

**MBT  
and pain reduction  
in subjects with knee osteoarthritis  
a randomized controlled trial**

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A research report for MBT to investigate the effect of the MBT in reducing pain in subjects with knee ostoarthritis

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## Executive Summary

### Introduction

Masai Barefoot Technology® (MBT®) is the manufacturer of a shoe that is used as a medical training device. The MBT shoe is assumed to be beneficial for subjects with initial knee joint arthritis and related pain and discomfort by serving as a home-based training device. The MBT shoe is unstable and demands, especially during standing, increased muscle activity in the lower extremities. This additional muscle activity is assumed to be associated over time with an increase in strength in these muscles and/or an improvement of locomotor stability. 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. However, conclusive evidence for this observation is missing.

The purposes of this study were to quantify (a) the effectiveness of the Masai Barefoot Technology (MBT) shoe in reducing knee joint pain in persons with knee osteoarthritis and (b) changes in static and dynamic balance, ankle and knee range of motion, and isokinetic ankle strength as a function of time and compared to a high end walking shoe in a prospective study over the period of 12 weeks.

### Methods

The study was performed as a randomized controlled trial design. The test subjects were Calgary residents over the age of 50 who suffered from symptoms associated with knee osteoarthritis. 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. Each study subject was asked to complete a written WOMAC questionnaire quantifying pain, stiffness and dysfunction associated with knee OA .

Additionally, the following subject specific characteristics were quantified: Height in meters, Body mass in kg, Body-mass index, BMI, with  $BMI = \text{mass}/\text{height}^2$ , 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, dorsi-flexion, inversion, eversion, abduction and adduction, Balance time by quantifying the time in a static and a dynamic balance measurements, Knee flexion angle measured in supine using a Universal Goniometer, 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 and Knee extension deficit measured in prone using a heel-height difference measurement.

Subjects were randomly assigned to the test or control group using computer generated random numbers. Each subject in the intervention group was provided with an MTB shoe. They received an initial instruction training of 15 minutes to walk according to MBT instructions. Subjects were instructed to gradually increase the wear time of the MBT shoe over a 3-4 day period and use subjective comfort as the major guidance in this adjustment period. At week 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.

Data were analyzed using the Stata statistical software package (27).

### Results

**Pain:** Over the 12 week period, the Pain scores were reduced by 42/500 mm in the Masai group and 46/500 in the control group. The between group difference was not statistically significant for any of the individual pain or subscale scores. The total Pain subscale at three-week intervals showed a significant reduction in Pain in the Masai and the Control group between baseline and

3-weeks. The total Pain subscale between 3 and 6 weeks showed a significant reduction in the Masai group only.

**Balance:** There was a significant improvement in the static balance test results with eyes closed between baseline and 12-weeks in the Masai group but not in the control group.

**ROM:** There was no significant change in the knee ROM in either study group over 12 weeks.

**Peak Isokinetic Strength:** There was a significant improvement in peak isokinetic eversion strength in both the Masai group and the Control group over 12 weeks based on the mean of both ankles. There was no improvement in peak isokinetic inversion, dorsiflexion or plantarflexion strength over 12 weeks.

## Discussion

The most important results of this study were that

- (a) as hypothesized, the test group with the MBT shoes showed a significant reduction in total pain after three, six and twelve weeks,
- (b) a significant reduction of pain was also measured for the Control group for three and twelve weeks and
- (c) the MBT group showed a significant improvement in the balance test results.

These main results will be discussed in the following paragraphs.

### **(a) Pain reduction for the MBT shoe**

Subjects using the MBT shoe had on average a significant reduction of pain of 16.6 % for the first three weeks of the intervention and an additional significant reduction of 19.8 % between week 3 and 6. Additionally, subjects using the MBT shoe had a total reduction of pain of 25.6 % for the total 12 weeks of the study. Thus, subjects with moderate knee arthritis should expect a reduction of subjective pain when using the MBT shoe. For the MBT shoe the speculation is that the strengthening of the small muscles may be the functional reason for these changes. However, this speculation needs further research to be supported or rejected.

### **(b) Pain reduction for the control shoe**

The control shoe showed similar changes in pain reduction (except the 3 to 6 week period) as the MBT shoe. It is speculated that various different conservative methods can be used to positively affect pain in subjects with osteoarthritis in the knee. A high quality shoe may be one of these possible interventions. The current study was not set-up to analyse the functional differences between the two test shoes. Consequently, one can not conclude about the possible reasons why a certain intervention may have produced a condition that resulted in a reduction of knee pain. Further research is needed to answer this question.

