THE ALLIED HEALTH SCHOLAR

Changes in the Six Minute Walk Test and foot health using customised foot orthoses vs sham inserts in an adult flat foot population. A pilot randomised control trial.

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Abstract

Aim and background: The presence of flexible flat feet is often reported to negatively impact foot health, and endurance during walking. Foot orthoses are commonly prescribed for symptoms associated with flat feet. This study aimed to investigate the impact of individually prescribed foot orthoses on foot health and endurance measures when used in a flat foot population. **Methods:** This study was a pilot parallel-group single-blinded RCT comparing customised foot orthoses and sham inserts for impact on foot pain, fatigue and function following four weeks of use, and changes in distance travelled measures (m) during the six-minute walk test following four weeks of use and at immediate wear. **Results:** Thirteen participants were recruited (8 female), seven received foot orthoses and six received sham inserts. A statistically significant difference existed between groups at baseline for foot pain. No statistically significant results were observed for the use of foot orthoses or sham inserts after four weeks of use or at immediate wear. The sham insert group were observed to improve their distance travelled (median increase 23.5 m), and foot pain (VAS) in accordance with minimally importance difference when compared to the foot orthoses group (between group difference 15.5 mm) following four weeks of use, however, large variations in response were observed (IQR

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34.7 m and 50.5 mm respectively). The study was underpowered to detect change (range 0.05 to 0.20). No significant differences were found between the foot orthoses and sham insert group for foot health or endurance measures following four weeks of use, however, outcomes should be viewed with caution due to small sample size and variation in individual response. This study has provided valuable insight to investigating impact of foot orthoses in clinical cohorts. Recommendations for future study protocols are given.

Key words: Flat feet, Foot orthoses, endurance, foot health, six-minute walk test

Introduction

Flexible flat feet (*pes planus, pes planovalgus*) have long been considered synonymous with less than optimal foot health, including the notion that people with flat feet have reduced endurance (Esterman & Pilotto, 2005; Garrow, Silman, & Macfarlane, 2004; Kirby, 2000; Levy et al., 2006). Adults with flat feet have been observed to have higher levels of reported generalised lower limb pain (Buldt et al., 2013; Dyal, Feder, Deland, & Thompson, 1997; Southerland Jr & Losito, 1990), Achilles tendonitis (Franco, 1987), lower limb osteoarthritis (Shibuya, Jupiter, Ciliberti, VanBuren, & La Fontaine, 2010), patellofemoral and hip pain (Kosashvili, Fridman, Backstein, Safir, & Bar Ziv, 2008), yet to the best of the authors' knowledge, no investigations have been conducted using validated and reliable tests of endurance, such as the six-minute walk test (6MWT)("ATS Statement: Guidelines for the Six-Minute Walk Test," 2002).

Foot orthoses are the most frequently used intervention for flat feet (Chen, Lou, Huang, & Su, 2010). Foot orthoses purportedly 'alter magnitudes and temporal patterns of the reaction

forces... and thus allowing for a more normal foot and lower extremity function that decreases pathological loading forces' (Kirby, 2011 p.iv). Despite the frequently of foot orthoses use, there is only low level evidence to suggest they reduce pain (Zammit & Payne, 2007), improve rearfoot kinematics or ankle and foot kinetics associated with flat feet (Banwell, Mackintosh, & Thewlis, 2014), and moderate level evidence to suggest foot orthoses improve energy cost when walking in a flat foot population (Otman, Basgoze, & Gokce-Kutsal, 1988). Whilst this suggests that using foot orthoses may improve gait efficiency, no investigations were found that directly compared the impact of foot orthoses on endurance.

Overlying any investigation into foot orthoses is consideration of the type and prescription of the devices used. The foot orthoses prescribed in published studies are often criticised, as they may not reflect the 'targeted' approach used in clinical practice (Menz, 2009). Previous work by the authors has determined that the majority of studies investigating foot orthoses standardise the type and/or prescription of the foot orthoses used (Banwell, Mackintosh, & Thewlis, 2014). In contrast, an audit of a large teaching clinic found two-thirds of the foot orthoses dispensed were individualised, and significantly influenced by the rearfoot measures observed (Banwell, Thewlis, & Mackintosh, 2015).

The primary aim of this study was to investigate the effect of foot orthoses on endurance at initial use and following four weeks of use in adults with flexible *flat foot*. The secondary aim was to determine changes in reported foot health. To increase the external validity of this research, foot orthoses will be individually prescribed based on the FootPRoP (Banwell, Mackintosh, Thewlis, & Landorf, 2014), as consensus-based recommendations for prescribing foot orthoses for adults with flexible flat feet.

Methods

This study was a pilot parallel-group single-blinded RCT, completed as part of the lead author's PhD. The trial was registered with the Australian and New Zealand Clinical Trial Registry (ACTRN12613000920796) and reported in accordance with the CONSORT guidelines. The study protocol was approved by the University of South Australia's Human Research Ethics Committee (Protocol number 30996).

