Biomechanical Effects of Prefabricated Foot Orthoses and Rocker-Sole Footwear in Individuals With First Metatarsophalangeal Joint Osteoarthritis

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Competing interests

The authors declare that they have no competing interests.

Abstract

Objective

To evaluate the effects of prefabricated foot orthoses and rocker-sole footwear on spatiotemporal parameters, hip and knee kinematics and plantar pressures in people with first metatarsophalangeal joint osteoarthritis (1st MTPJ OA).

Design

102 people with 1st MTPJ OA were randomly allocated to receive prefabricated foot orthoses or rocker-sole footwear. The immediate biomechanical effects of the interventions (compared to usual footwear) were examined using a wearable sensor motion analysis system and an in-shoe plantar pressure measurement system.

Results

Spatiotemporal / kinematic and plantar pressure data were available from 88 and 87 participants, respectively. The orthoses had minimal effect on spatiotemporal or kinematic parameters, while the rocker-sole footwear resulted in reduced cadence, percentage of the gait cycle spent in stance phase, and sagittal plane hip range of motion. The orthoses increased peak pressure under the midfoot and lesser toes. Both interventions significantly reduced peak pressure under the 1st MTPJ, and the rocker-sole shoes also reduced peak pressure under the 2nd-5th MTPJs and heel. When the effects of the orthoses and rocker-sole shoes were directly compared, there was no difference in peak pressure under the hallux, 1st MTPJ or heel, however the rocker-sole shoes exhibited lower peak pressure under the lesser toes, 2nd to 5th MTPJs and midfoot.

Conclusion

Prefabricated foot orthoses and rocker-sole footwear are effective at reducing peak pressure under the 1st MTPJ in people with 1st MTPJ OA, but achieve this through different mechanisms. Further research is required to determine whether these biomechanical changes result in improvements in symptoms.

Key words: osteoarthritis; foot; footwear; orthoses; biomechanics

Running title: Orthoses and footwear biomechanics

Significance and Innovations

- This is the first study to compare the biomechanical effects of foot orthoses and rocker-sole shoes in people with 1st MTPJ OA
- Both interventions were similarly effective at reducing pressure under the 1st MTPJ during gait, but achieved this through different mechanisms
- Foot orthoses increased pressure under the midfoot and lesser toes
- Rocker-sole shoes decreased pressure under the 2nd to 5th MTPJs

Osteoarthritis (OA) is the most common musculoskeletal disorder in the world, affecting 10% of men and 13% of women over the age of 60 years (1). Although the knee is the most commonly affected lower limb region, foot involvement is also common. The most commonly affected region of the foot is the first metatarsophalangeal joint (1st MTPJ), with radiographic changes evident in up to 35% of people aged over 35 years (2). The population prevalence of symptomatic radiographic 1st MTPJ OA (i.e. both radiographic changes and symptoms) in people aged over 50 years has recently been estimated as 7.8% (3). First MTPJ OA has a detrimental impact on health-related quality of life (4), and 72% of those affected report associated locomotor disability (3).

Structural and biomechanical factors are thought to contribute to the onset, progression and symptomatic severity of 1st MTPJ OA. During the propulsive phase of gait, the 1st MTPJ dorsiflexes to assist in the forward transfer of bodyweight. However, in the presence of an overly long and/or wide first metatarsal or proximal phalanx, the proximal phalanx is unable to dorsally rotate on the first metatarsal head, resulting in joint compression and the development of a dorsal exostosis (5). In clinical practice, 1st MTPJ OA is often managed with foot orthoses, which are thought to decrease pain associated with this condition by allowing the first metatarsal to achieve sufficient plantarflexion in preparation for propulsion, thereby minimising joint compression (6). Alternatively, pain relief can be achieved using a footwear modification known as a rocker-sole, in which the sole of the shoe is curved (7). The aim of this modification is to allow the body’s centre of mass to ‘roll over’ the base of support, reducing the need for 1st MTPJ dorsiflexion and subsequently decreasing the loads placed on the forefoot and toes.

