

Barefoot Science Products and Services Inc.  
1 Port Street East, Suite 201  
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## **Biofeedback Insole can help to Increase Performance and Comfort, and Reduce Injury.**

During independent third party testing for consumer acceptance and evaluation purposes the device was found to provide the users with noticeable improvement in the following areas:

- 1) Bunion Pain reduction.
- 2) Reduction in overall foot fatigue.
- 3) Reduction in Knee pain
- 4) Reduction in Lower Back pain

Users reported improvements in

- 1) Comfort
- 2) Reduced Fatigue
- 3) Arch Support
- 4) Foot Strength
- 5) Pain/ Discomfort.

Within this Appendix you will find the summary data provided by:

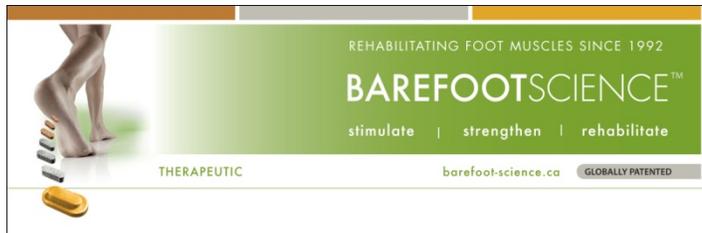
- 1) Scholl Japan
  - a. Objective: To evaluate the acceptance of the product by consumers, and observe and record the benefits cited by the users.
  - b. Design: Mass wear test of consumers with targeted lower limb or back discomfort.
  - c. Participants: N=251 adult subjects displaying hallux valgus, chronic foot fatigue, chronic knee pain or chronic back pain
  - d. Methods: Scholl Japan's Corporate Wear test questionnaire with self administered evaluation and third party interview evaluation
  - e. Outcome measures: Pre and Post usage self assessed pain and discomfort measures through a recorded questionnaire format. The collected data was analyzed using elementary data analysis techniques to observe average responses.
  - f. Results: 57.7% of the users rated their experience and satisfaction with the device as positive; 54.4% perceived a reduction in pain or discomfort when using the device; 55.5% reported an increase in their ability to walk with reduced pain or discomfort
  - g. Conclusions: The findings demonstrate that the use of the device provides benefits to the users in the areas of pain relief, comfort, and support and fatigue reduction. As the product is soft and compressive in nature and in that it does not interface with the apex of the foot's medial longitudinal arch, but rather the foot's center of mass in the region the nerve engorged plantar tissue, it can be put forth that these benefits have originated as a result of a strengthening and rehabilitative component of the device.

2) New Balance Athletic Footwear Inc.

- a. Objective: To evaluate the acceptance of the product by consumers, and observe and record the benefits cited by the users.
- b. Design: Mass wear test of consumers with participation in running and members of New Balance's running clubs,
- c. Participants: N=458 adult subjects participating in New Balance Athletic Footwear Inc's product testing programs
- d. Methods: New Balance's Standard Wear test questionnaire with self administered evaluation was used to collected data. The questionnaire format was such that it required subjective answering and in the review of the questionnaires response were categorised based on their relevance to ; Continues Use, Period of Adjustment, Comfort, Fatigue, Support, Motion Control, Strength, Pain Reductions, and Adverse Effects.
- e. Outcome measures: Pre and Post usage self assessed performance and preception measures through a recorded questionnaire format.
- f. Results: 97% of users would continue to use the product; Ranted a Primary benefit – Comfort = 12.26%, Reduce = 13.21%, Increased Support = 32.08%, Increased Strength 19.98%; 67.92% of Users adjusted to the product in less than 3 days; 83.96% rated the device as Comfortable or Very Comfortable.
- g. Conclusions: The findings demonstrate that the use of the device provides benefits to the users in the areas of pain relief, comfort, and support and fatigue reduction. The wear testers are experienced runners and as such the awareness of reduced fatigue and perceived increased strength is viewed as important as providing support to the product's underlying theory on the strengthening the foot's muscles.

Study Contacts:

- 1) New Balance Athletic Shoe – Ms. Edith Harmon, Brighton Landing 20 Guest St., Boston, MA 02135-2088, United States of America, (617) 783-4000
- 2) Scholl Japan – Tatsuo Miyake, URD Building, 4<sup>th</sup> Flr., ShiBuya-ku, Tokyo, Japan, (813)5466-2513



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## **Hospital Workers Find Relief in new Biofeedback Insole.**

### **Third Party Pain Study Conducted at Toronto East General Hospital, Toronto Canada**

During independent third party at the emergency staff of one of Toronto's busiest hospitals significant reductions in pain and discomfort at key areas within the body. The outcome measures were determined using an analog pain scale.

