# Effectiveness of Foot Orthoses Versus Rocker-Sole Footwear for First Metatarsophalangeal Joint Osteoarthritis: Randomized Trial

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*Competing interests*

The authors declare that they have no competing interests.

**Abstract**

*Objective*

To compare the effectiveness of prefabricated foot orthoses to rocker-sole footwear in reducing foot pain in people with first metatarsophalangeal joint osteoarthritis (1st MTPJ OA).

*Design*

Participants (n=102) with 1st MTPJ OA were randomly allocated to receive individualized, prefabricated foot orthoses or rocker-sole footwear. The primary outcome measure was the pain subscale on the Foot Health Status Questionnaire (FHSQ) at 12 weeks. Secondary outcome measures included the function, footwear and general foot health subscales of the FHSQ, the Foot Function Index, severity of pain and stiffness at the 1st MTPJ, perception of global improvement, general health status, use of rescue medication and co-interventions to relieve pain, physical activity and the frequency of self-reported adverse events.

*Results*

The FHSQ pain subscale scores improved in both groups, but no statistically significant difference between the groups was observed (adjusted mean difference 2.05 points, 95%CI -3.61 to 7.71, p=0.477). However, the footwear group exhibited lower adherence (mean [SD] total hours worn 287 [193] *versus* 448 [234], p<0.001), were less likely to report global improvement in symptoms (39 *versus* 62%, relative risk [RR] 0.63, 95% confidence interval [CI] 0.41 to 0.99, p=0.043), and were more likely to experience adverse events (39 *versus* 16%, RR 2.47, 95%CI 1.12 to 5.44, p=0.024) compared to the orthoses group.

*Conclusion*

Prefabricated foot orthoses and rocker-sole footwear are similarly effective at reducing foot pain in people with 1st MTPJ OA. However, prefabricated foot orthoses may be the intervention of choice due to greater adherence and fewer associated adverse events.

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*Trial registration:* Australian New Zealand Clinical Trials Registry:
ACTRN12613001245785.

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

*Running title:* Orthoses and footwear effectiveness

## SIGNIFICANCE AND INNOVATIONS

- This is the first randomized trial to compare the effectiveness of foot orthoses and rocker-sole shoes in people with 1st MTPJ OA

- Both interventions were similarly effective at reducing foot pain

- Adherence was lower and adverse events more common in the rocker-sole footwear group

- Foot orthoses may be the preferred intervention for 1st MTPJ OA

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Osteoarthritis (OA) of the first metatarsophalangeal joint (1st MTPJ) is the most common form of foot OA. Radiographic changes within this joint are observed in up to 35% of people aged over 35 years (1), while the population prevalence of symptomatic radiographic 1st MTPJ OA has recently been estimated as 7.8% in people aged over 50 years (2). The condition is characterized by symptoms of joint pain and stiffness, formation of a dorsal exostosis, and progressive reduction in range of motion of 1st MTPJ dorsiflexion with increasing radiographic severity (3). As a consequence of these changes, 72% of those affected report associated locomotor disability (2), and the condition has been shown to have a detrimental impact on health-related quality of life (4).

Several treatments have been proposed for 1st MTPJ OA, including physical therapies, anti-inflammatory medications, intra-articular injections, foot orthoses, footwear modifications and surgery (5). However, the evidence for the effectiveness of these treatments is limited, with the most recent systematic review identifying only one very small, low-quality trial of two physical therapy programs with a short (four week) follow-up (6). Since the publication of this review, one additional trial has been conducted which found that intra-articular viscosupplementation with hyaluronan was no more effective than a placebo injection after three months of follow-up (7). Clearly, there is a need for additional well-designed trials into non-surgical interventions for 1st MTPJ OA.

Biomechanical factors are thought to contribute to 1st MTPJ OA (8), suggesting that mechanical interventions may hold some promise as an effective treatment for this condition. One of the most commonly used interventions are foot orthoses, which are thought to decrease 1st MTPJ pain by allowing the first metatarsal to plantarflex during the propulsive phase of gait, thereby minimising dorsal joint compression (9). A similar effect may also be obtained using a footwear modification known as a rocker-sole, which allows the body's centre of mass to 'roll over' the base of support, reducing the need for 1st MTPJ dorsiflexion. However, evidence to support the effectiveness of foot orthoses for 1st MTPJ OA is limited to case reports (10, 11) and one case series study (12). Similarly, the effectiveness of rocker-sole footwear is largely anecdotal, with only one small case series suggesting that rocker-sole footwear was effective when combined with intra-articular corticosteroid injection (13).