Evidence pertaining to the proposed mechanism of action of foot orthoses in the treatment of 1st MTPJ OA is limited to a case series study of nine participants which reported no change in 1st MTPJ dorsiflexion when the orthoses were worn (8). Studies of asymptomatic participants have been inconsistent, with two studies reporting a decrease in 1st MTPJ dorsiflexion (with medial wedging (9) and orthoses (10)) and a recent study demonstrating a small increase in the declination angle of the first metatarsal when participants wore an orthosis with material removed from beneath the 1st MTPJ (11). No studies have been undertaken to assess the biomechanical effects of rocker-sole shoes in participants with 1st MTPJ OA, although studies in asymptomatic participants indicate a reduction in sagittal plane motion of the forefoot (12) and ankle (12-15), reduced forefoot plantar pressures (15, 16) and reduced 1st MTPJ dorsiflexion (17) when walking compared to usual footwear.

Given the uncertainty regarding the mechanism of action of these two treatments, the objective of this study was to evaluate the immediate biomechanical effects of individualized, prefabricated foot orthoses and rocker-sole shoes in individuals with 1st MTPJ OA. To do this, we conducted baseline kinematic and in-shoe plantar pressure analyses of participants enrolled in a randomized trial (18) when wearing their usual footwear and their allocated intervention (i.e. orthoses or rocker-sole shoes).

Materials and Methods

The data presented in this paper were collected at the baseline assessment of a larger randomized trial (Australian New Zealand Clinical Trials Registry ID: ACTRN12613001245785). The La Trobe University Human Ethics Committee provided ethical approval (number 13-003) and all participants provided written informed consent prior to enrolment. The full trial protocol has been published previously (18).

Design

The study design was a parallel-group randomized trial comparing two interventions: prefabricated foot orthoses (Vasyli Customs™, Vasyli Medical, Queensland, Australia) *versus* commercially available rocker-sole footwear (MBT® Matwa, Masai Barefoot Technology, Switzerland). Permuted block randomisation with random block sizes, stratified by sex, was undertaken using an interactive voice response telephone service provided by the NHMRC Clinical Trials Centre at the University of Sydney, New South Wales, Australia to ensure allocation concealment. Participants were informed that they would receive either the foot orthoses or rocker-sole footwear (i.e. they were not blinded to their group allocation).

Participant recruitment, screening and eligibility criteria

To be included in the study, participants had to:

(i) be aged at least 18 years;

(ii) report having pain in the 1st MTPJ on most days for at least 12 weeks;

(iii) report having pain rated at least 20 mm on a 100 mm visual analogue scale (VAS);

(iv) have less than 64 degrees of dorsiflexion range of motion of the 1st MTPJ (19);

(v) have pain upon palpation of the dorsal aspect of the 1st MTPJ;

(vi) be able to walk household distances (>50 meters) without the aid of a walker, crutches or cane;

(vii) be willing to attend the Health Sciences Clinic at La Trobe University (Melbourne, Victoria) on two occasions and have their foot x-rayed;

(viii) be willing to not receive additional interventions (such as physical therapy, foot orthoses, shoe modifications, intra-articular injections, or surgery) for the 1st MTPJ pain during the course of the study;

(ix) be willing to discontinue taking all medications to relieve pain at their 1st MTPJ (analgesics and non-steroidal anti-inflammatory medications [NSAIDs], except paracetamol up to 4 g/day) for at least 14 days prior to the baseline assessment and during the study period.

Exclusion criteria for participants in this study were:

(i) pregnancy;

(ii) previous surgery on the 1st MTPJ;

(iii) significant deformity of the 1st MTPJ including hallux valgus (grade of 3 or 4 scored using the Manchester Scale) (20, 21);

(iv) presence of one or more conditions within the foot or ankle that could confound pain and functional assessments of the 1st MTPJ, such as metatarsalgia, plantar fasciitis, pre-dislocation syndrome, Achilles tendinopathy and degenerative joint disease (other than the 1st MTPJ);

(v) presence of any systemic inflammatory condition, such as inflammatory arthritis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, reactive arthritis, septic arthritis, acute pseudogout, gout or any other connective tissue disease;

(vi) any medical condition that, in the opinion of the investigators, made the participant unsuitable for inclusion (e.g., severe progressive chronic disease, malignancy, clinically important pain in a part of the musculoskeletal system other than the 1st MTPJ, or fibromyalgia);

