicily Statement defines evidence based practice as -
"Evidence-Based Practice requires that decisions about health care are based on the best available, current, valid and relevant evidence. These decisions should be made by those receiving care, informed by the tacit and explicit knowledge of those providing care, within the context of available resources"
(Dawes et al, 2005)

5. Do you use evidence-based practice in your clinical work?

- ◯ Yes
- ◯ No

6. How easy do you find it to **search for and locate** evidence from primary sources? (e.g. devising a search strategy and searching within individual journals, or using databases such as PubMed, EMBASE, AMED etc.) *

- ◯ Extremely easy
- ◯ Somewhat easy
- ◯ Neutral
- ◯ Somewhat difficult
- ◯ Extremely difficult

7. How easy do you find it to **critically appraise** evidence that you find from primary sources? (e.g. after you undertake a literature search from individual journals or databases, how easy do you find it to systematically assess the validity and context of individual pieces of evidence) *

- ◯ Extremely easy
- ◯ Somewhat easy
- ◯ Neutral
- ◯ Somewhat difficult
- ◯ Extremely difficult

8. How easy do you find it to identify **relevant** evidence from undertaking your own literature searches? *

- ◯ Extremely easy
- ◯ Somewhat easy
- ◯ Neutral
- ◯ Somewhat difficult
- ◯ Extremely difficult

9. How **time consuming** do you find it to undertake your own literature searches? *

- ◯ Extremely time consuming
- ◯ Somewhat time consuming
- ◯ Neutral
- ◯ Somewhat not time consuming
- ◯ Extremely not time consuming

10. How easy do you find it to base **clinical decisions** on the published research that you find when you undertake your own literature searches? *

- ◯ Extremely easy
- ◯ Somewhat easy
- ◯ Neutral
- ◯ Somewhat difficult
- ◯ Extremely difficult

11. Have you ever been involved in the publication of orthotic research in the field of Orthotic practice? *

- ◯ Yes
- ◯ No

12. What prevents you from using evidence-based practice in your clinical work? *

- [ ] I am unfamiliar with the concept of evidenced based practice
- [ ] I do not have access to the evidence base (i.e. you do not have an Athens password or Institutional login to access the published research in orthotics)
- [ ] I do not think that evidence based practice is worthwhile (i.e. you prefer to use your own experience and opinions to decide on treatment plans for your patients)
- [ ] I do not feel that I have the necessary skills to search, access, and / or appraise the orthotic evidence base
- [ ] Other

Section 3 - The Directory of Evidence Based Orthotic Practice

The Directory of Evidence Based Orthotic Practice (DEBOP), is resource designed to direct Orthotists to the evidence that supports specific Orthotic practice.

Each pathway within the directory covers a pathology or region of the body, designed to be easily understood by health care practitioners including Allied Health Professionals, GPs and those working for NHS 24.

The aim of the directory is to enable Orthotists to deliver the best possible care by providing easy access to the evidence base, relevant to their decision making.

13. Do you, or have you ever, accessed the Directory of Evidence Based Orthotic Practice (DEBOP)? *

- ◯ Yes
- ◯ No

14. Did you ever access DEBOP between the years of 2015-2017? *

- ◯ Yes
- ◯ No

15. *Background information:* The current version of DEBOP was developed and updated in 2017, and is maintained monthly.

    Do you find the current version of DEBOP easier to navigate than the 2015 version? *

- ◯ Yes
- ◯ No
- ◯ About the same

16. Do you find it easier to locate relevant evidence using the current version of DEBOP compared with the 2015 version? *

- ◯ Yes
- ◯ No
- ◯ About the same

17. Have you used DEBOP more regularly since it was updated? *

- ◯ Yes
- ◯ No
- ◯ About the same

18. Does having access to DEBOP make you **more likely** to access published research? *

- ◯ Yes
- ◯ No

19. Does having access to DEBOP make it **easier** for you to locate and access published research? *

- ◯ Yes
- ◯ No

20. Does having access to DEBOP make it **less time consuming** for you to access published research? *

- ◯ Yes
- ◯ No

21. Does DEBOP make it easier for you to identify **meaningful** published research, which is **relevant to your clinical practice?** *

- ◯ Yes
- ◯ No

22. How easy do you find it to base clinical decisions on the published research that you access via DEBOP? *

- ◯ Extremely easy
- ◯ Somewhat easy
- ◯ Neutral
- ◯ Somewhat not easy
- ◯ Extremely not easy

23. In day-to-day clinical practice do you chose to access published research through DEBOP rather than other sources?
(e.g. if you needed to access evidence for a treatment in your daily clinical setting, would you choose to use DEBOP rather than undertaking a literature search within individual journals / databases) *

- ◯ Yes
- ◯ No

24. *Background information:* The evidence within DEBOP is categorised by study type, utilising a hierarchy structure. This means the evidence for each body part or area of interest is listed under headings, showing the most robust evidence first (e.g. meta-analyses, systematic reviews, randomised controlled trials etc.)

    Given this layout, do you find it **easier** to **critically appraise** the evidence that you access via DEBOP, as opposed to the evidence that you access from your own literature searches? *

    - ◯ Yes
    - ◯ No
    - ◯ About the same

25. Has using DEBOP made you feel more **confident** in critically appraising the published research that you read? *

    - ◯ Yes
    - ◯ No
    - ◯ About the same

26. Has using DEBOP to access the evidence-base changed your clinical practice?
    (e.g. have you or your service become aware of evidence through DEBOP that has led to a change in patient treatment pathways or treatment options?) *

    - ◯ Yes
    - ◯ No

27. Have you ever used DEBOP to assist you with a project? *

    - ◯ Yes
    - ◯ No

28. *Background information:* The diabetes pathway was developed and published in 2018, designed to help clinicians access evidence relating to orthotic management of diabetic foot pathologies.

    How often do you access the DEBOP Diabetes pathway? *

    - ◯ Daily
    - ◯ Weekly
    - ◯ Monthly
    - ◯ Yearly
    - ◯ Never

29. *Background information:* The Adult MusculoSKeletal (MSK) pathway was developed and published in 2015, designed to help clinicians access evidence relating to orthotic management of MSK pathologies.

How often do you access the DEBOP MSK pathway? *

- ◯ Daily
- ◯ Weekly
- ◯ Monthly
- ◯ Yearly
- ◯ Never

30. Would you recommend DEBOP to other Orthotists and orthotic students? *

- ◯ Yes
- ◯ No

31. Would you recommend DEBOP to other health professionals such as GP's, NHS 24 workers and other allied health professionals? *

- ◯ Yes
- ◯ No

32. Overall do you consider DEBOP to be a useful resource for the Orthotic profession? *

- ◯ Yes
- ◯ No

33. What prevents you from using DEBOP? *

- ☐ I have never heard of it
- ☐ I have heard of it but don't know how to access it
- ☐ I have heard of it but don't know what it is
- ☐ I do not consider it to be a useful resource
- ☐ I prefer to access published research from other sources
- ☐ Other

34. What do you feel could be done to improve the usefulness of DEBOP? *

- [ ] More regular updates of the evidence contained within the directory
- [ ] Improving the interface for use on desktop and laptop devices
- [ ] Improving the interface for use on mobile devices
- [ ] Other

35. If you have any other comments about DEBOP which have not been covered in this survey please let us know in the free text box below

Appendix 39 - Thematic breakdown of free text comments regarding any aspect of the Orthotics Evidence Portal. The use of ellipses indicate the response has been truncated

Response \ Theme	Requires more promotion	Change to "point of care" style summary"	Difficult to locate the site	Interface requires improvement	Positive comment no action suggested	Comment is out with scope of the Portal
I haven't got into the habit of using DEBOP. I Haven't come across it in a long time	x					
I had never heard of debop until this year and I have been qualified for 8	x					
Hard and laborious to read. Needs better layout, links to stock products etc		x		x		
a better way to lay it out would be like physiopedia - to make it easier to search and to read... easier to apply to my own practice		x				
I don't have time to search for papers						x
It can be slow and difficult to search for via search engine.			x			

UX/ UI needs improving as not great visually or to use on mobile devices				x		
It is a very useful resource… I would usually conduct my own literature searches... I think it is more useful for busy clinicians					x	
Great tool that has improved our profession's consistency and evidence based practice.					x	
A fantastic resource… this has given me a reminder to get back into the routine of using it.	x				x	
I should use this more	x					
I forget it exists, otherwise I think I would use it more. Perhaps…share when it has been updated?	x					
I tried finding the site during this survey and it doesn't exist on search engines, the acronym is not helpful			x			
Developed in Scotland but needs to be advertises UK wide better	x					

I used to use this a lot but finding the pathways takes too long if you don't know the full name or have a link to hand			x			
An excellent resource and one which our profession is lucky to have.					x	
I have made our hospital library service aware of DEBOP and they advertise this as a resource to any staff.					x	
Unless a link is provided, it can be very difficult to access this so that makes it time consuming.			x			
Great work					x	
In clinical settings…I don't physically have time to access this, read the paper, make the decision as well as everything else on top!						x
More time allocated to the regular clinician would allow us to make more informed decisions						x

Impossible to find on google, I can never remember what debop stands for and searching takes you to dePOP!	x		x			
It is sometimes difficult to find the time to read full papers in clinic.						x
A summary would be very helpful.		x				
I only heard about DEBOP from a colleague about a year ago and it has been a game changer, I find it easier to quickly find relevant information for my patients.	x				x	
The only issue I have is trying to use it on my phone, it sometimes doesn't let you click on links and the layout isn't great on the phone…				x		
I am a practice placement supervisor and find DEBOP useful for guiding students to the literature… particularly the diabetes database which we use for teaching...					x	
Please consider modernising the layout of the website though as it is awkward to navigate.				x		
Overall a great resource.					x	
Totals	**7**	**3**	**5**	**4**	**9**	**4**

Appendix 40 - Article publication: *The effectiveness of custom hard-shell 3D-printed foot orthoses in a cohort of patients who did not respond to treatment with custom ethylene-vinyl-acetate (EVA) foot orthoses*. Barr L, Munro N, Watters K, McCaig R, Richards J, Chapman GJ. The Foot. 2024 Dec; 61:102142. doi: 10.1016/j.foot.2024.102142

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The effectiveness of custom hard-shell 3D-printed foot orthoses in a cohort of patients who did not respond to treatment with custom ethylene-vinyl-acetate (EVA) foot orthoses

Laura Barr [a,b], Nikki Munro [a], Kirsty Watters [a], Ross McCaig [a], Jim Richards [b], Graham J. Chapman [b,*]

[a] Orthotic Service, NHS Greater Glasgow and Clyde, Orthotic Department, Gartnavel General Hospital, G12 0YN, UK
[b] Allied Health Research unit, University of Central Lancashire, United Kingdom

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ABSTRACT

Background: Patients who do not achieve positive outcomes with custom ethylene-vinyl-acetate (EVA) foot orthoses will often be escalated to other services for treatment, which may include surgery.
Objective: This study aimed to explore the effectiveness of custom hard-shell 3D-printed foot orthoses for patients who did not respond to treatment with custom EVA foot orthoses and were being considered for treatment escalation.
Design: An eight-week clinical evaluation and a two-year review of relevant medical records.
Method: Thirty-six consecutive patients with a range of musculoskeletal lower limb pathology who remained symptomatic after 12-weeks use of custom EVA foot orthoses were fitted with custom hard-shell 3D-printed foot orthoses. The Foot Health Status Questionnaire was used to assess patients at baseline and eight-week follow-up in conjunction with the Client Satisfaction with Device module of the Orthotics and Prosthetics User Survey. Patients were categorised as responders or non-responders based on their change in pain scores. A review of relevant medical records two years after receiving their orthoses determined if patients required further treatment for their initial condition.
Results: Across the full cohort there were significant improvements in pain, function and foot health. At follow-up, responders reported significantly improved pain, function and foot health compared with non-responders. Twenty-six patients (12 responders, 14 non-responders) required no further treatment for their original condition after two years.
Conclusions: Custom hard-shell 3D-printed foot orthoses have the potential to improve pain, function, foot health, and provide satisfaction in patients with lower limb musculoskeletal conditions which do not improve with custom EVA foot orthoses.

1. Introduction

The use of compressible foams such as ethylene-vinyl-acetate (EVA) are the most common materials used in custom foot orthosis manufacture [1], and are often considered standard care [2]. Previous studies have highlighted the importance of comfort, kinematics and pressure reduction in relation to material hardness [3–5], however, these studies provide no consistent guidance for clinicians regarding assessment of patient suitability for hard-shell foot orthoses, and do not focus on the patient outcomes in terms of treating foot and ankle pathologies.

Custom foot orthoses are considered as a second or third-line intervention within musculoskeletal treatment pathways for foot pathologies [6], and when patients do not improve with orthotic treatment, the next step in the pathway includes escalation for a surgical opinion, pain management, or other invasive therapies such as steroid injections. Models of care focusing on improving patient outcomes for musculoskeletal conditions and minimising pressures on health services have been highlighted as a global priority [7], and in this respect it is important that patients are guided to the right care at the right time, avoiding unnecessary invasive treatments. In the UK, the National

* Correspondence to: Allied Health Research unit, Brook Building (BB125), University of Central Lancashire, Preston PR1 2HE, UK.
E-mail address: GChapman2@Uclan.ac.uk (G.J. Chapman).

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Health Service (NHS) set out the RightCare agenda, which aimed to optimise treatment pathways including those for musculoskeletal services. By focusing on patients receiving the right care, in the right place, at the right time, adoption of the RightCare approach has facilitated a reduction in secondary care referrals by 30 % [8].

In this study we propose the inclusion of hard-shell foot orthoses within the musculoskeletal treatment pathway, as an alternative to immediate escalation to other healthcare services, when the use of custom EVA insoles has been unsuccessful.

2. Objective

To the author's knowledge, no previous research has investigated the clinical outcomes of individuals with lower limb musculoskeletal conditions who did not respond well to custom EVA foot orthoses, and whether there is any benefit to including custom hard-shell foot orthoses in the musculoskeletal treatment pathway prior to escalating to other healthcare services. Therefore, the primary aim of this study was to explore the effectiveness of custom hard-shell 3D-printed foot orthoses in reducing pain and improving foot function in a heterogeneous patient cohort group with a lower limb musculoskeletal pathology that were non-responders to custom EVA foot orthoses. The secondary aim was to explore whether patients using custom hard-shell 3D-printed foot orthoses required treatment escalation to other healthcare services within a two-year period.

3. Methods

3.1. Patients

Patients were treated by three orthotists from the orthotic service in the NHS Greater Glasgow and Clyde (GGC) Health Board. Patients were eligible to be fitted with custom hard-shell 3D-printed foot orthoses if they were; aged $\geq$ 16 years old, presented with a musculoskeletal pathology of the lower limb, and did not report an improvement in pain following 12-weeks of treatment with custom EVA foot orthoses; this is in keeping with standard practice, with previous studies identifying that improvements with insoles are expected within this timescale [9–12]. There were no limitations regarding the specific clinical presentations or musculoskeletal pathology, resulting in a heterogeneous patient cohort, which represents a general orthotic clinical case-load. Patients were not eligible to be fitted with custom 3D-printed foot orthoses if they required full length foot orthoses as the 3D-printing system was limited to the manufacture of ¾ length orthoses, had an active ulceration or required foot orthoses with a top cover. All data were collected as part of routine patient care, in keeping with standard NHS GGC Orthotic Department processes, and approved by the Orthotic professional lead for NHS GGC.

3.2. Clinical assessment

Patients' age, sex, and musculoskeletal pathology were collected at baseline followed by a biomechanical assessment which included the validated manual supination resistance test [13], to establish the force (high, moderate or low) required to manually supinate the foot. Using a goniometer, passive ankle dorsiflexion range of motion was measured at the position of first detectable resistance when passively moving the ankle into dorsiflexion from a plantigrade position. Ankle range of motion was considered limited if less than 10° and considered normal if over 10° [14]. To assist with foot orthoses prescription, other biomechanical assessments were carried out if deemed clinically relevant for individual patients including visual gait analysis, Jacks test or the modified Jacks test for functional hallux limitus [15], and palpation to determine subtalar joint axis location [16].

3.3. Intervention

Podfo Ltd offered a compatible interface with the Paromanager V6.0 computer-aided-design modelling system in use at the study site. Custom 3D-printed hard-shell foot orthoses were manufactured to the same functional specification as the EVA orthoses by using the patients' pre-existing scan of their feet contained within the CAD/CAM system, from which their previous EVA foot orthoses had been manufactured. Custom 3D-printed foot orthoses were manufactured from Nylon 11 material, built through a selective laser sintering 3D-printing process [17] which provides harder foot orthoses (Shore D67.2) [18] compared to the previous custom EVA insoles (ranged from Shore A40 to Shore A70 [Shore D10 to Shore D20]) [19]. Fig. 1a and b show an example of the custom EVA foot orthoses and the custom 3D-printed hard-shell foot orthoses.

At baseline (pre-intervention), all eligible patients were consulted by one of three orthotists who were trained in the use of custom 3D-printed foot orthoses, and offered verbal and written information on the custom 3D-printed foot orthoses before commencing treatment. Patients were all provided with footwear advice from their orthotist prior to commencing treatment, and their footwear were checked by the orthotist at the fitting appointment and confirmed to be suitable for use with foot orthoses. Clinical and biomechanical assessments of each patient were carried out by the orthotist who then converted the pre-existing CAD/CAM foot orthoses model into the format for 3D-printing using the NHS GGC computer-aided-design system (Paromanager V6.0.2, Paromed). The orthotist confirmed that the functional elements used in the patient's original EVA foot orthoses remained appropriate for each patient's specific clinical presentation. Functional foot orthoses features included hindfoot and forefoot wedging [20], medial heel skiving [21], and heel raises [22] which were included in the foot orthoses design depending on the individual clinical presentation and biomechanical assessments. All computer-aided-design models were reviewed by the Orthotic department's musculoskeletal team lead prior to manufacture of the custom 3D-printed foot orthoses. Patients were asked to wear their custom 3D-printed foot orthoses at all times when wearing footwear and were asked to contact their orthotist for an interim review if any issues arose that prevented them from using their foot orthoses before their scheduled follow-up. The scheduled follow-up was then extended accordingly for those patients requiring an interim review. Follow-up was conducted by telephone or in a face-to-face clinic depending on patient preference, at a minimum of eight-weeks after foot orthoses fitting.