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Given the prevalence and impact of 1st MTPJ OA and the lack of evidence for existing interventions, the objective of this study was to compare the effectiveness of prefabricated foot orthoses to rocker-sole footwear in reducing foot pain in people with 1st MTPJ OA.

## METHODS

### Trial design

The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (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 (14). The study design was a parallel-group randomized trial comparing two interventions: prefabricated foot orthoses *versus* commercially available rocker-sole footwear (MBT®, Masai Barefoot Technology, Switzerland). 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). Due to the nature of the intervention, research staff administering the treatments were not blinded to group allocation. However, follow-up assessment of outcome measures was via self-completion questionnaires returned by mail, and staff entering outcome measure data and conducting statistical analyses were blinded.

### Participants

Between February and October 2014 we recruited participants via (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.

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 (15), (v) have pain upon palpation of the dorsal aspect of the 1st MTPJ, (vi) be able to walk household distances (>50 metres) without the aid of a walker, crutches or cane, (vii) be willing to attend the Health Sciences Clinic at La Trobe

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University (Melbourne, Victoria, Australia) 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, and (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 included (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) (16, 17), (iv) presence of one or more conditions within the foot or ankle, which, in the opinion of the investigators, could confound pain and functional assessments of the 1st MTPJ, such as metatarsalgia, plantar fasciitis, pre-dislocation syndrome, Achilles tendinopathy or degenerative joint disease (other than the 1st MTPJ), determined by a podiatrist, (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) (18), (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 (19).

**Randomization**

Permuted block randomization with random block sizes, stratified by sex, was undertaken using an interactive voice response telephone service provided by the NHMRC Clinical

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Trials Centre at the University of Sydney, New South Wales, Australia to ensure allocation concealment (14).

**Clinical and radiographic assessment**

All assessments and interventions were performed at the La Trobe University Health Sciences Clinic, Melbourne, Victoria, Australia. At baseline, participants underwent a clinical assessment including measurements of height, weight and body mass index (BMI), foot posture (using the Foot Posture Index (20)), passive non-weightbearing dorsiflexion range of motion at the 1st MTPJ (21) 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 (15).

The presence of radiographic 1st MTPJ OA was determined at baseline using a radiographic atlas developed by Menz *et al*. (22). 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). Radiographic OA using this atlas is defined as a score of 2 or more for osteophytes or joint space narrowing on either dorso-plantar and lateral views. 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) (22).

**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*. (12) 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 second to fifth toe sulci (Figure 1). In participants with pronated feet (defined as a Foot Posture Index [FPI] score of >7 (23)), full length, four-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 two points (12). The wedge was gradually bevelled so that it

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extended to the proximal margin of the cut-out section beneath the first metatarsal. The rocker-sole footwear group were provided with a pair of rocker-sole shoes (MBT[®] Mahuta/Matwa, Masai Barefoot Technology, Switzerland). These shoes are 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 (24). Fitting of the shoes was undertaken by trained assessors using the Brannock Device[®]. All participants received an information handout which outlined the appropriate use and care of their orthoses or footwear.

**Outcome measures**

The primary outcome measure was the foot pain domain of the Foot Health Status Questionnaire (FHSQ) (25), measured at baseline, 4, 8 and 12 weeks. The FHSQ is a foot-specific health-related quality of life outcome measure consisting of 13 questions that assess four domains of foot health including pain, function, footwear and general foot health. Questions within each domain are scored using a Likert response format, with an output score produced ranging from 0 to 100, with a score of 100 indicating optimum foot health and a score of 0 indicating very poor foot health. The FHSQ has been shown to have a high degree of internal consistency (Cronbach's $\alpha=0.88$) and test-retest reliability (intra-class correlation coefficient=0.86 (25)), and is a widely recommended outcome measure in clinical trials of rheumatological foot disorders (26). Participants treated for bilateral symptoms were asked to describe symptoms of their most painful foot. If both feet were equally painful, the right foot was selected as the index foot.