(vii) cognitive impairment (defined as a score of <7 on the Short Portable Mental Status Questionnaire) (22);

(viii) intra-articular injections into the 1st MTPJ in the previous 6 months;

(ix) currently wearing contoured foot orthoses (although flat insoles were permitted);

(x) currently wearing specialized footwear (footwear that has been custom-made or ‘prescribed’ by a health-care practitioner);

(xi) currently wearing shoes that would not be able to accommodate a foot orthosis, or;

(xii) older people with a history of recurrent falls (defined as two or more falls in the previous 12 months), as there is some evidence that rocker-sole shoes may have short-term detrimental effects on balance (23).

Participants were recruited by (i) radio advertisements, (ii) advertisements placed in local newspapers, magazines, and social media, (iii) posters placed at healthcare facilities, gymnasiums, senior citizens’ centres, fun runs and markets, and (iv) mail-out advertisements to patients attending the La Trobe University Health Sciences clinic and to local podiatry clinics. Baseline testing was performed between February and October 2014.

Clinical and radiographic assessment

At baseline, participants underwent a clinical assessment including measurements of height, weight and body mass index (BMI), foot posture (using the Foot Posture Index (24)), passive non-weightbearing dorsiflexion range of motion at the 1st MTPJ using a flexible plastic hand-held goniometer (25) and observation to determine the presence or absence of pain on palpation, a dorsal exostosis, joint effusion, pain during motion, a hard-end feel when the joint was fully dorsiflexed, and crepitus during movement. The reliability of these assessments has previously been documented (19). Footwear was assessed using the Footwear Assessment Form (26).

The presence or absence of radiographic 1st MTPJ OA was determined using a radiographic atlas developed by Menz *et al.* (27). The atlas incorporates weightbearing dorso-plantar and lateral radiographs to document the presence of OA based on observations of osteophytes and joint space narrowing. Osteophytes were recorded as absent (score = 0), small (score = 1), moderate (score = 2) or severe (score = 3). Joint space narrowing was recorded as none (score = 0), definite (score = 1), severe (score = 2) or joint fusion (score = 3). The atlas has been shown to have good to excellent intra- and inter-rater reliability for grading 1st MTPJ OA (κ range 0.64 to 0.95) (27).

Interventions

The prefabricated foot orthoses group received a pair of foot orthoses (Vasyli Customs Medium Density, Vasyli Medical™, Queensland, Australia) that were modified using a similar approach to that described by Welsh *et al*. (8). All orthoses were full-length, but were modified by adding a cut-out section beneath the first metatarsal and trimming the distal edge to the level of the 2nd to 5th toe sulci (Figure 1). In participants with pronated feet (defined as a Foot Posture Index [FPI] score of >7 (28)), full length 4-degree medial (varus) wedges were applied to the underside of the foot orthoses until there was a reduction in the FPI score of at least 2 points (8). The wedge was gradually bevelled so that it extended to the proximal margin of the cut-out section beneath the first metatarsal. This occurred for two participants.

The rocker-sole footwear group were provided with a pair of appropriately-sized rocker-sole shoes (MBT® Matwa; Masai Barefoot Technology, Switzerland). This shoe is characterized by a rounded sole in the antero-posterior direction and a soft cushioned heel (Figure 2). Across the full size range, the radius of curvature of the MBT is on average 33 cm overall, 18 cm at the forefoot, 43 cm at the midfoot, and 11 cm at the heel (29). After commencing the study, the MBT® shoe we used (the 'Mahuta' model) was discontinued by the company and replaced with the 'Matwa' model, resulting in 4 participants receiving the Mahuta and 42 receiving the Matwa. However, both models had the same sole curvature and only differed slightly in relation to the aesthetics of the upper.

Gait analysis

Both groups underwent the same biomechanical assessment. However, for the prefabricated foot orthoses group, comparisons were made when wearing their own shoes (with and without the prefabricated orthoses), while for the rocker-sole shoe group, comparisons were made between their own shoes and the rocker-sole shoes. The order of testing was randomized. After a familiarisation period of walking 250 m, participants completed four walking trials for each footwear condition over an 8 m distance. To exclude the effect of acceleration and deceleration steps, only the middle four steps from each trial were included for analysis. An average recording was determined from 16 steps for each condition. Walking speed was intentionally not controlled for in order to provide insights into how participants would function under real-world conditions.

