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Evaluation of the pressure-redistributing properties of prefabricated foot orthoses in older people after at least 12 months of wear

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ABSTRACT

Foot problems are highly prevalent in older people. To treat such problems in this age-group prefabricated ('off-the-shelf') foot orthoses are frequently prescribed. However, such devices are susceptible to material compression and deformation, which may reduce their effectiveness over time. Therefore, the aim of this study was to compare the pressure-redistributing properties of new prefabricated orthoses to orthoses worn for at least 12 months. Thirty-one adults (10 males, 21 females) aged over 65 years (mean 75.4, SD 5.2) participated. Plantar pressure data were collected under the rearfoot, midfoot and forefoot using the Pedar® in-shoe system while participants walked along an 8 m walkway wearing shoes only, new orthoses and old orthoses (orthoses were full length, dual-density prefabricated Formthotic™ devices). Compared to the shoe-only condition, both the new and old orthoses produced significant reductions in peak pressure and maximum force in the rearfoot with corresponding increases in force and contact area in the midfoot. Compared to the new orthoses, the old orthoses exhibited small but significant increases in peak pressure in the rearfoot (6%, $p = 0.001$) and maximum force in the rearfoot (5%, $p < 0.001$) and forefoot (2%, $p = 0.032$). These findings indicate that the prefabricated orthoses evaluated in this study are only slightly less effective at redistributing plantar pressure after at least 12 months of wear.

1. Introduction

Epidemiological studies indicate that one in three people over the age of 65 years old report foot problems [1–3]. Foot problems in this age group are associated with reduced walking speed, difficulty performing activities of daily living, impaired balance and increased risk of falls [4–6]. Various types of interventions are used to treat such problems, with foot orthoses commonly utilised [7–9]. Broadly speaking, there are two types of foot orthoses prescribed by clinicians: (i) customised devices, individually manufactured from impressions of the patient's foot, and (ii) prefabricated devices, which are mass-produced, generically contoured commercially available devices. Although a survey in Australia indicated that podiatrists were six times more likely to prescribe customised orthoses over prefabricated orthoses [10], several recent studies have indicated that prefabricated orthoses may be equally effective as customised devices in the treatment of some foot conditions [11–13].

A potential limitation of many prefabricated foot orthoses is that they are generally constructed using soft or semi-rigid materials that deform more readily than the more rigid materials typically used for customised foot orthoses [14,15]. Consequently, the biomechanical effects of prefabricated orthoses may be lost as the material fatigues [16,17]. As a result, prefabricated orthoses may need to be replaced more frequently than customised orthoses, which may reduce their cost-effectiveness [18]. However, the extent to which prefabricated foot orthoses maintain their effectiveness over time in a clinical context has not been objectively evaluated.

Therefore, the aim of this study was to evaluate the effect of extended wear on prefabricated orthoses by comparing plantar pressures in orthoses that had been worn for at least 12 months to new orthoses. We hypothesised that the old orthoses would be significantly less effective at redistributing plantar pressures compared to the new orthoses.

2. Methods

2.1. Participants

A sample size of at least 30 participants was selected because it was considered large enough to provide a normally distributed data set and therefore use parametric statistics [19]. Additionally, previous studies using similar methods have been adequately

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powered to detect statistically significant differences between devices with samples as small as $n = 15$ [20]. Participants were recruited by mail-out from a larger randomised controlled trial [21]. Inclusion in the study was determined with the following criteria: (i) aged 65 years and over, (ii) able to walk household distances (10 m) without the use of a walking aid, (iii) cognitively intact, defined as a score of ≥ 7 on the Short Portable Mental Status Questionnaire [22] and (iv) use of dual density Formthotic™ (Foot Science International, Christchurch, New Zealand) orthoses for at least 12 consecutive months. The orthoses were originally prescribed as part of the intervention in the randomised controlled trial for which the inclusion criteria also included self-reported disabling foot pain, defined as foot pain lasting for at least a day within the last month and a positive response to at least one item on the Manchester Foot Pain and Disability Index [23]. Participants were excluded if they had: (i) any self-reported neurodegenerative disorders such as Parkinson's disease or multiple sclerosis, or (ii) lower limb surgery in the previous three months. Ethics approval for this project was granted by the La Trobe University Faculty of Health Sciences Human Ethics Committee (Reference FHEC10/46). All participants gave written informed consent prior to being recruited into this project.

