Diploma Thesis at the Medical Technical Academy
for the Physiotherapeutic Service at the Educational Centre West for Health Professions
TILAK Ges.m.b.H.

Balance Training in Football using Masai Barefoot Technology®

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To my family

Werner, thank you for your support.

“I declare that I have written the present Diploma Thesis independently and that I have not used any other aids than those mentioned herein.”

Elisabeth Ritter ______________________

Contents

1 Introduction

"Das Gleichgewicht in den menschlichen Handlungen kann leider nur durch Gegensätze hergestellt werden."
(J. W. v. Goethe)

Johann Wolfgang v. Goethe concerned himself philosophically with the issue of balance and drew the above-mentioned conclusion. Today's medical textbooks basically state the same notion:

"Notre équilibre humain est fait d´équilibres instables."[1] *(M. Bienfait, Fascias et Pompages, 1995, 24)*

In fact, the balance of a body cannot be considered as a fixed characteristic. Rather, it is a flexible system and its functionality depends on a variety of parameters.

In its natural state, the human body is capable of dealing with imbalances, of accepting them, organising them and taking advantage of them. In the quest for balance, the key to success may well be to accept the imbalances as necessary...

[1] Translation: *Balance in human actions can unfortunately only be achieved by oppositions".
**"Our human balance is the result of imbalances"

2 Scope and objectives

To be in balance – this necessity runs like a threat through our lives. Starting from birth, with the very first uncoordinated movements, human beings gather experiences with balance. Balance is of great importance for the entire motor development in humans and forms the basis for movement. Here it plays a more important role than generally assumed. This balance is constantly under threat and continuously restored without us even noticing it. Only if we stumble, for example, or step into a void, our attention is drawn towards balance variations. Balance deficiencies are associated with insecurity and anxiety, a need for help and dependence. In contrast, a good balance leads to secure movements, avoids injuries and alleviates the results of traumas, especially in the elderly (Hirtz et al. 2000, 12). These facts show the importance of balance training. It has frequently been demonstrated that balance can be trained and that the corresponding transfer effects are attainable even in people of advanced age.

In my opinion, balance training should increasingly be considered as a basic physiotherapeutic measure in the area of prevention as well. Unfortunately, it often is limited to rehabilitation after injury. My motivation for conducting research on the subject of balance and, in doing so, drawing attention to its importance – especially in prevention – is based on these considerations. The various options for improving balance and their impact on the sport of football are of special interest to me. The risk of injury in this team sport is particularly high and, in my opinion, an improved balance could help to reduce this risk. The second idea is that balance constitutes an important factor of motor performance. Thus – I concluded – it could be possible that, through enhanced balance, motor performance of the players can also be improved.

While searching for an efficient training method, Masai Barefoot Technology® (MBT®) came to my attention. The concept of MBT is based on a training device in form of a modified shoe.

Because of the special design of its sole, any hard, flat surface is experienced as uneven. A professional introduction providing precise exercise instructions is required; later, the MBT® training device can be worn day-to-day according to one's individual needs. This concept is already deployed in physiotherapy; however, statistical analyses regarding balance training based on the use of MBT® are not yet available. This study focuses on a detailed investigation of this aspect. Thus, my hypothesis is:

By professional introduction to the MBT® concept and by its regular use, the balance in football players can be improved.

Whether the balance can be improved using this concept, and how significant the improvement might be, is tested in a group of subjects consisting of twenty football players. Only active players with no injuries, who are more or less on the same training level, have been included in this study. The study was conducted over a period of four weeks during which the players underwent a special MBT® training by a professional MBT® teacher in addition to their normal football training. Standardised sport motor tests according to Fetz/Kornexl (1993) carried out at the beginning and at the end of the study period are used to evaluate the changes in the player's balance capabilities. Data collection is carried out using the retest method. Based on the results, it will be discussed whether the Masai Barefoot Technology® can generally be recommended as a method of balance training in physiotherapy.

3 Balance

To keep one's balance in any position is a natural human ability which, however, needs considerable efforts to be established. Observing the first steps of an infant, one realises that all adults already underwent intensive balance training. There are many different definitions of balance/equilibrium in the literature. The most commonly used is that provided by physics. However, there is the problem that explanations from the perspective of physics cannot be simply applied to humans. The balance of the human body is not a defined parameter, but a constantly changing state that is influenced by a variety of factors. The following definition is based on a functional perspective.

3.1 Definition of Balance

"Rein physikalisch gesehen ist ein Körper im Gleichgewicht, wenn sein Körperschwerpunkt oder das Lot seines Körperschwerpunktes sich innerhalb seiner Unterstützungsfläche befindet"* (Schellhammer 2002, 36).

In a standing position, the human centre of gravity is located in the midline of the body between the 5th lumbar vertebra and the 1st sacral vertebra. The body's centre of gravity is the point in which the entire body mass is focussed. The support area is the area that results from connecting the points where the body is in contact with the floor (Schellhammer 2002, 36 et sqq.). Because a number of sensations are essential for keeping balance, it is – to give it its proper term – sensorimotor balance.

Translation: * "From a purely physical perspective, a body is in balance when its centre of gravity or the plumb line of its centre of gravity is within its support area."

3.2 Definition of Balance Ability

In the most commonly used definition, balance ability is defined as a “comparatively robust and generalised prerequisite of performance for keeping or regaining the body’s balance under changing environmental conditions, especially for solving motor tasks on small support areas accurately and fast or in case of very unstable balance circumstances” (Hirtz et al. 2000, 56). In the literature, the balance ability is put forward as an important factor of coordination and of coordination training.

3.3 Physiology of balance systems

The organisation of balance associated with motor actions comprises information acquisition, information processing, information output and permanent control. The present balance state (actual value) is measured by peripheral receptors, evaluated and reported to the central nervous system (CNS). As a result, adequate efferent signals are sent to perform possible corrections and to meet the desired target value. The balance system can be likened to a *perpetuum mobile*. The afferent signals from the periphery reach the corresponding structures of the CNS via complex pathways. Most of the processes aimed at keeping the balance have the form of regulatory circuits, which are unconscious. They are part of reflexes which, among others, oppose gravity in the form of postural reflexes. Here, two types of reflexes are differentiated:
a) Spinal reflexes and b) reflexes that are mediated via the brain. They are monosynaptic proprioceptive reflexes or polysynaptic reflexes, which are, however, influenced by modulating effects of supraspinal structures (Schöllhorn 1998, 102 et sqq.).

Furthermore, Schöllhorn emphasises that the limbic system plays an important role in all these central nervous processes. In this system, emotional processes are linked to motor processes. It consists of neuronal pathways between the hippocampus, thalamus, amygdala and hypothalamus. The hypothalamus is in contact with the cortical centres.

If the current situation of an individual triggers a certain emotional response, these stimuli are transferred from the cortex to the hypothalamus, which is the control centre for sensations.Motor nuclei of the cranial nerves and the voluntary skeletal muscles are influenced via its branches to all parts of the brain stem. That means that any type of emotion has a relevant impact on our motor functions - and thereby also on balance.

Three systems are involved in maintaing balance: somatosensory, vestibular and visual (Duus 2001, 165 et sqq.).

3.3.1 Somatosensory System

The somatosensory system allows us to perceive the position of our body and the relation of all body parts to each other at any time . It consists of proprioception and the tactile system (Gertz 2003, 32 f.).

The term **proprioception** refers to impulses that are produced in muscle spindles, tendon organs or by receptors in fascias, joints, and deep connective tissue. Joint receptors are present in articular capsules, pericapsular fascias and in ligaments. Free nerve endings, joint receptors type I and type II are found in the fibrous membrane of the joint capsule. The free nerve endings mainly transmit nociceptive stimuli to the CNS.

Joint receptors type I are also called Ruffini's corpuscles. They are static and dynamic receptors, i.e. they provide information on position and movements in the joint. Their threshold is low; however, they adapt slowly. The joint receptors type II, the Pacinian corpuscles, are dynamic receptors. They send information on joint movements to the CNS. Normally, they are found in the deeper parts of the capsule.

They also have a low threshold; however, they adapt rapidly (Van den Berg 1999, 134).

In the ligaments, the so-called Golgi corpuscles are found. Their threshold is very high, and they are comparatively slow to adapt. They are mainly located in the insertion and origin areas. According to Van den Berg (1999, 134), Golgi corpuscles in the peripheral joints are only activated in the presences of very strong stimuli and their main function is to warn and to protect the joint.

Muscular receptors in the form of free nerve endings, muscle spindles and Golgi tendon organ are present in the muscles. Free nerve endings send nociceptive stimuli to the CNS. Apart from these stimuli, information on present muscle length and speed of muscle length changes is sent to the spinal cord. The muscle spindles are responsible for this task (Van den Berg 1999, 186).

If a muscle is stretched, the equatorial[2] zone of the muscle spindle is stretched and an action potential is created at the sensitive end of the afferent nerve fibre and then conducted to the spinal cord. There, the afferent nerve fibre is directly – without interpolation of an interneuron – connected to a-motor neurons of the same muscle. The motor neurons are exited and produce, via the fast-conducting efferent nerve fibres, a contraction of the muscles. The initial stretched status of the muscles is thus reset. This very fast process is a monosynaptic deep tendon reflex that controls muscle length via a feedback mechanism. Since receptor and effector are in the same muscle, it is also called a muscular proprioceptive reflex (Golenhofen 2000, 508).

The Golgi tendon organs are located within the tendons and thus in series with regard to the work muscles. This way, they indicate muscle tension and the degree of muscle strength. If a muscle contracts, the collagen fibres of the tendon become tensed and get closer to each other, compressing the Golgi tendon organs and thus triggering a stimulus.

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[2] Mid part of the spindle which is not made up of actin and myosin filaments and therefore elastic. This area is innervated by so-called flower spray endings, group II nerve fibres (Golenhofen 2000, 508).

This information is transferred to the CNS. The receptors respond to both contraction and distension of muscles. The sensitivity of the Golgi tendon organs is less than that of muscle spindles; with increasing distension, initially a response of the muscle spindles is triggered, while the tendon organs response comes in later. The individual Golgi organ gathers the tension of a small group of muscle fibres. Therefore, it is more sensitive to active development of force than to uniform increase in tension of the entire muscle (Van den berg 1999, 189). The high sensitivity of these receptors shows that they play an important role in the constant fine-tuning process of the motor functions.