Participants

A sample of convenience was recruited from the clients of the University of South Australia's Podiatry teaching Clinic (Adelaide, South Australia) between March and October 2014. Potential participants, alerted to the study by flyers, were informed they would receive one of 'two types' of 'foot orthotic' at no cost if they were eligible for the study. Potential participants were assessed for eligibility by independent clinical tutors (registered podiatrists) prior to enrolment in the study and eligible for inclusion if they had a mean Foot Posture Index, six item version (FPI-6), score of ≥ +7 (from a possible range – 12 to +12), (Redmond, Crane, & Menz, 2008; Redmond, Crosbie, & Ouvrier, 2006) indicating flat feet, and had no further reported or observed biomechanical abnormality of the lower limbs, were able to comfortably walk for 20 minutes unaided, could attend four sessions at the podiatry clinic over an eight-week period, and supplied informed written consent.

Participants were excluded from the study if they had worn foot orthoses within the previous six months, had inflammatory, musculoskeletal, neurological or any other condition that impacted on their gait, or reported pain associated with their flat feet at the time of initial

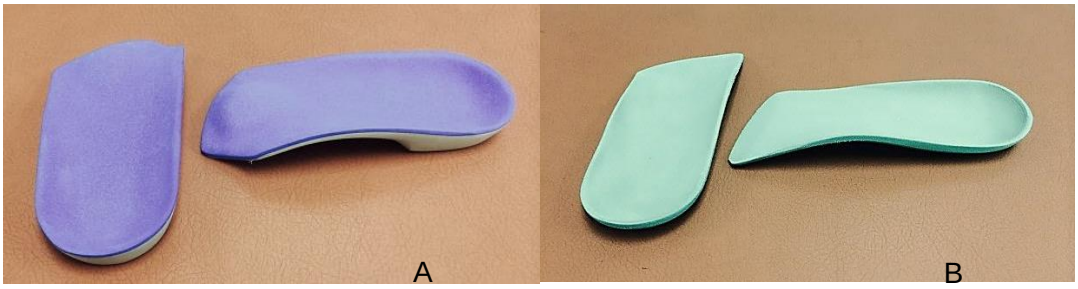
assessment as ≥ 60 mm on a 100 mm VAS (in consideration that co-interventions such as medication or other therapy may be required).

Interventions

Participants were randomly allocated to receive customised foot orthoses or sham inserts (Figure 1). Both devices were manufactured from plaster of Paris neutral suspension cast impressions taken from the participants' feet. This casting technique is commonly used (Landorf, Keenan, & Rushworth, 2001) and has been described in full elsewhere (Ball & Afheldt, 2002; Berenter & Kosai, 1994; Root, 1994). Cast impressions were taken by the student that conducted the assessment, approved by the tutor.

The cast impressions were sent to a commercial orthotic laboratory (Footwork Podiatric Laboratory Pty Ltd, Melbourne, Australia) for modification and manufacture of the devices depending on the allocation (customised foot orthoses or sham inserts). Customised foot orthoses were individually prescribed using the FootPRoP proforma (Banwell, Mackintosh, Thewlis, et al., 2014) by the student and tutor who assessed the client. Prescriptions were able to include the use of common prescription variables, including: an inverted or vertical (heel) cast pour; a minimal or standard medial arch expansion; the incorporation of a medial heel (Kirby) skive (Kirby, 1992); an intrinsic metatarsal dome; a plantar fascial groove; or a 1st metatarsophalangeal joint cut out. The shell of the customised foot orthoses was moulded in 4 mm polypropylene, included a rearfoot heel stabilizer and finished with a 3 mm (90 kg/m^2) multiform (EVA) top cover (Figure 1a).

Figure 1 Examples of a) the foot orthoses prescribed for the study, including a 1st metatarsophalangeal cut out and a metatarsal dome, and b) the sham inserts



Sham inserts were manufactured from 3 mm EVA (90 kg/m^2) and contoured to fit the modified positive cast. This material was chosen to maximise the visual resemblance to a customised foot orthosis, with minimal effect on foot posture or function, and to closely resemble sham inserts used in previous studies (Finestone et al., 1999; Landorf, Keenan, & Herbert, 2006; Munteanu et al., 2009). Both the customised foot orthoses and sham inserts were developed using a computer-aided design and manufacturing method (CAD-CAM), (Figure 1b).

Outcome measures

Six-minute walk test

The outcome of interest was the change in distance travelled in metres during the 6MWT. The 6MWT is a valid and reliable test of endurance (Enright, 2003) where participants are asked to walk as far as they can within six minutes (without running or jogging) over a hard, clear and flat surface ("ATS Statement: Guidelines for the Six-Minute Walk Test," 2002). The 6MWT was used to determine change in distance travelled with and without devices at dispense (immediate wear) and following four weeks of device use.

Foot health measures

Outcomes of interest were changes in foot pain (reported for 'today' and 'last week'), fatigue and function at initial wear and following four weeks of use.

Pain and fatigue were measured using two 100 mm visual analogue scales (VAS). Each VAS had word anchors signifying 'no pain (or fatigue)' at the far left of the scale and 'worst imaginable pain (or fatigue)' at the far right. Participants were asked to mark the line at the point that they thought corresponded to their pain or fatigue for 'today' (Price, McGrath, Rafii, & Buckingham, 1983). Reliability of visual analogue scales for pain is high with good repeatability (ICC 0·97 to 0·99) (Downie et al., 1978; Williamson & Hoggart, 2005).