Participant characteristics, anthropometrics and major medical conditions were documented, and hours of physical activity over the past week were recorded using the Incidental and Planned Activity Questionnaire [24]. Participants were also asked how often they wore their old foot orthoses (''most of the time'', ''some of the time'', ''a little of the time'' or ''none of the time'') and how satisfied they were with their orthoses (''very satisfied'', ''somewhat satisfied'', ''neither satisfied nor dissatisfied'', ''somewhat dissatisfied'' or ''very dissatisfied'').

2.2. Test conditions

All participants were assessed wearing their own footwear and hosiery. Three test conditions were analysed: (i) shoe only (i.e. no orthoses), (ii) shoe with new orthoses, (iii) shoe with orthoses issued more than 12 months previously ('old orthoses'). All orthoses used in the study were full length, dual-density prefabricated Formthotic™ devices (Fig. 1). The orthoses had density ratings for the two layers of 70 kg/m^3 for the softer top layer and 160 kg/m^3 for the harder bottom layer. Prior to completing the test condition with the new orthoses, the orthoses were heat moulded to the participants' foot shape as recommended by the manufacturer with no other orthotic modifications being undertaken.

Fig. 1. Prefabricated orthoses used in the study.

2.3. Pressure analysis equipment

The Pedar® in-shoe system (Novel GmbH, Munich, Germany) was used to assess plantar pressures while walking. This system is widely used for clinical foot pressure research, and previous studies have shown the system to have excellent reliability and validity [25–27]. The Pedar® system detects and records plantar pressures via a 2 mm thin flexible insole comprising 99 capacitive sensors arranged in a grid and inserted within the participant's shoe. Plantar pressure data were sampled at a frequency of 50 Hz. All insoles were calibrated according to manufacturer's (Novel GmbH, Munich, Germany) instruction with the Trublu® device prior to the commencement of the study.

2.4. Protocol

The Pedar® insoles were placed within each shoe between the foot and the orthosis (or between the foot and shoe for the control condition). After 'zeroing' the insoles according to manufacturers' instructions, the participants completed four walking trials for each of the three test conditions. The middle four steps (to exclude acceleration and deceleration steps) of the right foot were included in the analysis as this has been shown to be sufficient to ensure adequate reliability [28]. The order of the test conditions was randomised to minimise systematic order effects. The participants were instructed to walk along an 8 m walkway at a self-determined comfortable pace [28]. Walking speeds were recorded during data collection of the first measured condition. To minimise the effect of walking speed on plantar pressures between each condition, any trial that was not within 5% of the averaged walking speeds was eliminated and repeated.

Plantar pressure data were analysed and averaged within the Pedar® analysis program. Novel percentage masks were applied to the rearfoot (proximal 31% of foot length), midfoot (middle 19% of foot length), and forefoot (distal 50% of foot length) [29]. The primary outcome measures were peak pressure, maximum force and contact time beneath the rearfoot, midfoot, and forefoot for each of the three conditions (shoe only, new orthoses and old orthoses).

2.5. Statistical analysis

All statistical analyses were performed with SPSS Version 17.0 (SPSS Inc., Chicago, IL, USA). Normality of the data were confirmed

Table 1
Participant characteristics. Values are mean (SD) unless otherwise stated.

