TITLE

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

Authors

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Conflicts of interest

PODFO Ltd offered 40-pairs of foot orthoses for use in this evaluation at a discounted cost of 50%.

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HIGHLIGHTS

- 3D-printed insoles reduce pain, improve function and satisfaction if EVA insoles are not effective
- 3D-printed insoles offer an alternative to escalating to other healthcare services.
- Hard-shell 3D-printed insoles could minimise the patient healthcare journey

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.

Keywords: foot orthoses, 3D printed insoles, musculoskeletal lower limb pathology

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 has 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 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 health care services, when the use of custom EVA insoles has been unsuccessful.

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 the 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 health care services within a two-year period.

METHODS

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 ≥ 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 time scale (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.

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).

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). Figure 1a and 1b 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.

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 sub-domains; 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 (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.

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 FHSQ sub domain for pain, with a standard deviation of 23.9, at the 5% significance level, with 90% power, allowing for 10% drop out rate.

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).

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 sub-domains 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 sub-domain ($p=0.101$).

Further analysis of pain sub domain scores showed there were 16 responders and 20 non-responders to custom foot orthoses (Table 3, Figure 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 ($p<0.001$) 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.

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	3	3	0.213

(1, 2, 3)	(3; 3)	(2; 3)

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

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

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 health care 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 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 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 (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 FHSQ sub domain 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.

Figure Captions

Figure 1a. Example of a custom CAD/CAM EVA foot orthosis

Figure 1b. Example of a custom 3D printed hard-shell foot orthosis

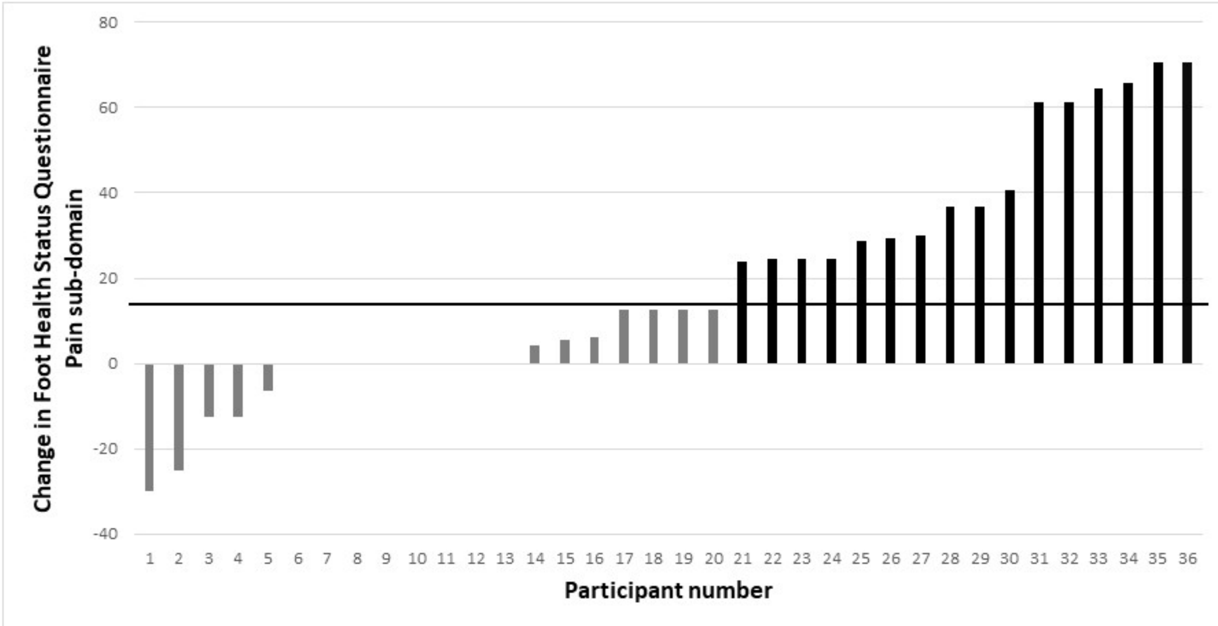
Figure 2. Responders and non-responders based on change in Foot Health Status Questionnaire pain response after wearing foot orthoses defined as a minimal important difference of ±13. Pain responders (black) demonstrate a positive change of 13 points and non-responders (grey) demonstrate a ≤12.99 change in pain between baseline and minimum eight week follow-up.

Figure 1a.

Figure 1b.

A

Figure 2.



Change in Foot Health Status Questionnaire Pain sub-domain
80
60
40
20
0
-20
-40
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36
Participant number

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