Secondary outcome measures included: (i) the function domain of the FHSQ, measured at baseline, 4, 8 and 12 weeks, (ii) the Foot Function Index - Revised (Short Form) (27), measured at baseline and 12 weeks, (iii) severity of pain at the 1st MTPJ while walking over a flat surface and during rest over the last week (each via a 100 mm visual analog scale [VAS]), measured at baseline, 4, 8 and 12 weeks, (iv) duration and severity of stiffness at the 1st MTPJ after first awakening in the morning, during the last week (via a 100 mm VAS), measured at baseline, 4, 8 and 12 weeks, (v) severity of stiffness after sitting, lying, or resting later in the day, during the last week (via a 100 mm VAS), measured at baseline, 4, 8 and 12

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weeks, (vi) global change in symptoms using a 15-point Likert scale (7=a very great deal better, 6=a great deal better, 5=a good deal better, 4=moderately better, 3=somewhat better, 2=a little better, 1=about the same, hardly any better at all, 0=no change, -1=about the same, hardly any worse at all, -2=a little worse, -3=somewhat worse, -4=moderately worse, -5=a good deal worse, -6=a great deal worse, -7=a very great deal worse, with a dichotomised score of $\geq 4$ representing improvement), measured at 12 weeks, (vii) health status (using the Short-Form-12 Version 2 questionnaire) (28), measured at baseline and 12 weeks, (viii) use of paracetamol rescue medication (number of participants and mean consumption) and co-interventions to relieve pain at the $1^{st}$ MTPJ, documented with a monthly diary throughout the 12 week study period, (ix) the frequency and type of self-reported adverse events (defined as an unwanted event that may or may not be related to the treatment) collected at 4 weekly intervals throughout the 12 week study period, and (x) the Incidental and Planned Activity Questionnaire, a self-report questionnaire that covers the frequency and duration of several levels of planned and incidental physical activity (29), measured at baseline and 12 weeks.

To maximize response to the postal questionnaire outcome measures, we sent emails or letters after one week to non-responders, and then followed-up with up to three attempted contacts by telephone and/or email over a two week period.

**Sample size**

The sample size for the study was determined using an *a priori* power analysis based on the primary outcome measure: the pain domain of the Foot Health Status Questionnaire (FHSQ) (25). We have previously determined that the minimal important difference for this measure in people with foot pain is 13 points (30). Using a standard deviation of 19 (derived from our recent trial (7)), a power level of 0.8, alpha level of 0.05 and accounting for a drop-out rate of 15%, we determined that a sample size of 80 participants (i.e. approximately 40 per group) was required.

**Statistical analysis**

Statistical analysis was undertaken using SPSS version 22.0 (IBM Corp, NY, USA) using the intention-to-treat principle for all randomized participants (31). Multiple imputation was used to replace missing data using five iterations, with age, baseline scores, and group allocation

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as predictors (32). The exception was the use of co-interventions, rescue medication and adverse events, where no data substitution was applied. Continuously-scored outcome measures were analysed using analysis of covariance (ANCOVA) with baseline scores and intervention group entered as independent variables (33). Dichotomously-scored outcome measures were compared using relative risk, and number needed to treat/harm (NNT/NNH). To avoid over-testing and to minimize the risk of Type I error associated with serial measurements, statistical analysis of the effectiveness of the interventions specifically focused on the change in outcome measures between baseline and 12 weeks (34, 35).

## RESULTS

### Participant characteristics

Figure 3 shows the flow of participants through the study. The sample consisted of 102 participants (45 men and 57 women) aged 22 to 78 years (mean 56.8, SD 11.1). Fifty-two participants were allocated to the orthoses group and 50 to the footwear group. Participants in the two groups had similar baseline characteristics (Table 1). Four participants in the footwear group withdrew consent after randomization and did not receive their allocated intervention. Of these, two could not tolerate the shoes, one had very large feet that could not be accommodated in the available size range, and one withdrew on advice from their chiropractor. Shortly 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 four 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. Two participants in the orthoses group had pronated feet (FPI>7), so had varus wedged applied to their orthoses according to the pre-specified protocol (14).