3.4. Data collection and outcome measures

To investigate the effect of custom 3D-printed foot orthoses on self-reported foot health, patients completed the validated Foot Health Status Questionnaire [23] at baseline and again at a minimum of eight-week follow-up. Baseline data was defined as data collected prior to any 3D-printed foot orthoses being fitted. For the Foot Health Status Questionnaire, patients answered all four subdomains; pain, function,

Fig. 1. a. Example of a custom CAD/CAM EVA foot orthosis. b. Example of a custom 3D-printed hard-shell foot orthosis.

general foot health and footwear, providing a score between 0 and 100, with higher scores representing less pain, better function, better foot health and more satisfaction with footwear. To measure patient satisfaction, at follow-up, patients also completed the validated Client Satisfaction with Device module of the Orthotics and Prosthetics User Survey, where satisfaction is measured on a scale of 0–36, with higher scores indicating greater satisfaction [24]. Adherence was not directly measured but patients were asked to contact the orthotic service if they had been unable to use their foot orthoses at all times within their footwear, and in these instances the foot orthoses were reviewed and redesigned until they could be worn at all times within the footwear. Two years following fitting of custom 3D-printed foot orthoses, relevant medical records were reviewed for all patients to establish if any further intervention was required for the initial presenting condition. Relevant medical records included review of Orthotic department records, referrals, clinical records relating to the Foot and Ankle Orthopaedic service, Podiatry service, musculoskeletal Physiotherapy service and Rheumatology service. In instances where a patient's treatment pathway was unclear after review of the medical records, patients were re-contacted via telephone to establish if or when they ceased using their orthoses, and if further treatment was required for their original condition.

3.5. Sample size

This study's primary aim was powered based on a previous study that explored the effectiveness of custom foot orthoses [25]. Forty patients were required to detect a difference of 18.5 in the Foot Health Status Questionnaire subdomain for pain, with a standard deviation of 23.9, at the 5 % significance level, with 90 % power, allowing for 10 % drop out rate.

3.6. Statistical analysis

All data were analysed using Shapiro-Wilk tests and found to be not normally distributed. Wilcoxon signed rank tests were performed to determine any whole group changes between the baseline and eight-week follow-up in Foot Health Status Questionnaire scores for pain, function, foot health and footwear. To explore response to 3D-printed foot orthoses, patients were also categorised as responders or non-responders to the custom 3D-printed foot orthoses based on each patients change in Foot Health Status Questionnaire pain scores from baseline to eight-week follow-up using the minimally important difference threshold of 13 points [26]. Responders were defined as patients that exhibited a positive change of 13 points or greater and non-responders as those patients that exhibited a change of 12.99 or less. Mann Whitney U tests were used to explore differences between responders and non-responders for Foot Health Status Questionnaire scores, satisfaction score, ankle dorsiflexion range (limited or normal), and supination resistance test scores (low, moderate, high), and separate within-group differences between baseline and eight-week follow-up were explored using Wilcoxon signed rank tests. Incidences where patients required additional interventions post-custom 3D-printed foot orthoses are presented. All statistical analyses were performed using SPSS version 29 (IBM Corp, Armonk, NY).

4. Results

Thirty-nine consecutive patients who met the inclusion criteria were fitted with custom 3D-printed foot orthoses from the NHS GGC orthotic service, however two withdrew from treatment before the end of the minimum eight-week evaluation period, and one was lost to follow-up, the data for these three participants were not included in the final analysis. Two patients reported problems with their first pair of custom 3D-printed foot orthoses and were subsequently fitted with a new pair of custom foot orthoses which were successfully worn for the minimum eight-week period before follow-up. Thirty-six patients (18 females) were included in the final analysis, keeping the sample size above the 10 % allowance for dropout, with a mean age of 50 years (range 19 to 75) and a median follow-up of 118 days (range of 61 to 340). Table 1 shows patients' primary musculoskeletal presentation and the clinical assessment of ankle dorsiflexion range of motion and supination resistance.

When the patients were pooled together, significant improvements were seen for the Foot Health Status Questionnaire pain, function and foot health subdomains from baseline to follow-up (Table 2, $p < 0.001$) which exceeded the minimally important difference threshold [26]. However, there was no significant change between baseline and follow-up for the Foot Health Status Questionnaire footwear subdomain ($p = 0.101$).

Further analysis of pain subdomain scores showed there were 16 responders and 20 non-responders to custom foot orthoses (Table 3, Fig. 2). The differences in ankle dorsiflexion range of motion, supination resistance, satisfaction scores, and Foot Health Status Questionnaire scores were examined between the responders and non-responders. Mann-Whitney U tests revealed significant differences between responders and non-responders for the Foot Health Status Questionnaire pain and foot health subdomains at baseline ($p = 0.008$, $p = 0.029$), with the responders reporting significantly more pain prior to treatment escalation. For the responders, Wilcoxon Signed Rank test revealed that there was a significant improvement between baseline and follow-up in Foot Health Status Questionnaire pain ($p < 0.001$), function ($p < 0.001$)

Table 1
Primary presentation, ankle dorsiflexion range and supination resistance.

Primary Presentation Responders*/Non-Responders^	Ankle dorsiflexion range of motion	Supination resistance
Knee		
Anterior knee pain & sciatica (n = 1^)	Limited (n = 1)	Low (n = 1)
Posterior knee pain & stroke (n = 1*)	Limited (n = 1)	Unable to assess
Leg		
Recurrent calf strain (n = 1^)	Limited (n = 1)	High (n = 1)
Ankle		
Lateral ankle instability (n = 2^)	Limited (n = 1); Full range (n = 1)	High (n = 1); Low (n = 1)
Deltoid tear (n = 1*)	Full range (n = 1)	Low (n = 1)
Subfibular impingement (n = 3*)	Limited (n = 2); Full range (n = 1)	High (n = 3)
Lateral ankle pain (n = 1^)	Full range (n = 1)	Moderate (n = 1)
Dorsal impingement pain (n = 1*)	Limited (n = 1)	High (n = 1)
Poster tibial tendon dysfunction (n = 3*, n = 4^)	Limited (n = 6); Full range (n = 1)	High (n = 7)
Poster tibial tendon dysfunction & ankle osteoarthritis (n = 1^)	Limited (n = 1)	High (n = 1)
Poster tibial tendon dysfunction & dorsal midfoot interosseous compression syndrome (n = 1*)	Not documented	High (n = 1)
Poster tibial tendon dysfunction & lateral impingement pain (n = 1^)	Limited (n = 1)	High (n = 1)
Poster tibial tendon dysfunction & rheumatoid arthritis (n = 1*)	Limited (n = 1)	High (n = 1)
Rearfoot		
Plantar heel pain (n = 1*, n = 2^)	Limited (n = 2); Full range (n = 1)	High (n = 1); Moderate(n = 2)
Midfoot		
Midfoot osteoarthritis (n = 3*, n = 2^)	Limited (n = 4); Full range (n = 1)	High (n = 3); Moderate (n = 2)
Midfoot pain (post-midfoot fusion) (n = 1^)	Limited (n = 1)	High (n = 1)
Dorsal midfoot pain (n = 1^)	Limited (n = 1)	High (n = 1)
Rheumatoid arthritis & Midfoot & hindfoot pain (n = 1^)	Full range (n = 1)	Moderate (n = 1)
Forefoot		
First metatarsal pain (inc. hallux valgus) (n = 1*, n = 2^)	Limited (n = 2); Full range (n = 1)	High (n = 1); Moderate (n = 1); Low (n = 1)

Table 2
Overall sample changes in Foot Health Status Questionnaire scores between baseline and follow-up.

Foot Health Status Questionnaire Scores	Median	25th	75th	p-value Wilcoxon
Pain at baseline	41.9	29.4	74.2	**< 0.001**
Pain at follow-up	75.3	43.4	87.5	
Function at baseline	56.3	31.3	85.9	**< 0.001**
Function at follow-up	87.5	43.8	100	
Foot Health at baseline	25	12.5	42.5	**< 0.001**
Foot Health at follow-up	60	25	85	
Footwear at baseline	75	41.7	91.7	**0.101**
Footwear at follow-up	70.8	33.3	83.3	

Table 3
Median and inter-quartile range between responders and non-responders differences in clinical outcomes and trial period.

	Responders (n = 16)	Non-Responders (n = 20)	p-value (2-tailed)
Trial Period (days)	118.5 (87.5; 147.5)	115.5 (93.5; 149.75)	0.987
Satisfaction score*	35 (32.5; 36.0)	30.5 (27.0; 34.0)	0.025
Ankle dorsiflexion range (1, 2)	2 (1; 2)	2 (1; 2)	0.831
Supination Resistance (1, 2, 3)	3 (3; 3)	3 (2; 3)	0.213

* significant difference $p < 0.05$ from Mann-Whitney U Test; 1 = low/limited; 2 = normal/moderate and 3 = high.

and foot health ($p = 0.008$). There was no significant difference in Foot Health Status Questionnaire footwear between time points ($p = 0.288$). For the non-responders, there was a significant improvement between baseline and follow-up for foot health ($p = 0.043$) and a trend towards significance for improved function ($p = 0.071$). However, there were no significant changes in pain ($p = 0.842$) nor footwear ($p = 0.195$) between baseline and follow-up. At follow-up, there was a significant difference in satisfaction scores between responders and non-responders ($p = 0.025$) with responders reporting significantly more satisfaction compared to non-responders (Table 3). However, no significant differences were seen between the responders and non-responders for the supination resistance or ankle dorsiflexion range ($p = 0.213$, $p = 0.831$), respectively.

Of the 36 patients included in the initial analysis, 26 (n = 14 non-responders and n = 12 responders) patients did not receive any further intervention for their original presenting condition in the two years following custom 3D-printed foot orthoses prescription. Nine patients ceased using their custom 3D-printed foot orthoses after their original condition fully resolved (n = 6 non-responders; n = 3 responders) and 13 patients continued to use their custom 3D-printed foot orthoses (n = 7 non-responders; n = 6 responders). One responder continued intermittent use of their 3D-printed foot orthoses in conjunction with an off-the-shelf insole for sports participation, three patients did not require further treatment for their original presenting condition but were unable to confirm if they continued to use their 3D-printed orthoses (n = 1 non-responder; n = 2 responders).

Ten patients required escalation for treatment of their original lower limb musculoskeletal condition within two years of being fitted with custom 3D-printed foot orthoses (n = 6 non-responders; n = 4 responders). Four patients were escalated to treatment with a custom ankle foot orthosis (n = 3 non-responders; n = 1 responder). Four patients were escalated to Orthopaedics and were listed for surgery (n = 3 responders; n = 1 non-responder). Of the remaining two patients (both non-responders); one was escalated to Orthopaedics and received corticosteroid injections and the other was converted to a different style of custom foot orthosis.

5. Discussion

This study explored the effectiveness of custom hard-shell 3D-printed foot orthoses to facilitate pain reduction, when used for patients with a lower limb MSK condition that had not improved with the use of custom EVA foot orthoses. The cohort of patients included a range of musculoskeletal lower limb pathologies providing a realistic representation of day-to-day NHS clinical practice. Across the full cohort there were significant improvements in self-reported pain, function and foot health, all exceeding the previously reported minimally important difference thresholds [26]. These encouraging findings support the clinical consideration of hard-shell 3D-printed insoles for patients whose condition did not improve with custom EVA insoles, prior to escalating to other healthcare services.

Reported pain scores demonstrated considerable variability, which is consistent with past research examining foot orthoses on symptomatic lower limb musculoskeletal conditions [27,28]. We therefore split the full cohort into responders and non-responders using minimally important difference threshold based on baseline to follow-up pain scores [26] to determine if pain response influences custom 3D-printed orthoses effectiveness. At baseline, responders reported significantly worse pain compared to non-responders ($p = 0.008$). However, at follow-up, responders reported significant improvements in pain (<0.001) resulting in a similar pain score to non-responders ($p = 0.117$). These findings suggest patients presenting with worse pain scores prior to treatment may respond better to custom 3D-printed foot orthoses. This is consistent with previous research demonstrating worse pain scores to be indicative of improved outcomes with foot

Table 4
Median and inter-quartile range, and Wilcoxon Sign Rank test within the responders and non-responders, and Mann-Whitney U-tests for between groups for Foot Health Status Questionnaire scores.

	Responders (n = 16)		Non-Responders (n = 20)		p-value	
	Baseline	Follow-up	Baseline	Follow-up	Between group baseline	Between group follow-up
Pain	29.4 (26.1, 41.9)	78.1 (66.3, 89.1)	66.3 (35.6, 83.6)	48.1 (30.9, 87.5)	**0.008***	0.117
Baseline vs. follow-up (p-value)	**< 0.001***		0.842			
Function	46.9 (25.0, 67.2)	87.5 (70.3, 98.4)	62.5 (37.5, 93.8)	84.4 (37.5, 100.0)	0.093	0.591
Baseline vs. follow-up (p-value)	**< 0.001***		0.071			
Foot Health	25 (0, 25.0)	60 (45.6, 81.9)	27.5 (25.0, 72.5)	60 (15.6, 85.0)	**0.029***	0.795
Baseline vs. follow-up (p-value)	**0.008***		**0.043***			
Footwear	75 (37.5, 81.2)	66.7 (27.1, 83.3)	75 (41.7, 91.7)	75 (35.4, 89.6)	0.747	0.872
Baseline vs. follow-up (p-value)	0.288		0.195			

* significant difference $p < 0.05$.

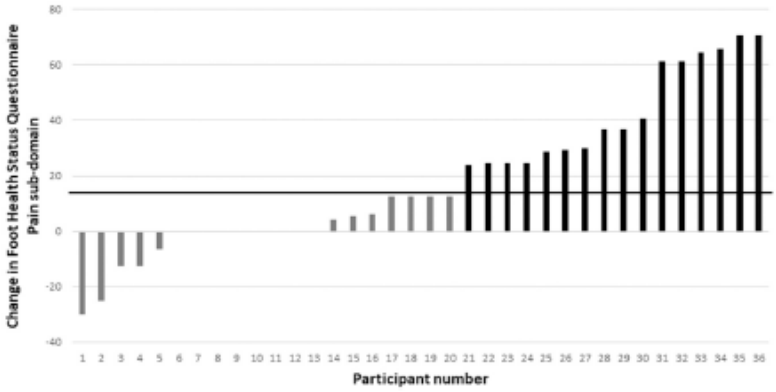

Fig. 2. Responders and non-responders based on change in Foot Health Status Questionnaire pain response after wearing foot orthoses defined as a minimal important difference of ± 13. Pain responders (black) demonstrate a positive change of 13 points and non-responders (grey) demonstrate a ≤ 12.99 change in pain between baseline and minimum eight-week follow-up.

orthoses [29,30]. Conversely better pain scores have been shown to be predictive for successful treatment with foot orthoses [31]. Therefore, more research is required to determine if reported pain scores can determine foot orthoses effectiveness across cohorts of non-specific musculoskeletal pathologies.

The responders also demonstrated significant improvements in function ($p < 0.001$), foot health ($p = 0.008$) and significantly greater satisfaction scores compared to the non-responders ($p = 0.025$). These findings support our hypothesis that custom hard-shell 3D-printed foot orthoses may be a viable treatment option for patients with musculoskeletal lower limb pathology that do not report improvements with their initial custom EVA foot orthoses. Interestingly, the non-responders demonstrated significant foot health improvements ($p = 0.043$) and a trend towards improved function ($p = 0.071$) suggesting some benefits to treatment escalation despite no change in self-reported pain scores. Despite only 16 patients demonstrating improved pain scores after 8-weeks, a two-year review disclosed that 26 of the 36 patients did not require any further intervention, therefore shortening their healthcare journey. However future research is required to understand why a subgroup of 10 patients did require further treatment escalation and additional intervention for their original musculoskeletal condition.

Ankle dorsiflexion range was not found to be clinically important when considering patient outcomes in this study, despite past research demonstrating increased pain to be associated both with increased ankle dorsiflexion range [32,33] and conversely decreased ankle dorsiflexion range [34,35]. In addition, we found no significant between-group differences for supination resistance despite reports suggesting those with higher supination resistance may benefit from the harder orthotic material [36]. The lack of significant clinical findings suggests these clinical tests may not be sufficiently sensitive to detect response to orthotic treatment. Further research is therefore required to identify more sensitive clinical measures that may predict response to orthotic prescription.

After eight-weeks, the non-responders' satisfaction scores were comparable with previous studies reporting benefits of foot orthoses [37,38] suggesting positive treatment perceptions despite no pain improvements. These satisfaction scores in addition to improved foot health ($p = 0.043$) and foot function scores ($p = 0.071$), could possibly explain why 14 non-responders did not require any further escalation for treatment within two years despite no significant pain improvement.

This study had a number of limitations which should be considered. Patients' foot orthoses adherence was not recorded and it is unknown whether increased adherence leads to improved outcomes. There was significant variance seen in the follow-up period across the patient cohort which may have affected the outcomes, this was due to patient cancellations and failure to attend initial follow-up appointments, which is a true representation of day-to-day clinical NHS practice. Within this analysis we only considered responders and non-responders to treatment, and not those who showed a negative change lower than −13 Foot Health Status Questionnaire subdomain for pain who could be described as a third group of "negative responders". Although this is an important group to consider a much larger sample size is required to perform a robust analysis. Finally, the two year follow-up included only a review of NHS GGC Health Board records, and excludes treatments sought by private healthcare providers.

In conclusion this study suggests that custom hard-shell 3D-printed foot orthoses have the potential to improve pain, function, foot health and provide patient satisfaction, when used as a treatment in the musculoskeletal Foot and Ankle pathway for patients who did not improve with custom EVA orthoses and were being considered for escalation to other services. The option of custom hard-shell 3D-printed foot orthoses for patients who do not report symptom improvement with custom EVA foot orthoses could offer a long-term alternative to medical or surgical treatment, minimise healthcare services pressures by limiting onward referrals, and ultimately minimise patients' journey through the healthcare system. Given the heterogeneous patient cohort described in this study, we have been unable to conclude if any specific pathologies or clinical presentations should be considered for hard-shell 3D-printed foot orthoses as a first line treatment, and therefore we suggest their use only if custom EVA foot orthoses have been unsuccessful in reducing pain. Further studies should focus on determining if specific characteristics affect the response to hard-shell 3D-printed insoles. Although this study considered pain response to treatment, the longer-term follow-up highlights the need to develop clinically relevant and implementable predictors of treatment success.

CRediT authorship contribution statement

Nikki Munro: Writing – review & editing, Resources, Methodology, Data curation. **Kirsty Watters:** Writing – review & editing, Methodology, Data curation. **Laura Barr:** Writing – review & editing, Writing – original draft, Methodology, Data curation, Conceptualization. **Graham J. Chapman:** Writing – review & editing, Supervision, Methodology, Formal analysis, Data curation. **Ross McCalg:** Writing – review & editing, Methodology, Data curation. **Jim Richards:** Writing – review & editing, Supervision, Methodology, Formal analysis, Data curation.