### **(c) Improvement of balance performance for the MBT group**

The Masai Barefoot technology shoe introduced a dynamic shoe-surface interface, with the goal to challenge and train the subject's proprioceptive system in standing and walking and to train the muscles of the lower extremities. The concept proposed by Masai Barefoot Technology suggests that especially the small muscles, the muscles used for balance control, will be strengthened when using the MBT shoe. 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. Subjects using the MBT shoe intervention showed a significantly improved balance performance with closed eyes while subjects using the control shoe did not show a significant change.

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## Introduction

Osteoarthritis (OA) is the most common type of arthritis and the most significant cause of disability from arthritis (1). The knee joint is a common site of OA and persons with knee OA demonstrate characteristic patterns of increased knee pain and stiffness and decreased physical function related to activities of daily living (1,2). Knee OA is responsible for more disability in walking, stair climbing and other activities of daily living in people over aged 50 than any other disease (1,2). Chronic knee OA will ultimately lead to decreased levels of physical activity (3), which is a strong predictor of multiple cause morbidity and mortality (4-7). 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 health care system.

Treatments for knee OA include surgery (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, for instance, using quadriceps exercises, designed to improve quadriceps strength, in patients with knee OA using the WOMAC OA Index as the primary outcome measure showed significant improvements in self reported knee pain and function (8).

Pain in a joint depends (among other factors) on the forces between the joint surfaces (9). The forces between the joint surfaces depend on the actual body weight and on the activity of muscles crossing a joint. Footwear can affect these muscle forces for the ankle, knee and hip joint. Thus, proper footwear may help reduce pain associated with knee OA by improving balance and or increasing the muscle strength in the lower extremities (10, 11). However, shoes have received little attention as therapeutic measures for symptomatic knee or hip OA. Few studies have investigated the effects of footwear on knee OA. One study (12) used resultant joint torques as a possible predictor of joint pain and showed that men's dress shoes and sneakers do not significantly affect resultant knee joint torques. 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 to be beneficial for subjects with initial joint arthritis and related pain and discomfort by serving as a home-based training device. The concept of the MBT shoe with its multi layered sole is that it changes 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 (9). This additional muscle activity is assumed to be associated over time with an increase in strength in these muscles. 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 (9) examining the influence of the MBT shoe on muscle activity showed for standing an average increase of 30% for the EMG activity of the four major lower extremity muscles and a trend of a reduction of knee joint loading during walking. These initial results suggest that it may be possible that the MBT shoe may influence pain in people with knee arthritis. However, conclusive evidence is missing.

Therefore, the purposes of this study were to assess

- (a) the effectiveness of the Masai Barefoot Technology (MBT) shoe in reducing knee joint pain and knee joint stiffness and improvement of physical function of the knee in persons with knee osteoarthritis and
- (b) changes in static and dynamic balance, ankle/subtalar ROM, knee ROM, and isokinetic ankle strength as a function of time and compared to a high end walking shoe in a prospective study over the period of 12 weeks.

The following hypotheses were tested:

- H1 Subjects using the MBT shoe will demonstrate a reduction of knee pain compared to the baseline pain level.
- H2 Subjects using the MBT shoe improve their balance ability compared to the balance ability at baseline.
- H3 Subjects using the MBT shoe will increase their maximal joint torques compared to baseline.

## Methods

The study was performed as a randomized controlled trial design. 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.

Subjects fulfilling the inclusion criteria were recruited from three sources, (1) sport medicine physicians in the Calgary Health Region (using the patient files from 2003/2004), (2) 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 50 who suffered from symptoms associated with knee osteoarthritis. 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 VAS for walking where the expected minimum change between baseline and 12 weeks is 10mm and the standard deviation of change is 20mm.

The inclusion criteria used for this study were:

- Idiopathic or secondary osteoarthritis of the knee as diagnosed by the Altman and co-workers (13) classification tree (83% sensitivity, 93% specificity).
- Grades II to IV severity of OA by radiographic evaluation using the modified Kellgren & Lawrence grading system (14).
- Symptomatic knee OA (i.e. knee pain) with at least 2 of the following criteria fulfilled for at least 6 months (morning stiffness < 30 minutes; crepitus; bony tenderness; bony enlargement with no palpable warmth).
- Age > 40 years
- 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 their feet for a total of 2-3 hours per day

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 post-infection arthritis of the knee.