### Participant retention and intervention adherence

By the 12 week follow-up, there were five drop-outs in the orthoses group (one withdrew as they could not tolerate the orthoses, and four were lost to follow-up) and five drop-outs in the footwear group (two withdrew as they could not tolerate the footwear, and three lost to follow-up), giving completion rates of 90 and 89%, respectively. Participants in the orthoses group reported wearing their intervention for a greater number of hours than the footwear

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group (mean [SD] total hours worn over study period = 448 [238] *versus* 287 [192]; p<0.001).

**Primary outcome**

Table 2 shows the mean (SD) scores and adjusted mean differences (95% CIs) between groups for the FHSQ pain domain at baseline and at 4, 8 and 12 weeks follow-up. Both groups demonstrated an increase in the FHSQ pain domain score (17 points in the orthoses group and 22 points in the footwear group), which is indicative of improved foot health. However, there was no difference between the groups at the 12 week follow-up (ANCOVA adjusted mean difference of 2.05 points, 95% CI -3.61 to 7.71, p=0.477).

**Secondary outcomes**

Table 2 shows the mean (SD) scores and adjusted mean differences (95% CIs) between groups for the secondary outcome measures (FHSQ function domain, FFI, pain and stiffness, SF-12 and physical activity levels). There were no differences between the groups at the 12 week follow-up for any of these measures. However, at the completion of the study, the perception of global improvement, defined as at least moderate improvement (score $\geq 4$) on the 15-point Likert scale, was lower in the footwear group (39 *versus* 62%, RR 0.63, 95% CI 0.41 to 0.99, p=0.043). The NNH was 5 (95% CI 2.3 to 43.9), meaning that one in every five participants treated with footwear had an unsuccessful outcome compared to those receiving orthoses.

**Use of cointerventions**

There was no difference in the proportion of participants reporting use of cointerventions between the orthoses and footwear groups (18 *versus* 15%; RR 0.87, 95% CI 0.33 to 2.28, p=0.770) and no difference in the proportion of participants who reported consuming rescue medications between the orthoses and footwear groups (24 *versus* 28%, RR1.15, 95%CI 0.56 to 2.36, p=0.696).

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**Adverse events**

Adverse events are reported in Table 3. The most commonly reported adverse events were new episodes of back or lower limb pain (n=44), blisters (n=5), discomfort associated with the intervention (n=5) and impaired balance (n=5). Participants in the footwear group were more likely to report at least one adverse event (39 *versus* 16%, RR 2.47, 95% CI 1.12 to 5.44, p=0.024; NNH 5, 95% CI 2.4 to 23.1) and were more likely to report a new episode of low back pain during the study than the orthoses group (17 *versus* 4%, RR 4.52, 95% CI 1.01 to 20.22, p=0.048; NNH 10, 95% CI 4.6 to 677.9).

**DISCUSSION**

This is the first randomized trial to evaluate the effectiveness of mechanical interventions in reducing foot pain in people with first metatarsophalangeal joint osteoarthritis (1st MTPJ OA). We found that both the orthoses and footwear groups demonstrated an increase in the Foot Health Status Questionnaire (FHSQ) pain domain score (indicative of an improvement in foot health), but there was no difference between the groups at the 12 week follow-up. However, the footwear group reported lower adherence, were less likely to report at least moderate improvement in symptoms, and were more likely to experience adverse events, particularly new onset low back pain, compared to the orthoses group. Taken together, these findings suggest that prefabricated foot orthoses may be the preferred intervention in the treatment of 1st MTPJ OA.

The primary outcome measure (FHSQ pain domain) increased in both groups at the 12 week follow-up: by 17 points in the orthoses group and 22 points in the footwear group. This change in FHSQ scores exceeds the minimal important difference for this measure (13 points) (30). However, because this is not a *controlled* trial, we cannot be certain of the extent to which the observed changes are true therapeutic effects as opposed to placebo effects, Hawthorne effects, regression to the mean, or natural resolution. We originally intended to provide sham orthoses (36) as the comparator to the rocker-sole footwear, however this was considered by our ethics committee to be withholding usual care and was not permitted (14). Nevertheless, our analysis of the biomechanical effects of these interventions at the baseline appointment indicated that both interventions were similarly effective at reducing peak

pressure under the 1$^{st}$ MTPJ compared to participants' usual footwear (37), which may at least partly explain the similar improvement in symptoms we observed at follow-up.

