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A clinical longitudinal evaluation of pre-fabricated, semi-rigid foot orthoses prescribed to improve foot function

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Abstract

Background: Custom-made foot orthoses whilst effective can be expensive and time-consuming to manufacture making ready made devices an attractive option. This study, with follow up after 12 months provides longitudinal data not frequently available.
Objectives: Longitudinal evaluation of the efficacy of a slim, ready made, 3/4th length semi-rigid foot orthosis.
Method: Data was collected from 21 participants at baseline, at 4 weeks and via postal questionnaire after 12 months. Powerstep orthoses (Cuxson-Gerrard & Co Ltd., Oldbury, UK) were given to participants with the therapeutic aim of resolving or reducing their lower limb symptoms.
Results: Participants reported an initial marked decrease in foot pain, found the orthoses fitted in footwear readily, had a sense of increased foot stability and a significant improvement in comfort ($p < 0.0001$). Some increase in pain levels reported after 4-weeks ($p = 0.01$), was accompanied by an equally significant increase in mobility ($p = 0.01$) which triangulated closely against diary records. After a mean of 15.1 months, 73% of participants still found the orthoses beneficial.
Conclusion: Participants found ready made orthoses enhanced sense of stability and generally reduced symptoms over a period of at least 1 year.

Keywords: Orthoses; Foot; Rehabilitation

1. Introduction

Functional foot orthoses are utilised by many health professionals as part of rehabilitation to enhance foot and lower leg function and to treat foot pain and other symptoms of the locomotor system. Functional foot orthoses have been used as a conservative alternative to foot surgery [1] to reduce pain and improve functional ability in rheumatoid arthritis [2] and pre or post foot surgery [3]. Foot orthoses are a helpful adjunctive therapy in the management of plantar heel pain [4] in osteopathy [5] as well as frequently used in sports medicine for their potential in reducing pain and injuries [6]. Although most health professionals would recommend complex mechanical foot or medical conditions are managed by the appropriate specialist, there are times when pre-fabricated (ready made) functional foot orthoses are helpful, for example, as an immediate method of managing symptoms whilst awaiting arrival of the bespoke orthoses. Buonomo et al. [7] suggest that the improvement in recent years in the quality of materials and pre-fabricated orthoses coupled with expertise of technicians and practitioners also justifies their use in simple and complex foot problems. There is some evidence that pre-fabricated functional orthoses appear to affect foot function during gait by controlling some rearfoot eversion [8,9].

In the UK many of the currently available pre-fabricated functional orthoses available are made of ethyl vinyl acetate

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or similar materials that in order to achieve functional control during gait have an inherent thickness. This additional thickness within footwear can be problematic, requiring the foot to be squeezed into the shoe. Whilst it is recognised that health professionals would provide appropriate advice about the orthoses, footwear and fit, it is also appropriate to be realistic about lifestyle and work demands and imperatives. It may not be possible, for a number of reasons, for an individual to promptly purchase a deeper pair of shoes to accommodate the required orthoses. Individuals may also elect to wear a variety of shoes which may not readily accommodate the pre-fabricated orthoses. Additionally some people with pre-existing foot deformity may find the extra-depth footwear they already own cannot accommodate pre-fabricated orthoses if they are too thick.

Pre-fabricated, slim-line functional orthoses could therefore have a place in the management of the symptomatic locomotor system. Powerstep orthoses fulfil many of the desirable features of a pre-fabricated functional orthosis (Table 1). This study utilised these ready made orthoses for people diagnosed with a variety of lower limb musculoskeletal complaints commonly seen during rehabilitation that are managed with foot orthoses. This study aimed to:

- identify any in-shoe changes in the static alignment of the leg in relation to the rearfoot, and rearfoot to ground alignment
- measure the effect of specific-re-fabricated orthoses on pain, comfort, foot stability and mobility
- survey the views of participants on the use of the Powerstep Orthoses over an initial 4 week period and a follow-up between 12 and 19 months.

