Appendix L:

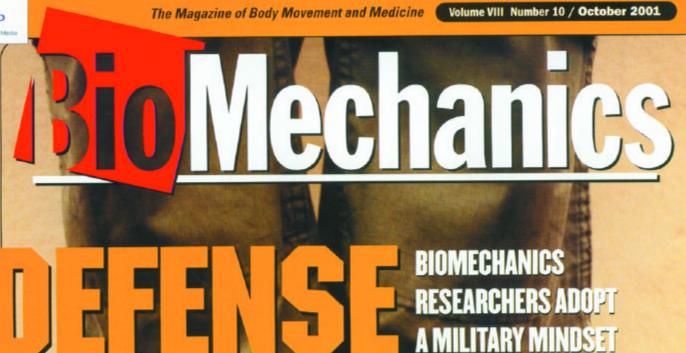
Insole System Decrease Plantar Surface Area.

Following is the published data collection which occurred in an effort to observe trends in footprint surface area reductions when Barefoot Science insoles are introduced as an in-shoe exercise system.

Within this Appendix you will find the published article in the October 2001 Issue of "Biomechanics":

- 1) Under Foot Surface Area pressure Mapping With F-Scan
 - a. Objective: To observe hypothesized changes in surface area of the plantar aspect of the foot associated with the use of the Barefoot Science insole product.
 - b. Design: A Cohort study introducing the use the Barefoot Science insole technology as an independent variable.
 - c. Participants: N=15, between the ages of 21 and 45 and displaying a moderate level. The gender breakdown was 7 males and 8 females.
 - d. Methods: Data was collected using a F-Scan in shoe pressure mapping system manufactured by Tekscan Inc. The test subjects used the Barefoot Science insoles for a period of 8 weeks during their normal activities and in their footwear of choice. Data was collected during static standing and dynamic walking activities in both a shod and unshod condition.
 - e. Outcome measures: Independent two-sample tests and repeated measures ANOVA using SPSS ver10 statistical software.
 - f. Results: A significant difference was observed for the Barefoot Walking condition at a P > 0.05. In the static shod and walking shod there were definite trends shown in the reduction of planate surface area at p= 0.069 for the static and p=0.082 for the walking.
 - g. Conclusions: The results demonstrate that through the use of the Barefoot Science insole it is possible to create structural changes to the foot and in particular the plantar surface area. It is safe to also propose that said reductions in plantar surface area would be the result of changes to the arch system of the foot. Although the structural changes can in theory be attributed to a combination of soft tissue and osseous factors it is highly logical that over such a short time period it is unlikely that any noticeable osseous remodelling would have occurred resulting in the structural changes observed. It is therefore logical and safe to conclude that the major contributor to the structural changes would be the strengthening and conditioning of the foot's supporting musculature.
 - h. Discussion: Further research needs to be done in the field and the findings here should be correlated with those found by proponents of barefoot exercise to observe any commonality between the results of truly targeted foot exercising and the results attained through the use of insoles devices such as Barefoot Science.





FUNCTION

Computer model sheds light on biomechanics of ACL

PREVENTA

Experts back away from industrial lumbar supports

PLUS

CHHHH

Baseball's comeback kids

Hits& Misses

Bio Mechanics



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L. Rochelle Roniger

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Computer model sheds light on ACL biomechanics

Rikki Lee Travolta

PREVENTIVE MEDICINE -

Experts back away from industrial lumbar supports



Rob Burke, BScKin,

Reggie Reyes, BKin,

and Tudor Bompa, PhD

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Martial arts take aim at falls in elderly



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Insole system decreases plantar surface area

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- Hanger financial statement puts Seattle business back on block
- · FDA advisory panel gives nod to Lilly's osteoporosis drug
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INSOLE SYSTEM

decreases plantar surface area

oot care specialists estimate that almost 85% of the North American population will at some time in their life experience problematic foot pathology severe enough to warrant consultation and treatment. Belief in a relationship between the incidence of foot-related problems and footwear use is growing. The incidence of foot-related problems in unshod populations is only a fraction of what it is in shod populations (Sethi, 1977). Furthermore, footwear may have severe detrimental effects on gait biomechanics and the development of foot structure from early childhood and into maturity. An historic example of this is the ancient Asian practice of foot binding, which caused deformation of the foot into the shape of the

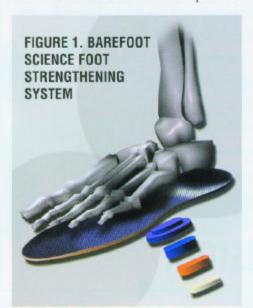
binding apparatus used.

