Unstable Shoe Construction and Reduction of Pain in Osteoarthritis Patients

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ABSTRACT

NIGG, B. M., C. EMERY, and L. A. HIEMSTRA. Unstable Shoe Construction and Reduction of Pain in Osteoarthritis Patients. *Med. Sci. Sports Exerc.*, Vol. 38, No. 10, pp. 1701–1708, 2006. **Purpose:** The purposes of this study were to assess a) the effectiveness of Masai Barefoot Technology (MBT) shoe in reducing knee pain in persons with knee osteoarthritis (OA) and (b) changes in balance, ankle and knee ROM, and ankle strength compared with a high-end walking shoe for 12 wk. **Methods:** The research design was a randomized controlled trial (123 subjects, knee OA). Subjects were randomized to a MBT ($N = 57$) or a control shoe ($N = 66$). A Western Ontario and McMaster Universities (WOMAC) OA index, BMI, balance, active ROM, and ankle torque were quantified at week 0, 3, 6, 9, and 12. Two-sample *t*-tests were done for between-group comparisons. **Results:** There was no significant difference between groups in total pain score. A significant reduction over the 12-wk period was found for both shoe conditions (−42/500 or 25.6% MBT, −46.2 or 27.1% control). There was no significant group difference in pain during walking ($t = -1.09$, $P = 0.28$). Pain during walking was significantly reduced by 5.2/100 mm in the MBT and 9.7/100 mm in the control group. Total pain showed a significant reduction for the MBT −27.4/500 (−16.6%) and the control group −28.9/500 (−17.0%) between baseline and week 3. Between week 3 and 6, there was a significant reduction for the MBT group only (−27.2/500 or −20.0%). There was a significant increase in the static balance between baseline and 12 wk in the MBT group only, although the difference between groups was not significant. **Discussion:** The results indicate that special shoe interventions can reduce pain in subjects with moderate knee OA. **Key Words:** MBT, MASAI, UNSTABLE FOOTWEAR, STABILITY, KNEE PAIN, MUSCLE TRAINING

The knee joint is a common site of osteoarthritis (OA). Subjects with knee OA demonstrate characteristic patterns of increased knee pain and stiffness and decreased physical function related to activities of daily living (9,12). Knee OA is responsible for more disability in walking, stair climbing, and other activities of daily living in people over age 50 than any other disease (9,12). Chronic knee OA will ultimately lead to decreased levels of physical activity (20), which is a strong predictor of multiple-cause morbidity and mortality (7,8,23). The annual direct and indirect costs associated with musculoskeletal conditions in Canada are high, second only to cardiovascular disease (2). Research that will lead to decreased pain and increased function in persons with knee OA is critical to the overall health and well-being of this population and the resultant decreased impact on the healthcare system.

Treatments for knee OA include surgery (arthroscopy, high tibial osteotomy, knee arthroplasty), pharmacological intervention to reduce pain and inflammation, conservative mechanical treatments such as knee bracing, specific footwear, and home-based physiotherapy programs. The effect of a simple home-based exercise program using quadriceps exercises, designed to improve quadriceps strength in patients with knee OA using the Western Ontario and McMaster Universities (WOMAC) OA index as the primary outcome measure, showed significant improvements in self-reported knee pain and function (22).

Pain in a joint depends on (among other factors) the forces between the contacting bones (21). The forces between the contacting bones depend on the actual body weight and the activity of muscles crossing a joint. Footwear can affect these muscle forces for the ankle, knee, and hip joints. Thus, proper footwear may help reduce pain associated with knee OA by improving balance and/or increasing muscle strength in the lower extremities (19,21,24). However, shoes have received little attention as therapeutic

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measures for symptomatic knee or hip OA. Few studies have investigated the effects of footwear on knee OA. One study (16) used resultant joint moments as a possible predictor of joint pain and showed that men's dress shoes and sneakers do not significantly affect resultant knee-joint moments. However, no studies have been conducted on the treatment of knee OA using walking shoes or shoes that have been specifically developed for these purposes.