The Foot Health Status Questionnaire (FHSQ) is a 13 question, 4 subscale questionnaire covering foot pain (over the 'last week), foot function, footwear and general foot health (Bennett, Patterson, Wearing, & Baglioni, 1998). The subscales of foot pain and foot function were of interest in this study and administered and scored as per directed (Bennett et al., 1998). Both subscales have high test-retest reliability (ICCs 0.92 and 0.86 respectively), have previously been validated (content, criterion and construct validity) for a variety of foot pathologies, and have a high degree of internal consistency (Cronbach α range 0.85 – 0.88) (Bennett et al., 1998).

Protocol

Participants remained clients of the University of South Australia's podiatry teaching clinic for the entirety of the study, following the standard protocols for that clinic. Accordingly, clients prescribed foot orthoses are required to attend a minimum of four sessions; initial assessment, casting of the feet, dispense of the devices and follow up. For the purposes of this study, participants were also asked to complete a total of six 6MWT and two surveys of their foot health across the four sessions (Figure 2).

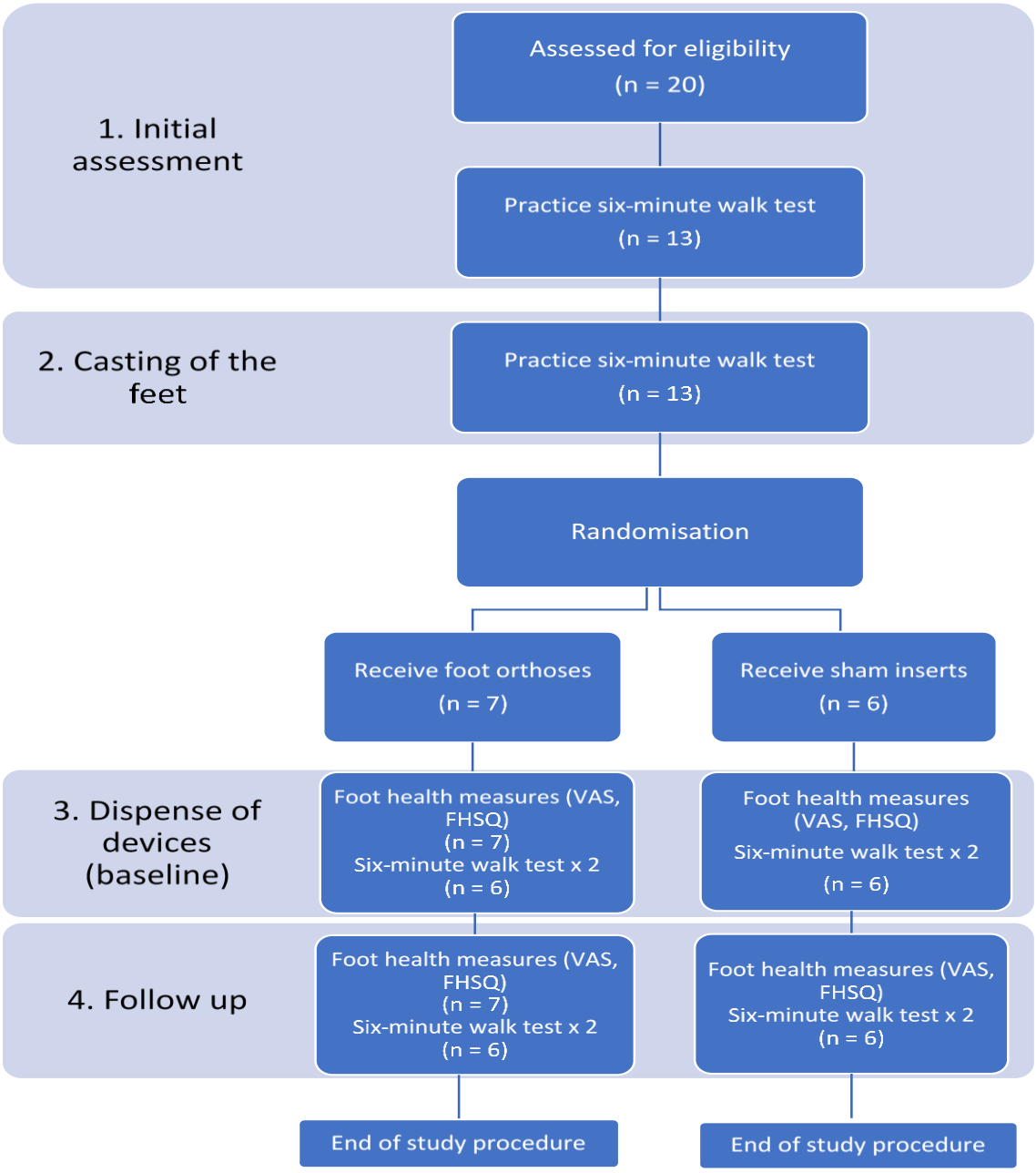


Figure 2 Protocol of the pilot RCT evaluating foot orthoses for flexible flat foot in adults

Two practice 6MWT were conducted; at initial assessment and following casting of the feet (Figure 2). Practice tests were performed to reduce the 'learned effect' on participant performance (Enright, 2003). All 6MWTs were conducted along the same 30 metre walkway using standardised instructions ("ATS Statement: Guidelines for the Six-Minute Walk Test," 2002). Participants were asked to walk as far as they could, around the 30-metre course, for six minutes. The assessor recorded how many laps were completed during the six minutes, alerted the participant at two, four- and five-minute time points and counted down for the last five seconds. The participant was instructed to stop when time was called while the assessor placed a marker at the heel of the right shoe. The marker was used to determine the distance covered in the final lap.