The second part of the somatosensory system is the **tactile system of receptors in our skin layers.** It includes mechanoreceptors (respond to touch and pressure stimuli), thermoreceptors (thermal stimuli) and nociceptors (painful stimuli). These tactile and pressure receptors of the skin play a special role with regards to triggering the postural reflexes, which are important for maintaining motor balance (Hirtz / Hotz /Ludwig 2000, 39). Apart from those mentioned above, there are a number of other receptor types in the skin; however, their function is not yet fully understood (Duus 2001, 3).

Proprioceptive information and tactile sensations are conducted to the CNS via the same tracts. A part of the fibres of the proprioceptive and tactile receptors reaches the cerebellum via the anterior spinocerebellar tract within the spinal cord. Thereby, a higher functional circuit is built upon the lower feedback circuits of the spinal cord, which influences motor function via extrapyramidal tracts. Muscle tone and synergistic action of agonists and antagonists is controlled this way. However, this is still an unconscious process (Gertz 2003, 32).

A further part of the fibres extends via the spinal cord into the posterior fasciculus and from there to the respective nuclei in the medulla oblongata. There, the signal is switched to the second-order neurons, which cross over to the other side of the medulla where they form the medial lemniscus. From there, they extend to the thalamus and, after switching to the third-order neurones, via the internal capsule to the postcentral gyrus of the cortex. This is the primary somatosensory region (Duus 2001, 21 et sq.). Any disturbances affecting the connection to this region result in the patient's inability to determine the position of his body parts or to explore objects using touch. Furthermore, the floor beneath the feet cannot be felt because of the disturbance of pressure sensations. This results in insecurity while walking and standing; balance can only be maintained with difficulty, the patient has to rely on visual control and compensatory reactions. The amount of strength needed for movements is very high and motor functions become inefficient.

3.3.2 Visual System

The visual system also has a great influence on motor balance. The human eye is capable of receiving and processing visual light (electromagnetic radiation with wave lengths ranging from 400 to 700 nm). Via photochemical processes, the radiation causes a stimulation of the sensory cells and the signal is then conducted via the optic pathway to the visual cortex of the cerebrum.

Visual information about relative changes of the surroundings in comparison with objects or one's own body significantly contribute to the organisation of balance (Sornay 2003, 7 et sqq.). We can estimate how far away from us objects are located and recognise and evaluate hindrances. Visual stimuli are major sensory points of orientation, especially under changing external conditions and during complex movements. In addition, constant control of balance situations is based on the visual system.

However, for this empirical study the visual system is of comparetively minor importance; it will therefore not be discussed in greater detail here.

3.3.3 Vestibular system

The vestibular system contributes to maintaining the balance of the entire body and to spatial orientation by influencing the muscle tone via the reflex system.

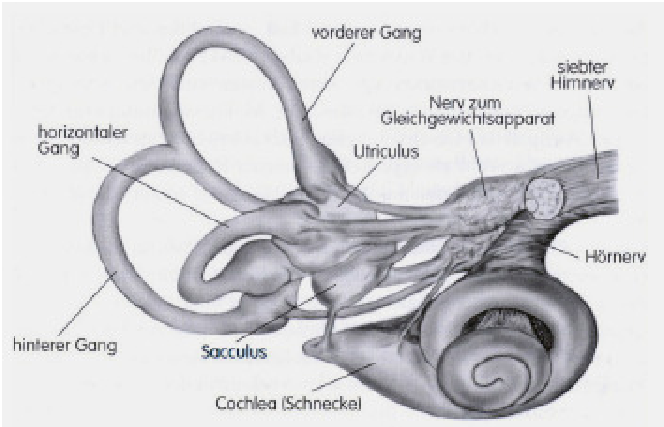

Fig. 1: Diagram of the vestibular apparatus
(Hirtz et al. 2000, 37)
[lateral, anterior, posterior semicircular canals, utricle, nerve to vestibular organ, auditory nerve, seventh cranial nerve]

The receptors of the vestibular organ are located in the utricle, the saccule and the enlargements at the ends of the anterior, posterior, and lateral semicircular canals, the so-called ampullae. The information provided by vestibular receptors reaches the vestibular nuclei and the cerebellum (archicerebellum) via the vestibular nerve in the brain stem. The vestibular nuclei process this diverse information together with the visual and tactile input. From there, efferent nerve impulses are sent to the ocular muscles, the spinal cord, and the skeletal muscles. There, they trigger reflex muscle contractions. From the cerebellum, efferent impulses are sent back to the vestibular nuclei or again the spinal cord. Therefore, vestibular nuclei and cerebellum form an important functional complex.

All these interconnections are set in reflex arcs so that the eyes as well as the neck and head muscles are coordinated in such way that balance is ensured in all positions and during all movements of the head (Duus 2001, 169 et sqq.).

3.4 Trainability of balance

It is part of human nature that people – unconsciously – constantly attempt to maintain their balancing abilities. Human beings possess basic resources and capacities for maintaining and also regaining their physical stability. However, according to Hirtz et al. (2000, 60), these can only be deployed if an individual is regularly exposed to real balance challenges and if he attempts to adequately cope with them.

Dr Ayres[3] discovered that balance training in particular activates inhibitory neurons, e.g. of the cerebellum, refines and improves movement patterns, and harmonises movement changes. In this process, bodily and spatial patterns are constructed and their tuning is enhanced. It was found that the vestibular sense also has a generally enhancing function on global integration. This global enhancement, including a more precise motor function thanks to improved integrative development of motor patterns, translates into an increase in neurite and dendrite formation by neurons, which reveals the plasticity of the brain (www.physiopaed.de, 15/03/04)

Thus, theoretical considerations suggest that the ability to maintain balance is trainable, provided there is proper stimulation of the receptors of the vestibular, visual or somatosensory apparatus.

Some examples for the trainability of balance are described by Hirtz et al. (2000, 126 f.). A study involving 30 subjects who participated in exercise groups for the elderly and had an average age of 60 years showed weakly significant improvements in balancing steadiness (balancing according to Fetz) after an exercise period of only six weeks. During this time, balance training of 15-20 minutes per week was carried out.

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[3] Founder of Sensory Integration Therapy

Fetz (1990) was able to empirically confirm improvements in balance ability in different age groups. For example, he found improved performance in balance ability while standing and walking after a six-week balance training with an actual training time of only three minutes per week in all studied groups aged between 10 and 60 years.

From the perspective of prevention, improving balance is definitely a relevant issue. By repeatedly performing exercises (in this study WALKING), movement patterns become automatic. If these automatic movement patterns are not used over prolonged periods of time, they become overlaid by other CNS functions; however, they can be quickly reactivated (Hüther-Becker 1996, 304). Thus, no balance exercise is without effect.

In my opinion, the role of balance trainability is of particular interest for injury prevention in serious sport. In this study, I would therefore like to evaluate a special type of balance training in football. This form of training and its effects on the motor skills of football players will be critically examined and evaluated from a physiotherapeutic viewpoint.

3.5 Importance of balance in the physiotherapeutic care of football players

The human body requires a comparatively high level of balance ability to enable functional postural and motor patterns.

According to Schellhammer (2002, 41 et sqq.), the balance system enables:

a) the upright posture of the body by tonic reflexes
b) erection of the body against gravity and an adequate spatial alignment by rightening reflexes
c) maintenance of postures during movements by statokinetic reflexes

d) reflex control of the muscles of extremities and trunk associated with changes in velocity during movements by the vestibulospinal reflex (makes it possible to learn to walk)
e) the compensatory counter-movements of the eyes associated with head turning

To make a movement, the state of stable balance has to be abandoned and a situation with unstable balance has to be assumed. During the movement, this unstable balance has to be continuously kept within controllable limits by specific muscle activity (Neumaier 2001, 34). The better the regulation of balance, the better is the coordination, and, thus, motor performance. With optimum coordination of the movement, the aim of the movement can be reached with little energy. Thus, an economical performance of movements is achieved by good coordination, resulting, for example, in reduced signs of fatigue (Schewe 1996, 299). Here, you encounter the first starting point for more emphasis on balance training in football. It is crucial for the game how coordinated the movements of the players are, and how efficiently they can be maintained across the entire duration of the game.

If movements are economical and functional, a muscular equilibrium that enables precise interaction between agonists and antagonists is present. In the presence of this intermuscular equilibrium, optimum stabilisation of joints across their normal extent of movement is achieved resulting in the protection of joints against abnormal loading. Especially in football players, muscular dysbalances are frequently brought about by one-sided or excessive training. This is another aspect in support of increased balance training.

Another point of great importance is injury prevention. Players with muscular dysbalances and/or coordinative weaknesses have a high risk of injury. However, the better a player's balance is trained, the more he will be able to automatically make involuntary balancing movements in case of a collision or a fall.

Thanks to balance training, he has various, stored movement patterns available that help him to stabilise himself in a dynamic balance. Unfortunately, balance training often only gains special attention after injuries, e.g. during the rehabilitation of ankle joint or knee problems.

I think that balance training should therefore be viewed as a basic therapeutic measure both in prevention and rehabilitation. It should not only be increasingly used in the care for athletes, but also in all other areas of physiotherapy.

Masai Barefoot Technology® may be one way to achieve this goal. This concept will be introduced in the present study. This investigation will be evaluated to what extent balance ability – and consequently coordination – can be improved by increasingly acting on the somatosensory system of the body.

4 Masai Barefoot Technology®

"MBT" is a new concept, a new approach and yet very old. Our instinctive knowledge of the right amount of movement has been lost. MBT returns to us some of that original intuition. Step by step." (Wessinghage, 2000).

4.1 Basic considerations in MBT®

MBT® stands for Masai Barefoot Technology®, a concept developed by the Swiss engineer Karl Mueller. He assumes that the human body evolved for locomotion on a natural, uneven surface. The unevenness of this natural surface challenges the locomotor system to the extent that, on the one hand the feet have to constantly adapt to changing conditions, and on the other hand, the entire body has to respond to these challenges.

