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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

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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

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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

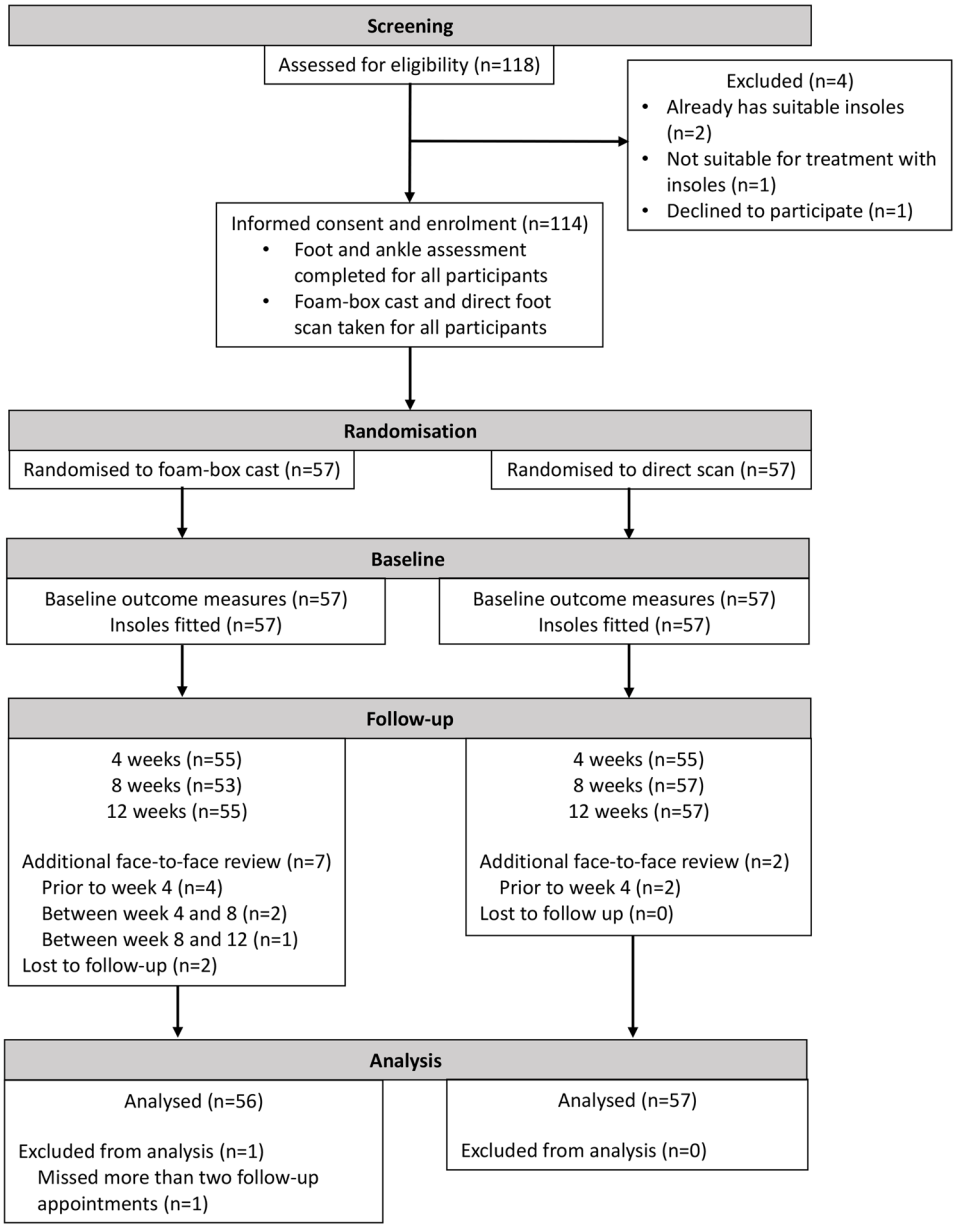

Fig 1 Study flow chart

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 mid-foot 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.

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