The prescription for customised foot orthoses was developed by the student and clinical tutor following casting of the feet but prior to participants being randomised into the customised Foot orthoses or sham insert group. Randomisation was managed by an independent administrator not involved in the study.

Devices were dispensed approximately a fortnight following the casting session (Figure 2). Prior to dispense, participants were asked to complete the VAS and FHSQ. Devices were dispensed following the podiatry clinic's standard protocols for the customised foot orthoses, and a standardised script that focused on fit to foot and fit to shoe for the sham inserts. Participants then completed two 6MWT, in the 'with device' and 'no device' conditions, with the order randomised by a flip of a coin. To reduce potential fatigue, participants were asked to rest between tests for a minimum of two minutes or until they felt comfortable to proceed. A researcher (HB) remained with participants between testing sessions to assist with shoes and/or

device fit, and to respond to any questions or concerns of the participants. This researcher was not involved in data collection.

At the fourth session, participants were asked to complete the foot health measures (VAS and FHSQ) again and completed two 6MWT consistent with the previous session. Participants remained blinded to their allocation for the length of the study. Assessors were blinded to group allocation.

Data management

The primary measures of interest were the differences in distance travelled (in metres) during the 6MWT between the 'no device' condition at baseline and the 'with device' condition after four weeks of use, and foot pain 'today' (foot pain (VAS)), foot pain 'over the last week' (foot pain (FHSQ)), fatigue (VAS), and foot function (FHSQ). Secondary comparisons of distance travelled (m) at immediate wear (i.e. 'no device' vs 'with device' measures at dispense) were also conducted.

Two authors (HB & SM), independently measured VAS data. FHSQ responses were entered into the software and managed according to instructions (Foot Health Status Questionnaire Data Analysis Software© Version 1.03).

Data analysis

Analysis was conducted in IBM SPSS 21 (IBM Corp, 2012, Armonk NY, USA). Descriptive statistics were used to describe participant characteristics at baseline. Inter-rater reliability of extracting VAS measures was assessed via ICCs (Model 3,1) demonstrating excellent reliability (ICCs range 0.97 to 0.99).

Normality of data were assessed using Shapiro-Wilks tests ($p \geq 0.05$). Where data were not normally distributed, non-parametric statistical testing was applied. Differences in participant

characteristics at baseline and determination of intervention effect, per group, were calculated using Mann-Whitney *U*-tests, with statistical significance set at $p \leq 0.05$. For analysis of intervention effects, data were inverted where required, so negative numbers consistently favoured the no-device condition.

As the outcome data was expected to be underpowered, medians and interquartile ranges were reported. In addition, boxplots at baseline and following intervention are presented to graphically display outcomes.

The minimally important differences for change in distance covered during the 6MWT was calculated by post hoc analysis as 12.07 m, where the minimally important difference = 1.96 x √2 x SEM (Jaeschke, Singer, & Guyatt, 1989). The minimally important differences in foot health changes were set as 8 mm for VAS pain, 13-point increase for FHSQ subscale of foot pain and 7-point increase for FHSQ subscale of foot function (Landorf & Radford, 2008; KB Landorf, Radford, & Hudson, 2010). There are no known minimally important differences for self-reported fatigue.

Post hoc power calculations for all outcome measures were conducted using GPower (two-tailed *t*-tests, power (1 - β) set at 0.80 and $\alpha = 05$) (Faul, Erdfelder, Lang, & Buchner, 2007).

Results

Participants

Twenty people expressed interest in the study, with 13 people enrolled. Seven participants received foot orthoses and six participants received sham inserts (Figure 2). All participants completed the study requirements, one set of walk test data were lost due to operator error, leaving data from 12 participants available for analysis of distance travelled

(Figure 2). Of the 13 participants, 8 were female (62%). The mean age of participants was 31 years (range 20 to 50). At baseline, those within the sham insert group reported a statistically significant higher level of foot pain (VAS) compared to the Foot orthoses group (median difference 19.0 mm, $p = 0.04$, Table 1). No further significant differences between the groups were observed.

Table 1 Participant characteristics at baseline (data are means and SDs, unless otherwise stated)

	Customised FO group	**Sham insert group**
Gender (M:F)	2:5	2:4
Age (years)	31.3 ± 9.3	30.2 ± 11.2
Body mass (kg)	73.6 ± 7.8	67.8 ± 11.0
Body Mass Index (BMI)		
Healthy weight (BMI < 25)	4	4
Overweight (BMI 25 – 29.9)	3	1
Obese (BMI 30+)	0	1
FPI-6 score	8.4 ± 1.7	8.4 ± 1.4
Distance travelled (m/s)	1.63 ± 0.3	1.63 ± 0.2
Median (IQR) foot pain (VAS) (mm)*	8.0 (12.0)	37.0 (46.0)
Median (IQR) foot pain (FHSQ) (points)	84.4 (21.3)	66.3 (40.0)
Median (IQR) fatigue (VAS) (mm)	18.0 (38.0)	33.5 (49.0)
Median (IQR) FHSQ foot function (points)	87.5 (25.0)	71.9 (35.9)

Notes: *Statistically significant difference in foot pain (VAS) at baseline at $p \leq 0.05$. IQR = interquartile range, FPI-6 = foot posture index – 6 item version, VAS = visual analogue scale (0 to 100mm), FHSQ = Foot Health Status Questionnaire (0 to 100 points, where 0 is the worst possible foot health and 100 is the best possible foot health), FO = foot orthoses.