	Mean (SD) or *n* (%)	Range
Age, sex and anthropometrics		
Age (years)	75.4 (5.2)	68–85
Women, *n* (%)	21 (68)	
Height (m)	1.64 (0.1)	1.5–1.84
Weight (kg)	82.1 (21.8)	51–131.5
Body mass index (kg/m^2)	30.1 (6.3)	19.9–41.0
Medical conditions, *n* (%)		
Diabetes	5 (16)	–
Osteoarthritis – lower limb (hip, knee, or foot)	19 (61)	–
Rheumatoid arthritis	2 (7)	–
Moderate to severe hallux valgus	12 (39)	–
Walking aids used outside home	5 (16)	–
Incidental and Planned Activity Questionnaire (h/week)		
Total physical activity	38.9 (15.6)	13.0–78.5
Incidental activity	36.2 (16.2)	12.9–77.0
Planned activity	2.7 (3.0)	0.0–11.3
Time since issue of old orthoses (weeks)	82.6 (19.3)	52.4–110.0

using the skewness statistic (>−1 to <1) prior to inferential analysis. A repeated measures one-way analysis of variance (ANOVA) with Bonferroni-adjusted *post hoc* tests was used to compare pressure measurements under various sites of the foot between the three test conditions. Differences between measured means of each condition were considered significant if $p < 0.05$.

3. Results

3.1. Participant characteristics

A total of 31 participants (10 males and 21 females) with an average age of 75.4 (SD 5.2) years and an average body mass index of 30.1 (SD 6.3) were recruited for this study. Participant characteristics are shown in Table 1. Of the 31 participants, 27 (87%) reported wearing their orthoses "most of the time" or "some of the time", and 26 (84%) reported that they were "very satisfied" or "somewhat satisfied" with their orthoses.