Adherence varied markedly between the two groups. We found that the footwear group wore their shoes for an average of 287 hours in total throughout the 12 week study period, compared to 448 hours for the orthoses group. This finding was not unexpected, as due to the pronounced sole curvature, the MBT$^{®}$ shoes have a characteristic appearance which may not have been aesthetically acceptable to all participants. Furthermore, because many of our participants were of working age, workplace attire constraints may have created a barrier to wearing the allocated footwear. Low adherence is a well-recognized problem with footwear intervention studies and has been attributed to the unique role of footwear as both an item of clothing and a health-related intervention (38). In contrast, the orthoses are transferrable, can be accommodated in most types of footwear, and are hidden from view, which may have facilitated them being worn more frequently. These observations suggest that orthoses may be a more practical intervention. However, given that the change in FHSQ pain scores was similar between the groups despite marked differences in adherence, it is possible that the rocker-sole shoes have the potential for greater effectiveness if barriers to adherence could be overcome.

Adverse events were more common in the footwear group. Most of these were relatively minor (such as blisters and general discomfort), however the increased risk of new onset low back pain is a notable finding. We cannot be certain that the footwear *caused* the low back pain reported by these participants, nor whether these cases were merely transient episodes reflecting a habituation period associated with wearing the shoes. Nevertheless, biomechanical studies have reported increased thoracic motion and lumbar erector spinae muscle activity when standing (39) and a trend towards increased activity of gluteus medius when walking (40) when wearing MBT$^{®}$ shoes. These changes have generally been interpreted as potentially beneficial for people with low back pain, as they are thought to represent a 'training' effect on pelvic and spinal muscles responsible for postural control (41). However, evidence pertaining to the effectiveness of MBT$^{®}$ shoes in the treatment of low back pain is equivocal (42, 43). It is also possible that such changes may be detrimental to those who do *not* have low back pain, and may explain the higher rate of new onset low back pain we observed in the footwear group.

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Key strengths of this study include the use of well-validated outcome measures, high participant retention and broad generalizability. However, our findings need to be interpreted in the context of several methodological limitations. Firstly, as previously discussed, this was not a controlled trial, so we cannot be certain that the observed changes in participant-reported outcome measures are true therapeutic effects. Secondly, it was not possible to blind participants to their intervention. Thirdly, not all participants met the case definition for radiographic OA described by Menz *et al.* (22), which requires a score of 2 or more for osteophytes or joint space narrowing on either dorso-plantar and lateral views. In order to minimize costs and radiation exposure, we did not use radiographs for eligibility screening, and instead used the clinical diagnostic tests described by Zammit *et al.* (15) to identify participants with likely OA. In our sample, this clinical model was sensitive but not specific, meaning that 28 participants included in the trial did not meet the Menz *et al.* (22) case definition. Nevertheless, these participants all showed at least some radiographic changes and exhibited other cardinal signs of 1st MTPJ OA. Finally, we used a specific model of MBT® shoe and prefabricated orthosis, so it is unclear whether our findings can be generalized to other types of rocker-sole shoes or orthoses which may have different biomechanical effects.

In summary, this randomized trial has shown that prefabricated foot orthoses and rocker-sole footwear are similarly effective at reducing foot pain in people with 1st MTPJ OA. However, the higher adherence and lower rate of adverse events we observed in the orthoses group suggests that prefabricated foot orthoses may be the preferred intervention for this condition. Future research should focus on examining the effectiveness of other types of orthoses and footwear interventions compared to a sham intervention, identifying who is most likely to benefit from mechanical interventions, and determining whether barriers to adherence with rocker-sole footwear can be overcome by addressing concerns related to aesthetics and comfort.

**COMPETING INTERESTS**

The authors declare that they have no competing interests.

**AUTHORS' CONTRIBUTIONS**

HBM, SEM and PL conceived the idea and obtained funding for the study. HBM, SEM and