Prescription of customised foot orthoses

Prescriptions were developed prior to randomisation. All 13 prescriptions were consistent for prescription of forefoot posts (balanced to perpendicular) and the base material (4 mm polypropylene) only. For the seven participants that were randomised into the customised foot orthoses group, one prescription remained consistent with a standardised device (i.e. vertical (heel) cast pour, standard medial arch fill, forefoot posts balanced to perpendicular) (14%), whereas five participants received a minimal medial arch fill (71%), three were prescribed an inverted (heel) cast pour (43%) or a medial heel (Kirby) skive (43%), and one participant received a first metatarsophalangeal joint cut out and a metatarsal dome as accommodations (14%), (Additional file 2).

Outcomes

The median (and IQR) differences in distance travelled during the 6MWT are summarised in Table 2. These outcomes represent the change in distance travelled between the no device condition at baseline and follow up (e.g. after four weeks of use), and between the device and no device condition at dispense (e.g. at immediate wear). Dispersion and spread of distance travelled measures at baseline (no device condition) and following four weeks of device use (with device condition), per group, are displayed in Figures 3a & 3b.

No statistical differences were observed with the use of customised foot orthoses or sham inserts ($p \geq 0.05$), after four weeks of device use or at immediate wear (Figures 3a & 3b, Table 2).

The sham insert group increased their distance covered during the 6MWT following four weeks of device use (median difference 23.5 m), when compared to the foot orthoses group (median difference 5.2 m) by an amount that exceeded the calculated minimally important

difference, with noted individual variability (IQR 34.7 m), (Figure 3a, Table 2). Statistical power to determine differences between the groups was low (range 0.10 to 0.23), (Table 2).

Table 2 Changes in the six-minute walk test (6MWT) measures (m) (median, (IQR)) between the no device and the with device condition following four weeks of use and at immediate wear

Time of device use	Customised FO group (m) (n = 6)	Sham insert group (m) (n = 6)	Power (*d*)	*P* value
After four weeks of use	5.21 (35.29)	23.48 (34.66)*	0.23	0.20
At immediate wear	2.36 (3.64)	-3.95 (20.50)	0.10	0.26

Negative numbers favour the no device condition. FO = foot orthoses

*difference in median change observed between groups exceeded the minimally important difference (MID).

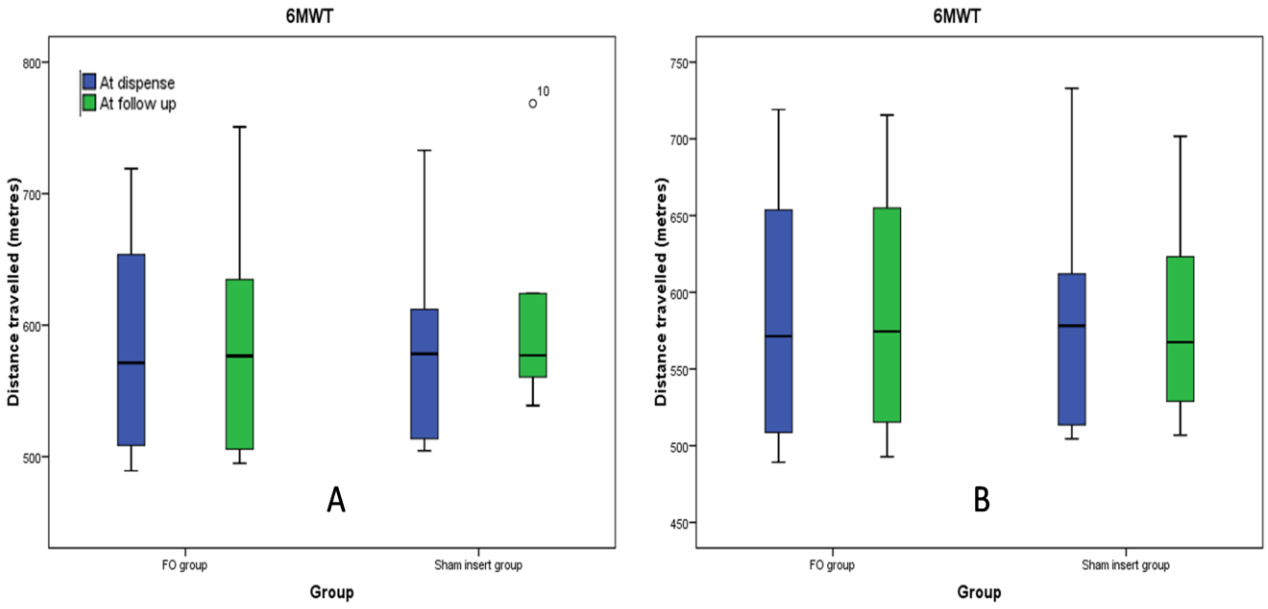


Figure 3 Boxplots for distance travelled. A = following four weeks of use. B = at immediate wear

Notes: The boxplots show the median (line within the box), the 25th percentile and the 75th percentile (box limits), and the 10th and 90th percentiles (whiskers) and the individual values that lie outside these limits. 6MWT = six minute walk test, FO = foot orthoses.