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Nikki Munro reports equipment, drugs, or supplies was provided by Podfo Ltd. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Appendix 41 - Article publication: *The use of computer-aided design and manufacture for foot orthoses: A cross-sectional study of orthotic services in the UK*. Barr L, Richards J, Chapman GJ. Journal of Foot and Ankle Research. 2025 Feb; 18(1). doi: 10.1002/jfa2.70031

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ORIGINAL RESEARCH

JOURNAL OF FOOT AND ANKLE RESEARCH

The use of computer-aided design and manufacture for foot orthoses: A cross-sectional study of orthotic services in the UK

Laura Barr[1,2] | Jim Richards[2] | Graham J. Chapman[2]

[1]Orthotic Department, NHS Greater Glasgow and Clyde, Gartnavel General Hospital, Glasgow, Scotland

[2]Allied Health Research Unit, University of Central Lancashire, Preston, UK

Correspondence
Graham J. Chapman, Allied Health Research Unit, University of Central Lancashire, Brook Building (BB128), Preston PR1 2HE, UK.
Email: GChapman2@Uclan.ac.uk

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Abstract

Objective: This study aimed to identify how computer aided design and manufacture (CAD/CAM) technologies are currently being used for insole production by UK orthotic services in the National Health Service (NHS), including any variation in the specific processes and identify barriers to implementation.

Design: A cross-sectional study was undertaken using freedom of information requests sent to all 214 NHS Trusts and Health Boards (HBs) across the UK. The request comprised 22 questions relating to CAD/CAM for insole production by UK NHS orthotic services during the 2021/22 financial year.

Outcome Measures: Analysis was undertaken and presented in terms of response rate to individual questions. Where free text responses were provided, thematic analysis was conducted.

Results: Responses were received from 186 (86.9%) Trusts/HBs, those who did not have an orthotic service were excluded, and 131 responses were included in the final analysis. 70.5% (91/129) of Trusts/HBs used CAD/CAM to manufacture bespoke insoles. The most common workflow associated with CAD/CAM insole production was foot-shape capture with a foam box impression cast (86.8% (79/91)); casts transported to another site (90.8% (79/87)); foam boxes scanned into a CAD/CAM system (81.6% (71/87)); insoles designed by a technician (73.6% (67/91)) and insole produced with reduction milling (59.1% (SD 37.92)). The greatest barriers to the use of CAD/CAM were those of equipment costs and staff experience and training.

Conclusions: UK orthotic services have widely adopted CAD/CAM insole production, but fully-digital workflow is uncommon. Hybrid-digital workflow involves physical casts and their transportation, generating waste and impacting sustainability. Further research is required to understand how hybrid-digital and fully-digital workflow affect patient treatment outcomes, costs and sustainability. Barriers to CAD/CAM including costs and staff training which should be considered alongside the growing body of research around CAD/CAM technologies.

KEYWORDS
CAD/CAM, foot orthoses, insoles, orthotics

1 | INTRODUCTION

Foot orthoses, known commonly as insoles, are used to treat many conditions of the foot and lower limb arising from various pathologies including musculoskeletal conditions, diabetic foot disease and traumatic injury [1–3]. Historically, bespoke insoles have been manufactured using traditional methods which require a physical cast of the foot using single use materials such as phenolic foam and plaster of Paris over which the final insole is then molded, this process can be time consuming, messy and produces waste products [4]. Since the 1980's the use of computer aided design and manufacture (CAD/CAM) has replaced certain elements of traditional manufacture in the prosthetic and orthotic industry, with an increasing trend towards the use of CAD/CAM throughout the medical industry in more recent years [5, 6]. The use of CAD/CAM in orthotic manufacture has long since conceptualised advantages with regard to improved accuracy of body shape capture, repeatability, improved quality and faster production times [4, 7, 8]. In addition to the initial advantages foreseen with the use of CAD/CAM, the Covid-19 pandemic also instigated a change in perception around the benefits of this technology for reduced patient contact time during the assessment process [7, 9], and in conjunction with other digital technologies, offered the ability to provide a fully virtual service for patients requiring duplicate or repeat prescription of their orthoses [4, 7]. Beyond the pandemic, these benefits can be appreciated in terms of reducing unnecessary patient travel for face-to-face hospital visits in the long-term [4].

Despite the purported benefits, barriers to CAD/CAM have been raised in the literature with regard to equipment costs, requirement for clinical training, and adaptation of orthotic workflow [10], fueled by a self-reported lack of CAD/CAM expertise in the orthotic workforce [11]. Doubt has also been cast on the change in clinical processes instigated by the perceived lack of clinical experience with CAD/CAM technology, resulting in the insole design often being undertaken by a technician at a central fabrication site rather than the orthotist at the point of patient contact [7]. To the authors' knowledge, it is still not understood how widely CAD/CAM is being used in the UK for the production of bespoke foot orthoses, and how the UK workforce has adapted to incorporate such digital workflows, specifically with regard to the individual processes used within the CAD/CAM supply chain. Questionnaires regarding CAD/CAM in the orthotic industry have typically focussed on both prosthetic and orthotic services without a specific focus on foot orthoses, and have not had a high response rate from the UK orthotic workforce [4, 12].

This study aims to improve our understanding of how CAD/CAM technologies are currently being used for insole production by UK National Health Service (NHS) orthotic services. We aimed to identify any variation in the specific processes associated with a CAD/CAM workflow, and any barriers for implementation, in order to determine where future research should be directed.

2 | METHODS

A cross-sectional study was undertaken using the UK freedom of information (FOI) act to gather data [13] and reported in accordance with the STROBE cross-sectional reporting guidelines [14]. From November 11, 2022 to December 2, 2022 FOI requests were sent to all 214 NHS Trusts and Health Boards (HBs) across the UK. The request comprised 22 questions (see Supplementary File 1 in Supporting Information S1) designed to gather information relating to UK NHS orthotic services during the 2021/22 financial year from April 6, 2021 to April 5, 2022. Not all questions required an answer, and Trusts/HBs were instructed on which specific questions they should answer depending on their particular responses. The request focussed on two main areas (1): CAD/CAM insoles and (2) barriers/facilitators to using CAD/CAM.

(1) CAD/CAM insoles

The aim of this section was to gather information on the volume of bespoke insoles prescribed by the Trust/HB, the methods used for manufacture, and the proportion of insoles manufactured by traditional and CAD/CAM methods. Further questions then explored the workflow relating to manufacture of CAD/CAM insoles; this included questions on the methods used to acquire digital foot models, the transportation of foot models, the design, and the manufacture of the insoles.

(2) Barriers/facilitators to using CAD/CAM

The aim of this section was to understand the reasons why services chose to use or not to use CAD/CAM as part of their insole manufacture process. Using previous publications which examined barriers and facilitators for the use of any CAD/CAM systems in the prosthetics and orthotics industries [4, 12, 15], a list of options was compiled from which respondents could either choose their answers, or provide a free text comment. Given recent considerations to the use of digital technology in supporting health services following the Covid-19 pandemic [4], we also chose to include options regarding any benefits that CAD/CAM insole systems provided to Trusts/HBs during and following the pandemic. Approval for the study was received from the Health Ethics Review Panel at the University of Central Lancashire (HEALTH 0365 Phase 2).

2.1 | Data analysis

An analysis was undertaken and presented in terms of response rate for the individual questions. Where free text responses were provided, the answers were reviewed and an inductive approach was

used to form a thematic analysis [16], the themes of which were agreed by the authors and presented alongside anonymised quotations. Where questions required a numerical answer, if a respondent provided a range of values then the mean of those values was used in the analysis. Where numerical answers were provided, distribution of those values was analyzed using Kolmogorov-Smirnov tests and presented as median values when data was not normally distributed. Where Trusts/HBs were asked to select one preferred method of shape capture, analysis was made on the assumption that a minimum of 51% of their CAD/CAM insole production would be manufactured using this method, and where two options were selected the subsequent analysis was based on the assumption that 50% of their CAD/CAM insole production would be manufactured using each method.

2.2 | Patient and public involvement

No patients or members of the public were involved in the design of this study. Before dissemination across the UK, the FOI request was piloted by orthotists in three Trusts/HBs who provided comments on the content and structure of the questions; all comments were addressed in the final version of the FOI request.

3 | RESULTS

3.1 | Response rate

Complete or partially complete responses were received from 186 (86.9%) Trusts/HBs, two (0.9%) declined to respond, and 26 (12.2%) provided no response. On preliminary review of the responses, 60 stated that they did not have an Orthotic Department in their Trust/HB and were excluded from the analysis. Within the received responses one was excluded due to lack of information as only one question was answered despite prompting to complete further questions. Three Trusts/HBs provided separate responses for their adult and pediatric services, three provided individual responses for two separate geographical areas within their Trust/HB, and one provided individual responses for three geographical areas within their Trust/HB. Therefore, the total number of responses included in the analysis was 131 (Figure 1). The geographical regions of the respondents are presented in Table 1. Not all Trusts/HBs provided answers to all questions requested of them, with the variation in response rate documented in Supplementary File 2 in Supporting Information S2.

3.2 | Overview of bespoke insole provision

Responses showed that a greater proportion of Trusts/HBs (61.8% (81/131)) provided a contracted orthotic service, whereby the NHS pays for orthotic services from an external company, with approximately 30% (31.3% (41/313)) of Trusts/HBs using an in-house service where orthotists are employed directly by the NHS, and a small number (6.9% (9/131)) used a combined contracted and in-house service (Figure 2a).

Of those Trusts/HBs that provided insoles, the majority (93.1% (122/131)) confirmed that they provided bespoke insoles to patients and a small number (5.3% (7/131)) did not respond (Figure 2b). Of those Trusts/HBs who did provide bespoke insoles, the majority

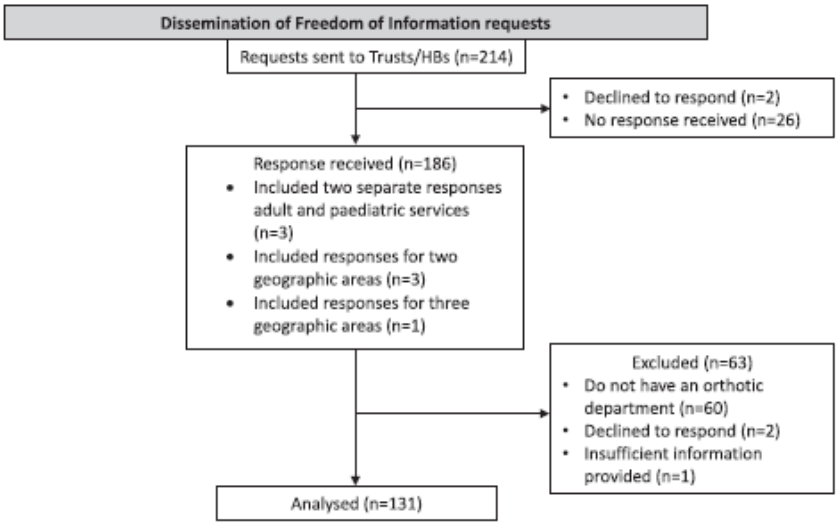


FIGURE 1 Study flow chart.

TABLE 1 Responses by geographical region.

Region	Number of respondents	Percentage of total (131)
Scotland	11	8.4%
Northern Ireland	4	3.1%
Wales	7	5.3%
England		
North East	7	5.3%
North West	14	10.7%
Yorkshire and Humber	11	8.4%
East Midlands	7	5.3%
West Midlands	10	7.6%
East	11	8.4%
London	17	13%
South East	19	14.5%
South West	13	9.9%

(80.6% (104/129)) provided details of the number of bespoke insoles ordered for patients in the 2021/22 financial year. Fifteen of the 129 Trusts/HBs provided an estimated number or a range of values. The total number of bespoke insoles provided by Trusts/HBs was 144,414 (median 904.50, IQR 360.50–1652.25). Of those Trusts/HBs who provided bespoke insoles, 70.5% (91/129) used CAD/CAM whereas ~20% (25/129) did not use CAD/CAM to manufacture the bespoke insoles and 10.1% (13/129) did not respond.

3.3 | CAD/CAM insoles

Of the 91 Trusts/HBs that used CAD/CAM for insole manufacture, the response rate varied from 79.1% to 86.8% for the breakdown of the manufacturing methods used in their services. Six (6.6%) Trusts/HBs were unable to provide specific details due to the insoles being manufactured externally without the Trust/HB having knowledge of the external processes. A full breakdown of the manufacture methods are shown in Table 2.

With regard to the number of years that CAD/CAM had been used as part of their insole manufacture process, 85.7% (78/91) Trusts/HBs reported a median of 10.00 years (IQR 7.5–15.00). The final set of questions in this section were designed to understand details of the CAD/CAM workflow. A high majority (95.6% (87/91)) of Trusts/HBs confirmed they sometimes used foam box impression casts when prescribing CAD/CAM insoles, and 3.3% (3/91) did not respond (Figure 2c). Of those who used foam box impression casts, 81.6% (71/87) scanned the cast directly into the CAD/CAM system, 1.4% (1/87) filled the cast with plaster before scanning, and 17.2% (15/87) did not know the specific processes due to this being undertaken by external manufacturers (Figure 2d). With regard to the location of scanning, 90.8% (79/87) reported that the foam box impression casts were transported and scanned into the CAD/CAM system on another site, 8.1% (7/87) reported that the casts were scanned on the site where the patient was assessed, and 1.2% (1/87) provided an invalid response by selecting more than one option (Figure 2e). Just over half (58.2%, (53/91)) of Trusts/HBs reported they occasionally used slipper/plaster casts to capture patients' foot shape when prescribing CAD/CAM insoles, and 3.3% (3/91) did not respond (Figure 2f). With regard to the location of scanning, 96.2% (51/53) of Trusts/HBs confirmed that the plaster/slipper casts would be transported to another site to be scanned into the CAD/CAM system, 1.9% (1/53) scanned the casts on the site where the patient was assessed, and 1.9% (1/53) provided an invalid response by selecting more than one option (Figure 2g).

The majority of Trusts/HBs (86.8% (79/91)) confirmed that they most commonly used foam box impression casts when manufacturing CAD/CAM insoles, 2.2% (2/91) did not respond, 1.1% (1/91) provided a free text answer of "direct scanner", 1.1% (1/91) selected direct 3D scan using a handheld scanner, 1.1% (1/91) chose direct 3D scan using a flatbed scanner, 1.1% (1/91) chose slipper cast/plaster cast, and 6.6% (6/91) selected two options (Figure 2h). For the 2021/22 financial year, the minimum total number of CAD/CAM insoles produced using foam box impression casts was 36,316, with 3252 produced with direct scanning, and 1288 produced using slipper casts.

With regards to rectifying/modeling the CAD/CAM insoles, 73.6% (67/91) were conducted by a technician, 8.8% (8/91) confirmed the modeling was completed by the orthotist who assessed the patient, 1.1% (1/91) used a clinical assistant, 1.1% (1/91) reported two options, 12.1% (11/91) did not know due to an external manufacturer being responsible for the process, 1.1% (1/91) entered a free text answer of "podiatrist," and 2.2% (2/91) did not respond (Figure 2i). Therefore the summation of responses from this section of the FOI request shows that the most common workflow for CAD/CAM insoles in UK NHS orthotic services is a hybrid workflow, comprising elements of traditional manufacture and digital techniques (Figure 5).

3.4 | Barriers and facilitators for CAD/CAM

In order to understand the barriers and facilitators that services experience when considering the use of CAD/CAM for insole manufacture, we asked those respondents who did not use CAD/CAM (25 of the 129 Trusts/HBs) to provide reason(s) for not using CAD/CAM. Multiple responses were permitted, and where a free text response was provided (48% (12/25)), these responses were collated into themes (Table 3). Responses were received from 88% (22/25) Trusts/HBs, with the most common barriers being the cost of scanning equipment (40.9% (9/22), and the cost of manufacturing

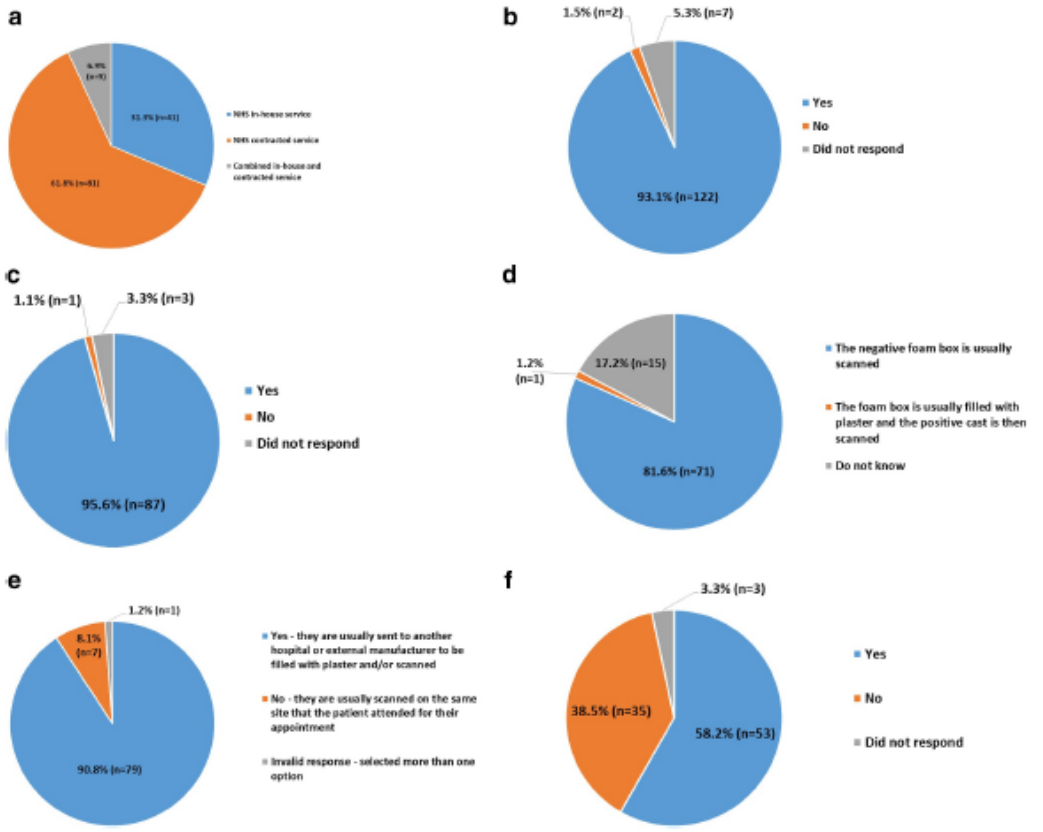


FIGURE 2 (a–i) Proportionate answers to individual questions from Trusts and Health Boards (HBs). (a) Which of the following best describe your orthotic service? (b) Does your orthotic service provide bespoke insoles to patients? (c) Does your orthotic service ever use foam box impression casts to capture the shape of the patient's foot, when prescribing CAD/CAM insoles? (d) Is the negative foam box impression cast usually scanned into the CAD/CAM system, or is it filled with plaster first and then the positive model scanned? (e) Are the foam box impression casts usually transported to another site to be scanned into the CAD/CAM system? (f) Does your orthotic service ever use slipper casts/plaster casts to capture the shape of the patient's foot, when prescribing CAD/CAM insoles? (g) Are the slipper casts/plaster casts usually transported to another site to be filled with plaster and scanned into the CAD/CAM system? (h) In your orthotic service, which is the most common method used to capture the shape of the patient's foot, when prescribing CAD/CAM insoles? (i) Who is usually responsible for performing the modeling/rectification of the CAD/CAM insoles that your orthotic service provide?

equipment (36.4% (8/22)), with all selected and thematic responses shown in Figure 3.