- Not currently seeking physiotherapy treatment
- Isolated medial compartment OA Grade III-IV with  $>10^0$  mechanical varus.
- Isolated lateral compartment OA Grade III-IV with  $>10^0$  mechanical valgus.
- Other medical condition within one year that would affect their ability to participate in this study (i.e. cancer).
- Major neurological deficit or disorder.
- Unable to speak or read English.
- Psychiatric illness that limits 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 study physicians. 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 orthopaedic 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 orthopaedic surgeon followed by a physical examination of the lower extremities using the standardized IKDC knee form. Xray's were ordered if none were available from within the last 1 year. The disease severity was established by one orthopaedic surgeon using the Altman (13) and the modified Kellgran and Lawrence classifications (14). Radiographs were also reviewed and classified independently by a radiologist trained in musculoskeletal radiology.

Each study subject was asked to complete a written Western Ontario and McMaster Universities (WOMAC) OA Index as recommended by the OMERACT (Outcome Measures in Rheumatoid Arthritis Clinical Trials) (15,16,17). 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 analogue-scaled format of WOMAC has been shown to be reliable for all three sub-categories pain, stiffness and function with ICC of 0.88, 0.87, and 0.88 respectively (19). The visual analogue scales were a 10 cm analogue line format (19). The outcome measurements of interest were scores between 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 kg,
- Body-mass index, BMI, with  $BMI = \text{mass}/\text{height}^2$ ,
- 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, dorsi-flexion, inversion, eversion, abduction and adduction, (20,21)
- Static and dynamic balance measurements, (22,23)
- Knee flexion angle measured in supine using a Universal Goniometer (24,25),
- 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 in 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, New York). Calibration of the system was performed at the start of testing as recommended by the system manual. Maximum torque produced, over 5 repetitions, at a speed of 30 degrees/second, 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 (20). Good to excellent reliability of peak torques for these procedures have been reported (ICC= 0.54 -0.92) using this system (21).

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 on one leg on the lab floor. The time of balance was used as a performance measure. For the dynamic test the identical procedure was followed using the Airex Balance Pad® as the support surface, a high density (50 kilogram/cubic meter) closed cell foam pad (50 x 41 x 6 centimetres, 0.7 kilograms), (L-group, St. Louis, Missouri). A fifteen second practice session was allowed on the Airex Balance Pad® prior to the start of the test session. The time of balance was used as performance measure. The maximum time allowed for each test was 180 seconds (22, 23). Loss of balance was defined by any of the following: (1) removal of one hand from the hip; (2) touching the test surface with the non-weight bearing foot; (3) movement of the weight bearing foot from it's original position or (4) movement of the Airex Balance Pad® from it's original position in the dynamic balance test (22).

Subjects were randomly assigned to the test or control group using computer generated random numbers. Each subject in the intervention group was provided with an MTB shoe. They received an initial instruction training of 15 minutes to walk according to MBT instructions. Subjects were instructed to gradually increase the wear time of the MBT shoe over a 3-4 day period and 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 (ie., 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 high end walking shoe (New Balance 756 WB model). The wear schedule was identical to that prescribed for the Masai shoe intervention group. At week 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 (27). Information on baseline covariates (age, gender, grade of OA, WOMAC scores, ROM, strength and balance) were reported for both the intervention and control group. 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 is not evaluated using hypothesis testing but rather judged as to whether or not they could reasonably be expected to influence the study findings. Rates of non-participation and losses to follow-up were reported for both groups. Rates of compliance to intervention (3 week period) were reported for the intervention and control group based on home journals. There was no interim analysis prior to the accumulation of all outcome data by the end of the 12 week study period.

To examine the effectiveness of the MBT shoe based on change in pain, stiffness and function over 12 weeks, 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. A multivariable regression analysis was used to further examine the relationship between “Change in Total Pain” based on the WOMAC Pain subscale scores at baseline and 12 weeks and independent variables including study group, gender, age, BMI, severity of OA based on the modified Kellgren & Lawrence grading system, and baseline static balance. Determining the model of best fit was done through a backwards elimination strategy. The possibilities of confounding and effect modification were both considered in determining the model of best fit. 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 Masai group and 66 in the Control group). Drop-out 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/m<sup>2</sup> higher value for the Masai group.

*Pain:* The baseline total pain values were 164.8/500 mm for the Masai and 170.0/500 mm for the Control group. Change in WOMAC scores between Baseline and 12 weeks 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 week period, the Pain scores were significantly reduced by 42.0/500 mm in the Masai group and 46.2/500 mm in the control group. The between group difference was not statistically significant for any of the individual pain or subscale scores. The total Pain subscale at three-week intervals showed a significant reduction in Pain in the Masai (-16.6 %) and the Control group (-17.0 %) between baseline and 3-weeks. The total Pain subscale between 3 and 6 weeks showed a significant reduction in the Masai group (-20.0 %) and no significant change for the control group (+3.2 %). This between group difference was statistically significant ( $t=2.48$ ,  $p=0.015$ ).