Modern footwear may have similar damaging effects by altering foot shape, resulting in decreased biomechanical efficiency. This is consistent with theories on bone remodeling in response to strain and stress stimuli. Today, fashion and protection are the two primary influences affecting footwear design and construction. This has resulted in the development of footwear that focuses on bracing principles that restrict foot movement.

Of primary concern is the weakening and/or atrophy of foot musculature. This reduces the foot's natural ability to control impact energy and to provide the body with a strong, stable base of multidirectional support. Second, sensory insulation effects of modern footwear prevent the nerves on the plantar surface from receiving and reacting to sensory input (Nyska et al., 1995). This restriction of biofeedback stimuli reduces involuntary muscle contractions and promotes muscle inactivity and weakening. Therefore, creating footwear that can negate the above-mentioned shoe, foot, and gait-related problems is a new focus of some manufacturers. We believe this should include designs that improve sensory responses at the plantar surface of the shod foot, which requires an understanding of the role of proprioception and biofeedback in stimulating muscle contraction.

The human body contains a myriad of cutaneous and subcutaneous receptors that respond to pain and pressure stimuli (Latash, 1998). The mechanoreceptors in the foot also respond to pressure stimuli and are important

Put to the Test is a forum for technology assessment studies of products and devices used within the biomechanics mainstream. BioMechanics magazine does not specifically endorse any of the products or devices tested.



for promoting muscular contraction (Robbins and Hanna, 1987). Kavounoudias et al. (1998) showed that cutaneous messages from the main supporting zones of the feet play an important role in communicating with the central nervous system about body position. More specifically, we believe that biofeedback from the sensory locations in the plantar surface of the foot are important for postural adaptations.

Further study needs to be conducted on the effects of different types and levels of pressure stimuli on the plantar surface of the foot and the resulting anatomical responses. This type of research can potentially revolutionize the shoe industry if positive anatomical remodeling of the foot ultimately becomes an important factor influencing footwear design, which we believe will help to alleviate the vast number of foot- and gait-related pathologies and injuries resulting from the everyday use of common footwear.

A pilot study at the University of Huddersfield in the U.K. on a proprioceptive insole device (being commercialized under the name Barefoot Science) has shown promising results. Shortening of the medial, lateral, and transverse arches, as well as reductions in the valgus index of the test group were observed (Robbins and Hanna, 1987). To investigate the usefulness of the insole concept for positive anatomical remodeling of the shod foot, we developed a protocol similar to that used in the Huddersfield study.

First, we believe that the presently atrophied foot of a typical-

ly shod person is capable of musculoskeletal rehabilitation. This can be compared to immobilization of a broken wrist, which causes the surrounding musculature (wrist flexors and extensors) to weaken and atrophy or shrink. Rehabilitation of the joint structures commences, however, as soon as the cast is removed. Full range of motion flexion, extension, and rotation exercises are used to redevelop the soft tissue in the surrounding area. As the muscles around the joint are strengthened in all ranges of motion, the joint itself becomes more stable.

Second, introducing monitored, controlled pressure to the plantar surface will catalyze musculoskeletal rehabilitation. Third, a reduction in plantar surface area will be observed. Reduced surface area is an indicator of increased arch height and arch shortening.

Materials and methods

The Barefoot Science foot-strengthening insole replaced the existing insoles of each subject's shoes. The insole was designed with a built-in dome-shaped contour strategically placed to sit directly beneath the arch apex of the individual's foot (Figure 1). A series of six progressively firmer inserts were placed within the underside of the dome area, one every two weeks. These inserts provided the subjects with the catalyst required for muscular contraction. The gradual progression allowed the muscles of the feet and lower leg to adapt in a conservative and effective pattern.

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The insoles were customized to each subject's foot and trimmed so that the dome area sat directly beneath the arch apex of the foot and the entire Barefoot Science insole lay completely flat within the shoe. The insoles come in six size ranges suitable for children's size 1 all the way up to men's size 14.

The F-Scan In-Shoe Pressure Measurement System (Tekscan) was used to quantitatively measure the plantar surface area of each of the subjects' feet. This bipedal system used a .007-inch film sensor to measure foot function and could be customized to match individual shoe sizes. Both static and dynamic conditions were recorded. The sensor was versatile enough to measure shod and unshod (with socks) conditions without interfering with normal gait biomechanics.

