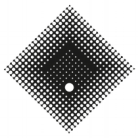
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Effectiveness of Foot Orthoses Versus Rocker-Sole Footwear for First Metatarsophalangeal Joint Osteoarthritis: Randomized Trial

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ORIGINAL ARTICLE

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

HYLTON B. MENZ,[1] MARIA AUHL,[1] JADE M. TAN,[1] PAZIT LEVINGER,[2] EDWARD RODDY,[3] AND SHANNON E. MUNTEANU[1]

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

Methods. **Participants (n = 102) with first MTP joint 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 first MTP joint; 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% confidence interval [95% CI] −3.61, 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% CI 0.41, 0.99; $P = 0.043$), and were more likely to experience adverse events (39% versus 16%; RR 2.47, 95% CI 1.12, 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 first MTP joint OA. However, prefabricated foot orthoses may be the intervention of choice due to greater adherence and fewer associated adverse events.**

INTRODUCTION

Osteoarthritis (OA) of the first metatarsophalangeal (MTP) joint is the most common form of foot OA. Radiographic changes within this joint are observed in up to 35% of people age >35 years (1), while the population prevalence of symptomatic radiographic first MTP joint OA has recently been estimated as 7.8% in people age >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 first MTP joint 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 first MTP joint OA, including physical therapies, antiinflammatory medications, intraarticular 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 1 very small, low-quality trial of 2 physical therapy programs with a short (4-week) followup (6). Since the publi-

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[1]Hylton B. Menz, PhD, Maria Auhl, PhD, Jade M. Tan, PhD, Shannon E. Munteanu, PhD: La Trobe University, Bundoora, Victoria, Australia; [2]Pazit Levinger, PhD: La Trobe University, Bundoora, Victoria, Australia, and Victoria University, Melbourne, Victoria, Australia; [3]Edward Roddy, MBBS, MRCP, DM, FRCP: Keele University, Staffordshire, UK.

Address correspondence to Hylton B. Menz, PhD, School of Allied Health, College of Science, Health and Engineering, La Trobe University, Bundoora, Victoria 3086, Australia. E-mail: h.menz@latrobe.edu.au.

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Significance & Innovations

- This is the first randomized trial to compare the effectiveness of foot orthoses and rocker-sole shoes in people with first metatarsophalangeal (MTP) joint osteoarthritis (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 first MTP joint OA.

cation of this review, 1 additional trial has been conducted, which found that intraarticular viscosupplementation with hyaluronan was no more effective than a placebo injection after 3 months of followup (7). Clearly, there is a need for additional well-designed trials into nonsurgical interventions for first MTP joint OA.

Biomechanical factors are thought to contribute to first MTP joint OA (8), suggesting that mechanical interventions may hold some promise as an effective treatment for this condition. One of the most commonly used interventions is foot orthoses, which are thought to decrease first MTP joint pain by allowing the first metatarsal to plantarflex during the propulsive phase of gait, thereby minimizing 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 center of mass to "roll over" the base of support, reducing the need for first MTP joint dorsiflexion. However, evidence to support the effectiveness of foot orthoses for first MTP joint OA is limited to case reports (10,11) and 1 case series study (12). Similarly, the effectiveness of rocker-sole footwear is largely anecdotal, with only 1 small case series suggesting that rocker-sole footwear was effective when combined with intraarticular corticosteroid injection (13).

Given the prevalence and impact of first MTP joint 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 first MTP joint OA.

MATERIALS AND METHODS

Trial design. The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (12613001245785). The La Trobe University Human Ethics Committee provided ethical approval (13-003) and all participants provided written informed consent prior to enrollment. The full trial protocol has been published previously (14). The study design was a parallel-group randomized trial comparing 2 interventions: prefabricated foot orthoses versus commercially available rocker-sole footwear (Masai Barefoot Technology [MBT]). 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, the followup 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 1) radio advertisements; 2) advertisements placed in local newspapers, magazines, and social media; 3) posters placed at health care facilities, gymnasiums, senior citizens' centers, fun runs, and markets, and 4) 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 1) be age $\geq$18 years, 2) report having pain in the first MTP joint on most days for at least 12 weeks, 3) report having pain rated at least 20 mm on a 100-mm visual analog scale (VAS), 4) have $<64^\circ$ of dorsiflexion range of motion of the first MTP joint (15), 5) have pain upon palpation of the dorsal aspect of the first MTP joint, 6) be able to walk household distances (>50 meters) without the aid of a walker, crutches, or cane, 7) be willing to attend the Health Sciences Clinic at La Trobe University (Melbourne, Victoria, Australia) on 2 occasions and have their foot radiographed, 8) be willing to not receive additional interventions (such as physical therapy, foot orthoses, shoe modifications, intraarticular injections, or surgery) for the first MTP joint pain during the course of the study, and 9) be willing to discontinue taking all medications to relieve pain at their first MTP joint (analgesics and nonsteroidal antiinflammatory medications, except paracetamol up to 4 gm/day) for at least 14 days prior to the baseline assessment and during the study period.