Masai Barefoot Technology® (MBT®) is the manufacturer of a shoe that is used as a medical training device. The MBT shoe is assumed by the manufacturer to be beneficial for subjects with initial joint OA and related pain and discomfort by serving as a home-based training device. The concept of the MBT shoe with its multilayered sole is to change flat, hard surfaces into natural, uneven ground. Most conventional training shoes support, guide, and/or cushion the foot. However, the MBT shoe is unstable and demands, especially during standing, increased muscle activity in the lower extremities (21). This additional muscle activity is assumed to be associated over time with an increase in strength in some of the muscles. However, during locomotion with the MBT shoe, where the joint loading is higher, the muscle activity showed a trend toward lower activation (21). Anecdotal evidence suggests that the proper and daily use of the MBT product significantly reduces pain and discomfort by strengthening the small muscles of the lower extremities and, possibly, the low back. An initial study (21) examining the influence of the MBT shoe on muscle activity showed an average increase of 30% for the EMG activity of five major lower-extremity muscles for standing and a trend of reduction in knee-joint loading during walking. These initial results suggest that the MBT shoe may reduce pain for people with knee OA. However, conclusive evidence is missing.

Therefore, the purposes of this study were to assess 1) the effectiveness of the MBT shoe in reducing knee-joint pain and knee-joint stiffness and improvement of physical function of the knee in people with knee OA and 2) changes in static and dynamic balance, ankle/subtalar ROM, knee ROM, and isokinetic ankle strength compared with a high-end walking shoe in a prospective study for a period of 12 wk. Secondarily, these changes were to be examined also as a function of time, with follow-up measurements done every 3 wk during a 12-wk study period.

The following primary hypotheses were tested:

H1. Subjects using the MBT shoe will demonstrate a reduction of knee pain while walking and overall knee pain compared with the baseline pain level, and a greater reduction in knee pain compared with subjects using the high-end walking shoe.
H2. Subjects using the MBT shoe will demonstrate a greater improvement in their balance ability during 12 wk compared with subjects using the high-end walking shoe.
H3. Subjects using the MBT shoe will demonstrate a greater increase in maximal joint torque during 12 wk compared with subjects using the high-end walking shoe.

METHODS

The study was a randomized controlled trial. All measurements were done in the Roger Jackson Centre for Health and Wellness Research at the Faculty of Kinesiology at the University of Calgary Human Performance Laboratory and Sports Medicine Centre. The study protocol was approved by the office of medical bioethics at the University of Calgary.

Subjects fulfilling the inclusion criteria were recruited from three sources: 1) sport medicine physicians and surgeons in the Calgary Health Region (using the patient files from 2003/2004), 2) the Sport Medicine Centre of the Faculty of Kinesiology, and 3) recruitment bulletins through the Canadian Arthritis Society and a Calgary Rotary Club. The test subjects were Calgary residents over the age of 40 who suffered from symptoms associated with knee OA. The target sample size for this study was 126 male and female adult volunteers (N = 63 per group). The sample size was based on the ability to demonstrate a difference between groups of 10 mm on the visual analogue scale (VAS) for walking, where the expected minimum change between baseline and 12 wk is 10 mm and the standard deviation of change is 20 mm.

The inclusion criteria used for this study were:

- Idiopathic or secondary OA of the knee as diagnosed by the Altman and coworkers (1) classification tree (83% sensitivity, 93% specificity).
- Grades II–IV severity of OA by radiographic evaluation using the modified Kellgren and Lawrence grading system (15).
- Symptomatic knee OA (i.e., knee pain), with at least with of the following criteria fulfilled for at least 6 months: morning stiffness < 30 min; crepitus; bony tenderness; and bony enlargement with no palpable warmth.
- Age > 40 yr.
- A verbal score of 3–10 out of 10 for pain while walking.
- Ability to walk independently without the use of assistive devices (community ambulatory).
- On one's feet for a total of 2–3 $h \cdot d^{-1}$.