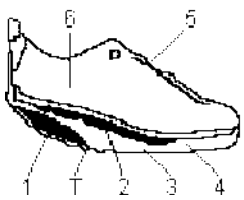
In our civilised world, however, we walk on hard, artificial surface for most of our lives. The ability to balance and keep ones balance has become of secondary importance. the opportunity to use the entire repertoire of motions and perceptions of our bodies. According to Karl Mueller, we take 100 million steps on hard, flat surfaces in the first 20 years of our livesalone .

In addition, we put our feet in corset-like shoes that guide, support and absorb shocks; thus, they act against the very nature of the human locomotor system in all its aspects. These shoes often restrict the freedom of motion in the foot joints; consequently, an abnormal load on the entire musculoskeletal system develops.

Our walking surfaces and shoes promote passive walking and standing right from the start. This leads to the automation of unnatural movement patterns. of the idea behind MBT® is to return to us a part of the original movement experience – with all its positive effects on physical balance.

4.2 Concept of MBT®

The Masai Barefoot Technology® aid is a shoe that has already been recognised as a medicinal product[4]. MBT® is characterised by its special design of the sole, which was developed especially for use on hard, flat surfaces.



12-layer construction from the MBT® research:
1: fatigue-proof feather key.
2: 3D-formed fibreglass / synthetic panel
T: rolling ramp with integrated skew foot fall (= tilting edge)
3: rubber sole
4: PU middle sole
5+6: outside leather or textile, inside leather or textile lining

Fig. 2: Design of MBT®, www.swissmasai.com, 15/03/04

[4] see appendix 11.4

Abb. 3: MBT® sport, www.swissmasai.com, 15.03.04

A characteristic feature of the MBT® training device is the heel that is brought to the front and the tilting edge where the foot is rolled off. Behind that, in the area of the heel, MBT® features a rolling ramp, the so-called heel sensor. In contrast to the stable heel cap of a normal shoe, this is very soft so that the user can guide the shoe himself. It is now possible to attach an MBT® sole construction to an orthopaedic shoe.

According to Swiss Masai AG (2004), neuromuscular reprogramming is achieved via the changed roll-off behaviour while walking with MBT®. The gait is said to become more natural, physiological and active, resulting in reduced restrictions of movements and less abnormal loading. The intended absence of guidance leads to an increase in proprioceptive stimuli, balance reactions are trained, and more muscle work is required.

Because MBT has no heel compared to normal shoes, an intense shock to the heel of the user's foot while stepping is prevented; in this way, shearing forces in the knee joint are reduced and fewer shocks reach the joints. Furthermore, the muscles of the calves are prestretched when the foot touches the ground. Based on this pre-stretch, an ideal and rapid delivery of force of the flexor muscles of the foot is said to be achieved (see muscle receptors).

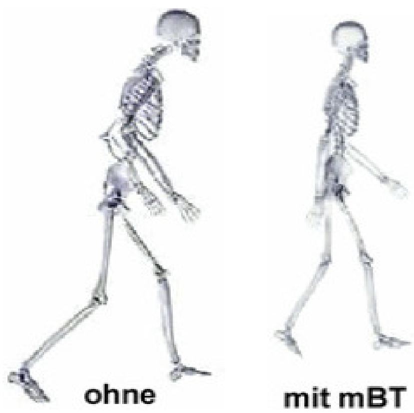
The muscles act as the body's own natural shock absorbers for the joints. If used properly, the normal pelvic rotation is compensated by a counter-rotation in the thoracic spine and reactive pendular movements of the arm. Thereby, it is claimed, rotation in the lumbar spine is diminished and fewer pressure and shearing forces act on the vertebral discs. In addition, the venous return from the legs can be supported by an increased activation of the calf muscle pump, helping to prevent circulatory disturbances, such as varicosis, calf cramps or PAOD.

According to the manufacturer, the use of Masai Barefoot Technology® is indicated in a wide range of disorders, including, for example, forefoot and toe joint problems, achillodynia, knee pain (e.g. anterior cruciate ligament graft, meniscectomies...), knee and hip total endoprostheses, arthrodeses, disorders of the spine (lumbar pain, cervical and thoracic syndrome, ankylosing spondylitis ...), costal blocks, Sudeck's disease, hemiplegia and obesity. Contraindications are polyneuropathy and disorders associated with impaired perception as well as isolated disturbances of proprioception. These disorders may lead to sore feet with walking and increased risk of falling. General contraindications for Masai Barefoot Technology® are improper, extremely irregular or excessive use. This may lead to an augmentation of already existing complaints or give rise to new ones.

The inventor Karl Mueller emphasises that the user of Masai Barefoot Technology® has to keep in mind that MBT® is no conventional sport shoe, but rather a specialised training and therapy device. Therefore, a professional introduction to using the devise provided by a qualified MBT® teacher is essential. After some weeks of use, a follow-up examination should be carried out and, if need be, a correction of use should be initiated so that an optimum result can be achieved (Swiss Masai AG 2002, 37 et sqq.).

4.3 Effects of MBT® on balance systems

When walking with MBT®, the step is always placed below the body's centre of gravity and placed further to the back than with other shoes. As a result, the tone of the calf, gluteal and abdominal muscles is increasingly activated, pulling the spine into a normal upright position. This is an ideal condition for maintaining balance, because the body's centre of gravity constantly remains within the area of support. In contrast, passive walking in conventional shoes involves placing the steps far in front of the body. The centre of gravity moves out of the centre of the support area. In order to keep the balance, compensatory movements of the trunk occur more frequently. This promotes an abnormal posture with lumbar hyperlordosis.



This picture shows the posture of a subject while walking with and without MBT®. The picture is taken from a film sequence of an investigation in a gait laboratory which involved computer-based recording of the subject's gait and a special video-technical processing method[5].

Fig. 4: Gait pictures [without - with mBT], www.swissmasai.com, 15.03.04

According to the manufacturer, inter- and intramuscular coordination and neuronal recruitment – especially of the leg muscles – is enhanced by wearing MBT®. As a result, the postural and abdominal muscles are strengthened. Keeping the body balanced is thereby achieved more easily. (Stegen, 2004)

This experience is also confirmed by Urs Kolly[6] after two months of training with MBT®. For Kolly, mainly the instability of the hip was reduced, which can be attributed to increased

5 Optic motion capture technology, Fa. Vicon in Munich

6 Urs Kolly, wearer of a under-the-knee prosthesis, five-times Olympic winner at the Paralympics and nine-times medal winner at the World Championships

inter- and intramuscular coordination. The better the supporting leg can be actively stabilised, the less circumduction of the leg in the swing phase occurs. Weight and tone distribution varies to a lesser degree, the body's centre of gravity remains steadier and more centred within the support area. Balance can be more easily maintained that way.
A further argument for the training effects of the MBT® device on the balance system is that the tactile receptors in the soles of the feet are stimulated. Because parts of varying hardness are incorporated in the construction of the sole (forefoot area, tilting edge, heel sensor), new tactile stimuli are constantly sent to the CNS. A study by Swissmasai AG has shown that wearing MBT® principally leads to pressure loads in the area of the midfoot and the outer edge of the foot, which are, however, lower compared to conventional shoes. In normal shoes, higher pressure loads are found in the heel and forefoot area (www.swissmasai.com, 05.03.04).

Increased ligament injuries in the area of the ankle joint and knee have been observed in football players. As described in chapter 3.3.1, proprioceptors are also found in ligaments. However, if ligaments are injured, proprioceptive deficits frequently develop. De Carlo and Talbot (1986) describe studies that provide evidence that after typical inversion injuries the afferent input of the ankle joint to the CNS is reduced. Because of diminished afferent information, functional deficits of joint-stabilising structures at the ankle joint develop. This leads to an instability problem. The risk of injury is therefore increased even further. As far as the rehabilitation process is concerned, I believe that the MBT® concept will show excellent results, because its use enhances the information provided for the nervous system by constantly stimulating the proprioceptors that are (still) present.

In addition to the rehabilitation of inversion injuries, the MBT® training device may also be useful for injury prevention. Because of its special sole construction, its use enforces permanent stabilisation of a dynamic balance. Every step is similar to an unstable one-legged stance, and therefore becomes a balance, endurance and strength training exercise.

At the same time, every step in MBT® leads to an intensive proprioceptive training of the entire body. With regular use, muscle dysbalances are evened out and the muscular activities for maintaining balance are more efficient. Signs of fatigue occur later and the risk of an inversion injury is lowered.
In general, it is found that repetitions of movement patterns lead to specific adaptations in the CNS. In this process, the tendency of excitations, which occur in the cortex along with muscle activation, to spread to neighbouring areas is reduced. The result is a successive reduction in unnecessary muscle activity when performing a movement pattern. In addition, stable adaptations form at the synapses of the nerve cells involved, such as hypertrophy and increase in transmitter substances (Hüther-Becker 1996, 303 et sqq.).

This phenomenon is used by the MBT® concept, because, on the one hand, it provides new stimuli for the receptors of the balance system, and, on the other hand, it provides the opportunity to feed in these stimuli in large numbers and over a prolonged period of time (e.g. during the entire day).

5 Methodology

The idea underlying this study is to improve balance in football players by training with Masai Barefoot Technology®. Because human balance is difficult to define and to measure, a standardised test method was chosen and the data were subsequently analysed.

5.1 Aim of the study

The aim of the present study is to evaluate whether the balance in football players can be significantly improved by using Masai Barefoot Technology®. Based on the results of a standardised re-test method, the use of the MBT® concept in the sport of football for injury prevention and for increasing performance will be discussed. Finally, it will be evaluated whether the MBT® concept in physiotherapy can be generally recommended as an efficient method of balance training.

5.2 Subjects

The subjects were football players of the football team FC-Eurotours Kitzbühel with an average age of 23 years. As part of their winter training, 21 players participated in an additional MBT® training. The MBT® training device were loaned by the company Lowa Sportschuhe GmbH for the entire study period, free of charge.

Inclusion criteria are that all subjects are active football players with approximately the same level of training. An additional requirement is that the subjects must have the opportunity to wear the MBT® training device daily for at least two hours during the study period.