- a. Objective: This study was conducted to evaluate the effect of a novel system of shoe inserts that stimulate foot function (Barefoot Science™ Foot Strengthening System [BSFSS]) upon musculoskeletal pain..
- b. Design: A prospective cohort study in which volunteers acted as their own controls. Data were recorded for a one-week baseline period and for the following four weeks while using the BSFSS. .
- c. Participants: Participants were nurses, administrative and medical staff. Forty-eight individuals initially agreed to participate in the study, 44 submitted pain logs for at least one week and 32 completed an exit questionnaire. The participants were recruited through the Emergency Department (ED) of the Toronto East General Hospital
- d. Methods: Data was collected through questionnaire during the use of the insole device during employment shifts at the hospital
- e. Outcome measures: Pain logs were used to record self-reported pain and "tiredness" for specific body parts on scales ranging from 0 to 10. Participants also completed entry questionnaires to provide basic demographic information and exit questionnaires that asked them about their experience with the BSFSS..
- f. Results: When data were analyzed using repeated measured analysis of variance, there were clinically and statistically significant declines in pain scores for the feet, knees, shoulders, lower back and shoulders, as well as significant declines for "tiredness" for all body parts except the hips (all p values <.05). There was also a significant decline in general fatigue (p<.05). Between the baseline and the end of the study, 73% of participants had a decline in foot tiredness, 69% in foot pain and 65% in general fatigue. Satisfaction with the product was high, with 87.5% of users reporting they thought it was "great" or "good."
- g. Conclusions: The study was able to demonstrate that the BSFSS can significantly reduce many types of musculoskeletal pain and fatigue

Result Summary - A significant number Users reported:

- 1) Significant decrease in fatigue of the foot.
- 2) Significant decrease in foot pain.
- 3) Significant decrease in overall fatigue
- 4) Significant decrease in knee pain
- 5) Significant decrease in lower back pain
- 6) Significant decrease in shoulder pain
- 7) Decreased pain and discomfort in the knee.

- 8) Decreased pain and discomfort in the lower back
- 9) Decreased pain and discomfort in the shoulders

These results are as expected in that the muscle activation, muscle firing and resultant exercise and strengthening produce a more stable foot structure. The presence of stronger more efficient foot muscles allows for increase management of energy within the foot and a reduction in the need for energy dissipation through harmful modes such as soft tissue destruction.

The reductions in fatigue are attributed to the better utilization and management of energy at the level of the foot as well as a resultant of improved muscular skeletal alignment through the body, thus necessitating less chronic muscular contractions at joints superior to the foot and ankle for purposes of stabilization of the relevant joint. The reduction in required muscle contraction reduces energy consumption and related metabolic processes.

The reductions in pain are attributed to better localized energy management and reduction of energy dissipation through soft tissue destruction as well as improved pressure distribution over articulating surfaces resulting from improved musculoskeletal alignment.

#### Study Contacts:

- 1) Ned Amendola, MD Director, University of Iowa Sports Medicine, Professor, Department of Orthopaedic Surgery and Rehabilitation University of Iowa Ph: 319 356 4230 Fax: 319 384 9305 E: ned-amendola@uiowa.edu
- 2) Corinne Hodgson, M.Sc. CSH Associates Inc. 378 Melores Drive Burlington, Ontario, Canada L7L 4T8 Ph: 905-634-4019 Fax: 905-634-3515 E: corinne@cshodgson.com



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## **Factory Workers and Employers Reap Benefits from Inexpensive Biofeedback Insole.**

### **Scholl Plc (UK) and Scholl Japan Wear Test of the \*Dynapro Insole**

Factory employees were asked to use a biofeedback insole during their time at work and record their experience with the device with respect to pain and discomfort localized to the area of the foot and back.