Those services who did use CAD/CAM ($n = 91$) were asked to select any relevant options from a list of facilitators. Responses were received from 86.8% (79/91) Trusts/HBs with one respondent stating that none of the options applied. The most popular reasons for using CAD/CAM were the perception that CAD/CAM insoles are easily repeatable than traditional insoles (81.0% (64/79)) and CAD/CAM is faster than traditional options (70.9% (56/79)) (Figure 4).

4 | DISCUSSION

This study was undertaken to gain an understanding of the current practices associated with the provision of CAD/CAM insoles in UK orthotic services. The majority of NHS Trusts/HBs confirmed they did use CAD/CAM as part of their bespoke insole manufacture process, which is in keeping with the anticipated increase in CAD/CAM technology reported in the literature [5, 6]. However, the workflow predominantly used by UK orthotic services (Figure 5) constitutes a

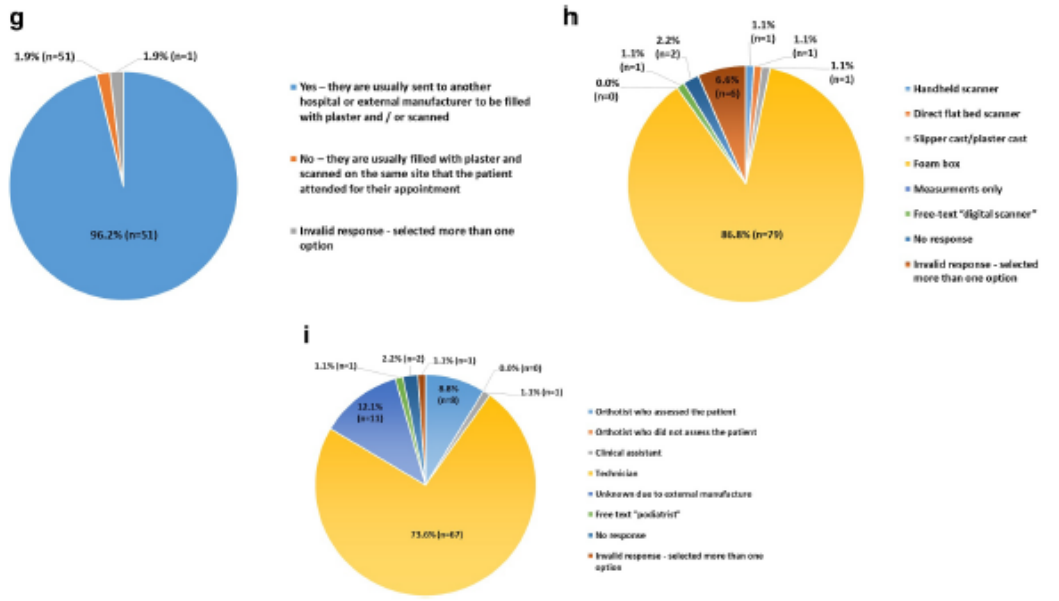


FIGURE 2 (Continued)

TABLE 2 Techniques used to manufacture bespoke insoles.

Method of insole manufacture (respondents)	Volume of insoles: Median percentage[a]	Volume of insoles: Total	Volume of insoles: Total	Volume of insoles: Median total[a]
In-house traditional (79/91)	0.0 (0.0–0.0)	11,006.89	27,296.65 (traditional manufacture)	0.00 (0.00–0.00)
Outsourced traditional (72/91)	3.0 (0.0–9.1)	16,289.76		11.71 (0.00–942.90)
In-house computer aided manufacture using reduction manufacture (79/91)	0.0 (0.0–0.0)	22,044.63	76,381.25(CAD/CAM manufacture)	0.00 (0.00–0.00)
In-house computer aided manufacture using additive manufacture (79/91)	0.0 (0.0–0.0)	5373.27		0.00 (0.00–0.00)
Outsourced computer aided manufacture using reduction manufacture (72/91)	78.0 (17.8–95.0)	44,320.25		400.00 (0.00–942.90)
Outsourced computer aided manufacture using additive manufacture (77/91)	0.00 (0.0–10.0)	4643.10		0.00 (0.00–49.61)

[a]Median (IQR 25–75).

hybrid-digital process rather than a fully-digital process, whereby some steps associated with traditional manufacture remain. This would potentially reduce some of the reported benefits associated with CAD/CAM such as waste production and speed of manufacture.

Past research has shown that hybrid digital processes, equivalent to the most common process used in the UK as described in this paper, produce greater waste products and pollution, and score less favorably in terms of sustainability than fully digital processes [17]. Furthermore, services using plaster casts and slipper casts within their CAD/CAM insole workflow, as well as those choosing to fill foam box casts with plaster prior to digital upload, further decrease sustainability of the insole production [17]. Although some studies have identified the potential for recycling of both gypsum and plaster of Paris, these techniques are not currently part of routine medical or industrial processes [18–20]. The production of such avoidable waste products should be strongly considered by orthotic services wishing to improve their environmental impact in terms of carbon emissions, and for those services in the UK to meet NHS net-zero goals [21, 22].

TABLE 3 Thematic breakdown of free text responses describing barriers to CAD/CAM from individual Trusts and Health Boards.

Trust/Health board response	Cost	Lack of training/ experience	Service priorities	Technical/ equipment limitations	No perceived benefit to CAD/CAM	Insufficient insole numbers to justify CAD/CAM	Unknown/ contractor decision	Currently trialling CAD/CAM
"We have equipment to consider using CAD/CAM but due to this not being top priority, lack of experience, cost for technical support and time, this has been put on hold"	•	•	•					
"They are currently trialling this"								•
"...The numbers of specialist custom made foot orthoses required are lower and thus the cost benefits and time saving of foot only CAD CAM systems are less"						•		
"Our current supplier does not use scanning"							•	
"Unable to answer as this would be a contractor decision"							•	
"This is being considered however the current computer set up may provide difficulties in supporting scanning devices"				•				
"Not offered by the company"							•	
"A good service is provided via the methods currently use"					•			
"We use a company who are just testing the technology"							•	•
"Sharing of information electronically with third parties, not a limiting factor, but one to be considered"				•				
"Poor results with previous CAD systems"					•			
"Unsure, as external contractor"							•	
Totals	1	1	1	2	2	1	5	2

Future studies comparing patient outcomes using hybrid digital and fully digital workflows may help to better inform orthotic services about the clinical impact of these different methods, in order to support the case for best practice in terms of clinical goals alongside sustainability policies. Despite the increasing development of additive manufacture techniques in the orthotic industry in recent years [23–25], this study found that additive manufacture was the least used manufacture method for insoles in UK NHS orthotic services. As this is still a relatively new manufacturing technique it is possible that health services have not yet had the opportunity to fully explore the position of additive manufacture in treatment pathways, and future studies will be required to demonstrate any change in practices in the years to come.

With the majority of orthotic services physically transporting casts externally prior to digital upload into the CAD/CAM system, consideration should be given not only to the manufacture delay incurred by this step, but also to the possible carbon emissions associated with transportation [26–28]. It would therefore be advantageous to compare this with alternative fully-digital workflows which remove the need for transportation, such as direct scanning, to assess if these processes produce equivalent outcomes in terms of patient treatment, in order to establish best practice for CAD/CAM insole production. The size of the medical foot orthotic industry is expected to increase globally with a compound annual growth rate of 4.6%, in excess of $3.9 billion by 2030 [17], establishing the optimal CAD/CAM processes in terms of clinical

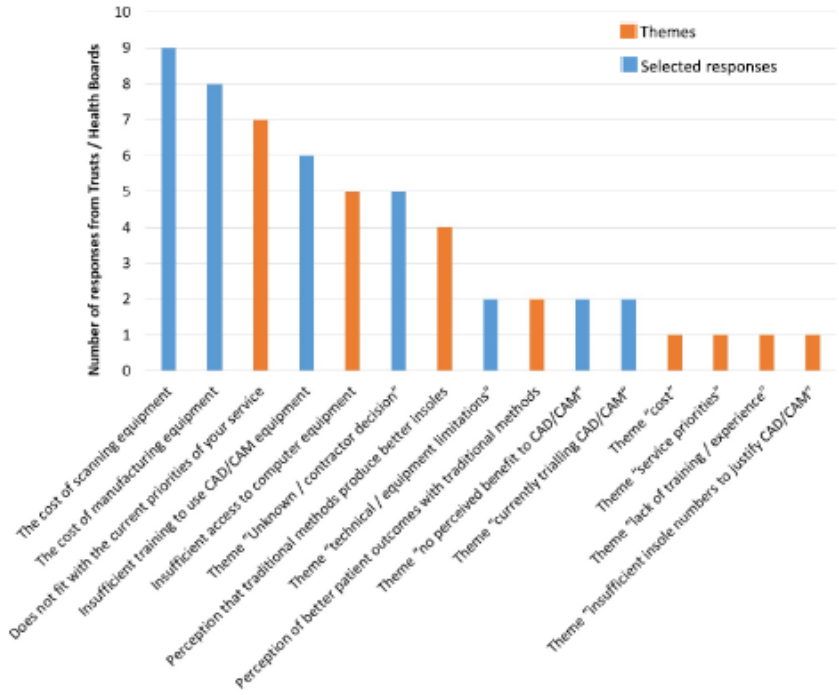


FIGURE 3 What are the barriers for using computer aided manufacture for custom insoles in your orthotic service?

effectiveness and sustainability should be a research priority for the orthotic profession.

The greatest barrier to the use of CAD/CAM for insole production was related to equipment costs (Figure 3), which was in keeping with the barriers identified in previous reports [4, 10, 12]. Despite this, cost was also identified as a facilitator to the use of CAD/CAM, with 34.2% (27/79) of Trusts/HBs reporting that using CAD/CAM for insole production was cheaper than traditional techniques. It is possible that those who had not yet introduced CAD/CAM into their service model were limited by start-up costs associated with the integration of equipment and training of the workforce which has historically incurred high in-house costs [5, 10]. However, the contradiction observed in this study between the perceptions of cost both as a barrier and a facilitator suggests that services may well be basing their cost concerns on a legacy of historical CAD/CAM prices, which have reduced significantly in recent years such that CAD/CAM technologies are now being recommended as the lowest cost option for low income countries [29].

Lack of experience and training related to the CAD/CAM process were highlighted as a barrier by six of 25 Trusts/HBs, accounting for 12.7% of the total reasons given by services for not using CAD/CAM for insole production. This lack of skills in the UK orthotic profession was also highlighted in the recent prosthetic and orthotic workforce survey, in which only 30% of orthotists reported that they had CAD/CAM skills [30]. Although within the current study, services who did use CAD/CAM were not asked to identify any barriers to their use of CAD/CAM processes, it is possible that the lack of clinical skills relating to scanning and digital modeling could partly explain why the current workflow in the UK favors a hybrid-digital model, whereby the scanning and modeling are undertaken at a central fabrication centre rather than by the orthotist in charge of the patients' care. In 2020, research on fully-digital workflows was more than three times greater than that on hybrid-digital workflows [17]. Workforce reviews have identified that improving clinicians CAD/CAM modeling skills could be a strategic advantage for the profession [11], and over 70% of orthotists believe that CAD/CAM skills will be required by the profession in the future [30]. As such, additional training and support will be necessary before UK orthotic services can transition to fully digital workflows.

In spite of the published benefits that CAD/CAM could offer during the time of the Covid-19 pandemic [4, 7, 9], none of the Trusts/HBs in our study reported increased use of CAD/CAM for insole production as a result of this, although eight Trusts/HBs were able to resume services more rapidly following the pandemic when they used CAD/CAM. These findings highlight that CAD/CAM processes were already established within these Trusts/HBs at the time

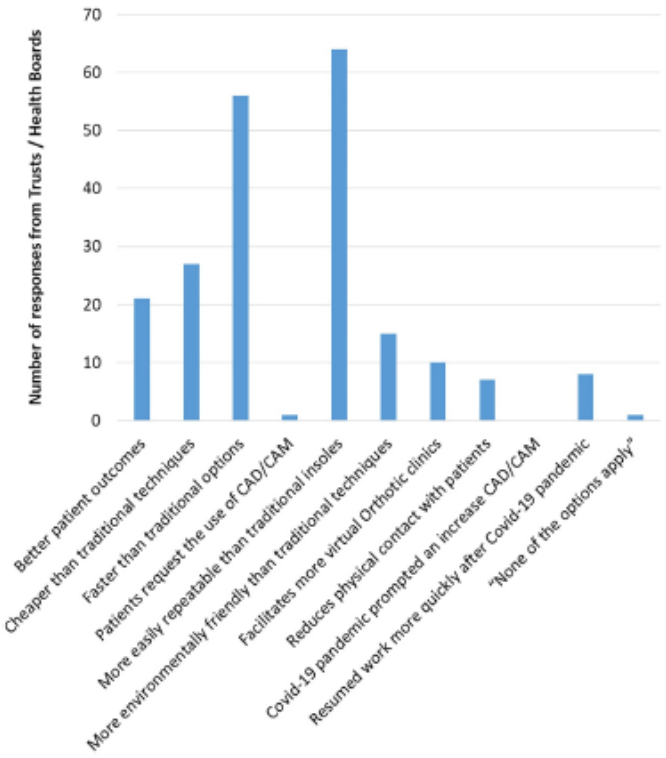


FIGURE 4 In your orthotic service, what are the reasons for using CAD/CAM insoles?

of the pandemic, with a median of 10 years duration of use and as such the benefits were already established. Despite the access to digital modeling systems, and increased speed of CAD/CAM modeling, this study found that the majority of services still use a technician to model the digital scans. Although it has previously been suggested that optimal orthotic design would be achieved if the modeling was undertaken by the clinician responsible for the patients' care [7], however it is unknown how this aspect of the manufacturing process impacts on the clinical effectiveness of the final insole. Further research is required to understand how a hybrid-digital workflow compares with a fully-digital workflow in terms of patient outcomes, overall costs, and long-term sustainability.

4.1 | Limitations

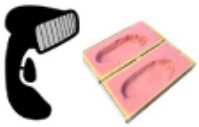
Some Trusts/HBs were unable to provide details for certain aspects of the insole manufacture process due to these being carried out by an external company. Only those Trusts/HBs who did not use CAD/CAM were asked to explain the barriers. This limited the ability to identify the barriers faced by those services who do use CAD/CAM processes within a fully-digital workflow.

5 | CONCLUSION

This study has identified considerable variations in processes currently associated with CAD/CAM insole production in UK orthotic services. A hybrid-digital workflow was found to be the most commonly used in the UK, which has been associated with increased waste products and greater transportation costs compared with a fully-digital workflow. Those services who are not currently utilising CAD/CAM in their insole workflow predominantly highlighted equipment costs and staff training as the main barriers. Services should consider engaging their staff in CAD/CAM training which has previously been identified as a priority for the future of the profession.

Shape capture - 86.8% (79/91) of services most commonly used foam box impression casts when manufacturing CAD/CAM insoles
The patient's foot is pressed into a phenolic foam box to produce a negative cast of their foot

Scanning - 90.8% (79/87) of services reported that the casts were transported and scanned into the CAD/CAM system at another site
The foam box cast is physically transported to a site with a digital scanner



Digital upload - 81.6% (71/87) of services scanned the negative cast into the CAD/CAM system
The negative foam box cast is scanned directly into the digital scanner without being filled with plaster

Insole design – in 73.6% (67/91) of services a technician modelled the CAD/CAM insole
The digital foot model is modified in the CAD/CAM system in order to create the final insole deign

Manufacture – mean 59.1% (SD 37.92) of all CAD/CAM insoles were produced by reduction milling
The physical insole is produced by a milling machine from the digital insole design which is milled into a block of material such as ethylene-vinyl acetate

FIGURE 5 The most common workflow for CAD/CAM insole production in UK orthotic services.

AUTHOR CONTRIBUTIONS

Laura Barr: Funding acquisition; conceptualization; methodology; data curation; formal analysis; writing—original draft; writing—review and editing. **Jim Richards**: Methodology; formal analysis; supervision; writing—review and editing. **Graham J. Chapman**: Methodology; formal analysis; supervision; writing—review and editing.

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Fellowship scheme from 2022 to 2023, and the NHS Research Scotland Career Researcher Fellowship scheme from 2023 to current.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Approval for the study was received from the Health Ethics Review Panel at the University of Central Lancashire (HEALTH 0365 Phase 2).

ORCID

Laura Barr https://orcid.org/0009-0002-3274-8139
Jim Richards https://orcid.org/0000-0002-4004-3115
Graham J. Chapman https://orcid.org/0000-0003-3983-6641

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

Appendix 42 - Freedom of Information Request sent to Trusts and Health Boards

This form has 7 pages. Unless you are prompted to skip a question or to stop answering, please ensure you answer **all** questions before returning the form.

Section 1

1. Does your Trust/Health Board have an orthotics department?

   ☐ Yes

   ☐ No

If the answer is "Yes" please answer section 2. If the answer is "No" no further information is required

---

Section 2

2.1 Which of the following best describe your orthotic service?
(select **all that apply** option by entering "X" in the left-hand column)

	NHS In-house service (This means the orthotists are directly employed by your Trust/Health Board)
	NHS Contracted service (This means an external contractor employs the orthotists)

2.2 Does your orthotic service provide bespoke insoles to patients?
(select **only one** option by entering "X" in the left-hand column)

	Yes *(continue to question 2.3)*
	No ***(end of questionnaire)***

2.3 How many bespoke insole orders did your orthotic service place in the 2021/22 financial year?
(In this context we assume that a "bespoke insole order" is likely to be either a pair of insoles for one patient, or a single insole for one patient)

2.4 Does your orthotic service ever provide bespoke insoles which have been **manufactured** using computer-aided processes, such as addition manufacture/3D printing, or reduction manufacture/milling insoles from a digital scan?
(Select **only one** option by entering "X" in the left-hand column)

	Yes *(skip to question 2.6)*
	No *(continue to question 2.5)*

2.5 What are the barriers for using computer-aided manufacture for custom insoles in your orthotic service? (Select **all that apply** by entering "X" in the left-hand column).