Exclusion criteria are previous experiences with the MBT® principle and working in a profession that generally has a high-level of balance requirements (carpenter, roofer, dancer, gymnast ...). Likewise excluded are players who, apart from football and MBT® training, participate in specific balance training. Furthermore, the participants are not allowed to learn another form of sport during the observation period. These criteria are applied to ensure the same training conditions for all subjects. Further exclusion criteria are acute injuries and any pain. Here, special attention is paid to cardiovascular problems, visual deficiencies, disturbed perception, angiopathies, vertebral complaints and pain following ankle joint or knee injuries.

5.3 Method of measurement

Subjects undergo two sport motor tests: the one-leg balance stand and one-legged balance stand in side stand (Fetz/Kornexl, Sportmotorische Tests 1993, 80 et sqq.). As testing devices, a stop watch and an edge of a board (2cm wide, 10 cm high) are required. The test is valid for subjects from 10 to 60 years of age. The key quality criteria objectivity, reliability and validity have already been studied by Fetz and Kornexl (1993, 10 et sqq.).

5.3.1 One-legged balance stand

"The subject is standing barefoot with one foot on a 2 cm wide and 10 cm high edge of a board, hand on hip. In response to a signal of the test manager, he lifts the non-supporting leg off the floor und attempts to stand as long as possible on the supporting leg on the edge of the board; while doing so, neither the hands must be taken from the hips, nor can the floor be touched with the other leg. The period of time from the start signal until taking the hands off the hips, until contact with the board is lost, or until the ground is touched is recorded in full seconds; after 60 seconds the test is terminated. The subjects are given 3 attempts.The arithmetic mean is calculated using the two best test results (Fetz / Kornexl 1993, 80 f.)

Several pre-attempts with a total duration of one minute are required. Static balance in an upright position with one-leg balance stand in side stand is the primary test parameter.

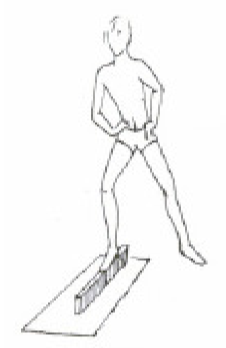


Fig. 5: One-leg balance stand (Fetz / Kornexl 1993, 81)

5.3.2 One-legged balance stand in side stand

The subject is standing in side stand with the ball of the toe of the preferred leg on the above-mentioned edge of the board and attempts to stand as long as possible on the board's edge. Time measurement is carried out under the same conditions as mentioned under **One-legged balance stand.** This test offers one attempt which is ended after 90 seconds; only one pre-attempt is allowed. Again, the arithmetic mean is calculated from the two best test runs (Fetz / Kornexl 1993, 83 f.). The static balance in an upright posture to the front and to the back is mainly tested.

Abb. 6: One-legged balance stand in side stand (Fetz / Kornexl 1993, 83)

In all test situations, a focussed, quiet test atmosphere is provided. Prior to the test, a general warming-up programme, which is not test-specific, is carried out for 10 minutes without an MBT® training devise. All subjects are tested during the initial test and the re-test in a one-legged stand on the same leg. This specific test situation, however, is not practiced during the study period; any learning effects can therefore be excluded.

5.4 Study design

The study was conducted over a period of four weeks. At the beginning of the study period, the sport motor tests One-legged Balance Stand and One-legged Balance Stand in Side Stand were performed by two independent examiners. Then the participants received one pair of hire MBT® each and a professional introduction by an MBT® teacher. Furthermore, they participated in a special MBT® training course under the supervision of an MBT® teacher. In parallel to the MBT® training, the subjects had to continue their usual football-specific training, which was the same for all in extent, intensity and duration. In addition, the participants had to wear the MBT® daily for at least two hours. This was controlled by spot checks. At the end of the study period, the two tests One-leg Balance Stand and One-leg Balance Stand in Side Stand were re-evaluated. The re-test was also performed by two independent examiners.

During the MBT® training programme, the main focus was on the proper performance of all exercises. The MBT® teacher corrected the participants to ensure proper use of the MBT® training device during the combination, everyday and sport exercises as well as all sport-specific exercises. A physiotherapist and a football trainer accompanied the exercise programme and offered – especially for sport-specific exercises – additional support. Learning and correction of the exercises took place in five units at one-week intervals and focused on the following key areas:

1. Visit	Initial test MBT® combination exercise
2. Visit	Repetition and correction of the MBT® combination exercise MBT® everyday exercises MBT® sport exercises
3. Visit	Repetition and correction of the MBT® everyday exercises Repetition and correction of the MBT® sport exercises Sport-specific training using MBT®
4. Visit	Sport-specific training using MBT®
5. Visit	Re-tests

Tab. 1: Schedule of MBT® training units

The following combination, everyday and sport exercises were developed by Swissmasai AG and are consistently used for the introduction to Masai Barefoot Technology®. All figures for the exercises are from the Swissmasai AG teacher's manual (2002, 42et sqq.).

The programme starts with combination exercises. Their aim is to teach walking and standing with MBT® and there are five exercise parts:

1) Compress heel sensors

With fully stretched body, compress the heel sensors alternately left and right. Do not allow the foot to give way towards medial, but rather direct the pressure to the external edge of the heel.

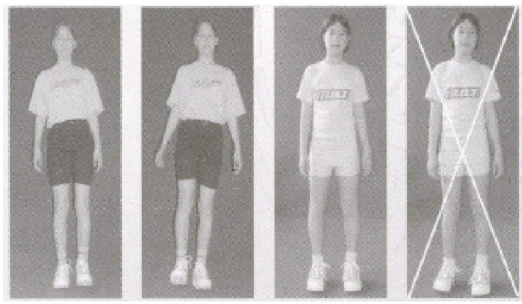


Abb. 7: Combination exercise (1)

2) Balancing of midfoot

Balance the stretched body on the MBT® tilting edge. Do not bend knee or hip. Use only small movements of the feet for balancing.

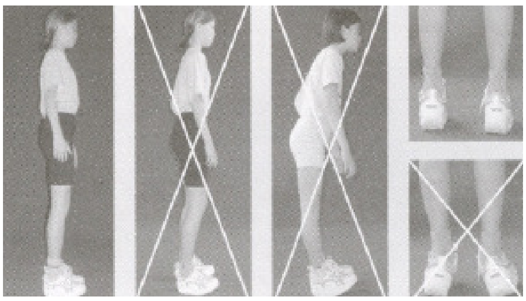


Abb. 8: Combination exercise (2)

3) Press midfoot into the floor

Press the tilting edge straight below the body slowly but forcefully into the floor. Keep the body straight. Do not allow the feet to give way towards medial but give extra load to the outer edge. Do not roll excessively but walk by balancing in the midfoot region.

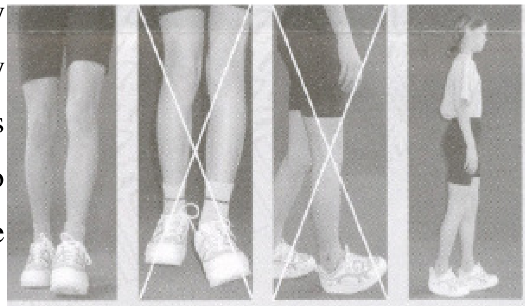


Abb. 9: Combination exercise (3).

4) Relaxed trotting

Jump upwards dynamically using the midfoot while holding the body straight. Let the thighs hang in a relaxed manner; do not lift them as with running. Allow counter-rotation of the upper part of the body and the pelvis.

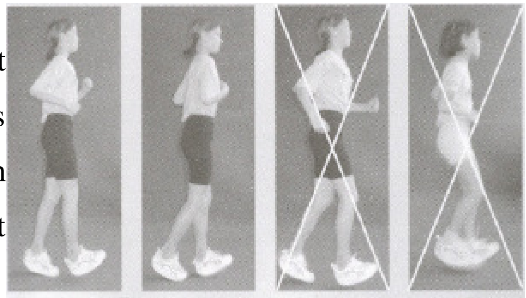


Abb. 10: Combination exercise (4)

5) **Walking-standing-trotting**

Train part **2, 3** and **4** of the exercise alternating.

During the second visit, the everyday exercises are learnt. Their purpose is to deepen the gait and postural patterns; they consistof six parts:

1) Standing in MBT®

While standing, do not place all your weight on the forefoot area, but always balance along the tilting edge. The body is kept straight, practise weight shifting in all directions and provoke lunges. With lunges, immediately search the tilting edge, put full load on it and step over it. Walk backwards as slowly as possible.

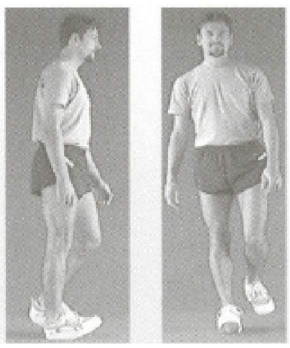


Fig. 11: Everyday exercise (1)

2) Balancing

Roll in slow-motion with straight body over the midfoot to the forefoot. Only start rolling when the heel sensor is completely compressed; put most of the weight onto the midfoot region. Do not bend feet inwards.

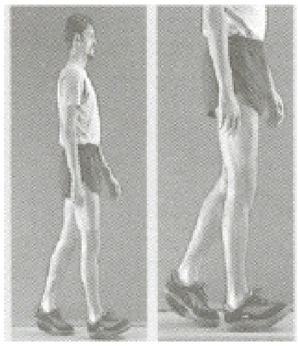


Abb. 12: Everyday exercise (2)

3) Pull steps backwards

Forcefully press the step straight under the body’s centre of gravity on the tilting edge into the floor. Then pull the leg back by deliberately contracting the gluteal and ischiocrural muscles.

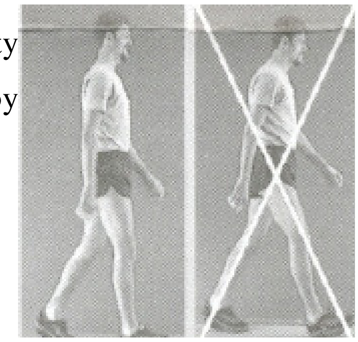


Fig. 13: Everyday exercise (3)

4) Walking upwards

Straighten the body to the greatest possible degree without bending the upper body forward. Again, start the step straight under the body's centre of gravity.