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

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

| | Orthoses group (n=52) | Footwear group (n=46) |
|---|---|---|
| Demographics and anthropometrics | | |
| Age – years | 57.1 (11.1) | 56.5 (11.1) |
| Female – n (%) | 29 (55.8) | 28 (60.9) |
| Height – cm | 166.0 (8.90) | 166.3 (8.3) |
| Weight – kg | 80.5 (14.9) | 78.5 (13.3) |
| Body mass index – kg/m$^2$ | 29.2 (4.8) | 28.4 (4.5) |
| General health | | |
| SF-12 – physical | 44.1 (10.7) | 45.0 (9.7) |
| SF-12 – mental | 55.8 (8.1) | 51.9 (9.0) |
| Toal physical activity – hours / week | 17.5 (14.6) | 15.4 (11.4) |
| Clinical features | | |
| Pain duration – months, median (range) | 33 (4 to 360) | 30 (6 to 420) |
| Foot Posture Index – mean (SD) [range] | 3.0 (2.4) [-2 to 11] | 3.4 (2.2) [-2 to 10] |
| 1$^{st}$ MTPJ ROM – degrees | 39.8 (12.5) | 40.5 (13.0) |
| Pain on palpation – n (%) | 52 (100) | 46 (100) |
| Palpable dorsal exostosis – n (%) | 50 (96.2) | 45 (97.8) |
| Joint effusion – n (%) | 17 (33.3) | 16 (34.8) |
| Pain on motion of 1$^{st}$ MTPJ – n (%) | 49 (94.2) | 41 (91.1) |
| Hard-end feel when dorsiflexed – n (%) | 47 (90.4) | 39 (84.8) |
| Crepitus – n (%) | 35 (67.3) | 30 (65.2) |
| Radiographic features – n (%)* | | |
| Dorsal osteophytes | 50 (96.2) | 39 (84.8) |
| Dorsal joint space narrowing | 43 (82.7) | 39 (84.8) |
| Lateral osteophytes | 42 (80.8) | 39 (84.8) |
| Lateral joint space narrowing | 45 (86.5) | 38 (82.6) |
| Radiographic 1$^{st}$ MTPJ OA† | 37 (71.2) | 33 (76.7) |

SF-12=Short Form 12 Health Survey; MTPJ=metatarsophalangeal joint; ROM=range of motion; OA=osteoarthritis

* score >0 using Menz et al. atlas

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

**Table 2.** Primary and secondary outcome measures at baseline and follow-up. Values are mean (SD).

|  | Orthoses group (n=52) | Footwear group (n=46) | Adjusted mean difference (95% CI)* | p |
|---|---|---|---|---|
| FHSQ – pain domain (0-100 points)† |  |  |  |  |
| Baseline | 56.7 (19.2) | 51.5 (20.3) |  |  |
| 4 weeks | 68.4 (15.8) | 64.5 (17.5) |  |  |
| 8 weeks | 73.2 (15.6) | 67.9 (17.9) |  |  |
| 12 weeks | 73.6 (16.8) | 73.7 (14.80) | 2.05 (-3.61 to 7.71) | 0.477 |
| FHSQ – function domain (0-100 points)† |  |  |  |  |
| Baseline | 70.8 (22.0) | 67.4 (25.5) |  |  |
| 4 weeks | 79.0 (20.8) | 76.9 (20.9) |  |  |
| 8 weeks | 81.5 (18.1) | 77.4 (17.3) |  |  |
| 12 weeks | 82.7 (18.6) | 80.5 (16.6) | -0.24 (-4.95 to 4.47) | 0.920 |
| FFI – pain (0-100 points)† |  |  |  |  |
| Baseline | 40.5 (17.0) | 41.9 (18.7) |  |  |
| 12 weeks | 42.4 (12.7) | 41.0 (12.5) | -1.80 (-6.14 to 2.55) | 0.418 |
| FFI – stiffness (0-100 points)† |  |  |  |  |
| Baseline | 33.4 (19.5) | 37.1 (23.4) |  |  |
| 12 weeks | 41.1 (13.0) | 42.0 (16.3) | -0.25 (-5.59 to 5.08) | 0.926 |
| FFI – difficulty (0-100 points)† |  |  |  |  |
| Baseline | 37.6 (24.5) | 40.0 (25.0) |  |  |
| 12 weeks | 43.7 (14.8) | 46.3 (16.0) | 1.69 (-3.11 to 6.49) | 0.489 |
| FFI – overall (0-100 points)† |  |  |  |  |
| Baseline | 37.0 (18.8) | 39.6 (20.7) |  |  |
| 12 weeks | 42.5 (11.3) | 43.1 (13.8) | -0.39 (-4.14 to 3.37) | 0.840 |
| Pain severity while walking (0-100mm)‡ |  |  |  |  |
| Baseline | 46.4 (21.9) | 47.5 (22.4) |  |  |
| 4 weeks | 27.0 (20.6) | 30.1 (21.9) |  |  |
| 8 weeks | 24.6 (19.9) | 24.8 (18.6) |  |  |
| 12 weeks | 23.0 (20.7) | 20.3 (16.0) | -2.89 (-10.40 to 4.61) | 0.450 |
| Pain severity at rest (0-100mm)‡ |  |  |  |  |
| Baseline | 32.4 (24.8) | 34.4 (25.4) |  |  |
| 4 weeks | 20.5 (18.7) | 21.7 (20.0) |  |  |
| 8 weeks | 15.8 (16.7) | 17.8 (18.5) |  |  |
| 12 weeks | 17.0 (19.6) | 16.4 (19.2) | -1.27 (-8.31 to 5.78) | 0.724 |
| Stiffness severity in morning (0-100mm)‡ |  |  |  |  |
| Baseline | 32.1 (26.3) | 39.3 (25.2) |  |  |
| 4 weeks | 19.5 (15.9) | 26.4 (25.1) |  |  |
| 8 weeks | 15.2 (14.5) | 20.5 (21.2) |  |  |
| 12 weeks | 18.9 (19.7) | 22.7 (22.9) | 0.95 (-7.93 to 9.82) | 0.832 |
| Stiffness severity later in the day (0-100mm)‡ |  |  |  |  |
| Baseline | 34.0 (27.0) | 37.6 (25.4) |  |  |
| 4 weeks | 17.8 (16.7) | 25.4 (24.4) |  |  |
| 8 weeks | 17.3 (17.1) | 19.8 (20.1) |  |  |
| 12 weeks | 18.1 (20.0) | 15.8 (17.8) | -2.99 (-10.53 to 4.59) | 0.441 |
| SF-12 – physical (0-100 points)† |  |  |  |  |
| Baseline | 44.1 (10.7) | 45.0 (9.7) |  |  |
| 12 weeks | 47.1 (9.2) | 46.7 (9.7) | -0.98 (-3.81 to 1.86) | 0.499 |
| SF-12 – mental (0-100 points)† |  |  |  |  |
| Baseline | 55.8 (8.1 ) | 51.9 (9.0) |  |  |