Exclusion criteria included 1) pregnancy; 2) previous surgery on the first MTP joint; 3) significant deformity of the first MTP joint including hallux valgus (grade of 3 or 4 scored using the Manchester Scale) (16,17); 4) presence of 1 or more conditions within the foot or ankle that, in the opinion of the investigators, could confound pain and functional assessments of the first MTP joint, such as metatarsalgia, plantar fasciitis, predislocation syndrome, Achilles tendinopathy, or degenerative joint disease (other than the first MTP joint), determined by a podiatrist; 5) 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; 6) 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 first MTP joint, or fibromyalgia); 7) cognitive impairment (defined as a score of <7 on the Short Portable Mental Status Questionnaire) (18); 8) intraarticular injections into the first MTP joint in the previous 6 months; 9) currently wearing contoured foot orthoses (although flat insoles were permitted); 10)

currently wearing specialized footwear (footwear that has been custom-made or "prescribed" by a health care practitioner); 11) currently wearing shoes that would not be able to accommodate a foot orthosis; or 12) older adults with a history of recurrent falls (defined as 2 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 National Health and Medical Research Council Clinical 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, foot posture (using the Foot Posture Index [FPI]) (20), passive non–weight-bearing dorsiflexion range of motion at the first MTP joint (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 first MTP joint OA was determined at baseline using a radiographic atlas developed by Menz et al (22). The atlas incorporates weight-bearing dorsoplantar 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 dorsoplantar and lateral views. The atlas has been shown to have good to excellent intra- and interrater reliability for grading first MTP joint OA ($\kappa = 0.64$–0.95) (22).

Interventions. The prefabricated foot orthoses group received a pair of foot orthoses (Vasyli Customs Medium Density, Vasyli Medical) 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 (for details of the foot orthoses, see Figure 1, ref. 23). In participants with pronated feet (defined as an FPI score of >7 [24]), full length, 4° 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 (12). The wedge was gradually bevelled so that it extended to the proximal margin of the cut-out section beneath the first metatarsal. The rocker-sole footwear group was provided with a pair of rocker-sole shoes (MBT, Mahuta or Matwa models). These shoes are characterized by a rounded sole in the anteroposterior direction and a soft, cushioned heel (for details of the rocker-sole shoes, see Figure 2, ref. 23). 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 (25). Fitting of the shoes was undertaken by trained assessors using the Brannock Device. All participants received an information handout that 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) (26), measured at baseline and at 4, 8, and 12 weeks. The FHSQ is a foot-specific, health-related quality of life outcome measure consisting of 13 questions that assess 4 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 (intraclass correlation coefficient 0.86) (26), and is a widely recommended outcome measure in clinical trials of rheumatologic foot disorders (27). 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 1) the function domain of the FHSQ, measured at baseline and at 4, 8, and 12 weeks; 2) the Foot Function Index Revised (Short Form) (28) measured at baseline and 12 weeks; 3) severity of pain at the first MTP joint while walking over a flat surface and during rest over the last week (each via a 100-mm VAS, measured at baseline and at 4, 8, and 12 weeks; 4) duration and severity of stiffness at the first MTP joint after first awakening in the morning, during the last week (via a 100-mm VAS), measured at baseline and at 4, 8, and 12 weeks; 5) severity of stiffness after sitting, lying, or resting later in the day, during the last week (via a 100-mm VAS), measured at baseline and at 4, 8, and 12 weeks; 6) global change in symptoms using a 15-point Likert scale (where 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, and −7 = a very great deal worse, with a dichotomized score of ≥ 4 representing improvement), measured at 12 weeks; 7) health status (using the Short-Form 12, version 2 questionnaire) (29), measured at baseline and 12 weeks; 8) use of paracetamol rescue medication (number of participants and mean consumption) and cointerventions to relieve pain at the first MTP joint, documented with a monthly diary throughout the 12-week study period; 9) 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 10) the Incidental and Planned Activity Ques-