Table 1
The desirable properties of a pre-fabricated, OTC/off the shelf functional foot orthosis (acknowledgements to D.S. Costain, T. Austen, K. Rome, K. Springett)

Orthosis shell is fit for purpose
- Achieves the desired functional control on foot and locomotor system
- Provides stability in controlling foot joint range of motion
- Semi-flexible to allow tolerance in prescription
- Adjustable to allow modification by practitioner, including adding pressure redistribution materials
- As slim-line as possible to fit in a range of footwear
- Not hard so as to be more readily tolerated by wearer
- Possibly with shock absorption

Material covering
- Cleanable/washable
- Does not increase skin surface coefficient of friction (increasing risk of moist fissures, blistering)
- Non-allergenic
- Non-staining
- Able to absorb excess sweat

Cost

Low cost to justify
- Interim nature of orthotic in management sequence
- Repeat purchase of the pre-fabricated orthotic if no further treatment is sought or intended

2. Ethical considerations

This study received ethical approval from the University of Brighton Research Ethics Committee. All participants, whether participating in pilot studies or in the main data collection had consented verbally and in writing to take part in the study, and indicated they had been fully informed of the nature and purpose of the study, and were aware they may withdraw from the study without giving a reason and without affecting current and future treatment.

Participants received the treatment appropriate to their foot/lower limb problem and where orthosis prescription was appropriate, were invited to take part in this study. No appropriate treatment was withheld and participants appreciated taking part may require more frequent visits for the duration of the study. Participants were informed, as part of the consent process that the study was to evaluate a commercially available product, and they would be offered a £10 voucher at the end of the mid-stage of the study.

Participants were not invited to take part if they had difficulty communicating as they were to be asked to comment verbally and in writing their perceptions on the effects of the foot orthoses.

3. Method

To ensure aims were adequately fulfilled, outcome measures from both quantitative and qualitative approaches were used. Methods included validated questionnaire-based outcome measures, participant-recorded diaries and static frontal plane measurement of the alignment of the foot and leg. It is acknowledged that reliable in vivo, clinical assessment and measurement of foot position is difficult [10,11] especially when the intention is to mimic as normal a situation for the participant as possible. Therefore, prior to the main data collection pilot studies were undertaken to ensure data capture was reliable and valid; these preliminary studies are described below. 3D gait analysis was not included as part of this assessment owing to the difficulties associated with accurate and repeatable rearfoot marker placement in shoe.

3.1. Powerstep orthoses (Cuxson Gerrard & Co Ltd., Oldbury, UK)

Three-fourth length pre-fabricated foot orthoses with semi-rigid shell, polyurethane foam and antibacterial fabric cover. RRP £22.99 (August 2006).

A pair of 3/4th length Powerstep orthoses of the correct size were given to each participant and checked for fit in-shoe.

3.2. Intra-tester variation in measurements taken

Pilot studies were undertaken to assess intra-tester variation in measurement of frontal plane rearfoot alignment against the leg and against the ground. As inter-tester vari-

ation in clinical repeatability measurement has been found to be generally high [12–14]; only one investigator (AB) took measurements for the duration of the study. Relaxed calcaneal stance position (RCSP), leg to ground alignment and leg to rearfoot alignment were measured using a tractograph [21]. One participant was measured ten times on each day for 10 days for each variable giving 200 data sets. There was demonstrable consistency in measurement (range of standard deviations 0.33–0.52 and coefficient of variation 2.61–8.25%) encouraging confidence in the repeatability of measurements made.

3.3. Reliability of measurements using the alignment device

In a second pilot study a device was introduced to allow visualisation and measurement of the rearfoot bisection in-shoe. This consisted of a firm but flexible parallel plastic strip 1 cm wide and 12 cm long. Applied to the rearfoot bisection with double sided tape, the device accommodated to the contours of the lower leg whilst maintaining its frontal plane position in-shoe (Fig. 1). The accuracy and reliability of this method of recording rearfoot alignment in-shoe was assessed using 10 participants, randomly selected from the student population at the University of Brighton. Each participant had their rearfoot alignment (leg to rearfoot, and rearfoot to ground) measured 10 times barefoot, standing on the pre-fabricated orthoses and in-shoe both with and without the plastic strip. Each set of these blinded measurements was analysed using a paired *t*-test and no significant differences ($p < 0.05$) were found in measurements obtained with and without the plastic strip in place. This indicated the plastic strip made no difference to measurements obtained and could be used during the main data collection to demonstrate whether the Powerstep orthoses changed rearfoot frontal plane alignment in the shoe.