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| | | | | |
|---|---|---|---|---|
| 12 weeks | 52.3 (9.6) | 52.0 (9.6) | -0.32 (-3.93 to 3.29) | 0.862 |
| Total physical activity (hours/week) | | | | |
| Baseline | 17.5 (14.6) | 15.4 (11.4) | | |
| 12 weeks | 21.9 (16.7) | 16.6 (12.1) | -4.46 (-10.10 to 1.17) | 0.120 |

FHSQ=Foot Health Status Questionnaire; FFI=Foot Function Index; SF-12=Short Form 12 Health Survey
* adjusted for baseline score and intervention group using analysis of covariance
† higher scores indicate better function
‡ higher scores indicate worse symptoms

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**Table 3.** Adverse events reported during the study. Values are n (%).

|  | Orthoses group (n=52) | Footwear group (n=46) | RR (95% CI) | p |
|---|---|---|---|---|
| Reported at least one adverse event | 7 (15.6) | 15 (38.5) | 2.47 (1.12 to 5.44) | 0.024* |
| Blisters | 2 (3.8) | 3 (6.5) | 1.34 (0.45 to 4.00) | 0.442 |
| Discomfort | 2 (3.8) | 3 (6.5) | 1.34 (0.45 to 4.00) | 0.442 |
| Impaired balance | 1 (1.9) | 4 (8.7) | 2.74 (0.47 to 15.98) | 0.145 |
| Experienced a fall during trial | 5 (11.1) | 4 (10.3) | 0.92 (0.27 to 3.20) | 0.900 |
| Developed new back/lower limb pain during trial | 31 (68.9) | 28 (73.7) | 1.07 (0.81 to 1.41) | 0.629 |
|    Low back | 2 (3.8) | 8 (17.4) | 4.52 (1.01 to 20.22) | 0.048* |
|    Hip | 1 (1.9) | 1 (2.2) | 1.13 (0.07 to 17.57) | 0.930 |
|    Knee | 4 (7.7) | 3 (6.5) | 0.85 (0.20 to 3.59) | 0.823 |
|    Lower leg | 6 (11.5) | 6 (13.0) | 1.13 (0.39 to 3.26) | 0.821 |
|    Foot/ankle | 22 (42.3) | 20 (43.5) | 1.03 (0.65 to 1.62) | 0.907 |

RR=relative risk

* significantly higher risk in footwear group compared to orthoses group

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**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. Figure from Menz *et al*. (14).