The exclusion criteria used for this study were:

- Acute knee injury or surgery within the last 6 months.
- Total knee arthroplasty.
- Change in NSAID, dietary supplementation use, or corticosteroid injection within the last 3 months.
- Hyaluronic acid injection within 6 months.
- Inflammatory or postinfection OA of the knee.
- Not currently seeking physiotherapy treatment.
- Isolated medial compartment OA Grade III–IV with > 10° mechanical varus.
- Isolated lateral compartment OA Grade III–IV with > 10° mechanical valgus.
- Other medical condition within 1 yr that would affect ability to participate in this study (i.e., cancer).
- Major neurological deficit or disorder.
- Unable to speak or read English.
- Psychiatric illness that would limit informed consent.
- Unwilling to be followed for the study for 3 months.

Subject recruitment and allocation to intervention started with an initial telephone conversation, with each potential subject identified by a study physician. Subjects who met the study criteria were asked to attend an initial screening examination.

At the initial baseline screening examination, the study was explained by the study coordinator and the subjects were asked to complete a general health information form. All subjects participating in the study signed an informed consent form (University of Calgary, Office of Medical Bioethics). An orthopedic surgeon completed the necessary clinical and radiographic assessments to confirm the diagnosis of OA at the initial screening examination. Clarification of history was performed by the orthopedic surgeon and followed by a physical examination of the lower extremities using the standardized IKDC knee form. X-rays were ordered if none were available from within the last 1 yr. The disease severity was established by one orthopedic surgeon using the Altman (12) and the modified Kellgren and Lawrence classifications (15).

Each study subject was asked to complete a written WOMAC OA index as recommended by the OMERACT (Outcome Measures in Rheumatoid Arthritis Clinical Trials) (4–6). The WOMAC scale quantifies pain, stiffness and dysfunction associated with knee OA by assessing five pain-related activities, two stiffness categories, and 17 functional activities (18). The visual analog-scaled format of WOMAC has been shown to be reliable for all three subcategories, that is, pain, stiffness, and function, with ICC of 0.88, 0.87, and 0.88, respectively (3). The visual analog scales were a 10-cm analog line format (3). The outcome measurements of interest were scores of 1–100 mm for pain while walking, 1–100 mm for pain going up and down stairs, 1–500 for the total pain subscale score, 1–200 for the stiffness subscale score, 1–1700 for the physical function subscale score, and 1–2400 for an overall WOMAC score.

Additionally, the following subject specific characteristics were quantified:

- Height in meters
- Body mass in kilograms
- Body mass index (BMI), determined by mass over height squared
- Leg dominance, determined by asking the subjects to kick a ball
- Active ROM for the ankle-joint complex
- Isokinetic torque for the ankle-joint complex for plantar flexion, dorsiflexion, inversion, eversion, abduction, and adduction (14,17)
- Static and dynamic balance measurements (10,13)