	The cost of scanning equipment	
	The cost of manufacturing equipment (millers, 3D printers, etc.)	
	Insufficient access to computer equipment to support CAD/CAM systems	
	Computer-aided manufacture does not fit with the current priorities of your service	
	Insufficient training to use CAD/CAM equipment	
	Perception that traditional methods produce better insoles	
	Perception of better patient outcomes with traditional methods	
	Other. Please provide a reason in the right-hand column	Free-text reason:

If you have completed question 2.5, this is now the end of the form.

If you were not asked to complete question 2.5 you should continue to the next page.

2.6 Which methods are used to **manufacture** bespoke insoles in your orthotic service? (Select **all that apply** by entering “X” in the left-hand column)

	In-house Traditional. You have staff on site in your service who use heat moulding / draping techniques to produce the insole
	In-house Computer-Aided Manufacture using Reduction Manufacture. You have milling equipment on site in your service and mill insoles from a block of material
	In-house Computer-Aided Manufacture using Additive Manufacture. You have a “3Dprinter” on site in your service and manufacture insoles using additive processes
	Outsourced Traditional. Your casts or models are sent to an external technical company who use heat moulding / draping techniques to produce the insole
	Outsourced Computer-Aided Manufacture using Reduction Manufacture. Your casts, models or scans are sent to an external technical company who mill insoles from a block of material
	Outsourced Computer-Aided Manufacture using Additive Manufacture. Your casts, models or scans are sent to an external technical company who manufacture the insoles using an additive process / “3D printer”
	Do not know - only select this option if your insoles are usually manufactured externally and you do not have knowledge of the external processes

Questions continue on next page

The definitions for the terms used in these questions, are explained on page 3.

2.7 In your orthotic service, what **percentage** of insoles were made using **In-house Traditional Manufacture** in the 2021/22 financial year?

	%

2.8 In your orthotic service, what **percentage** of insoles were made using **In-house Computer-Aided Manufacture with Reduction Manufacture** in the 2021/22 financial year?

	%

2.9 In your orthotic service, what **percentage** of insoles were made **using In-house Computer-Aided Manufacture with Additive Manufacture (3D-printed)** in the 2021/22 financial year?

	%

2.10 In your orthotic service, what **percentage** of insoles were made using **Outsourced Traditional Manufacture** in the 2021/22 financial year?

	%

2.11 In your orthotic service, what **percentage** of insoles were made using **Outsourced Computer-Aided Manufacture with Reduction Manufacture** in the 2021/22 financial year?

	%

2.12 In your orthotic service, what **percentage** of insoles were made using **Outsourced Computer-Aided Manufacture with Additive Manufacture (3D-printed)** in the 2021/22 financial year?

	%

Section 3

The following questions relate **only** to the insoles produced by computer-aided design and computer-aided manufacture (CAD/CAM). These may be manufactured in-house or externally. If your service and/or insole manufacturer do not use this method, you do not need to answer any further questions.

3.1 How long has your orthotic service provided bespoke insoles to patients, which were produced using computer-aided manufacture processes?

3.2 Does your orthotic service ever use foam-box impression casts to capture the shape of the patient's foot, when prescribing CAD/CAM insoles? (Select **only one** option by entering "X" in the left-hand column)

	Yes *(continue to question 3.3)*
	No *(skip to question 3.4)*

3.3 Is the negative foam-box impression cast **usually** scanned into the CAD/CAM system, or is it filled with plaster first and then the positive model scanned? (Select **only one** option by entering "X" in the left-hand column)

	The negative foam-box is usually scanned
	The foam-box is usually filled with plaster and the positive cast is then scanned
	Do not know – only select this option if your insoles are usually manufactured externally and you do not have knowledge of the external processes

3.4 Are the foam-box impression casts usually transported to another site to be scanned into the CAD/CAM system? (Select **only one** option by entering "X" in the left-hand column)

	Yes - they are usually sent to another hospital or external manufacturer to be filled with plaster and/or scanned
	No - they are usually scanned on the same site that the patient attended for their appointment

3.5 Does your orthotic service ever use slipper casts / plaster casts to capture the shape of the patient's foot, when prescribing CAD/CAM insoles?
(Select **only one** option by entering "X" in the left-hand column)

	Yes *(continue to question 3.4)*
	No *(skip to question 3.5)*

3.6 Are the slipper casts / plaster casts usually transported to another site to be filled with plaster and scanned into the CAD/CAM system?
(Select **only one** option by entering "X" in the left-hand column)

	Yes – they are usually sent to another hospital or external manufacturer to be filled with plaster and / or scanned
	No – they are usually filled with plaster and scanned on the same site that the patient attended for their appointment

3.7 In your orthotic service, which is the **most common method** used to capture the shape of the patient's foot, when prescribing CAD/CAM insoles
(Select **only one** option by entering "X" in the left-hand column)

	Direct 3D scan using a flat-bed scanner	
	Direct 3D scan using a handheld scanner	
	Foam-box impression cast	
	Slipper cast / plaster cast	
	Measurements only (using tracings or tape measures etc.)	
	Other. Please specify in the	Free-text:

	right-hand column	

Questions continue on next page

3.8 Who is **usually** responsible for performing the modelling/rectification of the CAD/CAM insoles that your orthotic service provide?
(Select **only one** option by entering “X” in the left-hand column)

	The orthotist who assessed the patient	
	Another orthotist who did not assess the patient	
	A clinical assistant	
	A technician	
	Do not know – only select this option if your insoles are usually manufactured externally and you do not have knowledge of the external processes	
	Other. Please specify in the right-hand column	Free-text:

3.9 In your orthotic service, what are the reasons for using CAD/CAM insoles?
(Select **all options that apply** by entering “X” in the left-hand column)

	Perception that CAD/CAM insoles produce better patient outcomes
	CAD/CAD production is cheaper for us than traditional techniques
	CAD/CAM insole production is faster than the traditional options
	The production of CAD/CAM insoles is more environmentally friendly than traditional techniques
	Patients request the use of CAD/CAM
	CAD/CAM insoles are more easily repeatable than traditional insoles
	Producing insoles with CAD/CAM facilitates us in running more virtual orthotic clinics
	Producing insoles with CAD/CAM allows us to reduce physical contact with patients

	The Covid-19 pandemic prompted us to increase the use of CAD/CAM insole production
	Producing insoles with CAD/CAM allowed our orthotic service to resume work more quickly following the onset of the Covid-19 pandemic

END OF QUESTIONS

Appendix 43 - Response rates for individual questions from Freedom of Information request sent to Trusts and Health Boards

Question 2.1: Which of the following best describe your orthotic service?

Service type % (number of replies)
NHS In-house service 31.3% (41/131)
NHS Contracted service 61.8% (81/131)
Both 6.9% (9/131)
No response 0% (0/131)

Question 2.2: Does your orthotic service provide bespoke insoles to patients?

Response % (number of replies)
Yes 93.1% (122/131)
No 1.5% (2/131)
No response 5.3% (7/131)

Question 2.3: How many bespoke insole orders did your orthotic service place in the 2021/22 financial year?*

Response % (number of replies)
Response received 80.6% (104/129)#
No response 19.4% (25/129)

*Those who responded “no” to question 2.2 were not required to answer the remainder of the questions, therefore the total number of possible respondents is 129

#Of these respondents 15/129 stated that their response was an estimate or a range rather than a known value

Question 2.4: Does your orthotic service ever provide bespoke insoles which have been **manufactured** using computer-aided processes, such as addition manufacture/3D printing, or reduction manufacture/milling insoles from a digital scan?

Response % (number of replies)
Yes 70.5% (91/129)
No 19.4% (25/129)
No response 10.1% (13/129)

Question 2.5: What are the barriers for using computer-aided manufacture for custom insoles in your orthotic service?*

Response % (number of replies)
Response received 92% (23/25)
No response 8% (2/25)

*Only those who responded “No” to question 2.4 were required to answer. Therefore the total number of possible respondents is 25.

Question 2.6: Which methods are used to **manufacture** bespoke insoles in your orthotic service?*

Response % (number of replies)
Response received 94.5% (86/91)
No response 5.5% (5/91)

* Only those who responded “Yes” to question 2.4 were required to answer the remaining questions. Therefore the total number of possible respondents is 91.

Questions 2.7 to 2.12: In your orthotic service, what **percentage** of insoles were made using

2.7 In-house Traditional Manufacture. **Response % (number of replies)**	2.8. In-house Computer-Aided Manufacture with Reduction Manufacture. **Response % (number of replies)**	2.9. In-house Computer-Aided Manufacture with Additive Manufacture. **Response % (number of replies)**	2.10 Outsourced Traditional Manufacture. **Response % (number of replies)**	2.11. Outsourced Computer-Aided Manufacture with Reduction Manufacture. **Response % (number of replies)**	2.12. Outsourced Computer-Aided Manufacture with Additive Manufacture. **Response % (number of replies)**
Response received 86.8% (79/91)	Response received 86.8% (79/91)	Response received 86.8% (79/91)	Response received 79.1% (72/91)	Response received 79.1% (72/91)	Response received 84.6% (77/91)
No response 13.2% (12/91)	No response 13.2% (12/91)	No response 13.2% (12/91)	No response 20.9% (19/91)	No response 20.9% (19/91)	No response 15.4% (14/91)

Question 3.1: How long has your orthotic service provided bespoke insoles to patients, which were produced using computer-aided manufacture processes?

Response % (number of replies)
Response received 85.7% (78/91)
No response 14.2% (13/91)

Question 3.2: Does your orthotic service ever use foam-box impression casts to capture the shape of the patient's foot, when prescribing CAD/CAM insoles?

Response % (number of replies)

Yes 95.6% (87/91)
No 1.1% (1/91)
No response 3.3% (3/91)

Question 3.3: Is the negative foam-box impression cast **usually** scanned into the CAD/CAM system, or is it filled with plaster first and then the positive model scanned?*

Response % (number of replies)
Response received 100.0% (87/87)
No response 0.0% (0/87)

* Only those who responded “Yes” to question 3.2 were required to answer this question. Therefore the total number of possible respondents is 87.

Question 3.4: Are the foam-box impression casts usually transported to another site to be scanned into the CAD/CAM system?

Response % (number of replies)
Response received 100.0% (87/87)
No response 0.0% (0/87)

* Only those who responded “Yes” to question 3.2 were required to answer this question. Therefore the total number of possible respondents is 87.

Question 3.5: Does your orthotic service ever use slipper casts / plaster casts to capture the shape of the patient's foot, when prescribing CAD/CAM insoles?

Response % (number of replies)
Yes 58.2% (53/91)
No 38.5% (35/91)
No response 3.3% (3/91)

Question 3.6: Are the slipper casts / plaster casts usually transported to another site to be filled with plaster and scanned into the CAD/CAM system?

Response % (number of replies)
Response received 100.0% (53/53)
No response 0.0% (0/53)

* Only those who responded "Yes" to question 3.5 were required to answer this question. Therefore the total number of possible respondents is 53.

Question 3.7: In your orthotic service, which is the **most common method** used to capture the shape of the patient's foot, when prescribing CAD/CAM insoles

Response % (number of replies)
Response received 97.8% (89/91)
No response 2.2% (2/91)

Question 3.8: Who is **usually** responsible for performing the modelling/rectification of the CAD/CAM insoles that your orthotic service provide?

Response % (number of replies)

Response received 97.8% (89/91)
No response 2.2% (2/91)

Question 3.9: In your orthotic service, what are the reasons for using CAD/CAM insoles?

Response % (number of replies)
Response received 86.8% (79/91)
No response 13.2% (12/91)

Appendix 44 - Article publication: *Comparing the effectiveness of computer-aided design/computer-aided manufacturing (CAD/CAM) of insoles manufactured from foam box cast versus direct scans on patient-reported outcome measures: a protocol for a double-blinded, randomised controlled trial*. Barr L, Richards J, Chapman GJ. BMJ Open. 2024 April; 14(4). doi: 10.1136/bmjopen-2023-078240

Article link: https://bmjopen.bmj.com/content/14/4/e078240.abstract

Open access Protocol

BMJ Open

Comparing the effectiveness of computer-aided design/computer-aided manufacturing (CAD/CAM) of insoles manufactured from foam box cast versus direct scans on patient-reported outcome measures: a protocol for a double-blinded, randomised controlled trial

Laura Barr,[1,2] Jim Richards ,[2] Graham J Chapman [2]

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[1]Orthotic Department, Gartnavel General Hospital, Glasgow, UK
[2]Allied Health Research unit, University of Central Lancashire, Preston, UK

Correspondence to
Dr Graham J Chapman;
GChapman2@uclan.ac.uk

ABSTRACT

Introduction Custom insoles are a routine treatment for many foot pathologies, and the use of computer-aided design and computer-aided manufacturing (CAD/CAM) is well established within clinical practice in the UK. The method of foot shape capture used to produce insoles varies throughout orthotic services. This trial aims to investigate the effectiveness of two common shape-capture techniques on patient-reported outcomes in people who require insoles for a foot or ankle pathology.

Methods and analysis This double-blinded randomised controlled trial will involve two intervention groups recruited from a National Health Service orthotic service. Participants will be randomly assigned to receive a pair of custom CAD/CAM insoles, manufactured either from a direct digital scan or a foam box cast of their feet and asked to wear the insoles for 12 weeks. The primary outcome measure will be the Foot Health Status Questionnaire (FHSQ) pain subdomain, recorded at baseline (immediately after receiving the intervention), 4, 8 and 12 weeks post intervention. Secondary outcome measures will include FHSQ foot function and foot health subdomains recorded at baseline, 4, 8 and 12 weeks. The Orthotic and Prosthetic User Survey Satisfaction with Device will be recorded at 12 weeks. The transit times associated with each arm will be measured as the number of days for each insole to be delivered after foot shape capture. Tertiary outcome measures will include participant recruitment and dropout rates, and intervention adherence measured as the daily usage of the insoles over 12 weeks. The change in FHSQ scores for the subdomains and insole usage will be compared between the groups and time points, and between group differences in time in transit, cost-time analysis and environmental impact will be compared.

Ethics and dissemination Ethical approval was obtained from the Health Research Authority, London Stanmore Research Ethics Committee (22/LO/0579). Study findings will be submitted for publication in peer-reviewed journals, conference presentations and webinars.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This trial aims to investigate routine interventions that are used within the National Health Service, therefore the outcomes have the potential to impact on the decision-making within orthotic services across the UK and beyond.
⇒ The double-blinded design reduces the risk of bias from the participant and the investigator.
⇒ Single-centre design may limit the cohort.
⇒ The multiple follow-up points may lead to drop outs.

Trial registration number NCT05444192.

INTRODUCTION

The integration of computer-aided design (CAD) and computer-aided manufacturing (CAM) technologies has increased in prevalence in the orthotic industry over the past two decades.[1] The manufacture of bespoke foot orthoses, commonly known as insoles, involves capturing an image of the foot from which an insole is ultimately created. A fully digital system involves replacing each step of the traditional manufacture process with a computer-aided counterpart. As such, the manufacture of insoles using fully digital systems involves taking a digital scan of the foot to create a three-dimensional (3D) model, as opposed to the traditional method which commonly involves capturing a physical impression of the foot using a foam box or plaster cast.[2] The evolution of insole production with the introduction of CAD/CAM has led to the creation of two industry standards within National Health Service (NHS) orthotic services across the UK with

some services manufacturing CAD/CAM insoles using traditional foam box casts, while others have chosen to use direct digital scanning.

Digitisation of orthotic devices conceptualised gains in production speed and reduction in waste materials when compared with traditional manufacture using physical shape capture.[3] Yet, the continued interim stages of foam box casting and physical transportation of these foam box casts to manufacturers, which is required by services who do not own or have access to scanning equipment, sacrifice these benefits. Motivation and hesitation in transitioning to a fully digital workstream have been assumed, but are currently unsupported in the literature. A common reluctance to adopt direct digital scanning is based on the assumption that direct digital shape capture and foam box casts do not produce like-for-like models, and therefore cannot result in the production of equally effective insoles. Although differences in volume have been shown,[4–6] differences in the accuracy and reliability between methods remain unclear,[7] and ultimately differences in the treatment efficacy and resulting effectiveness have not been evaluated. Other concerns centralise on costs associated with the acquisition of direct digital scanning equipment. Although prior cost analyses have shown a fully digital supply chain to be more expensive than a fully traditional supply chain,[3] this does not reflect the practices associated with a partially digital workflow as seen across the NHS. Furthermore, it does not consider a cost comparison over the lifespan of a direct digital scanner, or the environmental impact of the manufacture, transportation and disposal of traditional cast materials.

Overall, the evidence base relating to CAD/CAM insoles demonstrates little consistency or rationale behind the mode of shape capture used during the insole manufacturing process. Often the shape-capture method is undocumented or unclear,[8] or documented without any attributed clinical reasoning.[9–11] In 2019, Parker *et al*[8] investigated the differences in a fully digital workflow compared with fully traditional manufacturing techniques, but did not investigate the specific impact of shape capture in isolation. Furthermore, the aforementioned studies report no consideration as to the environmental impact of phenolic foam production and disposal required for traditional foot shape capture,[12 13] or the carbon footprint of transportation from manufacturer to digital upload of the foot shape from the foam box cast, a step which is not required when using direct digital scan techniques. In line with NHS Net Zero targets,[14] and the recognition of orthotic services throughout the UK that a large-scale change is required to achieve this,[15] the practice of single-use traditional shape-capture techniques requires scrutiny. It is clear from the literature and current widespread indiscriminate practices across NHS orthotic services that more research is required to assist with best practice and decision-making in the manufacture of CAD/CAM insoles.

In NHS Greater Glasgow and Clyde (GGC), the largest NHS Health Board in Scotland, CAD/CAM insoles represent 14% (n=2739, per annum in 2020) of all orthotic department provision. Assuming a similar proportion throughout the rest of the UK, this represents a significant proportion of orthotic service users and financial burden to the NHS. Given the proportion of orthotic service users who receive insoles from NHS orthotic services, this trial has the potential to guide practice towards beneficial changes in patient outcomes, as well as providing NHS orthotic departments with information to assist in the development of long-term service models in line with NHS and Government efficiency and net zero targets.

Study aims and objectives

The aim of this trial is to evaluate the clinical effectiveness of two commonly used foot shape-capture techniques for the manufacturing of custom CAD/CAM insoles over 12 weeks. The primary objective is to compare the changes in self-reported foot pain between two groups of participants randomly assigned to receive custom CAD/CAM insoles manufactured from direct digital foot scan or foam box casting. We hypothesise that the outcomes will be equivalent for the two methods. Secondary objectives include comparing the changes in foot function, foot health, satisfaction with treatment, time in transit, cost-time analysis and environmental impact between the two methods.