**Figure 2.** MBT® Matwa footwear. Figure from Menz *et al*. (14).

**Figure 3.** Flow of participants through study.

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Figure 1. Prefabricated foot orthoses used in the trial. Top: plantar surface of left foot orthosis. Bottom: dorsal surface of right foot orthosis. Figure from Menz et al. (14).
66x56mm (300 x 300 DPI)

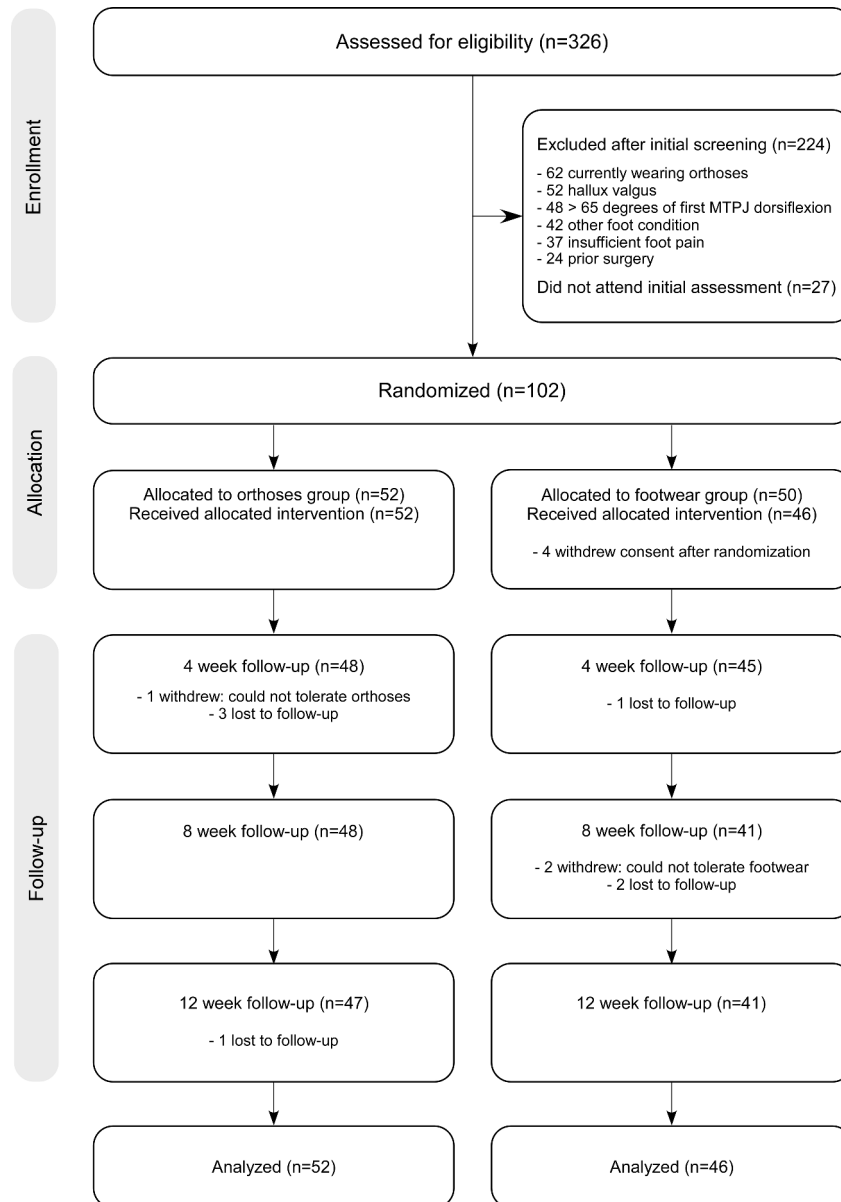Figure 2. MBT® Matwa footwear. Figure from Menz et al. (14).
77x38mm (300 x 300 DPI)

Figure 3. Flow of participants through study.
385x550mm (300 x 300 DPI)