5) Walking downwards

The body is straightened, the thighs should be relaxed and the midfoot area should work intensely, the pelvis should be able to rotate. Start the step straight under the body's centre of gravity and roll from the rearfoot to the forefoot as slowly as possible.

6) Ascending stairs

As with a normal shoe, take the step with the forefoot while ascending and descending and do not roll off.

The sport exercises were learnt based on the combination and everyday exercises.. They include roll trotting and roll jogging, and offer a form of training for almost all sports. These exercises are used to enhance performance and for regeneration, prevention and therapy of sport injuries.

a) Roll trotting

Start with 10 to 20 steps and alternate repeatedly with periods of walking. Jump upwards dynamically while keeping the body straight. The thighs remain relaxed and are not lifted actively. Allow upper body and pelvis to counter-rotate in a relaxed way. Start the step straight under the body's centre of gravity on the tilting edge and roll off. The foot must not touch down on the forefoot at the beginning of the supporting leg phase. Pull the step backwards by strongly extending the hip of the side of the supporting leg (approx. 6 km/h).

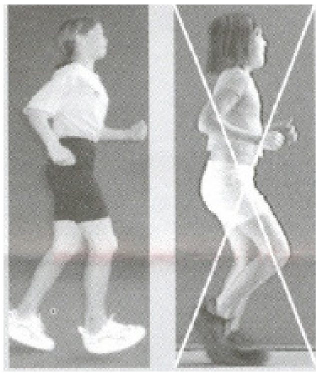


Fig. 14: Sport exercise (1)

b) Roll jogging

The movements of roll jogging largely resemble those of roll trotting. However, the movements are carried out at a faster pace (approx. 9-20 km/h).

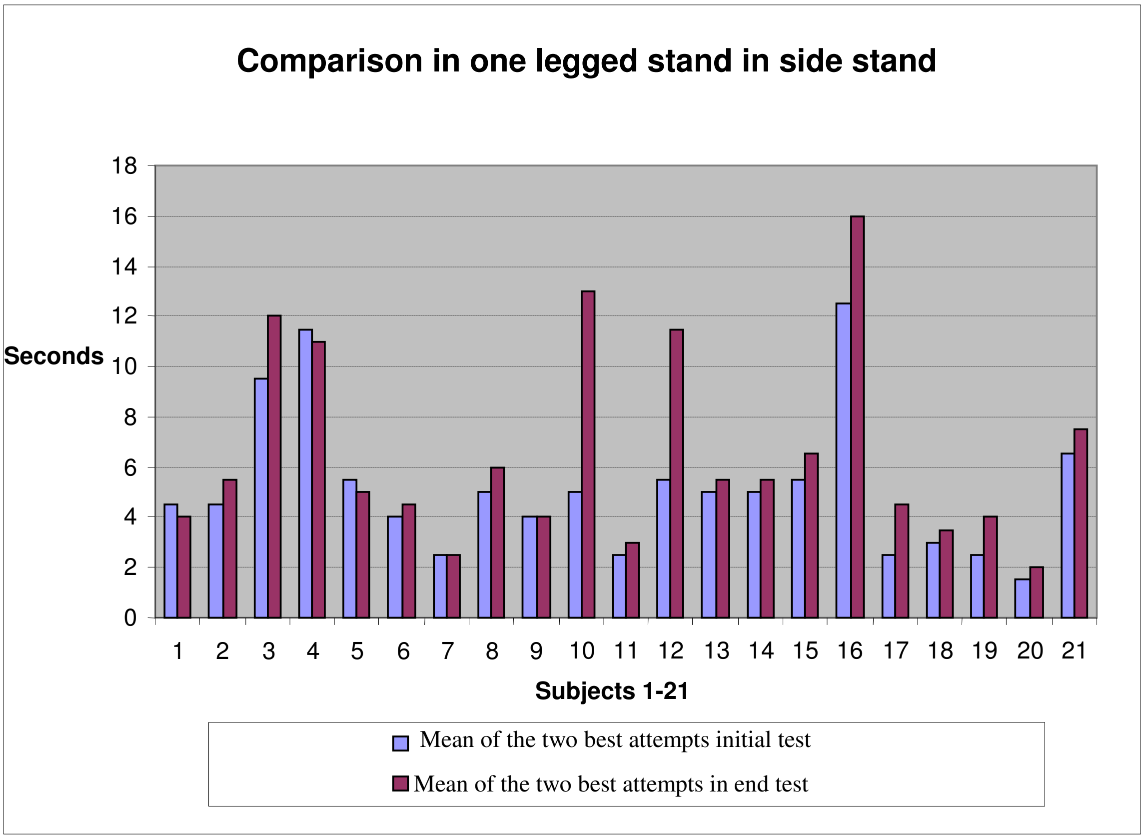
The sport specific MBT®-supported training comprises the following exercises:

- Modified jump ABC
- Modified run ABC
- One-leg stand exercises (with/without visual control)
- Knee-bends (with/without visual control)
- Trunk strengthening
- Automobilisation spine
- Stretch exercises of leg muscles and trunk

6 Presentation of the results

Data recording and statistical analysis were performed using the software programs MS Excel 2000 and SPSS[7]. The Kolmogorov-Smirnov test (goodness-of-fit test) showed that all means were normally distributed. In addition, it was evaluated whether or not there was a significant difference between individual parameters. For this purpose, the t-test for paired, normally distributed samples was used as test of significance. The result of the t-test revealed that all combinations showed significant changes.

The following diagrams compare the initial test and end test of the two test forms for each subject, as well as the percentage of the change achieved.



7 Raw data see appendix 11.2

This diagram shows that, with the exception of subjects 1, 4, 5, 7 and 9, an improvement of the ability to balance on one leg in side stand occurred. For the subjects 7 and 9, the end test results are the same as the initial test results. The subjects 1, 4 and 5 present slightly lower values in the end test compared to the initial test.

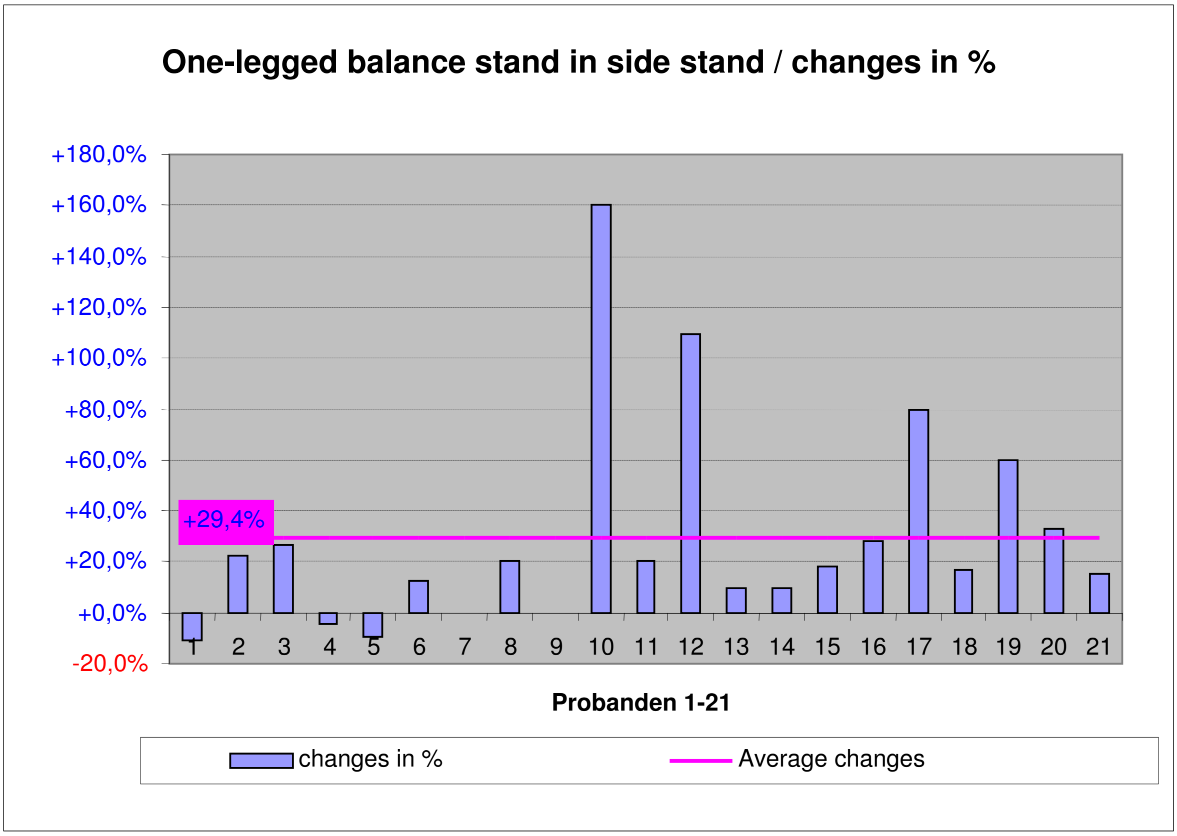


Diagram 2: One-legged balance stand in side stand / changes in %

In this diagram, the positive or negative changes in the one-leg balance stand in side stand test are depicted in percentage. The greatest increase was achieved by subject 10 with 160%. The value of subjects 7 and 9 remained unchanged. There are three subjects with negative changes; however, these are relatively small. These results are - 11.1% (subject 1), -4.3% (subject 4) and -9.1% (subject 5). In comparison, the average improvement achieved across all subjects was 29.4%.