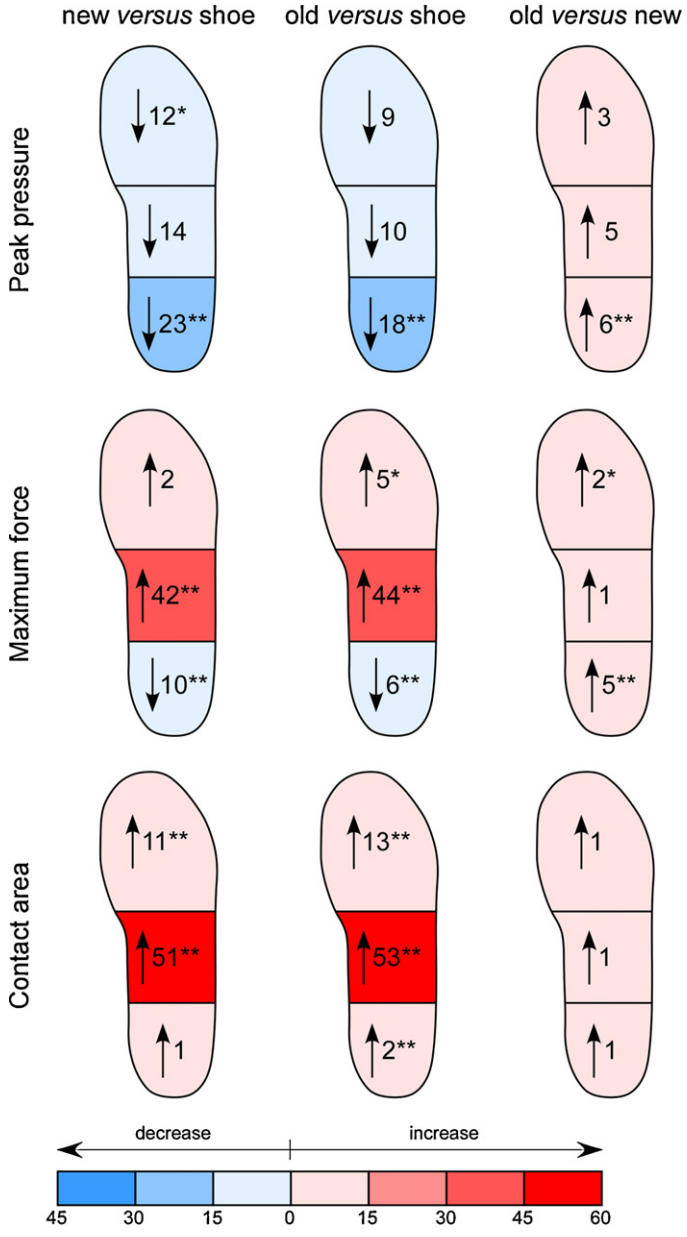

Fig. 2. Percentage differences in peak pressure, maximum force and contact area for the three conditions. *Significant at $p < 0.05$; **significant at $p < 0.01$.

Table 2
Mean (SD) contact time (ms) for each condition ($n = 31$).

Condition	Mean (SD)	%Change	*p*-Value
Shoe only	678.3 (69.2)	n/a	n/a
New orthoses	684.6 (72.8)	+1%	0.158
Old orthoses	679.5 (69.3)	0%	1.00

Note: %change is relative to the shoe only condition.

3.2. Plantar pressure changes

A number of significant differences in plantar pressures were found between the conditions (Fig. 2). There were no significant differences in contact times across the three conditions, indicating that the participants walked at a consistent speed (Table 2). Therefore, the plantar pressure differences found can be directly attributed to the test condition.

3.2.1. Rearfoot

Both the new and old orthoses produced statistically significant decreases in peak pressure and maximum force compared to the shoe only condition (Table 3). The old orthoses also produced a significant increase in contact area over the shoe only condition. Compared to the new orthoses, the old orthoses exhibited significantly higher peak pressure (6%) and maximum force (5%).

3.2.2. Midfoot

There were no differences in peak pressure across the three conditions. However, both the new and the old orthoses produced statistically significant increases in maximum force and contact area compared to the shoe only condition (Table 3). No significant differences were found between the new and old orthoses.

3.2.3. Forefoot

The new orthoses produced a statistically significant decrease in peak pressure, while the old orthoses produced a significant increase in maximum force compared to the shoe only condition (Table 3). Both the new and the old orthoses produced significant increases in contact area compared to the shoe only condition. Compared to the new orthoses, the old orthoses exhibited significant higher maximum force (2%).

4. Discussion

The aim of this study was to evaluate the effect of extended wear on prefabricated foot orthoses in older people by comparing plantar pressures in new orthoses to orthoses that had been worn for at least 12 months. To achieve this we tested full length, dual-density prefabricated Formthotic™ orthoses. The findings indicated that both the new and old orthoses had similar pressure-redistributing properties compared to the shoe-only condition. Specifically, the orthoses decreased peak pressure under the rearfoot, midfoot and forefoot, which was achieved primarily by increasing the maximum force and contact area under the midfoot. Similar results have been reported previously using a range of different devices [20,29,30], suggesting that the pressure-relieving effects of orthoses are at least partly due to the redistribution of force from the heel and forefoot to the midfoot.

Previous laboratory-based mechanical tests results have indicated that materials used for many prefabricated orthoses fatigue with repeated loading [14,15]. As such, we expected that the old orthoses would be substantially less effective in relieving pressure than the new orthoses. However, there were only three measured parameters that demonstrated statistically significant differences. The orthoses that had been worn for at least 12 months (i.e. the old orthoses) exhibited a 6% increase in rearfoot peak pressure, a 5% increase in rearfoot maximum force, and a 2%

Table 3
Mean (SD) values for peak pressure, maximum force and contact area for the rearfoot, midfoot, and forefoot for each condition.