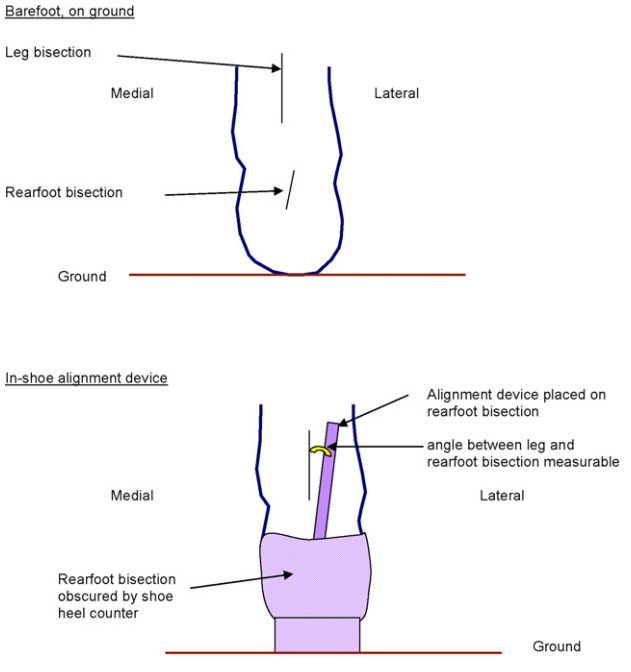

Fig. 1. Diagram of the positioning of the rearfoot device to allow in-shoe static measurement of frontal plane alignment changes with and without the orthoses. Posterior, frontal plane view, right ankle and rearfoot.

Table 2
The nature and incidence of participants presenting compliant

Presenting complaint	Number of participants ($n = 21$)
Pes plano-valgus	3
Pes cavus	3
Plantar fasciitis	3
Metatarsalgia	3
Ankle sprain/instability	3
Tibialis posterior tendonitis	2
Low back pain	2
Sesamoiditis	1
Hallux valgus	1

3.4. Main study

Potential participants were selected from general practitioner referrals to an out-patient podiatry clinic for conditions affecting the locomotor system over a 3-month period. The inclusion criteria were deliberately broad so as to include as wide a range of conditions commonly encountered in podiatric practice as possible. Participants were included if they presented with foot and leg pain for which the use of foot orthoses would be a suitable rehabilitation management approach. Details of the conditions treated in this study are provided in Table 2. Participants wore their own shoes throughout the study.

Participants were excluded if they had poor peripheral sensation, poor tissue viability, had worn orthoses previously, were unable to consent or had difficulty in communicating as they were to be asked to comment verbally and in writing during the study period.

At the first visit, base line measurements were taken. Rearfoot to ground frontal plane alignment was measured barefoot, barefoot on the orthoses, in-shoe with no orthoses and in-shoe with the orthoses in situ. The same measurements were taken after 4 weeks. The participants' heels were marked with indelible pen, therefore the same marks were used for all measurements. At baseline, after week 2 and after week 4 participants were asked to score their pain, sense of comfort, ease of use, hygiene and sense of security when wearing the orthoses using a Visual Analogue Scale. Effects on mobility of wearing orthoses were evaluated using the Manchester Foot Pain and Disability Index (MFPDI) [15]. In addition to aid verification of data, participants were asked to keep a diary of their levels of activity, footwear worn and any other comments they felt pertinent to the orthoses and their foot health over the first 4 weeks of the study.

Participants had used their orthoses for an average of 15.1 months (range 12–19 months) prior to a long-term fol-

low up being undertaken. To maximise data collection while minimising inconvenience to participants and maintaining anonymity a questionnaire-based follow up was selected. The questionnaires comprised three parts:

- Foot pain and associated disability were assessed using the MFPDI.
- Pain, comfort, mobility, hygiene and satisfaction were measured using visual analogue scales.
- A questionnaire consisting open and closed questions to ascertain whether orthoses were still being worn, the frequency of orthotic use and reasons participants discontinued with their orthoses.

3.5. Data analysis

3.5.1. Frontal plane measurements

Following routine clinical practice, leg to rearfoot alignment was measured as well as leg to ground alignment and rearfoot to ground alignment (illustrated in Fig. 1 and described in the method) with and without pre-fabricated orthoses, and differences assessed using paired *t*-tests.

3.5.2. Comfort, foot stability, pain and mobility

Scores from visual analogue scales were summed and mean scores calculated and are displayed in graphical format. Scores from the MFPDI were summed.

3.5.3. Participant's diaries

Qualitative data analysis was undertaken as described by van Manen [16].