Trial design

We propose a single-centre, double-blinded, randomised controlled trial comparing the effectiveness of two methods of foot shape capture to manufacture custom-made insoles. This is an interventional, equivalence trial using medical devices commonly known as insoles.

METHODS AND ANALYSIS

Study setting

Participant assessment and treatment will be provided in a hospital setting, within the NHS GGC orthotic department. There will be one trial site located at the Glasgow Royal Infirmary. This trial will minimise participant on-site visits by using telephone contacts throughout the participation period to collect relevant participant reported outcome measures. At the conclusion of the participants' involvement in the trial, they will transition back to usual care within the NHS GGC orthotic department. The study protocol has been reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials guidelines.[16]

Participant recruitment

Individuals referred to the NHS GGC orthotics service with a musculoskeletal (MSK) medical condition or lower limb biomechanical deficit which would commonly be treated with the use of insoles as a first or second line intervention following the NHS GGC MSK Foot and Ankle Pathway[17] will be offered the opportunity to enrol

Table 1 Participant eligibility criteria

Inclusion	Exclusion
► Aged 18 years or above. ► Referred to the NHS GGC orthotic service requiring a new assessment for insoles. ► Deemed suitable for CAD/CAM insoles as assessed by the PI or Co-I on clinical assessment. ► Able to commit to five appointments over a 16-week period (two face-to-face appointments and three telephone appointments). ► Have suitable own outdoor footwear that can accommodate a CAD/CAM insole as assessed by the PI or Co-I and can wear these for 12 weeks in accordance with standard practice. ► An adequate understanding of written and verbal information in English in order to provide informed consent and answer the study questionnaires.	► Scheduled elective surgery or other procedures which is likely to affect mobility during the trial. ► Scheduled steroid injections to the foot or ankle up to 3 months prior to joining or during the trial. ► Aged<18 years. ► Adults with incapacity, under The Adults with Incapacity (Scotland) Act. ► Participant unable or unwilling to consent. ► Medial longitudinal arch height of the foot exceeds depth of EVA blank (35 mm). ► Clinical assessment concludes that the participant requires an insole material other than EVA. ► Clinical assessment concludes that the participant does not require or will be unlikely to benefit from CAD/CAM insoles, as outlined in the NHS GGC Foot and Ankle Pathway.[17] ► The participant is unable to commit to the trial conditions. ► Peripheral neuropathy present. ► Active foot ulceration present. ► Participants with life expectancy of less than 6 months. ► Any other significant disease or disorder which, in the opinion of the PI or Co-I, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial. ► Participants who have participated in another research trial involving an investigation of foot orthosis in the past 12 weeks.

CAD, computer-aided design; CAM, computer-aided manufacturing; Co-I, co-investigator; EVA, ethylene vinyl acetate; GGC, Greater Glasgow and Clyde; NHS, National Health Service; PI, primary investigator.

in the trial. In order to provide a realistic representation of day-to-day clinical practice, participants' pathology will not be limited to one specific pathology, a similar approach taken in other studies investigating orthoses for non-specific lower limb MSK pathologies.[10 18 19] Table 1 provides detail of the inclusion and exclusion criteria.

Assessments

Figure 1 shows the study flow chart for eligible participants. At the initial visit, participants will attend a face-to-face hospital visit to be assessed and screened according to the inclusion and exclusion criteria. Having read the participant information sheet for the trial and having the opportunity to ask further questions, participants will sign a consent form and formally enrol in the trial. During the baseline assessment, relevant medical history will be recorded, as well as any routine medications taken by the participant. Physical examination of the foot and ankle will include the Foot Posture Index-6,[20] Jacks test for functional hallux limitus,[21] palpation technique for subtalar joint axis location,[22] passive assessment of ankle dorsiflexion stiffness by position of first detectable resistance,[23] supination resistance test[24] and a visual gait analysis in the sagittal and coronal planes. Following the clinical assessment, participants will undergo both a direct digital scan and foam box cast of their feet so that the participants are unaware of which manufactured insole group they will be randomly assigned to. Direct digital scans will be acquired using the Paromed ParoScan 3Dm mobile 3D scanner and foam box casts will be taken using 6 cm deep 'Foot Impression Boxes' (Algeos, UK). In order to minimise any differences between casting and scanning methods, all foam box casts and direct digital scans for all participants will be taken by the primary investigator (PI) who has over 15 years' experience in the assessment, shape capture and design of insoles. All foam box casts and direct digital scans will be taken in a semiweight bearing position, with the participant seated, and shape capture undertaken one foot at a time, with the contralateral foot positioned on the floor. The foot will be manipulated by the clinician into the optimal position as determined by the participant's clinical assessment, the presenting MSK pathology and the Foot Posture Index (FPI), before being placed into the foam box and the scanner. For example, in instances of pathologies affecting the medial aspect of the foot, ankle or leg, and where FPI values are between 0 and +12, an external rotational force will be applied to the participants leg by the clinician, effectively supinating the foot in the foam box cast and on the direct digital scanner. Conversely, in instances of pathology affecting the lateral

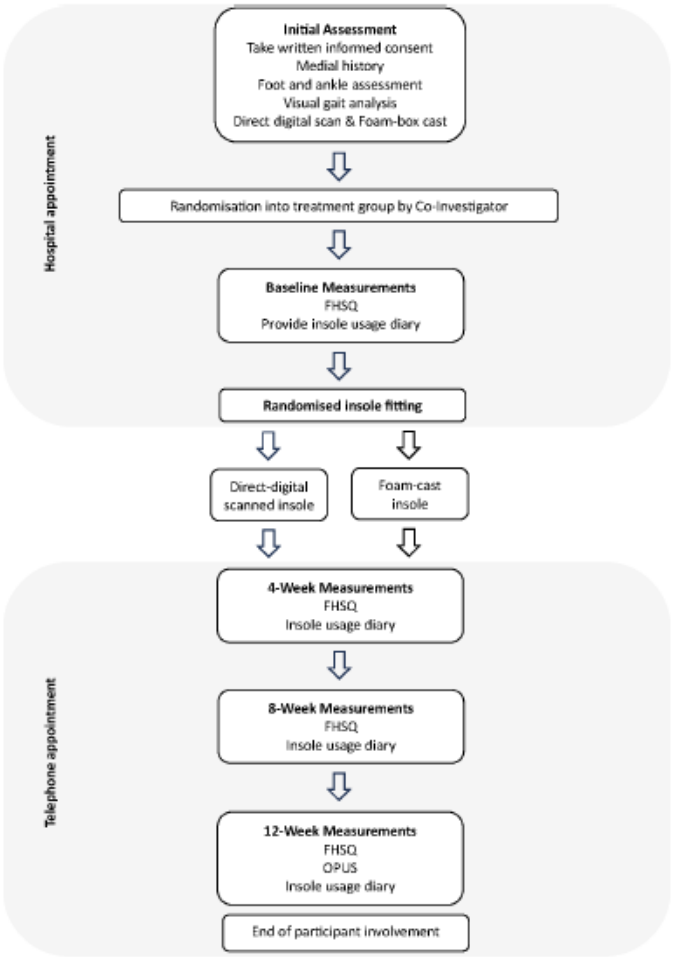

Figure 1 Study flow chart for eligible participants. FHSQ, Foot Health Status Questionnaire; OPUS, Orthotic and Prosthetic User Survey Satisfaction with Device.

aspect of the foot, ankle or leg, and where FPI values are between 0 and −12, an internal rotational force will be applied to the participants leg by the clinician, effectively pronating the foot in the foam box cast and on the direct digital scanner. Where the participant has mobility of the first ray and the insole prescription is to be designed to facilitate first ray plantarflexion, the clinician will manipulate the first ray into a plantarflexed position by applying a downward force to the first metatarsal head in the foam box cast and onto the direct digital scanner. These example techniques described for positioning the leg, foot and first ray are similar to those described in previous literature regarding the effectiveness and repeatability of casting and scanning techniques.[10 25]

Randomisation

At the end of the initial visit, participants will be randomised to either the direct digital scan or foam box cast manufactured insole group. Randomisation will be conducted according to a random number algorithm, contained in presealed envelopes. The envelopes will be opened on a 1:1 basis by the co-investigator (Co-I). The PI and the participants will be blinded to the treatment arm.

In the event of a participant experiencing an adverse event and/or the medical condition of a participant necessitates unblinding, a Co-I (not blinded to the randomised intervention) will access the CAD/CAM insole ordering system to confirm the treatment arm. This process will

not unblind the whole trial, nor will it disclose the randomisation schedule.

Interventions

All participants will receive a pair of custom CAD/CAM ethylene vinyl acetate (EVA) insoles. The insoles will be manufactured from the allocated randomised technique; either direct digital scan or foam box cast which will then be scanned into the CAD/CAM system (ParoManager Paro360 V.1.99, Paromed, Germany). All scanned CAD/CAM images will then be modelled by the PI, who is blinded to the treatment arm, and has over 15 years' experience using the ParoManager CAD/CAM modelling system. The insole prescription and design will be conferred by the PI and the Co-I who assessed the participant. The authors acknowledge that it is not possible to design a prescription protocol due to the variety of presentations that will be recruited to the trial. In accordance with standard practice, insole prescription will be determined by the physical and biomechanical assessment for each participant and will be conferred by two experienced clinicians at the time of assessment. Prescriptions are likely to include a variety of functional design features, for example, this may include the use of medial heel wedging for participants presenting with medial foot, ankle or lower limb pathology,[26 27] and medial heel skives may be considered if participants do not present with plantar heel pain.[28] Medial forefoot wedges will be considered for participants presenting with medial foot or ankle pathology and a concurrent forefoot varus.[29] Conversely, the use of lateral forefoot wedges may be included for participants with a lateral foot or ankle pathology.[30] Heel raises will be considered where there is reduced range of ankle dorsiflexion, posterior or plantar heel pain, or leg length discrepancy.[31] Metatarsal domes may be considered in conjunction with other functional design elements for participants with plantar forefoot pathology.[32] The EVA Shore hardness will be determined by the individual characteristics of the participant assessment. Participants with moderate-to-high supination resistance score or medially deviated subtalar joint axes will be considered for harder EVA insoles (50–70 Shore). Those participants with a low supination resistance score will be considered for insoles with a hardness 30–40 Shore. Participants with characteristics such as forefoot plantar fat pad atrophy will be considered for mixed 30/50 or 50/70 Shore EVA, where the Shore harness at the forefoot is softer.

Follow-up

After 3 weeks of the initial assessment, participants will return to the hospital setting for their insoles to be fitted. At this appointment, baseline outcome measures will be collected and participants will be provided with a diary to record their daily insole use. Outcome measures and insole use will be collected via telephone appointments at 4, 8 and 12 weeks post baseline. Any issues with the insoles can also be raised by participants at these time points, and appropriate action will be taken by the research team to resolve and record any issues or adverse events that may have arisen. Participants will also be provided with contact details for the NHS GGC orthotic department and the research team, to raise any issues out with these time points, and appropriate resolution will be agreed and recorded on a case by case basis.

Outcome measures

Patient-reported outcome measures will be collected at baseline, 4, 8 and 12 weeks of insole use. The Foot Health Status Questionnaire (FHSQ) has validated subdomains for pain, function and foot health,[33–35] which will be completed at each time point. These will be considered using inferential statistics and minimal important differences.[36] The primary outcome measure will be the FHSQ pain subdomain, with the subdomains for function and foot health being used as secondary outcome measures. The Orthotic and Prosthetic User Survey Satisfaction with Device (OPUS) will also be used as a secondary outcome measure, completed after 12 weeks of insole use, to evaluate the patient satisfaction.[37 38] A further secondary outcome measure will include the time in transit, measuring the number of days for each insole to be delivered to the trial site after foot shape capture. This will allow an analysis of insole production in NHS GGC during the trial period, relating to the environmental impact of the required phenolic foam production[13] and carbon footprint of transportation from manufacturer to digital upload of foam box cast using carbon footprint calculations.[12] Tertiary outcomes will include measurement of the recruitment rate and dropout rate for the duration of the trial, and participant adherence to the trial protocol whereby participants will be asked to keep a diary of daily wear time, in accordance with prior publications on measuring orthotic adherence.[39] The minimum threshold for adherence for this trial is considered to be >21 hours per week.[40]

Sample size

A sample size power calculation, based on data from Landorf *et al*[36] regarding FHSQ, was used to detect a clinically important difference between groups of 13 (SD=26.9) points in FHSQ scores using the pain subdomain as the primary outcome. Giving a required minimum sample size of 54 participants in each group and including a 5% dropout rate, 57 participants will be recruited into each group, thus requiring a total sample size of n=114.

Data management and auditing

On entering the study, participants will be given a unique trial number to ensure participant anonymity throughout the trial. The unique trial numbers and participant details will be stored securely and separate from the project files. All data and personal information will comply with the requirements of the General Data Protection Regulation 2018. Data handling will comply with standard operating procedures of the trial sponsor (NHS GGC) and the

University of Central Lancashire. Trial monitoring will be conducted by the sponsor (NHS GGC).

Adverse events

This trial is considered a low-risk trial for adverse events by the sponsor (NHS GGC). Any adverse events will be recorded and reported to the trial sponsor.

Withdrawal of participants from study

During the course of the trial, a participant may choose to withdraw from the trial at any time. This may happen for a number of reasons, including but not limited to the occurrence of what the participant perceives as an intolerable adverse event, inability to comply with trial procedures or participant decision without reason. In addition, the PI may discontinue a participant from the trial treatment at any time if the PI considers it necessary for any reason including, but not limited to ineligibility arising during the trial that is, development of a medical condition as outlined in the exclusion criteria, or significant non-compliance with treatment regimen or trial requirements that is, participant has not worn or unable to wear the insoles between appointments. The type of withdrawal and reason for withdrawal will be recorded in the case report form.

Missing data

Missing follow-up data for the primary and secondary outcome measures are likely to be minimal, with missing data potentially due to participant dropout. If one or more observations are missing, the last observation recorded will be carried forward in the primary analysis; however, for those patients who dropout, at least one follow-up time point will be required for the data to be carried forward. Data for participants who do not reach the minimum self-reported adherence threshold of >21 hours per week, calculated as an average across the 4-week, 8-week and 12-week time points, will still be included in the final between-group analysis to establish if adherence differs between groups.

Patient and public involvement

The study protocol and documentation were prepared with input from five patients who attended the NHS GGC orthotics service. On reviewing the patients' constructive feedback, the study design was refined to incorporate telephone follow-up appointments to minimise participant commitment to face-to-face appointments.

Statistical analysis

The primary and secondary outcome measures will be compared between groups at the specified data collection time points: baseline, 4, 8 and 12 weeks, using mix methods analysis of variance or Friedman tests with post hoc Wilcoxon tests for within group analysis and Mann-Whitney U tests for between group analysis if the data are not normally distributed. The change in OPUS scores for the subdomain of satisfaction with device will be compared between groups at the specified data collection time point of 12 weeks, using unpaired t-tests or Mann-Whitney U tests depending on the data distribution.

Ethics and dissemination

Ethical approval has been obtained from London Stanmore Research Ethics Committee (22/LO/0579), and the trial is registered on ClinicalTrials.gov and any protocol amendments will be numbered and uploaded to this site. This trial has been written and will be performed according to the Declaration of Helsinki. The results from the trial will be presented at national and international conferences, webinars and published in peer-reviewed journals. Authorship eligibility will be based on the recommendations from the International Committee of Medical Journal Editors.

Data sharing

Data generated from this study will be made available for research and academic purposes, after the publication of the trial results, on request via email to the corresponding author. Available data will include anonymised individual participant data, the study protocol, statistical analysis plan, informed consent and analytic codes.

Twitter Graham J Chapman @g_j_chapman

Contributors All authors contributed to the design of this protocol. LB conceived the randomised controlled trial. GJC provided methodological expertise. JR completed the sample size calculation and designed the plan for statistical analysis. LB wrote the first draft of this manuscript and all authors gave critical feedback for revisions of this manuscript and approved the final version of this manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

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Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Jim Richards http://orcid.org/0000-0002-4004-3115
Graham J Chapman http://orcid.org/0000-0003-3983-6641

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Appendix 45 - Article publication: *To scan or not to scan? Comparing the effectiveness and cost differential of insoles manufactured from foam-box casts versus direct scans in treating musculoskeletal conditions of the foot and ankle: A double-blinded, randomised controlled trial.* Barr L, Richards J, Dickson C, Tawse J, Munro N, Scott H, Holland A, Chapman GJ. BMC Musculoskeletal Disorders. 2025 March; 26(282). doi: 10.1186/s12891-025-08513-2

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To scan or not to scan? Comparing the effectiveness and cost differential of insoles manufactured from foam-box casts versus direct scans in treating musculoskeletal conditions of the foot and ankle: a double-blinded, randomised controlled trial

Laura Barr[1,2], Jim Richards[2], Colette Dickson[1], Jillian Tawse[1], Nikki Munro[1], Hannah Scott[1], Aimie Holland[1] and Graham J. Chapman[2*]

Abstract

Background Foot orthoses produced using computer-aided-design and manufacture (CAD/CAM) are commonly used to treat musculoskeletal conditions of the foot and ankle, however minimal evidence exists as to the most effective method used to capture the patients foot shape. This trial aimed to determine the effectiveness and cost of insoles manufactured from a direct scan of the foot compared with those manufactured from foam-box casts.

Methods This double blinded clinical trial randomly assigned participants with lower limb musculoskeletal pathologies into two groups and provided them with custom CAD/CAM foot orthoses manufactured either from a direct scan of the participants' feet (direct scan group) or from foam-box casts of their feet (foam-box cast group). 114 participants were recruited and asked to wear their foot orthoses for 12-weeks. The Foot Health Status Questionnaire (FHSQ) was completed at baseline, 4, 8 and 12-weeks to evaluate the primary outcome measure of pain, as well as secondary outcomes for foot function, foot health and footwear, and the Orthotic and Prosthetic User Survey Client Satisfaction with Device module (OPUS-CSD) was completed at 12-weeks. Adherence was measured using a daily wear-diary recorded over 12-weeks. The number of manual insole adaptations was also recorded, and staff time, material and transportation costs were evaluated.

Results 112 participants completed the trial. Despite no significant between-group differences, both groups reported significant improvements in pain, function and foot health from baseline to 4, 8 and 12-weeks, which all exceeded their respective minimum important differences. The direct scan group reported greater satisfaction at

*Correspondence:
Graham J. Chapman
GChapman2@Uclan.ac.uk

Full list of author information is available at the end of the article

12-weeks ($p = 0.04$), greater adherence ($p < 0.001$), and required less insole adaptations ($n = 4$) compared to the foam-box cast group ($n = 15$) ($p = 0.006$). Overall costs and staff time costs were higher in the foam-box cast group.