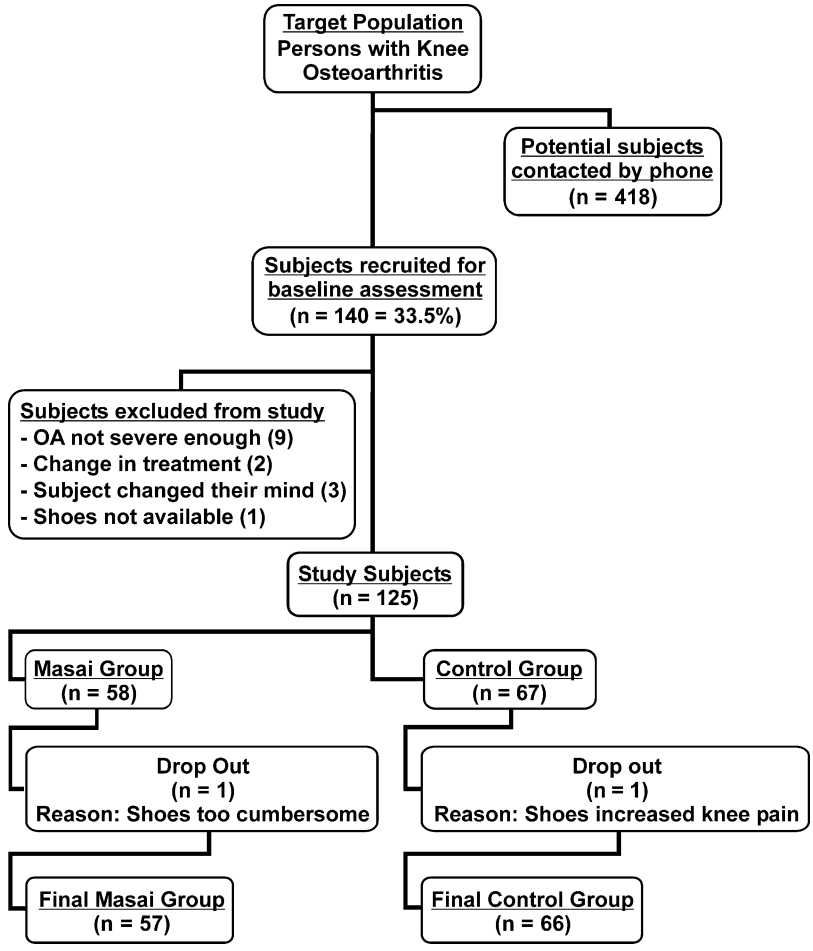

FIGURE 1—Flow diagram of the recruitment process.

- Knee-flexion angle measured in supine using a universal goniometer (11,25)
- Change in knee-flexion ROM was measured for the knee with OA in patients with unilateral OA and on the worst knee in patients with bilateral OA
- Knee-extension deficit measured while prone using a heel-height difference measurement (26)

Active ankle ROM measurements and isokinetic ankle torques were recorded on a Biodex System 3 dynamometer (Lumex Inc., Ronkonkoma, NY). Calibration of the system was performed at the start of testing as recommended by the system manual. Maximum torque produced over five repetitions at a speed of $30°\cdot s^{-1}$ through the full available active ROM was assessed for the left and the right ankle. Standardized positioning for this testing was followed with the subject in a supine position (17). Good to excellent reliability of peak torques for these procedures have been reported (ICC = 0.54–0.92) using this system at $30°\cdot s^{-1}$ (14).

Balance was assessed by quantifying the time in a static and a dynamic test. For the static test, subjects balanced as long as possible with closed eyes standing barefoot on one leg on the lab floor. The time of balance was used as a performance measure. For the dynamic test, an identical procedure was followed, using the Airex Balance Pad® as the support surface, a high-density ($50\ kg\cdot m^{-3}$) closed-cell foam pad ($50 \times 41 \times 6$ cm, 0.7 kg), (L-group, St. Louis, MO). A 15-s practice session was allowed on the Airex Balance Pad before the start of the test session. The time of balance was used as the performance measure. The maximum time allowed for each test was 180 s (10,13). Loss of balance was defined by any of the following: a) removal of one hand from the hip; b) touching the test surface with the non–weight-bearing foot; c) movement of the weight-bearing foot from its original position, or d) movement of the Airex Balance Pad from its original position in the dynamic balance test (10).

Subjects were randomly assigned to the test or control group using computer-generated random numbers. Each subject in the intervention group was provided with a pair of MTB shoes. They received an initial instruction training of 15 min to walk according to MBT instructions. Subjects were instructed to gradually increase the wear time of the MBT shoe over a 3- to 4-d period and to use subjective comfort as the major guidance in this adjustment period. Any subjects who experienced discomfort with the shoes were asked to return to the clinic so that the study investigators could determine any problems (i.e., fit, wear, comfort). Once they were able to wear the shoe comfortably for a full day, subjects were instructed to wear the shoes as much as possible. The control group received a pair of high-end walking shoes (New Balance 756 WB model). The wear schedule was identical to that prescribed for the MBT shoe intervention group. At weeks 3, 6, 9, and 12, each subject was asked to return to the clinic, and the clinical measurements were repeated (WOMAC OA index questionnaire, balance, isokinetic strength, active ankle ROM) by the laboratory assistant who was blinded to intervention group allocation.

Analysis. Data were analyzed using the Stata statistical software package (Stata Statistical Software, Release 8.0.

TABLE 1. Summary of baseline data for the test (MBT) and the control group.