4. Results

4.1. Demographic Data

A convenience sample of twenty-one symptomatic participants (13 female and 8 male; age range 21–72 years) took part in the study and all 21 completed the first 4 weeks of the study. This group formed 37.5% of all referrals over a 2 month period for musculoskeletal conditions suitable for management with pre-fabricated foot orthoses. A total of 15 (71.4%) participants responded to the follow up between 12 and 19 months (mean 15.1 months) after their orthoses were first issued.

4.2. Measurements of front plane alignment of foot and lower leg with and without orthoses

Measurements of frontal plane alignment indicated a significant change in rearfoot alignment ($p < 0.001$) once standing on the orthoses whether they were placed on the ground or in-shoe (Table 3). The orthoses changed frontal plane alignment, bringing the rearfoot bisection closer to a more vertical position. This did not change over the initial 4 weeks of the study, which suggests that the orthotic function is not altered over the short term.

4.3. Comfort, pain and mobility

At 4 weeks the majority of participants experienced a significant improvement in comfort ($p < 0.0001$) when wearing the orthoses. Participants reported a moderate increase in pain levels at 4 weeks ($p = 0.01$), however, this was accompanied by an equally significant increase in mobility ($p = 0.01$). Verified by their diary records, participants reported that increased comfort was accompanied by increased activity levels, which in turn may have affected their perceived pain. The MFPDI demonstrated a marked decrease in the amount of foot pain and associated disability; the mean MFPDI score was 11.14 (S.D. 6.8) at baseline, 5.8 (S.D. 7.3) after 4 weeks and 8.1 (S.D. 10.4) at the end of the study.

Participants consistently found the orthoses easy to use and hygienic, scoring between mean 8.6 (range 8–10) on visual analogue scale over the study duration. They were positive about their mobility with a mean visual analogue score of 8.1 (S.D. 2.5, range 3–10) indicating they appeared to be able to undertake most of the types of activities they wished. Equally respondents were positive about the enhanced sense of sure-footedness they noticed while wearing these pre-fabricated orthoses with a mean visual analogue score of 7.6 (S.D. 3.1, range 2–10).

4.4. Qualitative information from diary entries

Twelve out of 21 of the participants (57%) returned completed diaries. Participants had been asked for qualitative comments alongside the quantitative data provided by visual analogue scores and the MFPDI and this information did not form primary data.

Table 3
Differences in frontal plane rearfoot alignment with and without the pre-fabricated orthoses

Measurement taken	Measurements in degrees (mean and S.D.) (all were valgus position)	
	Left side	Right side
Barefoot rearfoot to ground	7.55 (S.D. 3.9)	5.57 (S.D. 3.38)
Barefoot on orthoses rearfoot to ground	5.86 (S.D. 3.59)	3.79 (S.D. 2.6)
In-shoe rearfoot to ground without orthoses	7.05 (S.D. 3.26)	9.17 (S.D. 2.92)
In-shoe rearfoot to ground with orthoses	4.88 (S.D. 2.46)	2.86 (S.D. 2.54)

NB: These differences remain at the end of the study, suggesting orthotic function is maintained.

4.4.1. Early stages of wearing orthoses (week 1)

All participants reported finding the orthoses comfortable but most experienced need to acclimatise to them. The only adverse comments related to '*pressure in the arch*', '*arch aching*' in the early stages of wearing the orthoses. These symptoms disappeared after a few days of wear.

4.4.2. Extracts from participants' diaries (weeks 2–3)

The majority of participants commented on the sense of support and how comforting the orthoses were – '*the insoles do feel very supportive*', '*we walked miles along the beach and I did not know they [the orthoses] were there*', '*they are feeling increasingly supportive*', '*feels supportive, much better walking with than without*'. However, the caveats to these comments demonstrated variability in perceived benefit of wearing the orthoses. For example one participant remarked upon the insoles being uncomfortable and '*could not wait to take them off*'. However, these comments aligned alongside information from the diary and the MFPDI indicated this participant had increased activity levels and had been able to negotiate uneven terrain more readily than before starting to wear the orthoses. Also in a minority of people presenting with low back or leg problems ($n = 3$), there was inconsistency in reporting benefit, nevertheless it is clear wearing the orthoses did not make those particular problems worse.