Spatiotemporal parameters and sagittal plane peak-to-trough range of motion of the hip and knee joints during gait were recorded using a wireless, wearable sensor motion analysis system (LEGSys™, Biosensics, Boston, USA). This system consists of accelerometers and gyroscopes attached with Velcro™ straps to each lower leg and thigh. The method for calculation of the spatiotemporal parameters of gait is described in detail elsewhere (30). To summarise, the gait phases are determined from the precise events of heel-strike (initial foot contact) until toe-off (terminal foot contact). These events are extracted from gyroscopes attached to each shank through a local minimal peak detection scheme. Based on each participant's height and using a biomechanical model, spatial parameters (i.e. stride length and stride velocity) and kinematics (hip and knee) are estimated by integration of the angular rate of rotation of the thigh and shank relative to the waist sensor. Gait analysis with this system has been validated in healthy young controls (30) and older people (31) and has been shown to exhibit acceptable reliability (32).

Peak plantar pressure under the hallux, lesser toes, 1st MTPJ, 2nd to 5th MTPJs, midfoot and heel were measured with the in-shoe Pedar® system (Novel GmbH, Munich, Germany), a reliable, valid and accurate measure of in-shoe pressure (33-35). The Pedar® insoles are approximately 2 mm thick and consist of 99 capacitive pressure sensors, arranged in grid alignment. Plantar pressure data were sampled at a frequency of 50 Hz.

Statistical analysis

Statistical analysis was undertaken using SPSS version 22.0 (IBM Corp, NY, USA). The most symptomatic foot was selected as the index foot for all analyses, or in the case of equivalent symptoms in both feet, the right foot was selected. All data were explored for normality using the skewness statistic (-1 to 1). To evaluate the effects of the interventions (i.e. prefabricated orthoses and rocker-sole shoes) compared to participants' own footwear, a series of within-group paired *t*-tests were conducted. To compare the effects of prefabricated orthoses and rocker-sole shoes, between-group analyses of covariance were conducted with the intervention group and participants' own footwear scores entered as independent variables (36). The effect size for within-group comparisons was calculated using Cohen's *d*, and the following interpretation of effect size was used: negligible (< 0.15), small (0.15 to 0.40), medium (0.40 to 0.75), large (0.75 to 1.10) and very large (>1.10) (37). Adjusted mean differences and 95% confidence intervals (CIs) were calculated for between-group comparisons.

Results

Participants

A total of 102 participants were randomized into the study. Five withdrew prior to the baseline assessment, leaving 97 who underwent gait analysis. Characteristics of these participants are reported in Table 1. Due to technical issues with data collection, spatiotemporal / kinematic data were missing from nine participants and plantar pressure data were missing from seven participants. Furthermore, upon initial screening of the data, it was noted that there were three significant outliers for peak pressure under the 1st MTPJ, where extremely high peak pressures were registered for one or two individual sensors on the most medial edge of the insole. Because the pressure readings obtained from these sensors were unilateral and markedly higher than adjacent sensors, it was concluded that they were due to the Pedar® insole being folded or compressed against the medial upper of the shoe. For this reason, 1st MTPJ peak pressure data from these three participants were excluded from the analysis. Therefore, complete spatiotemporal / kinematic and plantar pressure data were available from 88 and 87 participants, respectively.

Spatiotemporal and kinematic data

Spatiotemporal and kinematic data are shown in Table 2. Compared to participants' own footwear, the orthoses had minimal effects on spatiotemporal or kinematic parameters, with a reduction in velocity (Cohen's *d*=0.14; negligible effect) and knee ROM (*d*=0.36; small effect) observed, while the rocker-sole shoes resulted in reduced cadence (*d*=0.26; small effect), percentage of the gait cycle spent in stance phase (*d*=0.44; medium effect) and reduced sagittal plane hip ROM (*d*=0.44; medium effect). Between-group comparisons indicated that the percentage of the gait cycle spent in stance phase and sagittal plane hip ROM was lower in the rocker-sole shoe group compared to the orthoses group.