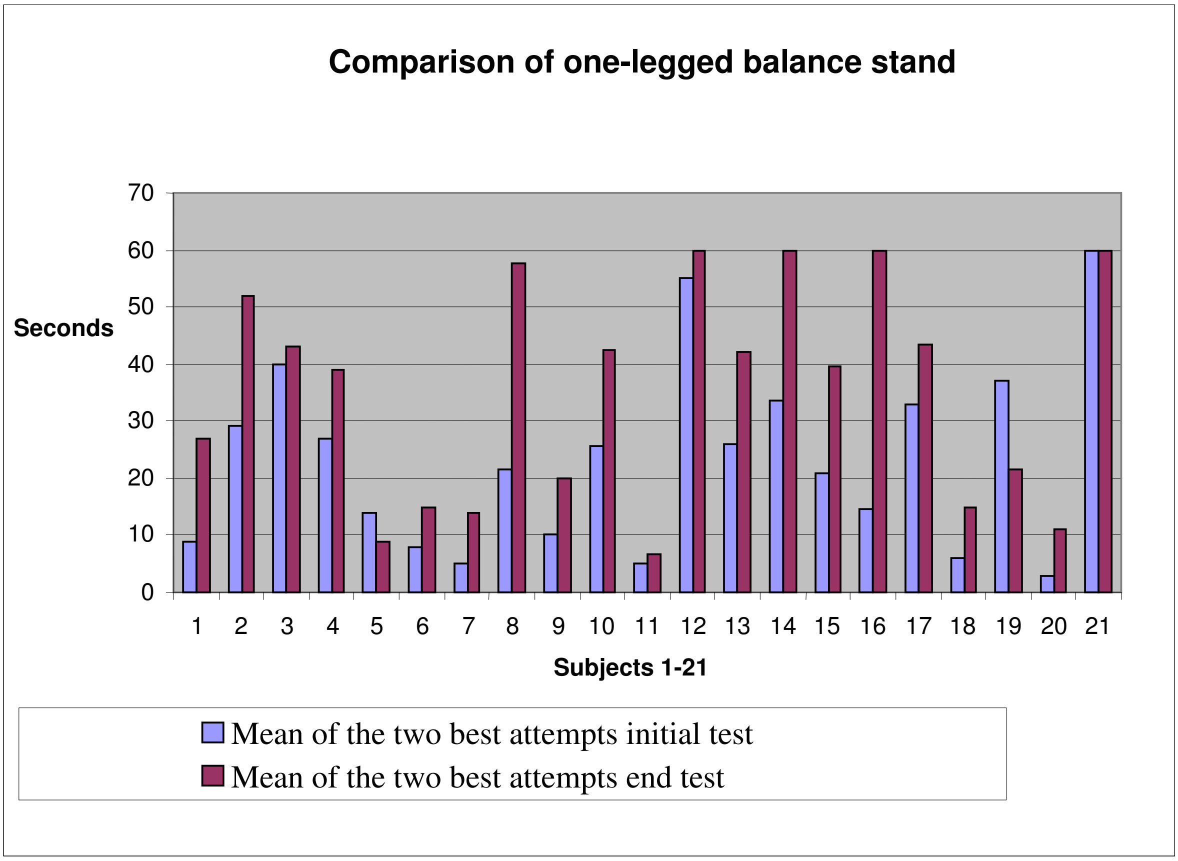


Diagram 3: Comparison of one-legged balance stand

In the one-legged balance stand test, 18 subjects showed marked improvements. The maximum values are 60 seconds, because the design of the test requires that attempts must be discontinued after 60 seconds. Subject 21 achieved the maximum in the initial test and the end test. Only subjects 5 and 19 had lower values in the end test compared to the initial test. In general, this test is much easier for the subjects than the test in side stand, a fact that is also backed by the higher average number of seconds.

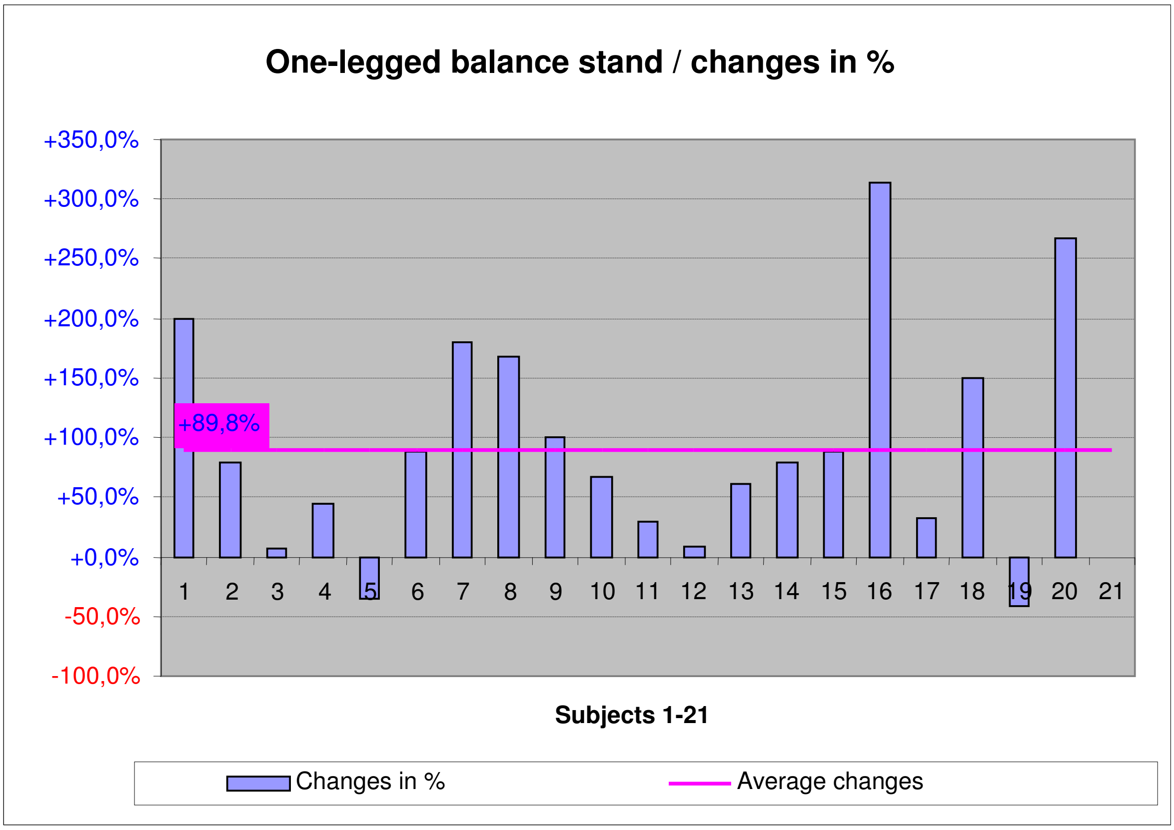


Diagram 4: One-legged balance stand / changes in %

The diagram of the percentage change shows that in the main, marked improvements were attained. The highest increase of 313% was found in subject 16. Six subjects in total achieved an improvement of more than 100%. This represents about a third of the group. The average improvement was 89.8 %. The values of the subjects 5 and 19 were -35,7% and -41,9%. These negative values are relatively high compared to the negative values of the test in side stand.

7 Discussion of the results

The analysis of this study shows clearly that effective balance training is possible with MBT®. Within the study period of four weeks, the football players achieved an improvement of balance. Average significant changes were observed for both one-leg balance stand and one-leg balance stand in side stand. The average increase of 89.8% for the one-leg balance stand shows that the lateral stabilisation of the "stirrup" muscles of the ankle joint (pronator and supinator muscles) improves with MBT® training. It should thus follow that the risk of injury, especially for inversion traumas, can be reduced. To test this, a longer-term observational study with an additional control group without MBT® use should be conducted.

The MBT® training also has a positive effect on the motor performance of the subjects. Some subjects reported faster recovery between the football training units and less muscle problems after as little as two weeks. However, a number of subjects complained about sore muscles or appearance of back pain. These problems resulted from excessive or inaccurate use and disappeared soon after correction. In this context it becomes quite obvious how important it is to do follow-ups to ensure the best-possible training. regular follow-ups by trained MBT® teachers are a fundamental feature of the MBT® concept.,They ensure that incorrect use can be prevented or corrected.

Regarding the length of time the MBT® training device was worn, this study reveals an interesting aspect. For various reasons (mainly job-related), some of the subjects were not able to comply with the targeted wearing duration of at least two hours per day.[8] However, improvements in the re-test were consistently found in these subjects too.

[8] It must be kept in mind that the information about the compliance with the agreed duration of wear was only controlled by spot checks and is, thus, mainly based on the statements of the subjects.

This leads to the assumption that proper use is more important than actual wearing time. A longer-term study would also shed light on this aspect. In any case, the manufacturer's requirement that no MBT® training devices must be sold without proper introduction is supported by this finding.

This study has also revealed that Masai Barefoot Technology® is a training method which, in comparison with other training methods, requires little extra time. Our everyday life is already packed with work and appointments and most people have only very little leisure time left. It is therefore understandable that they make careful use of this precious time. When patients visit a physiotherapist, time is also an important factor. Most patients can be more easily motivated to do something for their body if this method is not too time-consuming. This does not mean that the therapy has to be rushed, but rather that the time should be managed well. I believe that this is where Masai Barefoot Technology® offers a very good option in physiotherapy. Patients can integrate the concept with relative ease into their normal day-to-day activities. The success of the treatment is early evident early on and it requires no demanding or complicated methods. This is of importance on a psychological level as well, because the patient using MBT® does not feel he has to do "forced labour" and invest too much time into hard training. He can instead wear the MBT® during daily activities and, in doing so, efficiently and easily promote good health. Nevertheless, the MBT® should not be regarded as a cure-all. For each patient, it has to be individually decided whether Masai Barefoot Technology® should be used and according to which principles.

One aspect that should not be overlooked is muscle fatigue due to intensive use of this training device. Masai Barefoot Technology® applied correctly sets a very high level of requirements for the user; thus, fatigue of the muscle groups used can occur as with any other form of training. This applies especially for the muscles of leg and back. The MBT® should only be worn over a period of time during which the user feels good and can balance and walk correctly. Otherwise, abnormal stress and compensations may result, and the desired training effect can not be achieved, or complaints may even get worse. In the context of football training, MBT® should be deployed with very specific aims. The concept appears to be of special value as an additional balance training, as a preparation for the football season or to contribute to faster recovery after intensive stress. It has to be ensured that immediately before a match no demanding MBT® training is performed, because excessive muscle fatigue could occur. This, in turn, could lead to an increased risk of injury.