*Balance:* There was a significant increase in the static balance test time with eyes closed between baseline and 12-weeks in the Masai group (+7.4 sec; CI: 2.11, 12.69)] but not the Control group (+1.2 sec; CI: -3.4, 5.75). The between group difference was not significant ( $t=-1.79$ ,  $p=0.076$ ). There was also a significant improvement in eyes closed static balance in the Masai group between baseline and 3-weeks (4.7 sec; CI: 0.05, 9.41) but not in the Control group (-0.9 sec; 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 Masai group (+1.78 sec; CI: -5.3, 8.87) or the Control group (+0.6 sec; CI: -6.22, 7.41).

*ROM:* There was no significant change in the knee ROM in either study group over 12 weeks. 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 over 12 weeks 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.

Table 1 Summary of baseline data for the test (Masai) and the control group.

CI = Confidence Interval (95 %)

OA = osteoarthritis

T(ECS) = timed eyes closed static standing balance

T(EOD) = timed eyes open dynamic standing balance

/500 = determined from a VAS with maximum at 500 units

Knee extension was measured as heel height difference in prone with patellae off the table.

Variable	Unit	Masai			Control		
		Result	CI lower	CI upper	Result	CI lower	CI Upper
Number of subjects		57			66		
Male		26			30		
Female		31			36		
Age	years	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/m <sup>2</sup>	30.7	28.7	32.6	29.5	27.9	31.0
Knee flexion	deg	129	126	132	131	128	134
Knee extension	cm	2.6	2.0	3.3	2.6	2.0	3.2
Ankle inversion	deg	43.0	41.5	44.5	45.1	43.2	46.9
Ankle eversion	deg	40.5	38.7	42.3	41.9	39.8	44.1
Ankle PF	deg	49.9	48.0	51.8	50.6	49.0	52.2
Ankle DF	deg	22.2	20.7	23.6	22.2	20.3	23.6
M(ankle/inv)	Nm	43.0	41.5	44.5	45.1	43.2	46.9
M(ankle/ev)	Nm	40.5	38.7	42.3	41.9	39.8	44.1
M(ankle/PF)	Nm	49.9	48.0	51.8	50.6	49.0	52.2
M(ankle/DF)	Nm	22.2	20.7	23.6	23.3	22.0	24.6
T(ECS balance)	s	7.17	5.54	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	192.5
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

Table 2 Summary of mean changes with the confidence intervals (CI) for the 12 week period of measurements (top) and for the three week intervals (bottom).

Variable	Unit	Masai				Control			
		n	Change	CI lower	CI upper	n	Change	CI Lower	CI upper
WOMAC Score Baseline to 12 weeks									
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 Score WOMAC	/2400	53	-200.0	-310.1	-90.0	66	-226.5	-336.9	-116.0
Total Pain 3 week intervals									
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

*Peak Isokinetic Strength:* There was a significant increase in peak isokinetic eversion strength in both the Masai group (+2.7 Nm; CI: 0.82, 4.58) and the Control group (+2.81 Nm; CI: 1.15, 4.46) over 12 weeks based on the mean of both ankles. There was no improvement in peak isokinetic inversion, dorsiflexion or plantarflexion strength over 12 weeks. 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

- as hypothesized, the test group with the MBT shoes showed a significant reduction in total pain after three, six and twelve weeks,
  - a significant reduction of pain was also measured for the Control group for three and twelve weeks,
  - the MBT group showed a significant improvement in the balance test results and
- These main results will be discussed in the following paragraphs.

### **(a) Pain reduction for the MBT shoe**

Based on anecdotal evidence the hypothesis H1 was formulated for this study that subjects with osteoarthritic knees using the MBT shoe would have a benefit in a reduced pain level. The results of this study (Fig. 2) supported this hypothesis (H1). Subjects using the MBT shoe had in the average a significant reduction of pain of 16.6 % for the first three weeks of the intervention and an additional significant reduction of 19.8 % between week 3 and 6. Additionally, subjects using the MBT shoe had a total reduction of pain of 25.6 % for the total 12 weeks of the study.