	MBT			Control		
	Result	CI Lower	CI Upper	Result	CI Lower	CI Upper
Number of subjects	57			66		
Male	26			30		
Female	31			36		
Age (yr)	57.9	55.5	60.2	57.4	55.2	59.6
OA unilateral	44			46		
OA grade 2	16			18		
OA grade 3	26			29		
OA grade 4	15			19		
Height (m)	1.68	1.65	1.71	1.69	1.67	1.71
Mass (kg)	86.0	81.2	90.9	84.4	79.5	89.3
BMI ($kg\cdot m^{-2)}$	30.7	28.7	32.6	29.5	27.9	31.0
Knee flexion (°)	129	126	132	131	128	134
Knee extension (cm)	2.6	2.0	3.3	2.6	2.0	3.2
Ankle inversion (°)	43.0	41.5	44.5	45.1	43.2	46.9
Ankle eversion (°)	40.5	38.7	42.3	41.9	39.8	44.1
Ankle plantar flexion (°)	49.9	48.0	51.8	50.6	49.0	52.2
Ankle dorsiflexion (°)	22.2	20.7	23.6	22.2	20.3	23.6
M (ankle/inversion) (N·m)	43.0	41.5	44.5	45.1	43.2	46.9
M (ankle/eversion) (N·m)	40.5	38.7	42.3	41.9	39.8	44.1
M (ankle/plantar flexion) (N·m)	49.9	48.0	51.8	50.6	49.0	52.2
M (ankle/dorsiflexion) (N·m)	22.2	20.7	23.6	23.3	22.0	24.6
T (ECS) balance (s)	7.17	15.54	9.29	8.62	7.76	10.99
T (EOD) balance (s)	19.47	14.08	29.92	17.36	12.91	23.34
WOMAC pain (/500)	164.8	139.0	190.7	170.0	147.5	
WOMAC stiffness (/200)	91.6	77.5	105.6	95.2	84.4	106.0
WOMAC ADL (/1700)	556.3	475.2	637.4	592.8	508.3	677.3
WOMAC total (/2400)	821.2	709.3	933.0	858.0	749.5	966.4
Shoe wear w 0–3 (h)	125	105	144	110	91	129

MBT, Masai Barefoot Technology shoe; CI, confidence interval (95%); OA, osteoarthritis; M, maximum; T(ECS), timed eyes-closed static standing balance; T(EOD), timed eyes-open dynamic standing balance; WOMAC, Western Ontario and McMaster Universities index;/500, determined from a visual analogue scale (VAS) with maximum at 500 units;/200, determined from a VAS with maximum at 200 units;/1700, determined from a VAS with maximum at 1700 units;/2400, determined from a VAS with maximum at 2400 units; ADL, activities of daily living. Knee extension was measured as heel height difference in prone position with patellae off the table.

TABLE 2. Summary of mean changes with the confidence intervals (CI) for the 12-wk period of measurements (top) and for the 3-wk intervals (bottom).

	MBT				Control			
	N	Change	CI Lower	CI Upper	N	Change	CI Lower	CI Upper
WOMAC score, baseline to 12 wk								
Pain walking (/100)	53	−5.3	−10.4	−0.1	66	−9.7	−15.8	−3.6
Pain stairs (/100)	53	−12.8	−20.0	−5.7	66	−20.1	−26.1	−14.1
Pain total (/500)	53	−42.0	−64.4	−19.6	66	−46.2	−69.9	−22.4
Stiffness (/200)	53	−21.1	−33.5	−8.7	66	−35.4	−46.3	−24.5
Physical function (/1700)	53	−124.4	−200.9	−47.8	66	−143.1	−230.4	−56.8
Total WOMAC score (/2400)	53	−200.0	−310.1	−90.0	66	−226.5	−336.9	−116.0
Total pain, 3-wk interval								
Total pain 0–3 (/100)	50	−27.4	−46.4	−8.4	59	−28.9	−46.8	−11.6
Total pain 3–6 (/100)	41	−27.2	−46.2	−8.2	50	4.5	−12.9	21.8
Total pain 6–9 (/100)	38	13.6	−6.1	33.4	51	−1.5	−19.5	16.5
Total pain 9–12 (/100)	42	−3.7	−17.8	10.5	60	−9.3	−28.6	10.0

MBT, Masai Barefoot Technology shoe; CI, confidence interval; WOMAC, Western Ontario and McMaster Universities index.