Conclusions CAD/CAM insoles are effective in reducing pain, and improving foot function and foot health after 4-weeks, and sustained at 12-weeks, however the method of shape capture does not affect these responses. Over 12-weeks participant satisfaction and adherence was greater when using the direct scan approach, which also required fewer manual insole adaptations. There was a greater overall cost associated with foam-box insoles. Clinicians are therefore recommended to use direct foot scanning over foam-box casting when prescribing CAD/CAM insoles for patients with musculoskeletal foot and ankle conditions.

Trial registration ClinicalTrials.gov, trial number NCT05444192. Trial registration date 30th June 2022.

Keywords Foot orthoses, Insoles, CAD/CAM, Foot pain

Background

Foot orthoses, hereafter referred to as insoles, are often used as a treatment for musculoskeletal (MSK) conditions of the foot and ankle. Insoles have been shown to be effective in the management of pain associated with MSK conditions, and offer a non-invasive means of improving painful symptoms, leading to improved foot function, and quality of life [1–5]. In traditional insole manufacture the most common method of shape-capture involves the use of a foam-box to create a physical cast from which the insoles are then designed [6]. Advances in technology whereby insoles are produced using computer aided design and manufacture (CAD/CAM) offer an alternative shape-capture method by use of a direct scan of the patient's foot [7]. Publications that highlight the benefits of CAD/CAM assume a fully digitised approach to insole production where every step of the process from foot shape capture to final manufacture is undertaken using digital technology [8]. One of the primary focuses of CAD/CAM benefits is the reduction of waste products [9], which in the context of insole production would include single use items such as foam-box casts. However CAD/CAM systems allow clinicians to continue using traditional foot capture techniques, such as the use of foam-box casts, and then upload a digital image of the cast into the CAD/CAM system, rather than directly scanning the patient's foot. This interim step in the CAD/CAM process is common in the industry [10] and changes a fully digital process into a hybrid-digital process, and to the author's knowledge, the differences in treatment outcomes between the two methods is unknown. Studies focusing on CAD/CAM insole production interchangeably use digital direct scanning and traditional shape capture methods such as foam-box casts, or do not clarify the shape capture method used [3, 11–13]. Expense and clinical preference have been suggested as possible barriers to fully digital CAD/CAM systems in the orthotic industry [14–16], but the lack of evidence to help guide services and clinicians makes it difficult to address these barriers. Furthermore, publications examining different shape capture methods tend to primarily focus on the physical dimensions and morphology of the foot models [17], but to the author's knowledge, it is unknown if these differences affect the final insole in relation to treatment outcomes.

Trial aim

We conducted a randomised clinical trial with a double blinded design that compared the effectiveness of custom-made CAD/CAM insoles produced from foam-box casts to those manufactured from direct scans of the patient's feet. We hypothesised that there would be no difference in patient reported outcome measures between the groups at 12-week follow-up.

Methods

Trial design

The study was performed according to a previously published protocol [18]. In brief, we undertook a double blinded, equivalence, randomised controlled trial in a National Health Service (NHS) Orthotic Department, where the effectiveness of treatment with custom-made CAD/CAM insoles produced from foam-box casts were compared with custom-made CAD/CAM insoles produced from direct scans of the patients' feet, with follow-up at 4 weeks, 8 weeks and 12 weeks. This study followed the CONSORT guidelines and reported required information accordingly.

Participants

In this single centre study conducted in NHS Greater Glasgow and Clyde (GGC), the research team screened adults aged 18 years or above, who were referred to the Orthotic service for assessment due to a MSK condition or lower limb biomechanical deficit who required treatment with an insole according to the NHS GGC MSK Foot and Ankle treatment Pathway [19]. A pragmatic approach was taken with participant recruitment and presenting conditions yielding a cohort with heterogeneous MSK pathology, which reflects current day-to-day clinical NHS practice. Inclusion in the study was considered if participants were deemed suitable for treatment

with CAD/CAM insoles following assessment by the research team; were able to commit to two face-to-face appointments and three telephone appointments over a 16 week period; had footwear which were able to accommodate a CAD/CAM insole; and had an adequate understanding of verbal and written English. Participants were excluded from the study if they were scheduled for surgery which was likely to affect their mobility during the trial period; were scheduled for a corticosteroid injection to the foot or ankle up to three months prior to or during the trial; were registered as an adult with incapacity under the Adults with Incapacity (Scotland) Act; had a medial longitudinal arch height greater than 35 mm; required an insole manufactured from a material other than ethylene vinyl acetate (EVA); were unable to commit to the trial conditions; had peripheral neuropathy; had active foot ulceration; had a life expectancy less than six months; had a disease or disorder which would put them at risk because of participation in the trial; or had participated in another research trial involving investigation of a foot orthosis in the past 12 weeks. Potential participants were provided with verbal and written information and assessed for suitability before providing written informed consent.

Patient and public involvement

Prior to the trial, clinical staff in the NHS GGC orthotic service consulted with patients attending appointments to establish if the trial aims and design aspects were of importance to them. Following a review of this feedback the study design was refined to reduce the number of face-to-face appointments by including telephone follow-ups at the week 4, week 8 and week 12 time points.

Randomisation and blinding

Baseline assessment was carried out before randomisation. Following the baseline assessment, which was undertaken by the primary investigator (PI) and the co-investigator (Co-I), both a direct scan and foam-box cast were taken of all participants' feet so that the participants would be unaware of which insole group they would be randomly assigned to. Randomisation to either the direct scan group or the foam-box cast group was undertaken according to a random number algorithm, contained in pre-sealed envelopes. The envelopes were opened on a 1:1 basis by the Co-I only, ensuring that the PI and the participants remained blinded to the treatment arm for the duration of the study.

Interventions

Insole prescriptions were agreed on an individual participant basis by the PI and the Co-I during the baseline assessment. The PI (blinded to the treatment arm) modelled two pairs of insoles to the same prescription for each participant; one using the direct scan and one using the foam-box cast which was scanned into the CAD/CAM system following the baseline assessment. The Co-I (not blinded to the treatment arm) instructed the manufacturing team which insoles to manufacture according to the randomly assigned treatment arm. Participants attended a fitting appointment with the PI only where they were fitted with their custom CAD/CAM insoles.

Outcome measures

Baseline outcome measures were collected at the fitting appointment, follow-up outcome measures were collected during the telephone appointments at week 4, week 8 and week 12. The primary outcome measure was the pain subdomain of the Foot Health Status Questionnaire (FHSQ), which was collected at all time points. The FHSQ is a validated patient-reported outcome measure comprising of 13 questions, producing scores for 4 subdomains including pain, function, foot health and footwear, with possible scores from 0 (worst outcome) to 100 (best outcome) [20–22].

Secondary outcomes included the FHSQ subdomains for function, foot health and footwear, collected at all time points. Insole adherence was measured using a self-reported wear diary which all participants were asked to complete on a daily basis for the 12-week trial period indicating the number of hours they wore their insoles each day. The minimum threshold for adherence was >21 h per week, in keeping with a prior clinical study [23]. Insole satisfaction was measured during the final follow-up appointment at week 12, using the Orthotic and Prosthetic User Survey Client Satisfaction with Device module (OPUS-CSD) [24, 25]. The OPUS-CSD module is a patient-reported outcome measure including nine questions about the overall experience with the orthotic device, producing raw scores from 0 (least satisfaction) to 36 (most satisfaction) which were then converted to Rasch scores 0 (least satisfaction) to 100 (most satisfaction), as this produces a linear internal-level scale which accounts for the importance of the individual survey questions [26, 27].

Sample size

The sample size was calculated based on the minimally important difference (MID) for the primary outcome of pain using the FHSQ of 13 with a standard deviation of 26.9 [28]. As such, recruitment of 114 participants (57 per group) was required at a 5% significance level, with 90% power, allowing for 5% drop out.

Cost analysis

The cost of service use was determined using published national unit costs available from the time of data collection [29, 30]. Staff costs were calculated using mid-point

NHS Band 6 pay scales for clinical costs and mid-point Band 4 for technical costs (£52 and £35 per hour respectively), as recommended by Jones and Burns et al. [29] which accounted for overheads, capital overheads and inflated on-costs. Individual item costs for EVA blanks and foam-box casts included value added tax (VAT) and delivery charges.

Statistical analysis

Statistical analysis was undertaken at the end of the trial by a member of the research team (JR), who was blinded to the intervention allocation, using SPSS (version 29). In accordance with the statistical plan outlined in the protocol, where data was missing for no more than two follow-up appointments, the last observation recorded was carried forward in the primary analysis. To assess the potential impact of missing follow-up data, a sensitivity analysis was performed using worst-case and best-case scenarios; in the first scenario all missing data from the direct scan group were assumed to correspond to the least favourable outcome with all missing data from the foam-box cast group corresponding to the most favourable outcome, in the second scenario these assumptions were reversed. The results were compared to the primary analysis to evaluate the robustness of the findings.

The main analysis investigated between-group differences in the primary and secondary outcome measures for the treatment groups at all time points. The distribution of the data was determined using Kolmogorov-Smirnov tests. Normally distributed data with only one time point were analysed using independent sample t-tests, those with more than one time point were assessed using Mixed methods ANOVA and post hoc pairwise comparisons where significant main effects were seen. For non-normally distributed data with only one time point Mann Whitney U tests were performed, for data with more than one time point Friedman's tests were first used to establish any within-group differences with post hoc Wilcoxon signed rank tests for those where significant differences were identified, and Mann Whitney U tests were used to test for between-group differences with post hoc frequency tests for each time point. Minimally important differences were used at each time interval for the primary outcome measure, as well as the secondary outcomes of function, foot health and footwear.

With regard to the primary aim of the trial we felt it was clinically relevant to include any association between group allocation and the requirement for manual insole adjustment by the clinician during the trial period, and the effect of group allocation on the requirement for manual insole adjustment was assessed using a Chi-square test.

Results

Participants and attrition

Screening and recruitment was undertaken at the NHS GGC Orthotic service between 29 September 2022 and 06 July 2023. During this period 118 adults with an MSK pathology of the foot or ankle were screened. Of these, four either declined to participate or were excluded due to ineligibility. Overall 114 consented to participate in the trial and were randomly assigned to receive an insole manufactured from a foam-box cast ($n=57$) or a direct scan ($n=57$) (see Fig. 1). For the whole cohort, participants were predominantly female (72%, $n=82$), with a median age of 50 years, and median body mass index (BMI) of 29.78. The randomised groups were found to be well balanced across baseline characteristics (Table 1).

All participants in the direct scan group completed the trial and in the foam-box cast group, two participants were lost to follow-up before the trial end point, with an attrition rate of 3.5%, thus keeping the sample size above the 5% allowance for dropout. One of the two participants who were lost to follow-up before the trial end point missed more than two follow-up appointments and their data could therefore not be carried forward in the analysis, as such 56 participants were included in the final analysis of the foam-box cast group and 57 in the direct scan group. With regard to missing data, in the direct scan group the last observation was carried forward for two participants from baseline to week 4, and in the in the foam-box cast group the last observation was carried forward for two participants from week 4 to week 8, this data was used for the primary analysis. The worst-case and best-case sensitivity analyses produced results consistent with the primary analysis. While slight variations in the p-values were observed for some secondary outcomes, these changes were minor and did not affect the overall conclusions. No serious adverse events were reported. Nine participants reported adverse events which included discomfort in the arch area of the foot ($n=7$), the lateral midfoot ($n=1$) and the forefoot ($n=1$), and were resolved following review and manual adjustment of the insole; 7 participants in the foam-box cast group (4 within the first 4 weeks, 2 between week 4 and week 8, and 1 between week 8 and week 12), and 2 in the direct scan group (both within the first 4 weeks). Three participants experienced non-related adverse events; fell and sustained a broken toe ($n=1$), diagnosed with a tibial stress fracture after participating in high impact sport while not wearing insoles ($n=1$), fell and developed knee pain ($n=1$). 112 participants completed the final outcome measures at the 12-week follow-up appointment (Fig. 1).

Outcomes

The Kolmogorov-Smirnov tests showed that pain, foot function, foot health and footwear were not normally

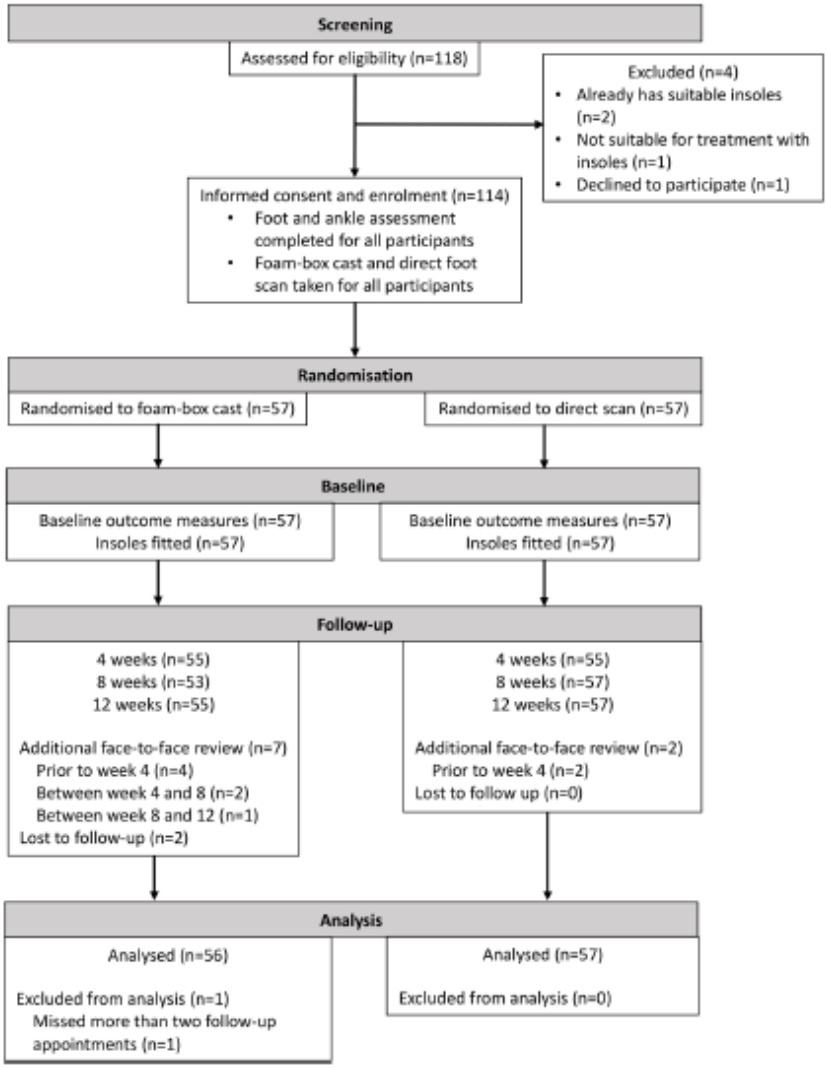

Fig 1 Study flow chart

distributed. OPUS-CSD and adherence both showed a normal distribution. For the primary outcome measure of pain, Friedman test demonstrated significant differences between time points for both the foam-box cast group ($p<0.001$) and the direct scan group ($p<0.001$). Post hoc Wilcoxon test demonstrated that compared to baseline, both the foam-box cast group and the direct scan group reported significant improvements in pain at week 4 ($p<0.001$ and $p<0.001$), week 8 ($p<0.001$ and $p<0.001$), and week 12 ($p<0.001$ and $p<0.001$) respectively, all of which exceeded the MID of 13. No significant change was observed between week 4 and 8 ($p=0.995$ and $p=0.509$), between week 4 and 12 ($p=0.312$ and $p=0.118$), or week 8 and 12 ($p=0.225$, and $p=0.117$) respectively. Mann-Whitney U tests demonstrated no significant between-group differences for pain at any time point (baseline $p=0.683$, week 4 $p=0.906$, week 8 $p=0.418$, week 12 $p=0.557$) (Table 2).

For foot function, Friedman test demonstrated significant differences between time points for both the foam-box cast group ($p<0.001$) and the direct scan group ($p<0.001$). Compared to baseline, post hoc Wilcoxon test demonstrated that the foam-box cast group and the direct scan group reported significant improvements in function at week 4 ($p<0.001$ and $p<0.001$), week 8 ($p<0.02$ and $p<0.001$), week 12 ($p<0.001$ and

Table 1 Baseline demographics and clinical characteristics of participants by allocated treatment group. Number of participants (percentage) unless otherwise stated

Characteristics	Foam-box cast ($n=57$)	Direct scan ($n=57$)	Overall ($n=114$)
Sex			
Male	16 (28)	16 (28)	32 (28)
Female	41 (72)	41 (72)	82 (72)
Ethnicity			
African	1 (2)	0 (0)	1 (1)
Other (mixed)	0 (0)	1 (2)	1 (1)
White	56 (98)	56 (98)	112 (98)
Age (median (IQR))	50 (32.0, 61.0)	50 (34.0, 59.0)	50 (33.00, 60.00)
BMI (median (IQR))	30.28 (24.91, 35.53)	29.13 (25.86, 35.32)	29.78 (25.70, 35.40)
Primary area of MSK pathology*			
Ankle	21 (37)	24 (42)	45 (39)
First ray	3 (5)	10 (18)	13 (11)
Forefoot	17 (30)	10 (18)	27 (24)
Lower leg	0 (0)	1 (2)	1 (1)
Midfoot	4 (7)	1 (2)	5 (4)
Plantar heel / plantar fascia	12 (21)	11 (19)	23 (20)
Affected side			
Left	28 (49)	26 (46)	54 (47)
Right	29 (51)	31 (54)	60 (53)
Medication			
Biologics	2 (4)	4 (7)	6 (5)
DMARDs	7 (12)	9 (16)	16 (14)
NSAIDs	6 (11)	8 (14)	14 (12)
Oral steroids	3 (5)	2 (4)	5 (4)
Analgesics	23 (40)	15 (26)	38 (33)

*Pathology detail: Ankle pathology including Achilles tendinopathy, lateral ankle ligament pathology, peroneal tendinopathy, peroneal subluxation, ankle joint osteoarthritis (OA), anterior ankle impingement, sub fibular impingement, talar fracture, deltoid ligament tear, posterior tibial tendon dysfunction. First ray pathology including first metatarsophalangeal (MTP) joint OA, symptomatic hallux valgus, symptomatic functional hallux limitus, first tarsometatarsal joint OA, sesamoiditis. Forefoot pathology including intermetatarsal neuroma / plantar digital neuritis, inflammatory arthropathy of the lesser MTP joints, plantar plate dysfunction, migration of plantar fat pad and forefoot overload. Lower leg including medial tibial stress syndrome. Midfoot pathology including dorsal midfoot impingement, talonavicular joint OA, spring ligament tear. Plantar heel / plantar fascia including calcaneal fracture, plantar fasciopathy, plantar fibroma, plantar heel pain associated with inflammatory arthropathy. DMARDs = Disease-modifying antirheumatic drugs. NSAIDs = non-steroidal anti-inflammatory drugs

$p<0.001$) respectively. For both groups, the MID of 7 was exceeded at all time points with the exception of baseline to week 8 for the foam-box group. A significant improvement in foot function was observed from week 8 to week 12 in the foam-box cast group ($p=0.019$). No significant changes were observed in either the foam-box cast group or the direct scan group from week 4 to week 8 ($p=0.234$ and $p=0.589$), week 4 to week 12 ($p=0.397$ and $p=0.412$) respectively, or week 8 to week 12 in the direct scan group only ($p=0.585$). Mann-Whitney U tests demonstrated no significant between group differences for foot function at any time point (baseline $p=0.556$, week 4 $p=0.818$, week 8 $p=0.077$, week 12 $p=0.322$).