- a. Objective: This study was conducted to evaluate the effect of a biofeedback insole system on pain and discomfort
- b. Design: A prospective cohort study in which a control group and a test group recorded experiences relating to pain and discomfort.
- c. Participants: 87 volunteers wore the insoles for 12 weeks. The volunteers (Control Group = 22, test Group = 65) were tested for their pain and discomfort levels prior to using the insole devices and at set periods during the test phase.
- d. Methods: The volunteers were tested for their initial pain or discomfort level, and periodically throughout the test period. The wear test data was compared to a control group who did not wear any special insole product other than that coming as original equipment in their safety footwear
- e. Outcome measures: Pain logs were used to record self-reported pain with respect to intensity, frequency and duration for the foot and back on a 10 point pain scale modified to address issues related to the foot and back..
- f. Results: We performed two factor repeated measures ANOVAs (ANalysis Of VAriance)(= 0.05) to test the effects of time (number of weeks in study), and the insole (presence or absence)(independent variables), on six F.I.T.variables describing the test subject's back and foot pain experience quantified using the Pain Scale(dependent variables).
- g. Conclusions: After a 12-week period the wear test data, for the three-foot and three back pain variables, was analyzed and tested for statistically significance. In all six cases the insole system reduced the frequency, duration and intensity of pain. It was noted the observed measurables for the Control Group increased. This may possibly indicate that to some extent low level daily pain and discomfort experiences become an accepted facet of daily life and thus go unnoticed until prompted to observe them.

A significant difference was observed in:

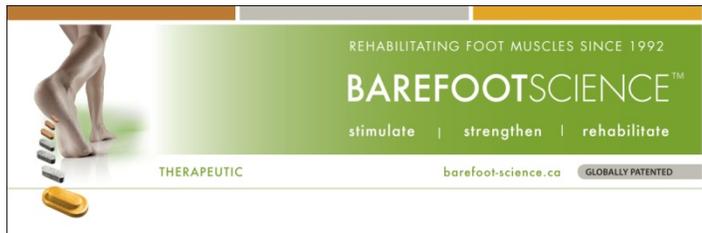
- 1) A reduction in frequency of foot pain.
- 2) A reduction in intensity of foot pain.
- 3) A reduction in duration of foot pain.
- 4) A reduction in frequency of back pain.
- 5) A reduction in intensity of back pain.
- 6) A reduction in duration of back pain.

These results are as expected in that the muscle activation, muscle firing and resultant exercise and strengthening produce a more stable foot structure. The presence of stronger more efficient foot muscles allows for increase management of energy within the foot and a reduction in the need for energy dissipation through harmful modes such as soft tissue destruction.

The reductions in pain are attributed to better localized energy management and reduction of energy dissipation through soft tissue destruction as well as improved pressure distribution over articulating surfaces resulting from improved musculoskeletal alignment.

As a result of the observed benefits it is anticipated that the impact on worker productivity, lost man hours and health insurance claims would all be affected in a manner as to benefit both the employer and the worker.

- - The Dynapro Insole was manufactured to the specification outlined in US Patent 5,404,659.



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## **Consumers Embrace New Insole Based on Bio-Feedback and Foot Strengthening**

### **The Topline Report on Concept and Product Test for \*Dynapro Insole.**

Factory employees were asked to use a biofeedback insole during their time at work and record their experience with the device with respect to pain and discomfort localized to the area of the foot and back.

- a. Objective: To obtain information from prospective consumers on the concept of a biofeedback insole device as well as collect information on their evaluation of the product after a trial period.
- b. Design: A prospective cohort study in which a test group recorded experiences relating to pain and discomfort, as well as effectiveness of the overall product concept.
- c. Participants: 194 volunteers wore the insoles for 2 weeks. The volunteers were recruited based on reported symptoms categorizing them as A) Bunion Sufferers, N=49; B) Foot Fatigue Sufferers, N=50; C) Knee Pain Sufferers, N = 48; and D) Low Back pain sufferers, N = 48.
- d. Methods: The volunteers were interviewed and responded to questions relating to their pain or discomfort levels.
- e. Outcome measures: A simple question was used with the pre-created responses set up as a 5 point analog scale to grade pain for data acquisition and grouping.
- f. Results: Simple and elementary data collection and analysis (Mean Analysis and % shifts), was used to simply observe trends in the changes in reported pain experience.
- g. Conclusions: 57.7% of the users rated their experience and satisfaction with the device as positive; 54.4% perceived a reduction in pain or discomfort when using the device; 55.5% reported an increase in their ability to walk with reduced pain or discomfort

The results shown occurred over a relatively short duration and we expect results of a higher magnitude had the product testing phase been extended to 6-8 weeks. In particular issues related to alignment may be more significant over a longer period as opposed to issues relating only to soft tissue adjustment. Under this premise it would be hypothesized that the values shown for the knee in particular would be significantly different than that shown here.