College Station, TX). Information on baseline covariates (age, gender, grade of OA, WOMAC scores, ROM, strength, and balance) was reported for both the intervention and control groups. Baseline characteristics were reported as means, geometric means, or counts and percentages (with 95% confidence intervals, CI) where appropriate. The significance of any observed differences was not evaluated using hypothesis testing but, rather, judged as to whether they could reasonably be expected to influence the study findings. Rates of nonparticipation and losses to follow-up were reported for both groups. Rates of compliance to intervention (3-wk period) were reported for the intervention and control groups based on home journals. There was no interim analysis before the accumulation of all outcome data by the end of the 12-wk study period.

To examine the effectiveness of the MBT shoe based on change in pain, stiffness, and function during the 12-wk period, two-sample *t*-tests were done to determine initial between-group comparisons, based on intent to treat analysis irrespective of compliance or inability to complete intervention. A multivariate linear regression, which used the individual as the unit of analysis and adjusted for covariates in the estimation of variability, was used to examine the effectiveness of the training program in improving the pain score on the WOMAC OA index. Data for subjects that did not return for one or more follow-up appointments were treated as missing data in the analysis.

RESULTS

Subjects. The total number of study subjects included in the analyses was 123 (57 in the MBT group and 66 in the control group) (Fig. 1). Dropout subjects included those subjects who were assessed at baseline but did not return for any further follow-up. There were no significant differences between study groups based on baseline characteristics (Table 1). However, the BMI showed a slight trend with a 1.24 $kg \cdot m^{-2}$ higher value for the MBT group.

Pain. The mean baseline total pain was 164.8/500 mm for the MBT and 170.0/500 mm for the control group. Change in WOMAC scores between baseline and 12 wk for pain with walking on a flat surface, pain going up and down stairs, total pain subscale score, total stiffness subscale score, total physical function subscale score, and total WOMAC score are summarized in Table 2. Over the 12-wk period, there was no significant difference between groups based on the pain with walking VAS score ($t = -1.09$, $P = 0.28$). Pain with walking was significantly reduced by 5.3/100 mm in the MBT group and 9.7/100 mm in the control group. Over the 12-wk period, there was also no significant difference between groups based on reduction in total pain score on the WOMAC ($t = -0.25$, $P = 0.8$). Total pain scores were significantly reduced in both groups, by 42.0/500 mm in the MBT group and 46.2/500 mm in the control group. The between-group difference was, in fact, not statistically significant for any of the individual pain or component scores, despite improvement seen in both the MBT and control groups. The total pain subscale at 3-wk intervals showed a significant reduction for both the MBT (−27.4/500 on the WOMAC total pain score, or −16.6%) and the control group (−28.9/500, or −17.0%) between baseline and week 3. The total pain subscale between 3 and 6 wk showed a significant reduction in the MBT group (−27.2/500, or −20.0%) and no significant change for

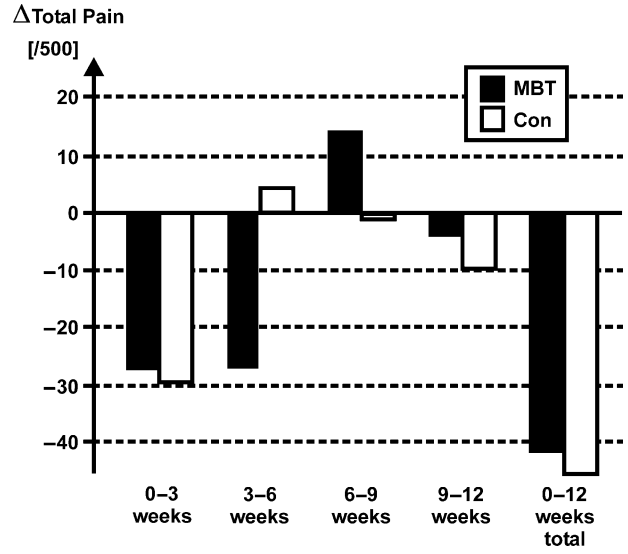

FIGURE 2—Changes in the pain based on Western Ontario and McMaster Universities (WOMAC) total pain subscale during the first 3 wk, between weeks 3 and 6, between weeks 6 and 9, between weeks 9 and 12, and overall change from baseline to week 12 for subjects using the MBT and subjects using the control shoe (Con).