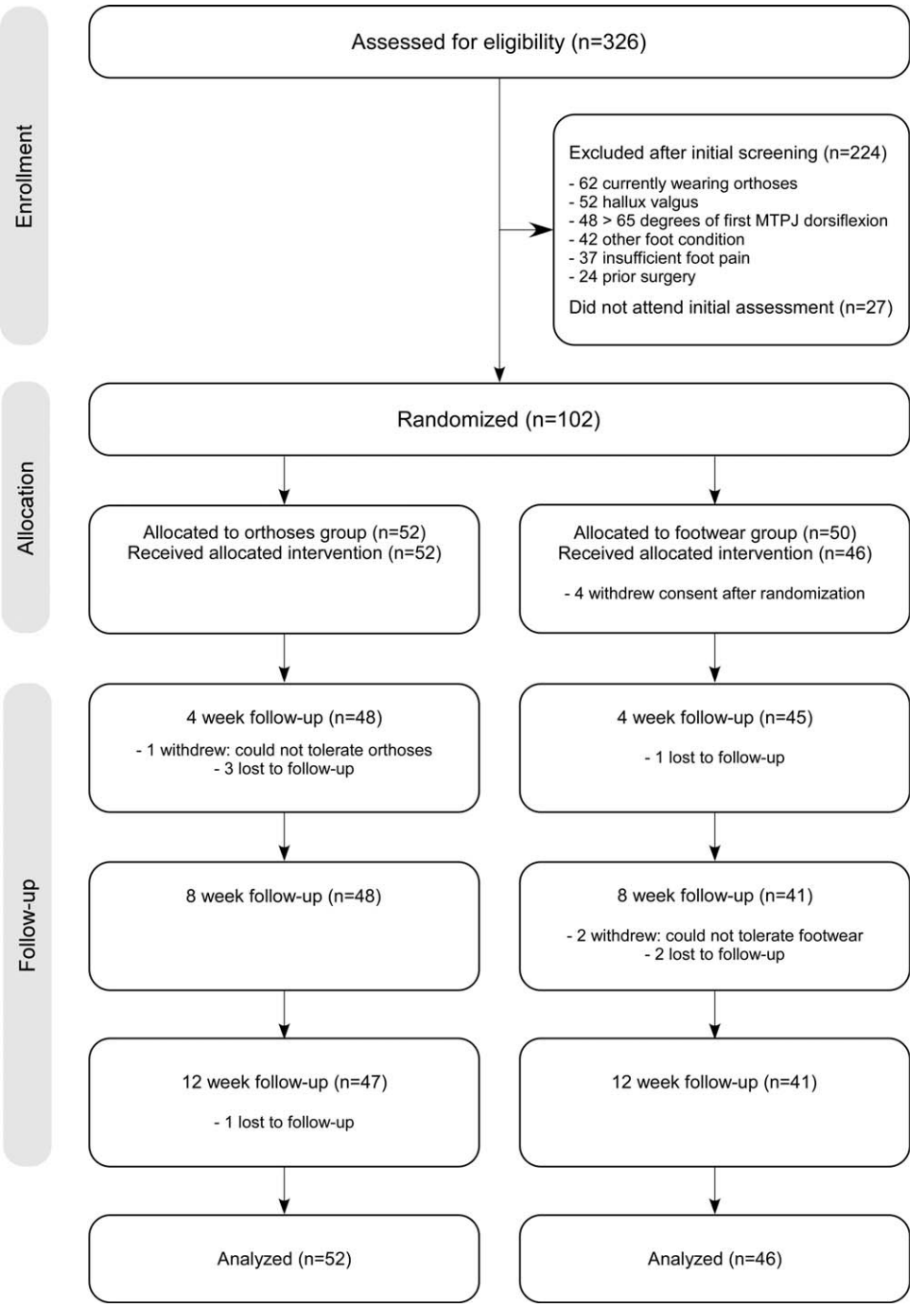

Figure 1. Flow of participants through study. MTPJ = first metatarsophalangeal joint.

tionnaire, a self-report questionnaire that covers the frequency and duration of several levels of planned and incidental physical activity (30), measured at baseline and 12 weeks.