The unusually high improvements seen in both balance tests prompt a detailed assessment of possible sources of error. The tests were performed precisely, according to the standardised instruction; the test situation and similar exercises were excluded from the training and the subject group was carefully selected according to the inclusion and exclusion criteria described above. One reason for the high level of improvements is that balance can in principle be trained comparatively rapidly. Fetz (1990) and Hirtz et al. (2000, 126 et sqq.) describe studies[9], in which short training periods of 3-20 min. per week sufficed to create significant increases. However, I think increases at such high levels can only be achieved if balance training is functionally designed for the purpose. In my opinion, MBT® is one of the most functional concepts in this field. The MBT® exercises are not isolated static balance exercises; quite the contrary, they are integrated into physiological movements (e.g. standing, walking, running…). In this way, during physiological exercise, the stimuli matching the respective situation – but amplified by MBT® – reach the balance system for processing. The brain integrates all impulses to a movement pattern and stores them for the future. I think that such a movement pattern is more frequently needed than, for example, an isolated balance exercise on a therapeutic top. It is more frequently called upon and used, and thus remains present.

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[9] see chapter 3.4

Especially in the test situations, the group dynamics played an important role as well. Each player had the aim to achieve the best possible increase. The subjects were not informed about the individual test results; however, it can be assumed that a certain degree of competitiveness (probably impossible to suppress among competitive athletes) had an impact on the test data as well.

8 Conclusions

The training device of Masai Barefoot Technology® is a type of sport shoe with a special construction of the sole. While wearing the MBT® training device, the foot is neither supported nor guided, so that any type of surface is perceived as being uneven. With balancing being required with every step, walking resembles permanent balance training. Especially in football, improved balance is important, on the one hand to reduce the risk of injury, and on the other hand to increase the motor performance of the players. The study was intended to determine whether Masai Barefoot Technology® is suitable as efficient balance training in football. Finally, it was planned to evaluate whether MBT® can generally be recommended as a method of balance training in physiotherapy.

The aim of the present study was to improve the balance of football players within four weeks using Masai Barefoot Technology® (MBT®). The hypothesis that **by means of professional introduction to the MBT® concept and its regular use the balance of football players can be improved** was confirmed.

The subjects were active football players of the football team FC-Eurotours Kitzbühe who all underwent the same sport-specific training and were in roughly the same training condition. Exclusion criteria were previous experiences with MBT® and acute injuries or pain of any kind. Apart from the MBT® training, the players were not allowed to perform any balance training. Players working in a profession with a high-level of balance requirements were also excluded.

The study period lasted for four weeks, during which the players performed a special MBT® training in addition to their normal football training. At weekly intervals, a training session with MBT® was carried out. The one-leg balance stand and one-leg balance stand in side stand according to Fetz/Kornexl (1993) were used as sport motor tests. Both tests were performed prior to the introduction to MBT® and at the end of the study period.

Data analysis revealed improvements of up to 160% in 18 of 21 subjects for the one-legged balance stand in side stand. The average increase is 29.4%. In the one-legged balance stand, improvements of up to 313% were seen in 19 subjects. The average increase here is 89.8%. The number of subjects with poorer performance on retest is markedly lower. In the one-legged balance stand in side stand, 3 subjects had lower re-test results. On average, the poorer performance was only 8.2%. In the one-legged balance stand, 2 subjects performed more poorly by 38.8% on average.

The ease of use of the Masai Barefoot Technology® deserves special mention. The prerequisite is that the technology is properly employed. It is important that the user receives individual instruction and that introduction and follow-ups are only provided by qualified professionals, that is, doctors or physiotherapists qualified in MBT®. If this is the case, the user is offered the opportunity of effective and functional training that can easily be integrated into everyday life .

As a follow-on from this study, it would be interesting to obtain empirical data on the extent to which an improved balance in football players has an impact on injury risk and motor performance. For this, monitoring over a prolonged period of time, at least one term, should be considered. Another possible study approach would be to give the participants various coordination tests. This could support the finding that, through improved balance, movement coordination is also enhanced (see chapter 3.5).

Furthermore, it would be of interest to find out what a statistical graph of balance improvements over a prolonged period of time would look like. Within the four-week study period, it was not possible to establish whether the observed increases were an adaptive mechanism that shows rapidly increasing values in the initial training phase and later flattens to a plateau, or whether an exponential increase is indeed possible.

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10 List of figures, diagrams and tables

11 Appendix

The appendix contains a copy of the informed consent form for the subjects and the raw data of the test series, as well as additional information on Masai Barefoot Technology®.

11.1 Informed consent form

Akademie für Physiotherapie
Ausbildungszentrum West für Gesundheitsberufe der Tilak GesmbH
Innrain 98
A-6020 Innsbruck

Diploma thesis for the Diploma of Physiotherapy

Title: Balance training with Masai Barefoot Technology®

Investigator: Elisabeth Ritter
Supervisor: Dipl.PT Erika Schifferegger, Dipl.PT Wolfgang Kaiser

I have read the information sheet; type and aim of the study have been explained to me. I understand the project and agree to participate in it.

I am aware that information derived from this study will be published but that I will not be named personally and that my personal data will remain protected.

I understand that I can discontinue my participation at any time without suffering any disadvantage because of this.

I am aware that I will not suffer any injury to my health as the result of my participation.

I am aware that I will not receive any payment for participating in this study.

Name: ....

Signature: ....

Date: ....

I affirm that I have explained the project to the participant and that the participant has understood it.

Investigator: ....

11.2 Raw data Test series

Test series 1 – <u>Initial test</u> One-legged balance stand in side stand
Test series 2 – <u>Initial test</u> One-legged balance stand
Test series 3 – <u>End test</u> One-legged balance stand in side stand
Test series 4 – <u>End test</u> One-legged balance stand

	Test series 1				**Test series 2**				**Test series 3**				**Test series 4**			
	Attempt 1	Attempt 2	Attempt 3	Mean of the best 2 attempts Initial test	Attempt 1	Attempt 2	Attempt 3	Mean of the best 2 attempts Initial test	Attempt 1	Attempt 2	Attempt 3	Mean of the best 2 attempts Endl test	Attempt 1	Attempt 2	Attempt 3	Mean of the best 2 attempts Endl tes
Subject 1	4	5	3	4,50	8	10	5	9,00	3	5	3	4,00	27	4	27	27,00
Subject 2	4	5	3	4,50	46	7	12	29,00	3	8	3	5,50	60	44	23	52,00
Subject 3	12	3	7	9,50	39	41	28	40,00	6	18	3	12,00	38	48	12	43,00
Subject 4	5	9	14	11,50	6	40	14	27,00	12	10	6	11,00	4	60	18	39,00
Subject 5	6	5	5	5,50	14	14	7	14,00	5	4	5	5,00	8	9	9	9,00
Subject 6	4	4	4	4,00	11	3	5	8,00	6	3	3	4,50	14	5	16	15,00
Subject 7	2	3	2	2,50	6	4	4	5,00	2	2	3	2,50	10	18	5	14,00
Subject 8	2	5	5	5,00	2	39	4	21,50	5	7	4	6,00	15	55	60	57,50
Subject 9	3	5	3	4,00	4	8	12	10,00	3	4	4	4,00	15	8	25	20,00
Subject 10	5	2	5	5,00	9	10	41	25,50	6	13	13	13,00	60	2	25	42,50
Subject 11	1	2	3	2,50	3	4	6	5,00	2	3	3	3,00	3	5	8	6,50
Subject 12	4	6	5	5,50	2	60	50	55,00	8	15	5	11,50	5	60	60	60,00
Subject 13	6	2	4	5,00	22	30	13	26,00	4	7	4	5,50	34	50	16	42,00
Subject 14	4	1	6	5,00	12	10	55	33,50	3	6	5	5,50	60	60	0	60,00
Subject 15	4	7	2	5,50	3	31	11	21,00	3	4	9	6,50	39	40	14	39,50
Subject 16	5	18	7	12,50	8	19	10	14,50	14	18	5	16,00	60	60	0	60,00
Subject 17	3	2	2	2,50	6	60	6	33,00	5	4	4	4,50	50	7	37	43,50
Subject 18	3	1	3	3,00	5	4	7	6,00	2	1	5	3,50	6	7	23	15,00
Subject 19	1	2	3	2,50	60	14	10	37,00	3	3	5	4,00	27	6	16	21,50
Subject 20	1	1	2	1,50	3	2	3	3,00	2	2	2	2,00	10	10	12	11,00
Subject 21	4	4	9	6,50	60	60	0	60,00	9	4	6	7,50	60	60	0	60,00

Test series 1 – Initial test One-legged balance stand in side stand
Test series 2 – Initial test One-legged balance stand

Test series 3 – End test One-legged balance stand in side stand
Test series 4 – End test One-legged balance stand

	Change			
	Test series 1 to 3 in seconds	in %	Test series 2 to 4 in seconds	in %
Subject 1	-0,50	-11,1%	18,00	+200,0%
Subject 2	1,00	+22,2%	23,00	+79,3%
Subject 3	2,50	+26,3%	3,00	+7,5%
Subject 4	-0,50	-4,3%	12,00	+44,4%
Subject 5	-0,50	-9,1%	-5,00	-35,7%
Subject 6	0,50	+12,5%	7,00	+87,5%
Subject 7	0,00	+0,0%	9,00	+180,0%
Subject 8	1,00	+20,0%	36,00	+167,4%
Subject 9	0,00	+0,0%	10,00	+100,0%
Subject 10	8,00	+160,0%	17,00	+66,7%
Subject 11	0,50	+20,0%	1,50	+30,0%
Subject 12	6,00	+109,1%	5,00	+9,1%
Subject 13	0,50	+10,0%	16,00	+61,5%
Subject 14	0,50	+10,0%	26,50	+79,1%
Subject 15	1,00	+18,2%	18,50	+88,1%
Subject 16	3,50	+28,0%	45,50	+313,8%
Subject 17	2,00	+80,0%	10,50	+31,8%
Subject 18	0,50	+16,7%	9,00	+150,0%
Subject 19	1,50	+60,0%	-15,50	-41,9%
Subject 20	0,50	+33,3%	8,00	+266,7%
Subject 21	1,00	+15,4%	0,00	+0,0%
Means:	1,38	+29,4%	12,14	+89,8%

11.3 MBT® Clinical Evaluation

„mbTechnologie AG Technical Documentation TD 7-1
Conical evaluation of MBT

1. Preliminary notes

The present evaluation concerns Masai Barefoot Technology which combines a special shoe construction with a movement programme. The MBT shoe construction forces the user to balance and to assume an upright posture – thus the wearer is constantly carrying out a "training programme". Data on wearing MBT revealed positive results regarding various health problems. Because of the resulting success stories and the directions for use, MBT is a medicinal product. Medicinal products have to be manufactured and distributed in a qualified manner, risk of use and medical efficacy have to be evaluated so that conformity of a medicinal product with the Fundamental Requirements for Medicinal Products can be confirmed.