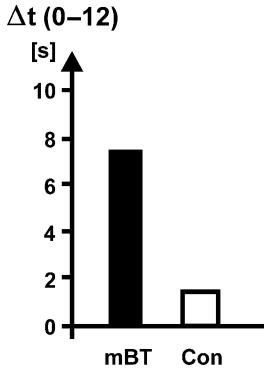

FIGURE 3—Differences in balance time for the test with eyes closed between baseline and week 12.

the control group (+4.5/500, or +3.2%). This between-group difference was statistically significant ($t = 2.48$, $P = 0.015$) (Fig. 2).

Balance. The between-group difference with respect to change in the static balance test time with eyes closed between baseline and 12 wk was not significant ($t = -1.79$, $p = 0.076$). However, there was a significant increase in the static balance test time with eyes closed between baseline and 12 wk in the MBT group (+7.4 s; CI: 2.11, 12.69) but not the control group (+1.2 s; CI: −3.4, 5.75) (Fig. 3). There was also a significant improvement in eyes-closed static balance in the MBT group between baseline and 3 wk (4.7 s; CI: 0.05, 9.41) but not in the control group (−0.9 s; CI: −5.02, 3.21). The between-group difference was not significant ($t = -1.82$, $P = 0.072$). There was no significant change in the dynamic balance with eyes open in either the MBT group (+1.78 s; CI: −5.3, 8.87) or the control group (+0.6 s; CI: −6.22, 7.41).

ROM. There was no significant change in the knee ROM in either study group during the 12-wk period. There was no significant between-group difference for change in knee flexion ($t = 0.27$, $P = 0.79$) or knee extension ($t = -1.49$, $P = 0.14$). Furthermore, there was no significant change in ankle ROM during the 12-wk period based on the mean of both ankles. There was also no significant between-group difference based on change in ankle plantar flexion ($t = 0.85$, $P = 0.6$), ankle dorsiflexion ($t = -1.01$, $P = 0.32$), subtalar inversion ($t = -0.53$, $P = 0.6$), and subtalar eversion ($t = 0.08$, $P = 0.93$). This finding did not change when considering the change in ankle ROM based on the ankle ipsilateral to the side with knee OA or the worst knee OA.

Peak isokinetic strength. There was a significant increase in peak isokinetic eversion strength in both the MBT group (+2.7 N·m; CI: 0.82, 4.58) and the control group (+2.81 N·m; CI: 1.15, 4.46) during 12 wk based on the mean of both ankles. There was no improvement in peak isokinetic inversion, dorsiflexion, or plantarflexion strength during 12 wk. There was no significant between-group difference based on the change in plantarflexion ($t = -1.09$, $P = 0.28$), dorsiflexion ($t = 0.87$, $P = 0.39$), inversion ($t = -0.18$, $P = 0.86$), and eversion ($t = -0.73$, $P = 0.47$). This finding did not change when considering the change in isokinetic strength based on the ankle ipsilateral to the side with knee OA or the worst knee OA.

DISCUSSION

The most important results of this study were that:

a. There was no significant difference between the MBT shoe and a good walking shoe in the reduction in total pain or pain with walking in persons with knee OA.
b. The study group with the MBT shoes showed a significant reduction in total pain after 3, 6, and 12 wk.
c. A significant reduction in pain was also measured for the control group for 3 and 12 wk only, with the only significant between-group difference found between 3 and 6 wk.
d. Despite no significant difference found between groups in change in static balance ability over 12 wk, the MBT group showed a significant improvement in static balance ability during 12 wk, and the control group did not.

These main results will be discussed in the following paragraphs.