Foot health status changes

The median differences of foot health outcomes from baseline to following four weeks of device use are displayed in Table 3.

Table 3 Changes in foot health status (median, IQR) for both groups between the no device and device condition following four weeks of device use

Outcome	Customised FO group (n = 7)	Sham insert group (n = 6)	Power (*d*)	*P* value
Foot pain (VAS) (mm)*	-2.00 (20.00)	13.50 (50.50)	0.08	0.57
Foot pain (FHSQ) (points)	9.38 (39.38)	5.00 (48.29)	0.05	0.58
Fatigue (mm)	1.00 (46.00)	-1.50 (50.50)	0.11	0.62
Foot function (points)	0.00 (31.25)	9.38 (50.50)	0.15	0.17

Notes: IQR = interquartile range, VAS = visual analogue scale (0 to 100mm), FHSQ = Foot Health Status Questionnaire (0 to 100 points, where 0 is the worst possible foot health and 100 is the best possible foot health). Negative numbers represent a decrease in foot health, FO = foot orthoses. *Difference in median change observed between groups exceeded the minimally important difference (MID).

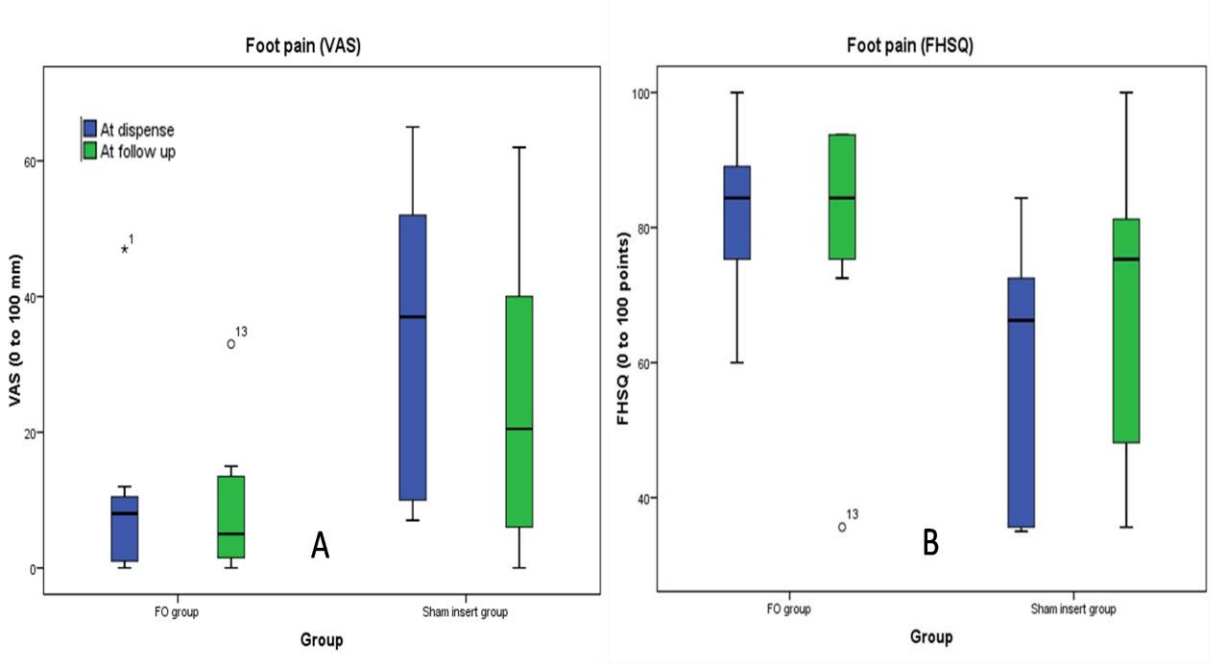


Figure 4 Boxplots for foot pain (VAS) and foot pain (FHSQ)

Notes: The boxplots show the median (line within the box), the 25th percentile and the 75th percentile (box limits), and the 10th and 90th percentiles (whiskers) and the individual values that lie outside these limits. VAS = visual analogue scale (0 to 100mm), FHSQ = Foot Health Status Questionnaire (0 to 100 points, where 0 is the worst possible foot health and 100 is the best possible foot health), FO = foot orthoses.

Dispersion and spread of foot health measures at baseline and following four weeks of device use are displayed for each group in Figures 4a, 4b, 5a and 5b.

There were no statistically significant differences observed between the groups for pain, fatigue or foot function outcomes ($p > 0.05$), (Table 3). The sham insert group experienced an improvement in foot pain (VAS) after intervention (median difference 13.5 mm), when compared to the foot orthoses group (median difference -2.0 mm), by an amount that exceeded the minimally important difference, however there was substantial individual variability (IQR 50.5 mm), (Figures 4a, Table 3). Statistical power to determine a difference between the groups was very low (range 0.05 to 0.15), (Table 3).