For foot health, Friedman test demonstrated significant differences between time points for both the foam-box cast group ($p<0.001$) and the direct scan group ($p<0.001$). Compared to baseline, post hoc Wilcoxon test demonstrated that both the foam-box cast group and the direct scan group reported significant improvements in foot health at week 4 ($p<0.001$ and $p<0.001$), week 8 ($p<0.001$ and $p<0.001$), and week 12 ($p<0.001$ and $p<0.001$) respectively, all of which exceeded the MID of 0. A significant improvement in foot health was observed from week 4 to week 12 in the direct scan group only ($p=0.026$). No significant change was observed in either the foam-box cast group or the direct scan group from week 4 to week 8 ($p=0.261$ and $p=0.069$), week 8 to week 12 ($p=0.172$ and $p=0.417$) respectively, or week 4 to week 12 in the foam-box cast group only ($p=0.052$). Mann-Whitney U tests demonstrated a significant between-group effect at week 8 ($p=0.039$), with the direct scan group reporting significantly better foot health (median 72.5, IQR 25.00 to 85.00) compared to the foam-box cast group (median 46.25 IQR 25.00 to 69.38) (Table 2). No significant between group differences were observed for the other time points (baseline $p=0.336$, week 4 $p=0.158$, week 12 $p=0.080$).

For footwear, Friedman test demonstrated significant differences between time points for the foam-box cast group ($p=0.009$) but no significant differences were seen for the direct scan group ($p=0.344$). Post hoc Wilcoxon test demonstrated that, compared to week 4 the foam-box cast group reported significant worsening footwear scores at week 8 ($p=0.005$) and week 12 ($p=0.004$) exceeding the MID of -2. No significant change was observed from baseline to week 4 ($p=0.072$), baseline to week 8 ($p=0.59$), baseline to week 12 ($p=0.529$) or week 8 to week 12 ($p=0.682$). Mann-Whitney U tests demonstrated a significant between-group effect for footwear at week 8 ($p=0.047$) and week 12 ($p=0.022$), with the direct scan group reporting significantly better footwear scores compared to the foam-box cast group (Table 2). No significant between group differences were observed for baseline ($p=0.084$) or week 4 ($p=0.365$).

For OPUS-CSD Rasch scores, independent sample t-tests demonstrated a significant between group difference (mean difference 6.88, 95% CI 0.31 to 13.45, $p=0.04$) with the direct-scan group reporting greater satisfaction with their insoles at week 12 (Table 3). For adherence the Mixed methods ANOVA demonstrated a significant main effect of group ($p<0.001$), and no significant main effect of time ($p=0.515$), and no significant interaction effect between time and group ($p=0.731$). Post hoc analysis demonstrated that the direct scan group

Table 2 FHSQ pain, function, foot health and footwear subdomains. Values are median (IQR 25, 75) unless otherwise stated

FHSQ subdomain	Visit	Foam-box cast		Direct scan		Between-group *p*-value
		n	Median (IQR)	*n*	Median (IQR)	Mann Whitney U
Pain	Baseline	57	48.13 (29.38, 71.88)	57	53.75 (27.19, 72.5)	0.683
	Week 4	56	72.50 (57.19, 84.38)[a]	57	78.13 (48.13, 84.38)[a]	0.906
	Week 8	56	72.50 (49.53, 84.38)[a]	57	78.13 (54.06, 85.00)[a]	0.418
	Week 12	56	78.13 (53.75, 92.97)[a]	57	78.75 (53.75, 93.75)[a]	0.557
Within group p-values			**< 0.001***		**< 0.001***	
Function	Baseline	57	68.75 (43.75, 87.50)	57	62.50 (37.50, 90.63)	0.556
	Week 4	56	87.50 (57.81, 93.75)[a]	57	87.50 (62.50, 100.00)[a]	0.818
	Week 8	56	75.00 (51.56, 93.75)[a]	57	93.75 (59.38, 100.00)[a]	0.077
	Week 12	56	87.50 (68.75, 100.00)[a,c]	57	93.75 (65.63, 100.00)[a]	0.322
Within group p-values			**< 0.001***		**< 0.001***	
Foot Health	Baseline	57	25.00 (0.00, 60.00)	57	42.50 (0.00, 72.50)	0.336
	Week 4	56	42.50 (25.00, 72.50)[a]	57	60.00 (25.00, 85.00)[a]	0.158
	Week 8	56	46.25 (25.00, 69.38)[a]	57	72.50 (25.00, 85.00)[a]	**0.039***
	Week 12	56	60.00 (25.00, 81.88)[a]	57	72.50 (25.00, 85.00)[a,b]	0.080
Within group p-values			**< 0.001***		**< 0.001***	
Footwear	Baseline	57	33.33 (16.67, 58.33)	57	50.00 (25.00, 75.00)	0.084
	Week 4	56	41.67 (25.00, 64.58)	57	50.00 (25.00, 75.00)	0.365
	Week 8	56	25.00 (16.67, 58.33)[b]	57	50.00 (25.00, 75.00)	**0.047***
	Week 12	56	25.00 (10.42, 56.25)[b]	57	50.00 (25.00, 83.33)	**0.022***
Within group p-values			**0.009***		0.344	

* denotes significance; a denotes significantly different from baseline; b denotes significantly different from 4 weeks; c denotes significantly different from 8 weeks

IQR = Interquartile range

FHSQ = 0 to 100, higher scores indicate less pain

Table 3 Secondary outcome measures: OPUS-CSD Rasch scores, adherence (hours per day), manual insole adjustment (number of participants requiring insole adjustment). Results are presented as mean (95% CI) unless otherwise stated

Outcome Measure	Foam-box (95% CI)		Direct scan (95% CI)		Mean difference (95% CI)	*p*-value
	n		*n*			
OPUS-CSD	55	69.48 (64.59 to 74.36)	57	76.35 (71.84 to 80.86)	6.88 (0.31 to 13.45)	**0.04***
Adherence	56	5.08 (4.66 to 5.50)	57	6.09 (5.68 to 6.51)	1.02 (0.43 to 1.61)	**< 0.001***
Total number of manual adjustments (n)	57	*n* = 15	57	*n* = 4		**0.006* (Phi 0.26)**

* denotes significance

OPUS-CSD Rasch scores = 0 to 100, higher scores indicate greater satisfaction

showed greater adherence, wearing their insoles for a mean of 1.02 h longer per day (mean 6.09 h per day, 95% CI 5.68 to 6.51) compared to the foam-box cast group (mean 5.08 h per day, 95% CI 4.66 to 5.50) (Table 3). A chi-squared test found a significant association between group and requirement for insole adjustment ($p = 0.006$), with the foam-box cast group requiring more adjustments ($N = 15$) than the direct scan group ($N = 4$), with a moderate effect size (Phi 0.26) (Table 3).

Differential cost analysis

The hybrid-digital process for the foam-box cast group cost an average of £55.46 per participant compared with an average of £44.94 per participant using the fully digital process in the direct scan group, resulting in a 23.41% (£10.52) cost difference per participant between the groups (Table 4). Staff time accounted for most of the variation observed between the groups, with the foam-box cast group requiring an additional 9 h 4 min of staff time throughout the duration of the trial period (total staff time for foam-box cast group hh: mm = 51:03) compared with the fully digital process (total staff time for direct scan group hh: mm = 41:59), leading to a difference of £422.85 in total staff time costs.

Discussion

To the authors' knowledge, this is the first randomised controlled trial comparing the effectiveness of CAD/CAM insoles produced from two different shape capture techniques. Both groups reported significant improvements in pain, function and foot health scores within 4 weeks of wearing their allocated insole, which were sustained at 12 weeks, which supports our hypothesis of equivalence between techniques. Importantly, the direct scan group reported significantly greater satisfaction, better adherence and required significantly less manual

Table 4 Cost (£) and time (hh: mm) associated with different aspects of the hybrid-digital process for the foam-box cast group and the fully digital process for the direct scan group

Fully digital process: Direct-scan group								
Item/Activity	**Item cost per participant**	**Total item cost per group**	**Mean staff time (SD) per participant**	**Total staff time per group**	**Mean staff cost per participant**	**Total staff cost per group**	**Total cost per participant**	**Total cost per group**
Clinical time for foot shape capture	N/A	N/A	00:02 (00:00)	01:36	£1.47	£83.79		
Clinical modelling	N/A	N/A	00:14 (00:02)	12:59	£11.84	£674.97		
Technical manufacture	N/A	N/A	00:28 (00:10)	26:24	£16.21	£923.97		
EVA blank	£14.52	£827.64	N/A	N/A	N/A	N/A		
Service use (additional 30 min review appointment)	N/A	N/A	00:01	01:00	£0.91	£51.87		
Total	£14.52	£827.64	00:44	41:59	£30.42	£1,734.60	£44.94	£2,562.24
Hybrid-digital process: Foam-box cast group								
Foam-box	£1.97	112.29	N/A	N/A	N/A	N/A		
Clinical time for foot shape capture	N/A	N/A	00:01 (00:00)	00:57	£0.83	£47.31		
Transit per day (foam-box cast from trial site to manufacture site)#	£1.11	£29.97	N/A	N/A	N/A	N/A		
Technician cost for digital upload of foam-box cast	N/A	N/A	00:03 (00:01)	03:07	£1.92	£109.44		
Clinical modelling	N/A	N/A	00:18 (00:03)	17:30	£15.96	£909.72		
Technical manufacture	N/A	N/A	00:27 (00:09)	25:59	£15.95	£909.15		
EVA blank	£14.52	£827.64	N/A	N/A	N/A	N/A		
Service use (additional 30 min review appointment)	N/A	N/A	00:04	03:30	£3.19	£181.83		
Total	£17.60	£969.90	00:54	51:03	£37.86	£2157.45	£55.46	£3127.35

*Excluding disposal costs #Calculated in miles using RAC Calculator [31] based on NHSGGC Fleet vehicle Ford Transit Connect using unleaded 95 Octane petroleum for city driving, with fuel economy of 24 miles per gallon, for one journey per day for the 27 days of recruitment. Price per litre calculated as an average using AA Fuel Price Reports for Scotland throughout the recruitment period = 149.33 pence per litre [32]

adaptations to their allocated insoles compared to the foam-box cast technique. In addition, insoles manufactured from direct scans cost less, and produced less waste products compared with insoles made from single-use, non-recyclable foam-box casts.

The direct scan group reported significantly better satisfaction and adherence compared to the foam-box cast group. Both groups exceeded previously published patient satisfaction scores with insoles (mean OPUS-CSD Rasch score 64.2) [2] and lower limb orthoses (mean OPUS-CSD Rasch score 45.4) [33]. Similarly, adherence for both groups was above the predefined threshold of >21 h per week. Thus, it is plausible to suggest a link between greater satisfaction and better adherence whereby participants in the direct scan group wore their insoles for longer and were more satisfied with insole function while carrying out day-to-day activities compared to the foam-box cast group. This notion is contradicted by previous studies [2, 34] potentially due to participants encountering more diverse and/or complex tasks while wearing their orthosis which could result in lower satisfaction. More research is required to determine the relationship between adherence and satisfaction specifically focussing on insole use in heterogenous lower limb musculoskeletal patient groups. The lower satisfaction and adherence scores in the foam-box cast group could be due to greater requirement for manual adjustments ($n = 15$) compared with the direct scan group ($n = 4$) which could potentially be explained by past research showing greater shape variability between foot models obtained from foam-box casts and direct scans [6, 35]. Sensitivity analysis using worst-case and best-case scenarios confirmed the robustness of the main findings. Although some secondary outcomes exhibited minor changes in p-values, these changes were not clinically meaningful. This suggests that the influence of missing data on the study conclusions is minimal. The results from our study suggest that a more comfortable device was achieved when using direct scans; although our study did not include comfort as a specific outcome measure, this effect could be explained by a previous study which demonstrated superior offloading properties in the midfoot when wearing insoles produced from direct scans compared with insoles from foam-box casts [36]. This, in keeping with another study showing superior offloading performance of CAD/CAM insoles from direct scans

in diabetic patients [37], suggests a possible reason for the arch discomfort which was most frequently experienced by participants in the foam-box cast group in the current study. Thus, we suggest that the difference in model shape produced by the direct scan in the current study may be more favourable than the foam-box cast in terms of patient comfort and plantar pressure, which is reflected in greater satisfaction and greater adherence.

Direct scanning costs less and required less staff time compared to the foam-box cast group. This in conjunction with the improved satisfaction and adherence also observed in the direct scan group would support the use of direct scanning in orthotic services. The reduced costs associated with direct scanning as demonstrated in this study, may assist those services wishing to explore innovation in terms of adopting a fully digital supply chain for CAD/CAM insoles. While costs are likely to be sensitive to local service and manufacture arrangements as well as staff experience and training [8], costings were based on established Orthotic services who already use either fully digital CAD/CAM or hybrid-digital CAD/CAM techniques (Table 4). Costs associated with the scanning equipment are not included, and perceived as a reasonable exclusion as scanning equipment is a requirement for both methods. Services intending to make a case for integrating direct scanning equipment in to their service, need to consider equipment costs. The transportation of foam-box casts in this study are representative of standard practice for services who do not have access to scanners. However we acknowledge that transportation distance varies dependent on the orthotic centre, and the short distance in this study may actually underrepresent this aspect. Further research is required to understand how other orthotic services transport foam-box casts for scanning in order to evaluate cost implications across different geographic regions. While the authors acknowledge the importance of monetary and environmental costs associated with phenolic foam production [38, 39], these costs could not be acquired from international manufacturers for this study, similarly transportation cost per item were unknown. Healthcare industries are being widely encouraged to meet net zero carbon emission targets and to achieve this goal, previous research highlights the importance of minimising waste products, unnecessary travel [40], and unwarranted treatment variation [41]. In the orthotics industry, direct scanning for insoles decreases waste from non-recyclable single-use foam-box casts and reduces the necessity for transportation. The current study provides new insight into the benefits of direct scanning in relation to treatment outcomes and suggests shorter, four week treatment evaluations, thus providing vital information to support Orthotic services aiming to reduce waste, transportation, costs, and treatment variation when prescribing CAD/CAM insoles. Given that previous studies have shown 86.8% of orthotic services in the UK use foam-box casts rather than direct scans, with over 36,000 foam-boxes used annually to produce CAD/CAM insoles [42], it is crucial to consider the environmental impact of this hybrid-digital workflow. Studies show that workflows involving foam-box casts have lower sustainability scores compared to fully digital processes using direct scanners [43]. Considering the positive clinical outcomes associated with direct scanning as demonstrated by the current study, along with the less favourable sustainability scores, transportation needs, and waste associated with foam-box casts; services should be encouraged to evaluate the environmental impact of using such waste products in their own service, in relation to net-zero targets [40, 41].

Limitations

The main limitation of this study was the single centre design, which led to a lack of diversity among participants, and is also known to potentially overestimate intervention effects [44]. While demographic characteristics were similar between groups, overall diversity was limited, with the majority of participants being white (98%) and female (72%), with a high BMI (median 29.78). Given that previous studies have shown an association between higher BMI and some MSK foot and ankle pathologies [45], and that MSK conditions are more prevalent in females [46], this aligns with the study population. However, to maximise participant diversity, we recommend future multicentre studies to determine whether the observed effects are consistent in a more diverse population. This study chose to recruit patients referred to the orthotic service yielding a heterogeneous MSK pathology cohort to reflect current day-to-day clinical NHS practice, as such this study was not able to explore the effect of the randomised insole design methods on specific pathologies, and it is suggested that future multicentre trials be undertaken with sufficient participant numbers to enable sub-group analyses.

Conclusion

This trial showed that shape capture with foam-box casts and direct scans are equally effective in producing CAD/CAM insoles which improve pain, function and foot health in MSK patients, and these effects occur within the first 4 weeks of insole use regardless of shape capture method. However, direct scan insoles showed benefits over those from foam-box casts when considering factors such as satisfaction, adherence, footwear and requirement for manual insole adaptions. In addition, direct scans also reduce the waste products associated with foam-box casts with the latter being more expensive than those produced by direct scan when considering staff time, transport, and foam-box purchase. As such, it is

recommended that orthotic services explore the potential to use direct scanning for CAD/CAM insoles when treating MSK foot and ankle conditions, rather than using foam-box casts.

Abbreviations

BMI	Body mass index
CAD/CAM	Computer-aided-design and manufacturer
Co-I	Co-Investigator
EVA	Ethylene-vinyl acetate
FHSQ	Foot Health Status Questionnaire
GGC	Greater Glasgow and Clyde
IQR	Interquartile range
MID	Minimally important difference
MSK	Musculoskeletal
NHS	National Health Service
OPUS-CSD	Orthotic and Prosthetic User Survey Client Satisfaction with Device module
PI	Primary Investigator
SD	Standard deviation
VAT	Value added tax

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Author contributions
LB, GC and JR designed the protocol for the RCT. LB, CD, JT, HS and AM contributed to the acquisition of the data. JR completed the primary statistical analysis. LB and GC contributed to secondary analysis. All authors were involved in the interpretation of the data. LB wrote the first draft of the manuscript and all authors provided critical feedback for revisions and approved the final version of this manuscript.

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Data availability
The datasets analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Ethical approval for this trial was obtained from London Stanmore Research Ethics Committee (22/LO/0579), and the trial is registered on ClinicalTrials.gov. All participants provided written informed consent to participate in the study prior to data collection. This trial was performed according to the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Orthotic Service, Orthotic Department, NHS Greater Glasgow and Clyde, Gartnavel General Hospital, Glasgow, Scotland G12 0YN, UK
[2]Allied Health Research Unit, University of Central Lancashire, Brook Building (BB128), Preston PR1 2HE, UK

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