	Peak pressure (kPa)			Maximum force (%BW)			Contact area (cm^2)		
Condition	Mean (SD)	%Change	*p*	Mean (SD)	%Change	*p*	Mean (SD)	%Change	*p*
Rearfoot									
Shoe only	245.2 (59.6)	–	–	66.5 (11.6)	–	–	38.7 (3.8)	–	–
New orthoses	189.5 (47.2)	−23%	<0.001	60.0 (10.6)	−10%	<0.001	39.2 (3.4)	+1%	0.123
Old orthoses	201.7 (51.8)	−18%	<0.001	62.7 (10.5)	−6%	0.001	39.5 (3.5)	+2%	<0.001
Old *vs* new	–	+6%	0.001	–	+5%	<0.001	–	+1%	0.454
Midfoot									
Shoe only	94.5 (41.4)	–	–	11.3 (4.9)	–	–	17.7 (5.6)	–	–
New orthoses	80.8 (26.5)	−14%	0.073	16.1 (5.9)	+42%	<0.001	26.8 (3.8)	+51%	<0.001
Old orthoses	85.0 (34.0)	−10%	0.309	16.3 (5.5)	+44%	<0.001	27.0 (3.6)	+53%	<0.001
Old *vs* new	–	+5%	0.456	–	+1%	1.000	–	+1%	1.000
Forefoot									
Shoe only	312.8 (91.3)	–	–	85.2 (11.3)	–	–	69.0 (8.2)	–	–
New orthoses	276.0 (103.4)	−12%	0.038	87.1 (14.0)	+2%	0.371	76.9 (6.2)	+11%	<0.001
Old orthoses	283.8 (96.3)	−9%	0.283	89.1 (14.4)	+5%	0.022	77.7 (5.9)	+13%	<0.001
Old *vs* new	–	+3%	0.996	–	+2%	0.032	–	+1%	0.721

increase in forefoot maximum force compared to the new orthoses. At this stage there is no evidence as to whether this magnitude of difference is clinically important or not.

The apparent resilience of the prefabricated orthoses used in this study may in part be due to the specific materials and manufacturing process used in their construction, and as such, our results may not be generalisable to other prefabricated orthoses. Rather than being injection moulded or heat formed in the initial manufacturing process, the orthoses we used are manufactured from chemically cross-linked polyethylene and are milled from blocks to ensure uniform density throughout the material despite variations in thickness. This process may reduce the tendency for thicker regions to compress disproportionately to thinner areas, which may assist in maintaining the shape of the device over a longer period. However, a direct comparison of different prefabricated orthoses using a range of materials and manufacturing processes would be required to confirm this.

There are some important limitations within this study that need to be considered. Firstly, the participants represented an older demographic and therefore the findings cannot be directly extrapolated to younger people, who may place greater mechanical demands on their orthoses due to increased physical activity. Indeed, the Incidental and Planned Activity Questionnaire scores indicated that the sample undertook very little planned physical activity. Secondly, the style of footwear and hosiery varied greatly between participants, possibly causing the orthoses to respond differently for the different footwear worn by each participant. However, this study compared the plantar pressure differences of the orthoses within each participant, so this was not a confounding factor. Thirdly, two separate pairs of orthoses ('new' and 'old') were used to provide an insight into the potential changes in pressure-relieving properties over time, rather than evaluating the same orthoses at two time points. While the two pairs of orthoses were identical, variation in heat-moulding may have influenced the results, although a standard heat moulding process was used for all orthoses. Finally, participants had been issued the orthoses at least 12 months before testing and the majority stated that they wore them frequently, however we cannot be certain of the precise duration of wear. Variation in both the frequency and duration of episodes of use could have potentially influenced the mechanical properties of the orthoses, but we were unable to accurately ascertain this.

5. Conclusion

The findings of this study indicate that prefabricated foot orthoses issued to older people at least 12 months previously are similarly effective at reducing plantar pressures compared to new orthoses, suggesting that there is limited deformation over a 12 month period. Therefore, in this age group, there may not be a need to replace the orthoses within this timeframe. These findings are specific to the full length, dual-density prefabricated Formthotic™ devices we tested, so further research is required to determine if our results are similar for other prefabricated orthoses.

Conflicts of interest

All authors declare that there are no known conflicts of interest related to this project that could have influenced this manuscript.

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