Plantar pressure data

Typical examples of peak pressure recordings are shown in Figure 4, and complete peak plantar pressure data are shown in Table 2. Compared to participants' own footwear, the orthoses increased peak pressure under the lesser toes (*d*=0.59; medium effect) and midfoot (*d*=0.45; medium effect), and decreased peak pressure under the 1st MTPJ (*d*=0.55; medium effect) and heel (*d*=0.72; medium effect), while the rocker-sole shoes decreased peak pressure under the 1st MTPJ (*d*=0.44; medium effect), 2nd to 5th MTPJs (*d*=0.92; large effect) and heel (*d*=0.91; large effect). Between-group comparisons indicated that the peak pressure under the lesser toes, 2nd to 5th MTPJs and midfoot was lower in the rocker-sole shoes compared to the orthoses, but there was no difference in peak pressure under the 1st MTPJ.

Discussion

The objective of this study was to compare the immediate biomechanical effects of individualized prefabricated foot orthoses and rocker-sole footwear in people with osteoarthritis (OA) of the first metatarsophalangeal joint (1st MTPJ). Our findings indicate that both interventions were effective at reducing peak pressure beneath the 1st MTPJ, which may be one of the mechanisms responsible for their apparent beneficial effects in the treatment of OA affecting this joint. However, they appear to achieve this through different mechanisms. The prefabricated orthoses had minimal effect on spatiotemporal or kinematic parameters, while the rocker-sole footwear resulted in reduced cadence, percentage of the gait cycle spent in stance phase and sagittal plane hip range of motion. Plantar pressure assessment also revealed that the prefabricated foot orthoses produced an increase in peak pressure under the lesser toes and midfoot and a decrease under the heel, while the rocker-sole shoes were associated with decreased peak pressure under the 2nd to 5th MTPJs and heel.

The prefabricated orthoses in this study were modified by the addition of a cut-out section beneath the first metatarsal, as described by Welsh *et al*. (8). The rationale behind this approach is to facilitate first ray plantarflexion, thereby allowing the proximal phalanx to dorsiflex on the first metatarsal head and minimise joint compression during propulsion (6). However, the gait analysis component of the Welsh *et al*. study found no differences in 1st MTPJ dorsiflexion when orthoses were worn, despite participants reporting a reduction in symptoms. Our in-shoe plantar pressure data suggest that orthoses may instead achieve their apparent beneficial effects by redistributing load away from the 1st MTPJ, possibly by shifting it towards the medial longitudinal arch during midstance and towards the lesser toes during propulsion. Increased midfoot load appears to be a consistent and predictable effect of wearing orthoses which contour the arch (38, 39). However, the shift in load towards the lateral toes observed in this study is a novel finding and may be specific to the style of orthosis we used (incorporating a cut-out section beneath the first metatarsal) and/or the condition being studied (1st MTPJ OA).

The biomechanical effects of rocker-sole footwear have been examined in several studies, but none have specifically examined individuals with 1st MTPJ OA. Our observation of reduced hip joint range of motion is consistent with previous investigations using a variety of rocker-sole designs (13, 40-42), and has primarily been attributed to the adoption of a shorter stride length. In our study, stride length was not significantly altered when wearing the rocker-sole shoes. However, there was a reduction in cadence and a trend (*P*=0.08) towards reduced velocity, both of which may reflect the adoption of a 'cautious' gait pattern which has been shown to result in reduced sagittal plane hip motion during gait (43). The combination of a posterior heel rocker, shock absorbing heel and anterior rocker in the MBT® shoe may also have a direct influence on hip motion, as less hip flexion may be required for the foot to clear the ground in preparation for initial heel contact (40), the decrease in vertical ground reaction force during contact phase (42) may reduce the internal hip extensor moment, and the relatively 'passive' push-off may require less hip extension during propulsion.