These results are as expected in that the muscle activation, muscle firing and resultant exercise and strengthening produce a more stable foot structure. The presence of stronger more efficient foot muscles allows for increase management of energy within the foot and a reduction in the need for energy dissipation through harmful modes such as soft tissue destruction.

The reductions in pain are attributed to better localized energy management and reduction of energy dissipation through soft tissue destruction as well as improved pressure distribution over articulating surfaces resulting from improved musculoskeletal alignment.

\*- The Dynapro Insole was manufactured to the specification outlined in US Patent 5,404,659.



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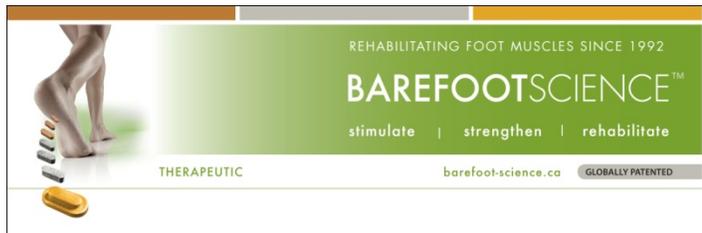
## **Biofeedback Insole Usage Creates Morphological Changes to Foot Structure**

### **Under Foot Pressure and Impact Observations using a F-Scan Data Collection System.**

Following is Pre-Clinical data collected in an effort to observe trends and assist in refining data collection protocols for larger scale studies.

Within this Appendix you will find the summary data provided by:

- 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=12 adult males aged 25-40 of medium activity level and non symptomatic for foot pathologies.
  - 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.
  - e. Outcome measures: Pre-test and Post-test plantar surface area was collected and the results were analyzed using elementary statistical analysis to observe trends .
  - f. Results: When the raw data was analysed to compare the pre-test surface area and the post-test surface area it was found that on average there was a 36.36% reduction in surface area. Filtering was done on the raw data by symmetrically removing the extreme 30% of the raw data for the purpose of eliminating anomalies. After filtering the overall average reduction was found to be 32.40%. The variability between the extremes revealed a 9.8% plantar surface area reduction and a 55.63% reduction. 100% of the subjects showed a reduction in plantar surface area.
  - g. Conclusions: The findings conclusively demonstrate that through the use of the Barefoot Science insole it is possible to create morphological changes to the foot and in particular the arch system resulting in plantar surface area reduction.. Although morphological changes can in theory be attributable to a combination of soft tissue and osseous remodelling it is the opinion of the testers that over such a short time period it is unlikely that any noticeable osseous remodelling would have occurred resulting in morphological changes to the magnitudes observed. It is therefore logical to conclude that the major contributor to the morphological changes would ebb the strengthening and tightening of the foot's support musculature.
  - h. Discussion: Changes of this magnitude were not hypothesized however when compared to an article detailing the results of making a transition to barefoot running accompanied by Harris Mat ink imprint records, the analysis of those surface areas showed a plantar surface decrease of 50% simply by making a transition to being barefoot.



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## **Biofeedback Insole Usage Produces Improved Gait Kinematics**

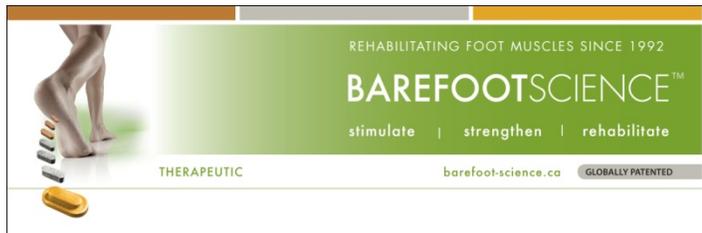
### **Rearfoot Motion Observations using a FootTrak Data Collection System.**

Following is Pilot Study data collected in an effort to observe trends and assist in refining data collection protocols for larger scale studies.