Thus, subjects with moderate knee arthritis should expect a reduction of subjective pain when using the MBT shoe. This finding is consistent with the reduction in pain found in another randomized control study over 6 months with the introduction of a simple home quadriceps strengthening program (8). It is obviously possible through conservative interventions to reduce the pain level for subjects with moderate knee osteoarthritis. The results of this study and other published results (8) indicate that physiotherapy interventions and changes in footwear are potential candidates for such positive results. This study and others have not been designed to answer the question about the mechanisms responsible for such changes. In most cases, the answer to this question is still speculation. For the MBT shoe the speculation is that the strengthening of the small muscles may be the functional reason for these changes. However, this speculation needs further research to be supported or rejected.

**(b) Pain reduction for the control shoe**

Subjects using the Control shoe, one of the leading walking shoes currently on the market, showed for the first three weeks a similar reduction in pain (-17 %) as the MBT group. For the second three weeks period (week 3 to 6), the control group did not show a reduction anymore but a slight (not significant) increase in the pain assessment (Fig. 2). For the total period of 12 weeks the control shoe showed a similar reduction in pain (27.1 %) as the MBT shoe. This result is, at first glance, surprising. However, if the statement in the previous paragraph is correct that various conservative interventions may have a positive effect in reducing pain in subjects with moderate knee arthritis, the conclusion must be that this excellent walking shoe is one of these possible interventions. The current study was not set-up to analyse the functional differences between the two test shoes. Consequently, one can not conclude about the possible reasons why a certain intervention may have produced a condition that resulted in a reduction of knee pain. However, it is possible that different mechanisms produce a reduction in pain. Further research is needed to answer this question.

Furthermore, it is not known whether there are some placebo effects included this result. The time duration of 12 weeks may suggest that possible placebo effects are filtered out. However, this is a speculation.

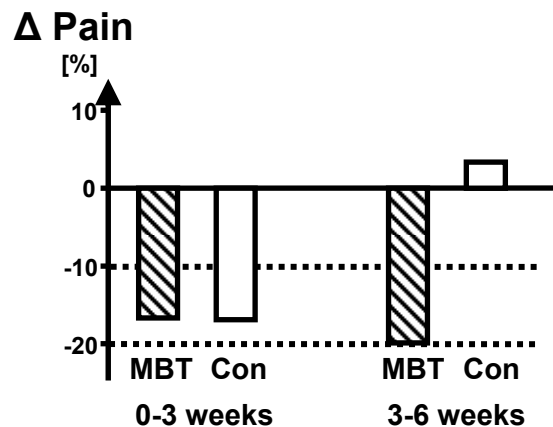


Fig. 2 Relative changes in the pain assessment during the first three weeks (left) and between week 3 and 6 (right) for subjects using the MBT and subjects using the control shoe (Con).

**(c) Improvement of balance performance for the MBT group**

The Masai Barefoot technology shoe introduced a dynamic shoe-surface interface, with the goal to challenge and train the subjects proprioceptive system in standing and walking and to train the muscles of the lower extremities. The concept proposed by Masai Barefoot Technology suggests that especially the small muscles, the muscles used for balance control, will be strengthened when using the MBT shoe (9). 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. Subjects using the MBT shoe intervention showed a significantly improved balance performance with closed eyes while subjects using the control shoe did not show a significant change (Fig. 3). The balance tests 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.

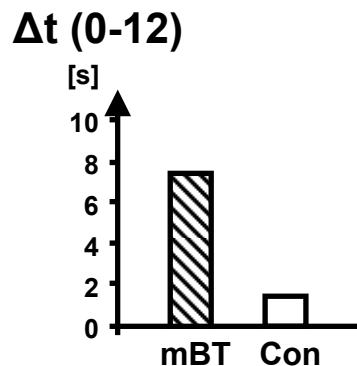


Fig. 3 Differences in balance time for the test with eyes closed between baseline and week 12.

It is interesting to realize that the changes in the joint moments were with one exception not significant. This result would 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 moments tests).

**(d) 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 & Lawrence grading system and none required walking aides. The mean pain scores at baseline were 170/500 suggested moderate levels of pain. As such, improvements in pain would not be expected to be as great as in a population of persons with more severe OA symptoms.

**Conclusions**

MBT shoes are effective in reducing knee pain in persons with knee OA after three, six and twelve weeks of wear. A good walking shoe is also effective in reducing pain after three and twelve weeks. Persons with knee OA who wear an MBT shoe, improve their standing balance ability over 12 weeks. Wearing a good walking shoe does not result in any improvement in balance ability. The subjects of this study will be assessed after one year. The results of this assessment will hopefully provide information on long term effect of these unstable shoes.

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