Consistent with several previous studies of a range of rocker-sole shoes (44-46), the in-shoe plantar pressure evaluation revealed a significant reduction in forefoot peak pressure. This finding, combined with our observation of a smaller relative proportion of the gait cycle spent in stance phase, suggests that this style of footwear facilitates forward momentum by enabling the body's centre of mass to passively 'roll over' the base of support, rather than achieving propulsion through ankle power generation at push-off. Indeed, studies of gait kinetics when wearing rocker-sole footwear have reported reductions in peak internal ankle plantarflexor moment (42) and plantarflexor power generation (41) during late stance phase, which is indicative of reduced concentric function of the triceps surae. Given that a reduction in forefoot pressures has been shown to be associated with pain relief in people with forefoot pain (47), it is possible that such a change may also be therapeutically beneficial in people with symptomatic 1st MTPJ OA by offloading the painful area and reducing joint compression.

The findings of this study need to be considered in the context of several design limitations. First, it was not possible to blind participants to their intervention allocation. Second, the observed changes are immediate effects only, as all gait assessments were performed at the baseline assessment. Although we allowed participants a familiarisation period to adapt to their orthoses and footwear, we acknowledge that the effects of the interventions are likely to change over time. Indeed, Stoggle *et al*. (48) have shown that the gait variability induced by MBT® shoes significantly reduces after 10 weeks of daily wear, suggesting that some degree of habituation occurs. Third, our gait analysis technique did not allow for in-shoe assessment of 1st MTPJ kinematics, as this requires the permanent modification of the upper of the shoe to enable placement of reflective markers or electromagnetic sensors. This approach can compromise the structural integrity of the shoe (49) and is clearly not feasible in the context of a prospective trial where participants are expected to wear the shoes during daily activities over several weeks. Fourth, the wearable sensor motion analysis system we used is restricted to sagittal plane evaluation of the knee and hip. Finally, an inherent limitation of commercially-available in-shoe plantar pressure measurement systems such as the Pedar® is that they only measure force perpendicular to the sensor surface. Therefore, the accuracy of measurements made along curved surfaces (such as the medial arch of foot orthoses) may be limited.

In summary, this study has shown that prefabricated foot orthoses and rocker-sole footwear are effective at reducing peak pressure under the 1st MTPJ in people with first MTPJ OA, however they appear to achieve this through different mechanisms. The planned 12 week follow-up will determine whether these interventions are acceptable to participants and are effective at reducing joint pain.

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Contributions

HBM, SEM and PL conceived the idea and obtained funding for the study. HBM, SEM and PL designed the trial protocol with input from JMT, MA and ER. HBM drafted the manuscript with input from SEM, PL, MA, JMT and ER. All authors have read and approved the final manuscript.

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

	Orthoses group (n=51)	Rocker-sole group (n=46)
Demographics and anthropometrics		
Age – years	57.0 (11.2)	56.5 (11.1)
Female – n (%)	28 (54.9)	28 (60.9)
Height – cm	166.2 (8.8)	166.3 (8.3)
Weight – kg	80.7 (15.0)	78.5 (13.3)
Body mass index – kg/m^2	29.2 (4.8)	28.4 (4.5)
Clinical features		
Pain duration – months, median (range)	36 (4 to 360)	30 (6 to 420)
Foot Posture Index – mean (SD) [range]	3.0 (2.5) [-2 to 11]	3.4 (2.2) [-2 to 10]
1^{st} MTPJ dorsiflexion ROM – degrees	39.8 (12.7)	40.5 (13.0)
Pain on palpation – n (%)	51 (100.0)	46 (100)
Palpable dorsal exostosis – n (%)	49 (96.1)	45 (97.8)
Joint effusion – n (%)	17 (34.0)	16 (34.8)
Pain on motion of 1^{st} MTPJ – n (%)	49 (96.1)	41 (91.1)
Hard-end feel when dorsiflexed – n (%)	46 (90.2)	39 (84.8)
Crepitus – n (%)	35 (68.6)	30 (65.2)
Radiographic features – n (%)*		
Dorsal osteophytes	48 (96.0)	38 (84.0)
Dorsal joint space narrowing	43 (86.0)	36 (80.0)
Lateral osteophytes	43 (86.0)	35 (77.8)
Lateral joint space narrowing	42 (84.0)	38 (84.4)
Radiographic first MTPJ OA – n (%)†	38 (79.2)	30 (66.7)
Footwear characteristics		
Walking / athletic / Oxford shoe – n (%)	32 (62.7)	26 (56.5)
Mary Jane / courtshoe / boot – n (%)	9 (17.6)	13 (28.2)
Sandal / slipper / moccasin – n (%)	10 (19.6)	7 (15.2)
Heel height – mm	23.8 (7.9)	22.4 (10.5)
Forefoot height – mm	12.2 (5.1)	12.2 (5.7)
Sole flexion point – n (%)		
At level of MTPJs	35 (68.6)	28 (60.9)
Proximal to MTPJs	10 (19.6)	12 (26.1)
Distal to MTPJs	6 (11.8)	6 (13.0)