2. Construction

The MBT construction mainly concerns the construction of the sole that contains, below a comparatively stiff fibreglass plate, the heel sensor and the tilting edge – and the rounded sole, which has its maximum thickness in the area of the tilting edge. The upper part is the same as in traditional constructions of finely adjustable sandals, sport shoes or leather shoes.

3. Area of use

MBT is a device intended to enclose the feet so that it influences the neuromuscular and skeletal systems during motion. The marketed areas of use are directed at target groups in which the change in movement patterns helps to reduce symptoms or cause symptoms to disappear, or in which sport-related or general improvements in well-being shall be achieved. Preferred medical uses include back, hip, leg and foot complaints, treatment of joint, muscle, ligament and tendon pain. Further areas are illnesses or impairments that result in muscle tension or restricted movement that can be reduced by the balance reaction triggered by wearing MBT.

Product promotion in brochures and via the internet is based on references or user reports. Presently (20 June 2002), indications from the following areas are listed on the internet: Achilles tendon pain, arthritis, arthrosis (foot, knee, hip), foot pain, hip pain, knee pain, meniscus, Bechterew's disease, multiple sclerosis, patellar tendon pain, PAOD, physiotherapy, smoker's legs, rheumatic disorders, back pain, intermittent claudication, overweight, venous problems.

The use of MBT technology in these alphabetically listed conditions is no indication in a medicinal sense – the medicinal product MBT combined with movement training, however, can have positive effects as a physiotherapeutic treatment. Iindication are divided into three levels:

Strict indication

Disorders or impairments of the walking and postural system that respond to the other "softer" process of MBT Technologie.

Extended indication

Disorders or impairments which are positively influenced by the training or movement effects of MBT Technology – e.g. by the "calf muscle pump effect" of the active muscles. Concomitant therapy: Disorders or impairments in which the training or movement effects of MBT Technology have a supporting effect, e.g. by the compensatory use of other muscle areas in partial pareses. The indications of these three levels are not clearly separated – however, this does not seem to be required for this product.

4. Directions for use

The MBT is delivered with directions for use (new), an exercise sheet for combination exercises and sport exercises (see TD 2) as well as a videotape or a CD-ROM for learning exercises. All documents advise cooperation with an MBT trainer or therapist.

5. Side effects, contraindications

MBT Technology leads to different movements and thus activates other muscle areas. In addition to the higher energy expended while walking, initially faster fatigue or, with forced introduction, also muscle pain (stiff muscles) may occur. In certain disorders or with certain handicaps, there is a risk of falling at the beginning of the therapy; excessive use may also result in worsening of the symptoms.

6. Discussion of rating and classification

Primarily, MBT is an article of use (footwear, shoe); it is also a sport device (balance training) and a medicinal product because of its intended use as a treatment, method of alleviation (of pain) of illnesses, or as a treatment, method of alleviation or compensation of injuries or impairments. According to the classification of the Directive 93/42/EEC Appendix IX, it falls into the category of medicinal products for temporary or short-term use of class I rule 1, since no other rule is applicable.

7. Clinical information

7.1 Clinical trial

A clinical trial according to section 2 of appendix X of directive 93/42/EEC was not conducted. From the wording of the first section of appendix X, it can be derived that all existing evidence and clinical data and the results of all clinical trials, including the studies, have to be evaluated according to appendix X.

7.2 Ethical aspects

In clinical trial, ethical aspects have to be considered – and, according to the Heilmittelgesetz (Medicinal Product Law), the opinion of an ethics committee must be sought. In the context of market surveillance by the authorities, the customer questionnaire as a method of clinical data collection in the sense of a clinical trial was questioned and an evaluation by an ethics committee was requested. The ethics committee of the canton Thurgau classified this questionnaire as an observation of use. (see attachment, TD 7-2). In consideration of the present reports and opinions it appears reasonable to conclude that an actual clinical trial for conformity evaluation of the present medicinal product MBT is not required because of the existing information and therefore not justifiable from an ethical point of view.

7.3 Specialists' reports and opinions

Under TD 7.3, newly-produced and signed opinions of 9 doctors are available, which address various aspects and report on results of treatments of patients and, in many cases, also on their own clinical results or self-test experiences. Dr Olaf Then, Orthopaedic Specialist, Consultant Clinic for Rehabilitation of the BRK, reports on observations of the use of MBT. Besides experiences with his own malleolar fracture-related symptoms, he reports results obtained in patients with achillodynia, lumbar pain go, kyphosis. In his conclusion, he describes Masai Barefoot Technology as an ideal aid for training the body's neuronal, muscular and skeletal system. He thinks MBT should be used in almost every form of physical therapy with detailed introduction and under supervision. Dr Michael Fierz, Assistant doctor in sport medicine, Med. Zentrum Bad Ragaz, initially prescribed the MBT for his patients and experienced with personal use improvement of persistent lumbar pain. He describes the MBT with instructions by trained staff as a sensible alternative in the rehabilitation of the locomotor system. Dr F Brunner, ParaCare, Orthopaedic University Hospital Balgrist, 8008 Zurich, gives a positive opinion on Masai shoes based on his own experiences and recommends their use. Dr Stephan Eberhard has been wearing MBT regularly for 18 months and has observed a stabilisation of his heel pain, enabling him to carry out regular running training. Dr Roger Berbig, Dr Ursus Lüthi and Dr Bruno Waespe of the Sport Clinic Zurich use MBT specifically, especially with overload injuries of the lower extremities, but also postoperatively. They emphasise the importance of using the device under supervision of a physiotherapist. Dr Christian Widmer describes the MBT from a GP's perspective who use MBT mainly for joint complaints, achillodynia, abnormal foot positions, symptoms associated with varicosis and other complaints and seldom to promote walking and standing coordination. Dr Markus Schmid, internal specialist with a focus on rheumatology and sport medicine, has made good experiences with MBT shoes in patients and is also treating his own lumbar tension and complaints with it.

Apart from the statements of these doctors, others made by physiotherapists are available as well: Physiotherapy B. Jordi and Team; Riehen, 4 patient results. Physiotherapy Ch. Wehrle, Speiche, 2 patient results. Physiotherapy Martina Eitner, St. Gallen, patient and own successes, emphasises the importance of instructions. Physiotherapy, Dusan Radanovic, jogging analysis, evaluation of 3 patients. Apart from these new evaluations, reports of further doctors (Dr. R. Spanderer, Dr. J. Zech, Dr. Wessinghage and Dr. Bornhäuser) and physiotherapists (e.g. K.H. Lipp) are available on the company's homepage www.masai.ch.

7.4 Gait analysis, Diploma thesis J. Bär,

The matter was addressed in a diploma thesis as part of physoptherapy diploma course at the Medizinisch-technischen Akademie für den physiotherapeutischen Dienst at the Ausbildungszentrum West für Gesundheitsberufe TILAK Ges.m.b.H, Innsbruck: Gait analysis for the movement therapeutic evaluation of the concept of Masai Barefoot Technology. In the context of this literature study, which is attached, the author gives a positive opinion on MBT.

8. Conclusion

From the existing documents it can be deduced that MBT is a suitable system for the training of the body's neuronal, muscular and skeletal systems. To some extent, disorders of the skeletal system can be causally reduced and, to some extent, there is a positive influence on other illnesses. Thus the use of MBT in therapy, rehabilitation, orthopaedics, prevention as a medicinal product, and in the fitness sector is sensible. Adverse effects and contraindications can be prevented by providing sufficient information on use and by seeking, as strongly recommended, the advice of therapists or doctors. I hereby confirm that MBT, according to my belief and my present level of knowledge, fully complies with the requirements for medicinal products.

9. Information on the author of the expert opinion

Dipl. Ing. Dr.techn. Alfred Illigen is a chemist who has be involved in chemical development, food testing, synthesis fibre production, and, since 1982, in the dental industry in the field of manufacturing and registration. He worked as a member in the DIN Normenausschuss Dental, Biologische Werkstoffprüfung, in Germany (1983 - 1989) and was a co-founder of Normengruppe Dental, Biologische Werkstoffprüfung, in the Schweizerischer Normenverband and member until 1992. Training in quality management. Consultant in the certification of medicinal product companies (more than 20 companies with various medicinal product classes IIa and above) and creation of technical documentation.

Heebrugg, 26/06/2002, Dr Alfred Illigen

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(www.swissmasai.com, Date of query 15.03.04)

11.4 MBT® Certificate Medicinal Product

Principality Liechtenstein Department of Food Control and Veterinary Affairs

Certificate of

We hereby confirm

a) that mBTechnologie AG is a properly registered company which markets medicinal products Class I in Liechtenstein.

b) that mBTechnologie AG, Gagoz 73 Balzers is the manufacturer of the product "mBT® Orthese Fuss/Knöchel"according to article 1 of the Directive 93/42/EEC on medicinal products.

c) that the product "mBT® Orthese Fuss/Knöchel" according to the conformity statement of the company mBTechnologie AG of 26 June 2002, meets the basic requirements of the Directive 93/42/EEC of the council of 14 June 1993 on medicinal products.

d) that medicinal products for export and medicinal products for the market in Liechtenstein must meet the same requirements.

e) that mBTechnologie AG after complying with the procedure according to appendix VII of the Directive 93/42/EEC and after issuing the conformity statement for "mBT® Orthese Fuss/Knöchel" is authorised to affix the CE label to this product.

Schaan, 21 November 2002

Department of
Food Control and
Veterinary Affairs

[Seal of the Department]

[Signature]
Yvonne Spano

(www.swissmasai.com, Date of query 15/03/2004)