To maximize response to the postal questionnaire outcome measures, we sent e-mails or letters after 1 week to nonresponders, and then followed up with up to 3 attempted contacts by telephone and/or e-mail over a 2-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 FHSQ (26). We have previously determined that the minimal important difference for this measure in people with foot pain is 13 points (31). Using an SD of 19 (derived from our recent trial [7]), a power level of 0.8, an alpha level of 0.05, and accounting for a dropout 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, using the intent-to-treat principle for all randomized participants (32). Multiple imputation

Table 1. Participant characteristics at baseline*

	Orthoses group (n = 52)	Footwear group (n = 46)
Demographics and anthropometrics		
Age, years	57.1 ± 11.1	56.5 ± 11.1
Female, no. (%)	29 (55.8)	28 (60.9)
Height, cm	166.0 ± 8.9	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
Total physical activity, hours/week	17.5 ± 14.6	15.4 ± 11.4
Clinical features		
Pain duration, median (range) months	33 (4–360)	30 (6–240)
Foot Posture Index, mean ± SD (range)	3.0 ± 2.4 (−2–11)	3.4 ± 2.2 (−2–10)
First MTP joint ROM, degrees	39.8 ± 12.5	40.5 ± 13.0
Pain on palpation, no. (%)	52 (100)	46 (100)
Palpable dorsal exostosis, no. (%)	50 (96.2)	45 (97.8)
Joint effusion, no. (%)	17 (33.3)	16 (34.8)
Pain on motion of first MTP joint, no. (%)	49 (94.2)	41 (91.1)
Hard-end feel when dorsiflexed, no. (%)	47 (90.4)	39 (84.8)
Crepitus, no. (%)	35 (67.3)	30 (65.2)
Radiographic features, no. (%)†		
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 first MTP joint OA‡	37 (71.2)	33 (76.7)

* Values are the mean ± SD unless indicated otherwise. SF-12 = Short Form 12 health survey; MTP = metatarsophalangeal; ROM = range of motion; OA = osteoarthritis.
† Score >0 using atlas in ref. 22.
‡ At least one score of 2 for osteophytes or joint space narrowing from either view, using case definition from atlas in ref. 22.

was used to replace missing data using 5 iterations, with age, baseline scores, and group allocation as predictors (33). The exception was the use of co-interventions, rescue medication, and adverse events, where no data substitution was applied. Continuously scored outcome measures were analyzed using analysis of covariance (ANCOVA), with baseline scores and intervention group entered as independent variables (34). Dichotomously scored outcome measures were compared using relative risk (RR), and number needed to treat/harm (NNH). To avoid overtesting 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 (35,36).

RESULTS

Participant characteristics. Figure 1 shows the flow of participants through the study. The sample consisted of 102 participants (45 men and 57 women), ages 22–78 years (mean ± SD age 56.8 ± 11.1 years). Fifty-two participants were allocated to the orthoses group and 50 to the footwear group. Participants in the 2 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, 2 could not tolerate the shoes, 1 had very large feet that could not be accommodated in the available size range, and 1 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 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. Two participants in the orthoses group had pronated feet (FPI >7), so had varus wedges applied to their orthoses according to the prespecified protocol (14).

Participant retention and intervention adherence. By the 12-week followup, there were 5 dropouts in the orthoses group (1 withdrew as they could not tolerate the orthoses, and 4 were lost to followup) and 5 dropouts in the footwear group (2 withdrew as they could not tolerate the footwear, and 3 were lost to followup), giving completion rates of 90% and 89%, respectively. Participants in the orthoses group reported wearing their intervention for a greater