* score >0 using Menz *et al*. (27) atlas

† at least one score of 2 for osteophytes or joint space narrowing from either view, using case definition from Menz *et al*. (27) atlas

Table 2. Effects of orthoses and rocker-sole shoes on spatiotemporal / kinematic and plantar pressure parameters.

	Within-group comparisons						Between-group comparisons	
	Orthoses group			Rocker-sole group				
	Own footwear	Own footwear + orthoses	*P*	Own footwear	Rocker-sole footwear	*P*	Adjusted mean difference (95% CI)*	*P*
Spatiotemporal / kinematic								
Velocity (m/s)	1.06 (0.15)	1.04 (0.14)	0.039	1.04 (0.13)	1.00 (0.14)	0.075	-0.02 (-0.06 to 0.02)	0.374
Stride length (m)	1.16 (0.15)	1.15 (0.14)	0.280	1.11 (0.13)	1.10 (0.14)	0.408	-0.02 (-0.06 to 0.02)	0.396
Cadence (steps/min)	109.72 (8.09)	108.46 (8.42)	0.055	112.02 (8.65)	109.85 (8.54)	0.015	-0.53 (-2.58 to 1.53)	0.610
Stance phase (%)	59.69 (2.03)	59.90 (2.14)	0.479	59.66 (1.77)	58.84 (2.03)	0.021	-1.04 (-1.84 to -0.25)	0.010
Sagittal knee ROM	60.89 (8.30)	57.94 (8.31)	0.027	59.75 (11.69)	59.06 (9.71)	0.576	1.76 (-1.27 to 4.78)	0.252
Sagittal hip ROM	47.93 (5.03)	47.61 (5.95)	0.587	46.44 (4.90)	44.46 (4.26)	0.006	-2.11 (-3.80 to -0.42)	0.015
Plantar pressure (kPa)								
Hallux	231.22 (92.94)	243.11 (98.95)	0.120	244.11 (92.47)	252.68 (112.14)	0.533	-1.42 (-31.49 to 28.65)	0.925
Lesser toes	116.94 (39.40)	139.50 (37.51)	<0.001	131.90 (56.04)	126.25 (37.92)	0.502	-19.21 (-33.31 to -5.10)	0.008
1^{st} MTPJ	161.99 (54.44)	132.95 (51.98)	<0.001	166.06 (50.44)	146.19 (39.48)	0.002	10.56 (-3.07 to 24.20)	0.127
2^{nd}-5^{th} MTPJs	223.67 (57.15)	236.89 (63.26)	0.056	223.45 (60.83)	173.69 (48.26)	<0.001	-63.08 (-82.96 to -43.20)	<0.001
Midfoot	95.89 (32.51)	109.61 (29.13)	<0.001	86.43 (29.36)	90.54 (23.78)	0.356	-14.21 (-23.49 to -4.92)	0.003
Heel	226.78 (69.71)	187.67 (34.42)	<0.001	213.51 (49.05)	174.11 (37.36)	<0.001	-10.01 (-23.38 to 3.81)	0.153

* mean difference between interventions, adjusted for own footwear (control) condition

Figure legends

Figure 1. Prefabricated foot orthoses used in the trial. Top: plantar surface of left foot orthosis. Bottom: dorsal surface of right foot orthosis. Image from Menz *et al*.(18).

Figure 2. MBT® Matwa footwear. Image from Menz *et al*.(18).

Figure 3. Gait analysis set-up.

Figure 4. Typical plantar pressure recordings taken from a participant allocated to the orthoses group (top) and to the rocker-sole footwear group (bottom). Images represent the mean of eight steps for the index (right) foot. Note the reduced peak pressure under the forefoot and heel, and increased pressure under the midfoot associated with both interventions compared to the participant's own footwear.