4.4.3. Extracts from participants' diaries (after week 4)

Eight of the 12 participants (67%) who completed and returned their diaries claimed clear benefit through wearing the orthoses. Some found benefit in the sense of security and support provided; '*I like the support the insoles give and it feels odd now without them*' while other participants gained a more general benefit '*Friends told me I'm walking better which cheered me up*'. One participant summarised many participants' comments in writing '*After initial getting used to the insole I would now not be without them*'. There were 3 adverse comments; one participant reported being '*wary about walking in the insoles*', and two considered their foot pain had not improved over the duration of the study period, and one person was unclear about benefit.

4.5. Use of the pre-fabricated orthoses at the end of the study

At the end of the study period (mean 15.1 months) 15 participants (73%) responded to the follow-up questionnaire, and of these eleven were still wearing their orthoses for at least some of the time, as detailed in Table 4. Four respondents no longer wore their orthoses for a wide variety of reasons, ranging from complete resolution to no improvement, with only one respondent reporting their orthoses had worn out. There was no clear trend highlighting any problems with the orthoses.

Table 4
Current use of Powerstep orthoses

Do you still wear your Powerstep insoles?			
Yes 11			No 4
If **yes** how often do you wear your insoles?			
RARELY	*SOMETIMES*	*ALWAYS*	
0	9	2	
If you **do not** wear your insoles, why not?			
They were not helpful			1
They wore out			1
They caused more pain			1
My symptoms got better			1
I have had surgery			0
I had special shoes made instead			0
They did not fit in my shoes			0

5. Discussion

Powerstep orthoses have been shown to change frontal plane alignment significantly (99.99% confidence level, Table 3) and maintain this alignment over 4 weeks. Participants found a significant improvement in comfort (99.9% confidence level) regardless of the nature of presenting complaint. However, some reported an increase in pain during the first 4 weeks, but this coincided with increase in levels of activity. The participants' diaries provided useful verification of quantitative data. There are additional incidental findings from the qualitative data for example '*friends told me I'm walking better which cheered me up*'. which need exploring further, particularly as most published reports on foot orthoses tend to use objective, quantitative data for their outcome measures. The qualitative approaches used in this study yielded useful and interesting information that would otherwise have been missed and are of value in informing clinical management. It appears that the participants increased their levels of activity until pain perceived stopped them; thus pain in this instance is not a particularly sensitive outcome measure to determine improvement. Instead, distance walked, range of activity, mobility, etc., may be more accurate measures of change. Indeed most participants (66%) did demonstrate improvement by the end of the study period using these types of parameter. Data obtained at the end of the study indicated some participants did not wear orthoses all the time and the reasons for this are worthy of further investigation.

The majority of participants reported finding the pre-fabricated orthoses comfortable but most experienced a need to acclimatise to them. The majority of adverse comments related to *'pressure in the arch'*, or *'arch aching'* in the early stages of wearing the orthoses. Similar comments can be made by those wearing bespoke orthoses and are a known feature and which has resulted in practitioners giving advice to wear bespoke orthoses in slowly to allow this time for adaptation. In common with bespoke/custom-made devices there should be strong emphasis on the need to gradually acclimatise to the orthoses.

It appears from these findings and those of others, that the low cost of pre-fabricated foot orthoses for management

of foot and leg pain (compared with that of custom-made orthoses) may justify their use [17]. With regard to pre-fabricated orthosis use for heel pain, Landorf et al. [18] report *'it is not possible to recommend either pre-fabricated or customized orthoses as being better and it cannot be inferred that customized orthoses are more effective over time and therefore have a cost advantage'*. Rome et al. [19] conversely record cost-effectiveness analysis demonstrated functional orthoses, although initially more expensive, to result in a better quality of life for individuals with heel pain than did use of accommodative insoles. Rigorous cost – benefit analysis should to be carried out for the Powerstep orthoses, as it appears these are inexpensive (April 2006 = £22.99) and durable pre-fabricated orthoses. However, there remains a need to undertake larger, randomised controlled studies as recently identified by Farrow et al. [20] and Clark et al. [2].

6. Conclusion

In this study, pre-fabricated Powerstep orthoses improved pain, comfort, sense of foot stability and mobility over both the short term and over at least 1 year. In addition these devices changed frontal plane alignment. These orthoses generally appeared to fit into a range of footwear, are durable, easy and hygienic to use. It would seem appropriate for health professionals to prescribe these orthoses for relief of symptomatic problems affecting the locomotor system.

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Competing interests

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