A) Pain reduction. Based on anecdotal evidence hypothesis, H1 was formulated for this study, stating that subjects with moderate knee OA who used the MBT shoe would experience a pain reduction and have a greater benefit in experiencing a reduced pain level than subjects using a good walking shoe during a 12-wk study period. There was no significant difference between groups in this reduction in pain. The results of this study (Fig. 1) demonstrated a reduction in pain with walking and total pain in both study groups during 12 wk. It should be noted in examining 3-wk intervals, however, that subjects using the MBT shoe had, on average, a significant reduction of pain of 16.6% for the first 3 wk of the intervention and an additional, significant reduction of 19.8% between weeks 3 and 6. Subjects in the control group demonstrated a similar reduction in pain in the first 3 wk (17%) only, but had no subsequent reduction. This finding suggests that reductions in pain are more immediate (over 6 wk) using the MBT shoe and more gradual using a high-end walking shoe, given that the overall reduction in pain during the 12-wk period was similar in both groups. Thus, subjects with moderate knee OA should expect a reduction of subjective pain when using the MBT shoe for 6 wk.

At first glance, this result is surprising; however, practical experience as well as results from the literature suggest that various conservative interventions may have a positive effect in reducing pain in subjects with moderate knee OA. A significant reduction in pain was found, for instance, in a randomized control study of 6 months with the introduction of a simple home quadriceps-strengthening program (22). The results of this study and other published results (22) indicate that physiotherapy interventions and changes in footwear are potential candidates for such positive results. Footwear may especially be effective when everyday shoes that are not very functional are replaced by shoes that provide a functional environment for the foot and the lower

extremities. However, the current study was not set up to analyse the functional differences between the two test shoes. Consequently, one cannot conclude why the two tested interventions may have both produced a reduction of knee pain. Further research is needed to answer this question. Furthermore, it is not known whether there are some placebo effects included the presented results. The subjects in this study will be tested again after 1 yr, and the results of this long-term assessment will indicate how much of these reported changes were actually long term.

This study has not been designed to examine the mechanisms responsible for the measured changes in pain. For the MBT shoe, the strengthening of the small muscles (and the related reduction of joint loading) may be the functional reason for these changes. However, further research is necessary before this functional explanation can be supported or rejected.

B) Improvement of balance performance for the MBT group. The MBT shoe introduced a dynamic shoe-surface interface, with the goal to challenge and train the subjects' proprioceptive systems in standing and walking and to train the muscles of the lower extremities. The concept proposed by MBT suggests that especially the small muscles, the muscles used for balance control, will be strengthened when using the MBT shoe (21). An indirect support for this suggested training concept has been provided through an improvement in the standing balance ability with closed eyes for the MBT shoes. Despite no significant difference between study groups on improvement in balance performance with closed eyes, subjects using the MBT shoe intervention showed after 12 wk a significantly improved balance performance with closed eyes, whereas subjects using the control shoe did not show a significant change (Fig. 2). The balance test on the foam surface (for the open-eyes test) was found to be extremely challenging in this population of persons with knee OA and did not provide conclusive results.

In this context, it is interesting to realize that the changes in the joint moments were, with one exception, not significant. This result may support the Masai concept that the training effect (if any) of the MBT shoe does not affect primarily the large muscles (which were tested with the joint moments) but, if anything, the small muscles of the lower extremities (which were not tested with the joint moment tests).

C) Pain level. The subjects in both study groups were similar with respect to all baseline characteristics measured including age, severity of pain, and radiological change. Overall, the majority of subjects recruited were grade 2 and 3 using the modified Kellgren and Lawrence grading system, and none required walking aides. The mean pain scores at baseline were 165/500 (MBT) and 170/500 (control), suggesting moderate levels of pain. As such, improvements in pain may not be as great as potentially in a population of persons with more severe OA symptoms. Further research is required to investigate the effect of MBT shoes in people with more severe knee OA.

FINAL COMMENTS

There were no significant differences in pain reduction or improvement in static balance between an MBT shoe and a good walking shoe in people with knee OA during a 12-wk period. However, MBT shoes are effective in reducing knee pain in people with knee OA after 3, 6, and 12 wk of wear. A good walking shoe was also effective in reducing pain after 3 and 12 weeks only. People with knee OA who used an MBT shoe improved their standing balance ability during the 12-wk period. Wearing a good walking shoe did not result in any improvement in balance ability. Ongoing research will quantify the effect of the two tested shoes on knee pain during a period of 1 yr. Future research should concentrate on understanding the functional changes responsible for the reduction of pain.

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