Seven males and eight females between the ages of 21 and 45 were recruited from a local recreation center. Their activity levels ranged exercising between two and four times per week and included a combination of walking, jogging, cycling, and resistance training. All footwear included conventional running shoes and cross trainers. Prior to wearing the Barefoot Science foot strengthening system, all subjects were asked to describe any foot- or gait-related injuries. The general symptomatic complaints included heel pain, lower back pain, knee pain, flat feet, shin pain, and foot pain following long bouts of physical activity. However, a medical professional did not formally diagnose these conditions.

Procedures

Plantar surface areas of 15 test subjects were measured at specified time intervals over an eight-week period. Prior to insole use (at week zero) all participants were measured for our three test protocols (static unshod standing, dynamic unshod walking, dynamic shod walking) to obtain baseline plantar surface area data. The participants were then randomly split into two groups to participate in one of two experiments.

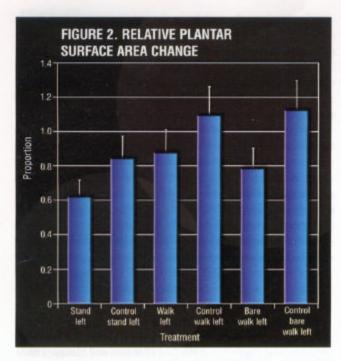
Experiment 1: Relative plantar surface area change

Ten subjects were randomly split into two treatment groups. Four subjects were placed into the control group and six subjects in the experiment group. All experimental group subjects wore the Barefoot Science foot strengthening system insoles and were instructed to change to progressively firmer plantar inserts every two weeks. After eight weeks, plantar surface area was measured again for both the control and experimental groups for the six test conditions (Figure 2). This was done to test for any differences in changes to plantar surface area over time in the experimental group relative to the control group for each test condition.

Experiment 2: Proportional plantar surface area change over time

As an addendum to experiment 1, plantar surface area was measured for the remaining five subjects over an eight-week period. All participants wore the Barefoot Science foot strengthening





system insoles throughout the duration of this experiment. Fscan measures of all six test conditions (STAND-L, STAND-R, B-WALK-L, B-WALK-R, W-L, W-R) were taken at weeks zero, two, four, six, and eight after progressing through phases 1-2, 3-4, 5-6, and 6 of the Barefoot Science foot strengthening system insoles. The bimonthly measurements were done to test the effectiveness of the insoles at each phase of use.

Static unshod standing test. This test protocol measured plantar surface area in a static state. Each subject was set up with the sensors placed between the bare foot and a light sock and asked to stand for 16 seconds, or 800 frames at 50 frames per second. Left and right foot data were measured individually (STAND-L, STAND-R)

Dynamic unshed walking test. The second test protocol required each subject to walk unshod with the sensors between the bare foot and a light sock for 30 seconds, or 1500 frames at 50 frames per second. Plantar surface areas were recorded for each foot (B-WALK-L, B-WALK-R).

Dynamic shod walking test. While wearing shoes, each subject walked with the sensors between the bare foot and a light sock for 30 seconds, or 1500 frames at 50 frames per second. Again, plantar surface areas were recorded for both the left and right feet (W-L, W-R).

Data analysis

Independent, two-sample t-tests were used to analyze experiment 1 (relative plantar surface area change-control vs. test group) data. This tested for differences in foot surface area change over time among the control and experimental groups. T-tests were also performed within each treatment group to test for changes in surface area before and after insole use.

Repeated measures ANOVA (ANalysis Of VAriance between

groups) was used for experiment 2 (proportional plantar surface area change over time) data to test for any changes at discrete time intervals.

Prior to analysis, raw data were changed to proportions, all relative to the initial baseline measurements for each test protocol. The appropriate transformations were then made on the data set to enable us to run an accurate analysis using the SPSS 10.0 for Windows statistical package.

Subjects 03 and 06 were not included in experiment 1 analysis as well as subject 08 in experiment 2 due to insufficient initial surface area recordings. Also, right foot data were not analyzed because of technical problems with the F-scan measuring device.