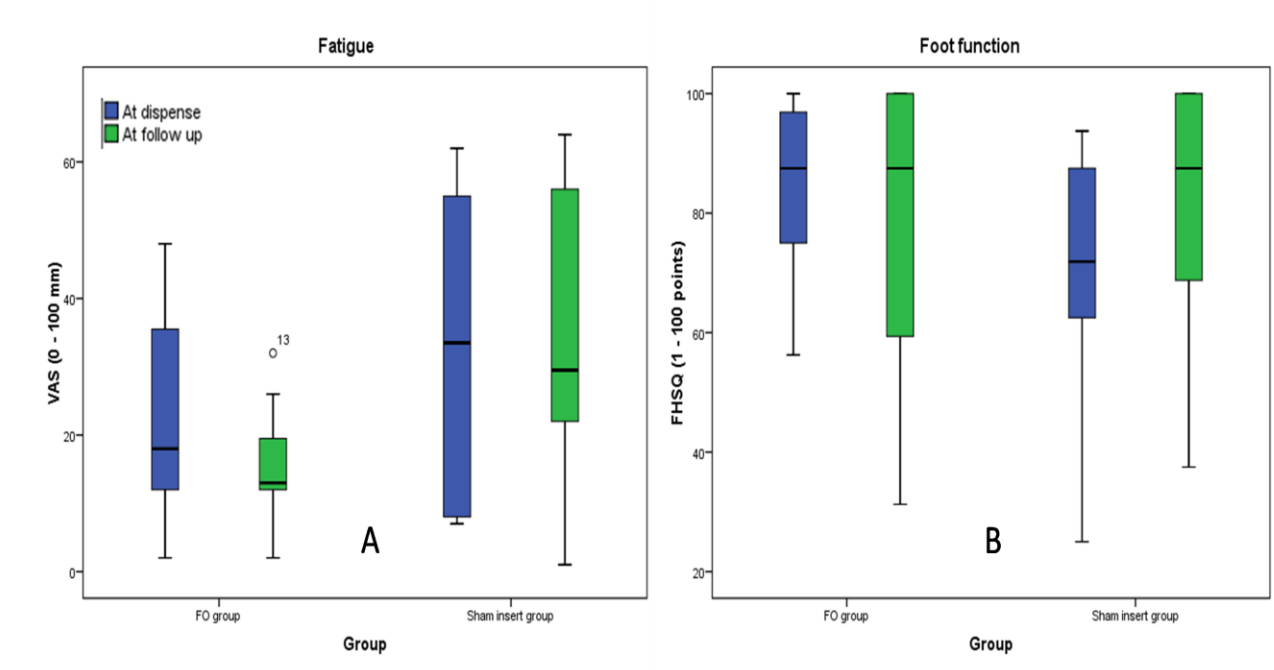


Figure 5 Boxplots for fatigue and foot function

Notes: The boxplots show the median (line within the box), the 25th percentile and the 75th percentile (box limits), and the 10th and 90th percentiles (whiskers) and the individual values that lie outside these limits. VAS = visual analogue scale (0 to 100mm), FHSQ = Foot Health Status Questionnaire (0 to 100 points, where 0 is the worst possible foot health and 100 is the best possible foot health), FO = foot orthoses.

Discussion

This pilot RCT aimed to investigate changes in foot health and endurance in people with flexible flat foot using foot orthoses individually prescribed for participants. The trial was underpowered to statistically determine if differences in foot health or endurance were achieved after four weeks of foot orthoses use or at immediate wear, however, the outcomes provide valuable direction for future studies and raise cause for discussion regarding the use of sham inserts.

The sham insert group were observed to improve their distance travelled during the 6MWT (+ 23.5 m) and reduce their foot pain, when compared to the foot orthoses group (VAS) (-13.5 mm) in amounts consistent with minimally important differences. However, these outcomes need to be considered with caution. Firstly, minimally important differences for the 6MWT should be interpreted for the target population (Wise & Brown, 2005). For people with chronic heart failure or respiratory disease, minimally important differences are 30 and 54 m, respectively, whereas in young health participants, 70 to 170 m has been used (Enright & Sherrill, 1998; Guyatt et al., 1985; Wise & Brown, 2005). The minimally important differences for our population were based on post-hoc calculations and were considerably smaller than the other distances reported. On face value, our minimally important differences appear too small. Secondly, the sham insert group were observed to have significantly higher foot pain (VAS) at baseline compared to the foot orthoses group (median values 37.0 mm vs 8.0 mm respectively). Increased pain levels at baseline has been associated with rapid regression to the mean, potentially impacting on our outcomes (O'Connell, Moseley, McAuley, Wand, & Herbert, 2015). With that said, it is important to acknowledge that sham inserts, although designed to have as minimal effect as possible, are not inert. EVA inserts similar to those used in this study have previously demonstrated decreases in peak plantar pressures (186.7 ± 41.9 kPa vs 215.5 ± 52.3 kPa, (13% reduction)) and maximum force (body weight (BW)) (34.8 % BW vs 38.2 % BW, (9% reduction)) in the heel area (but not the midfoot or forefoot) when compared to shoes alone (McCormick, Bonanno, & Landorf, 2013). Therefore, it is feasible that these changes were sufficient to impact on foot health and function. Unfortunately, the methodological choice to address a sham insert effect would be to use a ‘no control’ condition (i.e. shoes alone). This option may introduce ascertainment bias and resentful demoralisation as it is impossible to blind

participants (Bonanno, Landorf, Murley, & Menz, 2015). Given, however, that sham inserts have been demonstrated to be equivalent to customised orthoses in reducing pain in populations with juvenile idiopathic arthritis (at 3 months), rheumatoid arthritis (at 3 years), and plantar fasciitis (at 3 or 12 months) (Hawke, Burns, Radford, & du Toit, 2008) further investigations may be beneficial.