Table 2. Primary and secondary outcome measures at baseline and followup*

	Orthoses group (n = 52)	Footwear group (n = 46)	Adjusted mean difference (95% CI)†	*P*
FHSQ pain domain (1–100 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 ± 14.8	2.05 (−3.61, 7.71)	0.477
FHSQ function domain (1–100 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, 4.47)	0.920
FFI pain (1–100 points)‡				
Baseline	40.5 ± 17.0	41.9 ± 18.7		
12 weeks	42.4 ± 12.7	41.0 ± 12.5	−1.80 (−6.14, 2.55)	0.418
FFI stiffness (1–100 points)‡				
Baseline	33.4 ± 19.5	37.1 ± 23.4		
12 weeks	41.1 ± 13.0	42.0 ± 16.3	−0.25 (−5.59, 5.08)	0.926
FFI difficulty (1–100 points)‡				
Baseline	37.6 ± 24.5	40.0 ± 25.0		
12 weeks	43.7 ± 14.8	46.3 ± 16.0	1.69 (−3.11, 6.49)	0.489
FFI overall (1–100 points)‡				
Baseline	37.0 ± 18.8	39.6 ± 20.7		
12 weeks	42.5 ± 11.3	43.1 ± 13.8	−0.39 (−4.14, 3.37)	0.840
Pain severity while walking (0–100 mm)§				
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, 4.61)	0.450
Pain severity at rest (0–100 mm)§				
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, 5.78)	0.724
Stiffness severity in morning (0–100 mm)§				
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, 9.82)	0.832
Stiffness severity later in day (0–100 mm)§				
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, 4.59)	0.441
SF-12 physical (1–100 points)‡				
Baseline	44.1 ± 10.7	45.0 ± 9.7		
12 weeks	47.1 ± 9.2	46.7 ± 9.7	−0.98 (−3.81, 1.86)	0.499
SF-12 mental (1–100 points)‡				
Baseline	55.8 ± 8.1	51.9 ± 9.0		
12 weeks	52.3 ± 9.6	52.0 ± 9.6	−0.32 (−3.93, 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, 1.17)	0.120

* Values are the mean ± SD unless indicated otherwise. 95% CI = 95% confidence interval; 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.

Table 3. Adverse events reported during the study*

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

* Values are the number (percentage) unless indicated otherwise. RR = relative risk; 95% CI = 95% confidence interval.
† Significantly higher risk in footwear group compared to orthoses group.

number of hours than the footwear 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% confidence intervals [95% CIs]) between groups for the FHSQ pain domain at baseline and at 4, 8, and 12 weeks followup. 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 followup (ANCOVA-adjusted mean difference of 2.05 points; 95% CI −3.61, 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 followup for any of these measures. However, at the completion of the study, the perception of global improvement, defined as at least moderate improvement (score ≥4) on the 15-point Likert scale, was lower in the footwear group (39% versus 62%; RR 0.63, 95% CI 0.41, 0.99; $P = 0.043$). The NNH was 5 (95% CI 2.3, 43.9), meaning that 1 in every 5 participants treated with footwear had an unsuccessful outcome compared to those receiving orthoses.

Use of cointerventions and adverse events. 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, 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%; RR 1.15, 95% CI 0.56, 2.36; $P = 0.696$).

Adverse events are reported in Table 3. The most commonly reported adverse events were new episodes of back or lower extremity 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 1 adverse event (39% versus 16%; RR 2.47, 95% CI 1.12, 5.44; $P = 0.024$; NNH 5, 95% CI 2.4, 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, 20.22; $P = 0.048$; NNH 8, 95% CI 3.9, 71.0).

DISCUSSION

This is the first randomized trial to evaluate the effectiveness of mechanical interventions in reducing foot pain in people with first MTP joint OA. We found that both the orthoses and footwear groups demonstrated an increase in the FHSQ pain domain score (indicative of an improvement in foot health), but there was no difference between the groups at the 12-week followup. 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 first MTP joint OA.

The primary outcome measure (FHSQ pain domain) increased in both groups at the 12-week followup 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) (31). 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 (37) 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 first MTP joint compared to participants' usual

footwear (23), which may at least partly explain the similar improvement in symptoms we observed at followup.

Adherence varied markedly between the 2 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 that 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 toward 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.

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. First, 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. Second, it was not possible to blind participants to their intervention. Third, 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 dorsoplantar 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 case definition according to Menz et al (22). Nevertheless, these participants all showed at least some radiographic changes and exhibited other cardinal signs of first MTP joint 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 that 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 first MTP joint 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.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Menz had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Menz, Levinger, Roddy, Munteanu.
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Analysis and interpretation of data. Menz, Auhl, Tan, Levinger, Roddy, Munteanu.

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