

# **The effectiveness of the Masai Barefoot Technology (MBT) shoe in the reduction of pain in subjects with knee osteoarthritis. A randomized controlled trial.**

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**MBT Model:** Sole 2004

## **ABSTRACT**

**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 (27). 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.

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,
- Static and dynamic balance measurements,
- Knee flexion angle measured in supine using a Universal Goniometer (28,29),
- 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 (30).
- Balance time by quantifying the time in a static and a dynamic test.

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 (26).

## 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.

**Multivariate Analysis:** The linear regression model of best fit examining the relationship between "Change in Total Pain" based on the WOMAC Pain subscale scores at baseline and 12 weeks and other independent variables showed a significant correlation ( $R^2 = 0.07$ ) between the Change in Pain over 12 weeks and the body mass index, BMI (Fig. 1). The resulting regression equation was:

$$\Delta P(12) = -145.74 + 3.38 \cdot \text{BMI}$$

where

$$\Delta P(12) = P(12) - P(0)$$

$P(12)$  = Pain Score at week 12

$P(0)$  = Pain Score at Baseline

BMI = BMI measured at baseline

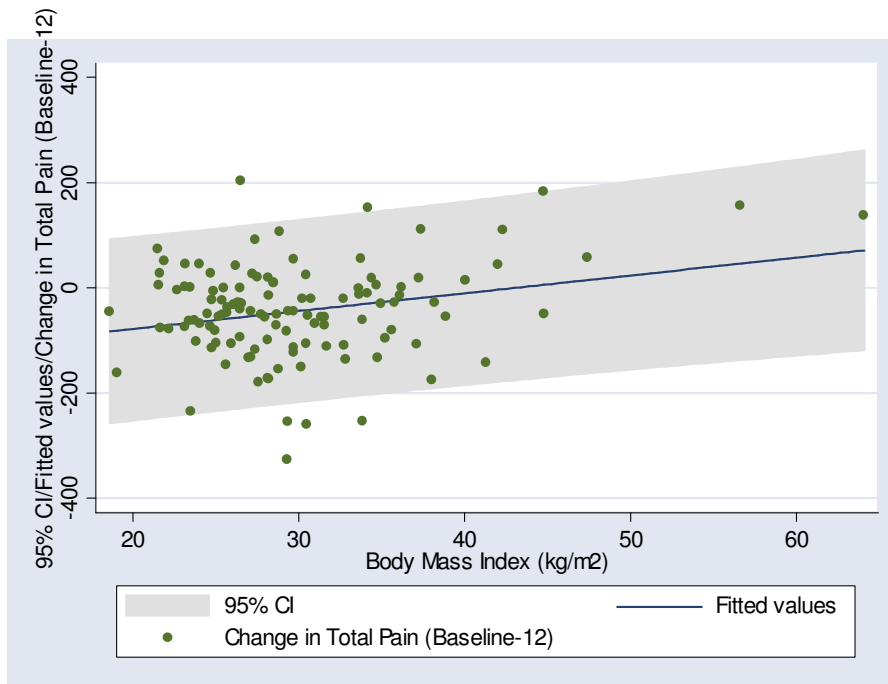


Fig. 1 Linear correlation model for the relationship between the body mass index, BMI, and the Change in Pain between the baseline measures and week 12.

**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,
- (c) the MBT group showed a significant improvement in the balance test results and
- (d) BMI influenced the amount of pain reduction significantly.

These main results will be discussed in the following paragraphs.

*(a) Pain reduction for the MBT shoe*

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. 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.

***(d) The influence of BMI***

The in depth analysis of the data revealed that the pain reduction was significantly affected by the body mass index, BMI. For our test group, persons with a lower BMI

benefited more with respect to reduction of pain from the introduction of a good walking shoe or the Masai Barefoot technology shoe. Persons with knee OA who were overweight ( $>25 \text{ kg/m}^2$ ) to obese ( $>30 \text{ kg/m}^2$ ) benefited significantly less from the introduction of either shoe. This result has implications for the treatment of pain due to knee osteoarthritis. First, body weight should be reduced as much as possible for obese subjects to have a chance to experience a pain reduction due to a shoe intervention. Second, shoe interventions should not be administered to obese people with the goal to reduce subjective pain. However, a shoe intervention such as the MBT shoe has a good probability to be successful when applied to subjects with a low body mass index.