The use of endurance measures in studies investigating people with flat feet and the effect of foot orthoses also needs further consideration. Flat feet were traditionally considered enough of a hindrance to be exclusion criteria for Australian, British and American military service up to and including World War II (Evans, Nicholson, & Zakarias, 2009). Whilst this is no longer the case, anecdotally, fatigue in the lower limb is a frequently reported symptom of flexible flat feet in clinical practice. This raised the concern that fatigue may indicate a 'lack of endurance'. Fatigue has been associated with reduced gait efficiency (Dierks, Manal, Hamill, & Davis, 2008), altered muscular activity (Boozari, Jamshidi, Sanjari, & Jafari; Kellis & Liassou, 2009) and increased likelihood of injury during running (Koblbauer, van Schooten, Verhagen, & van Dieën, 2014), yet whether increased fatigue is a sign of reduced endurance in people with flat feet has not been investigated. Furthermore, a systematic search of the literature (Banwell, Mackintosh, & Thewlis, 2014) failed to find any studies evaluating either of these factors in adults with flexible flat feet, nor any that reviewed the use of foot orthoses to mitigate fatigue or endurance concerns. One study, comparing voluntary and electrically evoked muscle contractions prior to and following a one-hour treadmill run in a non-flat foot cohort (Kelly, Girard, & Racinais, 2011), concluded that foot orthoses may assist in reducing fatigue induced rapid force contractions of the plantar flexors. Whether they would also assist in reducing fatigue induced muscle 'work' for those with flexible flat feet is not known but gives credence to further

investigations being beneficial. The findings of our investigations determined the 6MWT is easy to administer, widely used within healthy and pathological populations, and has normative data available. Given the concern with fatigue and endurance within flat foot populations, the inclusion of valid and reliable measures of both factors in future powered robust RCTs is recommended.

This was the first study to pilot the use of the FootPROP proforma (Banwell, Mackintosh, Thewlis, et al., 2014) to direct the prescription of customised foot orthoses for individual participants. Prior to making recommendations on the use of the FootPROP, studies investigating the reliability and ease of use of the tool are required. However, the use of the proforma allowed for clear recording and transparent rationale for the prescription variables used for each participant and improved external validity of the devices prescribed. It should be noted that 11 of the 13 prescriptions developed for this study were not consistent with a 'standardised' device. It should also be noted that the impact, if any, of the prescription and individual variables used in customised foot orthoses remains unknown. Further research in this area is required.

This study had several limitations. The primary limitation to interpreting the results from this trial is that it was underpowered to detect change for all outcome measures. It should be acknowledged that whist this study was purposely designed as a pilot, recruitment was slower than expected for the allotted time period. During the 8 months (30 teaching weeks) of study recruitment, the University of South Australia's Podiatry Clinic offered 1240 appointments and saw over 300 individual clients. Despite extensive in-clinic advertising, recruitment interest represented approximately 13% of the cohort only. The generalisability of outcomes may also be limited given that the University of South Australia's Podiatry Clinic may not be reflective of all podiatry clients. Furthermore, although the timeline adopted within this protocol (i.e. four weeks

of device use) is consistent with alternative trials (Murley & Bird, 2006; Zammit & Payne, 2007), it is not extensive. Particularly of concern is the foot health changes may not have been apparent over the (relative) short time period of the trial.

Future studies involving multi-centre recruitment with longer time periods of use (e.g. 3 and 12 months) would assist by obtaining adequate sample sizes, determine outcomes that are reflective of the greater flexible flat foot community, and establish the long-term effect of the use of foot orthoses specific to this population.

Conclusion

Due to the pilot nature of this trial, the changes in the outcomes were underpowered to statistically detect clinically meaningful changes. No significant differences were found between the foot orthoses and sham insert group for any outcome following four weeks of use. If the limitations acknowledged in this pilot study were addressed, a larger (appropriately powered) RCT comparing customised foot orthoses and sham inserts for their effect on foot health and endurance in the adult flexible flat foot population may determine more significant outcomes and allow for further understanding on what effect, if any, flat feet has on endurance.

Four key messages

- Fatigue and a lack of endurance is often considered associated with flat feet, yet little research has occurred in this area.
- Endurance and foot health status change is highly variable within the use of customised foot orthoses or sham devices in an adult flat-footed population.

- Customised foot orthoses prescribed in the podiatry teaching clinic where recruitment occurred were varied, with only two of 13 devices being consistent with a standardised device.
- Future studies should consider using individually prescribed orthoses over standardised devices to improve external validity.

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