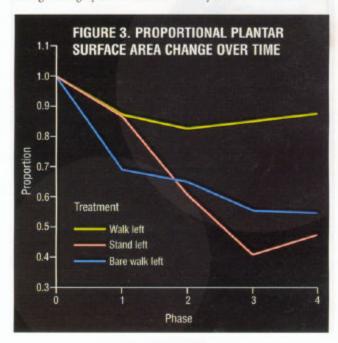
Results

Experiment 1: A significant difference between the test and control groups was observed for the B-WALK-L condition (p < 0.05). The test group showed a decrease in surface area while the control group did not change after eight weeks (Figure 1). No significant differences were observed among the test and control group for the STAND-L and W-L conditions (p > 0.05). However, a general trend indicating a decrease in surface area over time for the STAND-L and W-L conditions was observed as p = 0.069 and 0.082 respectively (Figure 2).

Experiment 2: An interaction was observed between treatment type and phase (p < 0.05). Both STAND-L and B-WALK-L showed a marked decrease while W-L decreased only slightly over time (Figure 3).

Discussion

The decrease in surface area observed in experiment 1 can be attributed to an anatomical restructuring of the foot's supportive musculature in response to the gradual biofeedback foot strengthening system insole created by Barefoot Science. The





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Phone: 800.772.7401 • 817.589.7811 FAX: 800.445.7282 • 817.589.5959 insole stimulates the muscles in the feet and lower leg to fire in sequences similar to those attained during unshod gait. (As will be discussed later, the effectiveness of this simulation is mitigated by the design of the footwear whereby looser-fitting shoes reap greater benefits.)

To stimulate the plantar surface of the foot, progressively firmer inserts are placed under the dome-shaped contour situated beneath the center of the foot at the arch apex (Figure 3). The pressure exerted by the insert acts as a catalyst to stimulate the body's proprioceptive mechanisms to signal the foot to pull away from the stimulus. This avoidance response is carried out via a contraction of the lower leg and foot's intrinsic musculature, namely the tibialis anterior, peroneus tertius, adductor hallucis, and extensor hallucis longus. As these muscles contract in the "windlass effect," the great toe is dorsiflexed and the longitudinal arch both shortens and heightens creating a stronger base of support (Nyska et. al, 1995, Winter, 1987). As these events are repeated on a regular basis, the muscles eventually become stronger (much like a resistance training workout) and more efficient with respect to force dissipation and musculoskeletal remodeling. The resulting muscular development enhances the structure and alignment of the foot (Robbins and Hanna, 1987). Evidence of muscular development is demonstrated as a decrease in the plantar surface area of the foot, as observed in our participants wearing the insole.

This type of tissue response can be coupled with a central nervous system response as the body's proprioceptive mechanisms sense a biomechanical change in the external environment (i.e., pressure beneath the foot). The result is a change in gait pattern as a defense mechanism (Nurse and Nigg, 1999). We believe that continuing research quantifying and qualifying the extensive relationship between neural feedback and gait patterns will serve to solidify the need for redesigning common footwear by implementing a foot strengthening insole such as the one designed by Barefoot Science.

As indicated in experiment 2, an interaction occurred among treatment types and phases. This can be explained by the differences in the magnitude of surface area decrease over time among the three test protocol conditions. The W-L condition improved slightly then leveled off, showing only an approximate 10% reduction in surface area while surface areas in both the unshod left standing and unshod left walking conditions dramatically decreased (Figure 3).

With respect to the unshod standing results, the smaller decrease in plantar surface area (relative to the unshod walking condition) may have occurred because of the foot's static position. In this environment, structural alignment is less critical because the force throughout the body is less than is seen in dynamic conditions. Therefore, the foot would be in a more relaxed state in the standing position causing an increase in plantar surface contact. With respect to the shod walking results, the lesser decrease in plantar surface area (relative to the unshod walking condition) can be explained by the constricting effect of footwear.

Effect of footwear

The unshod foot represents the ideal with respect to natural biomechanical function since it is free from any range of motion restriction and is forced to adapt to varying environments. However, as footwear is a necessity in most environments, design parameters are important. Factors such as toe box shape, midsole height, and heel flare must all be revisited to attack the root cause of most foot- and gait-related pathologies.

As discussed earlier, restrictive toebox designs inhibit the effectiveness of the windlass effect and the foot's ability to stabilize prior to initial contact with the ground, predisposing the foot to excessive arch collapse and overpronation. The resulting hypermobile environment is compounded through the rest of the body as the forces typically controlled by a structurally sound foot are absorbed by other joints. This repetitive stress can lead to many overuse injuries in the knees, hips, and lower back.