Within this Appendix you will find the summary data provided by:

- 1) Rearfoot Kinematic Analysis of the Foot/Shank using a FootTrak motion capture device
  - a. Objective: To observe hypothesized changes in rearfoot kinematics of the foot and shank associated with the use of the Barefoot Science insole product.
  - b. Design: A Pilot Cohort study introducing the use of the Barefoot Science (aka DynaPro) insole technology as an independent variable.
  - c. Participants: N=1 adult male aged 36 of medium activity level and non symptomatic for foot pathologies.
  - d. Methods: Data was collected using a FootTrak motion analysis system. The test subject was asked to run on a treadmill at a speed determined by the subject to be a comfortable 5Km pace (10.5km/h) and data was collected in 5 different running shoes, with their original insoles and replaced with the Barefoot Science insole product using level 3 of the Barefoot Science progressive insole system.
  - e. Outcome measures: Rear foot motion capture data was collected in the 10 combinations and the results were analyzed using elementary statistical analysis to observe trends.
  - f. Results: When the FootTrak output data was analysed to compare rearfoot kinematic characteristics of the 5 shoes, tested with and without the Barefoot Science insoles, it was found that the average maximum pronation of the shoes in the original insole condition was  $16.5^{\circ}$  compared to  $9.1^{\circ}$  for the Barefoot Science condition, a reduction in maximum pronation of  $7.4^{\circ}$  or 44.85%. The average total pronation of the shoes in the original insole condition was  $11.7^{\circ}$  compared to  $5.9^{\circ}$  for the Barefoot Science condition, a reduction in maximum pronation of  $5.8^{\circ}$  or 49.57%. In the original insole condition the subject remained in pronation during propulsion displaying  $8.3^{\circ}$  of pronation while in the Barefoot Science condition the subject assumed a supinated take off position with  $3.4^{\circ}$  of supination
  - g. Conclusions: The findings conclusively indicate that for the subject there was a definite reduction in the magnitude of pronation occurring during the stance phase when the Barefoot Science insole was introduced into the subject's shoe replacing the originally equipped insole. In addition the use of the Barefoot Sciences insole promoted a more efficient foot position for takeoff and propulsion
  - h. Discussion: As pronation, and in particular excess pronation, is often cited as a factor contributing to gait related pathologies and as such reductions in this pronation have been presented by others as potentially reducing gait related injuries and pathology, the Barefoot Science insole demonstrates remarkable abilities in immediately reducing the potentially harmful pronation and also enhancing a less injurious and more efficient foot position for takeoff.

\*- The Dynapro Insole was manufactured to the specification outlined in US Patent 5,404,659.



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## **Plantar Surface Area of the Foot Reduced Through Use of Biofeedback Insole.**

### **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 plantar 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.



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**Insole with Biofeedback Properties Produces Foot Shape Changes.**

**Scholl PLC / University of Huddersfield: Impact of the Dynapro Insole on Foot Shape.**

Following is the third party data collection on foot arch characteristic changes resulting from the use of the Barefoot Science (aka Dynapro) insole system sanctioned by Scholl PLC and conducted at the University of Huddersfield in the UK..

Within this Appendix you will find the results of the above noted data collection.

- 1) Foot Arch and Structural Changes Associated with Barefoot Science Usage
  - a. Objective: To observe hypothesized changes in foot arch characteristics 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=20 said to be living an active lifestyle.
  - d. Methods: Data was collected by taking 3 primary linear measures of the foot, the Foot Length, the Metatarsal Width and the Lateral Arch Width, along with a measure of the Valgus Index of the foot.
  - e. Outcome measures: Elementary data analysis to show primary outcomes of means, variance etc. was performed on the data collected.
  - f. Results: Definitive trends were shown in reducing the linear measures of foot length and width. Trends increasing the value of the valgus index were also demonstrated.

	week 0	week 3	week 8	% diff
Foot length (cm)	25.048	25.003	24.939	-0.4352%
Metatarsal Width (cm)	8.93	8.895	8.732	-2.2172%
Lateral Arch Length (cm)	3.52	3.438	3.371	-4.2330%
Valgus Index	4.713	4.906	4.856	3.0342%

- g. Conclusions: The results indicate that through the use of the Barefoot Science insole it is possible to create changes in the foot shape. The reductions in the length and width of the foot’s main measures can be logically linked to a increase in height of the foot’s arch complex involving the interplay between the lateral, medial and transverse arches.
- h. Discussion: The foot types commonly attributed to higher arch characteristics (pes cavus) are considered by those skilled in art of foot health and foot diagnoses to more stable and less prone to, or characteristic of, a “pronated” (pes planus) foot. The trends shown here in the reduction of these pes planus foot characteristics may possibly be linked to reductions in the pain, discomfort and pathologies considered to be more common to those with pes planus attributes than those with pes cavus attributes.

\*- The Dynapro Insole was manufactured to the specification outlined in US Patent 5,404,659.