With respect to footwear, midsole configuration plays an important role in influencing biomechanics. In an effort to introduce mechanical devices to improve comfort, stability and cushioning, the rear foot of the shoe has been targeted because of its ease of access. The introduction of these devices has often resulted in the increase of midsole heel thickness or height. This is ironic since it is generally understood that the foot becomes less stable the further away it is from the ground. Furthermore, this unstable environment requires more effort on the part of the foot's supporting musculature which can lead to premature fatigue and increased susceptibility to injury.

As to heel flare, normal initial contact is characterized by the foot touching the ground on the lateral, posterior aspect of the heel, subsequently rolling medially prior to toe-off. Many shoe designs now feature a flared heel to provide extra cushioning at impact and attempt to control excessive pronation. This design component physically provides a wider base of support, however, increases torque on the ankle joint by increasing the distance between the point where the shoe makes initial contact with the ground and the foot's long axis of rotation. Analogous to this is the difference in power when holding a tennis racquet at the end of its handle rather than halfway up the handle; more force is generated with a longer lever. Similarly, the increased distance between the long axis of rotation and the ground as a result of the heel flare creates more acceleration and increased energy each time the foot strikes the ground, requiring more contribution from the supporting muscles (within the same amount of time) in an attempt to stabilize the foot.

It is not only the design of footwear that places undue stress on the body, but also improper use. Hence, another factor that plays an important role is tightness of the laces (which is inversely related to the effectiveness of the insole). As the laces are tightened, the downward pressure forces the foot to flatten out and limits its range of motion. Eventually this will prevent the foot from functioning effectively with respect to force dissipation and energy return. Essentially, tightening the laces compounds the bracing effect of common footwear.



Overall, the results of both experiments suggest that the decrease in plantar surface area over time can be attributed to the use of the Barefoot Science foot strengthening system insole. This supports our first and second hypotheses concerning the possibility of restructuring typically atrophied foot muscles.

Despite increasing evidence of the negative effects of modern footwear, unshod walking most of the time is just not feasible. In reality, footwear is a necessity in most societies. This has led to the development of many strategies to alleviate the symptoms of shoe-related foot problems including cushioning insoles, supportive orthotic devices, and restructuring of footwear (motion control). The problem with these solutions is that they attack the symptoms, not the cause, of the problem. This leads to a further weakening of the structure as well as increased dependence on the artificial support.

As illustrated by our results, a significant decrease in plantar surface area was achieved with the use of the Barefoot Science foot strengthening system insole. However, it is important to note that this result occurs only to the maximum degree allowable within the footwear design; e.g., limited toebox room or tight laces may limit the insoles' effectiveness.

Applications and future research

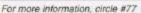
Subjects for our study were recruited from a local recreational facility. This group represents a reasonable sample of the physi-

cally active population between the ages of 21 and 45. Their results can be further applied to individuals outside of the respective demographics; as long as an individual walks or runs using conventional footwear, the concept of decreasing plantar surface area through foot strengthening can be applied.

Further research concerning foot structure remodeling through natural strengthening should be done to verify and support our findings. It is crucial to point out that the above results were attained with a small sample size. Nonetheless, significant positive changes in foot musculature were observed in our experimental groups using the Barefoot Science insole system, supporting previous observations by Robbins and Hanna (1987), and giving credibility to the insole. Important information concerning arch height and arch length changes, and the inherent biomechanical consequences of these changes, should be gathered and compiled to further support the use of the insole system.

Further research should also address the effect of the insole system on individuals with various foot- and gait-related pathologies. Data collection in this direction can be coupled with current knowledge to help cultivate and foster much needed changes in modern footwear design. Future applications should look into combining proper footwear design and stimulatory plantar surface devices into one entity to eliminate the majority of common foot- and gait-related injuries.



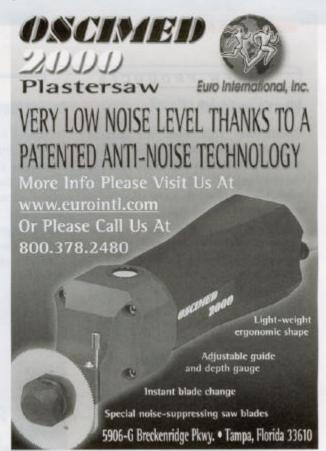




Rob Burke, BScKin, is president of Tarsatech in Barrie, Ontario; Reggie Reyes, BKin is a research partner at Peak Applied Research in Toronto, Ontario; and Tudor Bompa, PhD, is the president at the Tudor Bompa Training System in Sharon, Ontario, all in Canada.

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