The Future of Foot Care™

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Medical and Scientific Overview

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Good Health Starts From The Ground Up™

The Future of Foot Care™

Optimizing Innate Body Intelligence

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Introduction

Biopods Inc. was incorporated in 2010 to develop foot care technologies and products after over thirty years of research on foot function and related pathologies. This research has focused on four key areas:

- Review of relevant studies (global and multi-disciplinary in scope);
- Analysis of current philosophies and treatment methods;
- Development of a more accurate method of measuring the three-dimensional musculo-skeletal dynamics of the foot structure during full weight bearing, in both static and dynamic environments; and
- Effects of various environmental influences on foot function (i.e., shod and barefoot).

Our findings in these key areas highlighted an abundance of contradictory theories, many of them currently accepted as fact, regarding foot function and common treatment methods (i.e, support and cushioning).

What surprised us, however, was the volume of scientific evidence validating the conclusion that, aside from trauma, footwear is the leading cause of foot-related pathologies, mostly preventable and treatable (rehabilitative).

Over 500 years ago, Leonardo da Vinci asserted, "The foot is a masterpiece of engineering and a work of art." His statement stands in stark contrast with the prevailing view that the foot is poorly designed and requires artificial support and/or cushioning to function properly.

The "foot is poorly designed" theory first surfaced in the mid-1800's, accompanied by foot function NORMS as defined by practitioners of the day. These hypotheses have remained virtually unchanged over the years, sustained by a mountain of white papers and journal articles. In 2000, the Journal of the American Podiatric Medical Association challenged the reliability of these articles, noting that only 1% of the 322 articles reviewed displayed consistent, reputable, and scientific evidence-based information. The authors concluded that the majority of these published articles focused on generating, rather than testing, hypotheses [1].

In order to advance more applicable and quantifiable science, Biopods Inc. in consultation with a growing number of medical professionals, has developed and continues to develop new hypotheses, state-of-the-art assessment protocols, and educational tools that illustrate an evidence-based, "best-fit" model of:

- Ideal gait biomechanics;
- Biomechanical causes of most foot-related pathologies; and
- Pros, cons, and effectiveness of various treatment methods.

Combining existing research in the fields of foot function, mechanical and bone remodeling physics, neurology and rehabilitative medicine has led to new hypotheses on ideal foot function – most significantly – that *the vast majority of foot-related problems in the lower limbs, hips and lower back are caused and/or exacerbated by maladapted neuromuscular function from habitual footwear use.*

"Typical foot motion does not obey descriptions of triplanar motion such as 'pronation' and 'supination'."

Hunt A, Smith R, Torode M, Keenan A. Inter-segment Foot Motion and Ground Reaction Forces Over the Stance Phase of Walking. Clinical Biomechanics 16 (2001) 592-600

Our research has been applied to the design of a dynamic device – unlike a static orthotic – that promotes optimal structural integrity of the foot through all ranges of three-dimensional movement. Rigorous testing of our new hypotheses and the dynamic device has led to the introduction of Biopods Inc.'s patent pending Variable Reflex Technologies™ (VRT®) and their application to Biopods® insole and footwear products.

Based on proven principles of modern musculoskeletal rehabilitation and sports training programs, Biopods VRT provide subtle, varied stimuli to the soles of the feet to bring about optimal neuromuscular function throughout the feet, legs, hips and lower back. Regular use of Biopods products retrains the required "Protective Reflex" muscle-firing sequences that optimize and dynamically stabilize the foot's arch system and lower limb skeletal alignment. This alignment automatically takes place prior to each step's ground contact throughout a multitude of three dimensional movements and levels of activity.

Biopods products are safe, easy to use, and recommended for prophylactic, rehabilitative and diagnostic applications. Before VRT was invented, earlier Foot Strengthening Insole Systems developed by Roy Gardiner had been tested worldwide with over 90% effective-ness reported. These insoles are still being worn by world class and professional athletes, recommended for their rehabilitative, preventative and performance enhancement benefits. *Biopods' Variable Reflex Technologies elevate these benefits to a new level.*

Biopods Inc. recognizes the imperative to address doubts and concerns about the validity of our claims. At present, we submit that validation of existing research and examination of our new protocols will unequivocally confirm the new, "optimal foot function" science.

The following pages update and expand upon Roy Gardiner's 2004 publication, "Foot Care Steps in a New Direction." They offer a more comprehensive overview of Gardiner's research findings, supported by relevant science that clearly advances theories on foot function and dysfunction, resulting pathologies and appropriate treatment options. We invite you to join the growing number of medical professionals who welcome the value of the new science and technology presented herein. We also encourage your comments, criticisms, and contributions to Biopods' "Future of Foot Care™."

1.0 Background

Impairments to the musculoskeletal system are the leading cause of limitations in activity for people of all ages [2, 3, 4]. They can affect not only an individual's general health and quality of life, but are also responsible for a substantial portion of health care costs. Considerable research has shown that the maintenance of a healthy musculoskeletal system is usually simpler and less expensive than repair after injury or disease [5, 6, 7]. Therefore, a better understanding of the development and function of the musculoskeletal system in the non-diseased state is crucial in the prevention and treatment of related pathologies.

The feet, as with any other musculoskeletal structure in the body, are positively or negatively affected by environmental stresses. For example, it is commonly accepted that exercising through a full range of motion promotes a balance of strength and flexibility in opposing muscle groups [8, 9]. It also encourages optimal bone density and ideal alignment at the joints. The net result is a stronger, more dynamically efficient musculoskeletal structure that exhibits little or no degenerative stress and that is capable of optimal performance with the lowest risk of injury.

"...an estimated eight out of ten people in the U.S. have undetected gait problems that cause sore feet, aching backs and hips, and pains in the leg and neck."

Gait Analysis Steps Into New Fields, Mechanical Engineering

Conversely, it is also commonly understood that chronic restriction or bracing of the musculoskeletal structure leads to muscle atrophy, loss of bone mass, and joint stiffness. The net result is a weaker, less efficient structure that is predisposed to degenerative stress and injury due to poor structural alignment/function. Over time, impaired musculoskeletal function becomes the conditioned or trained "norm" via desensitization, habituation, and adaptation. Therefore, the body is no longer capable of effectively responding to the ever changing environment. Aside from trauma, the resulting degenerative stresses can cause or contribute to the majority of musculoskeletal pathologies. Common symptoms include pain, stiffness, and swelling in joints and other supporting structures of the body, such as muscles, tendons, ligaments, and bones, along with muscle atrophy (underuse), muscle hypertrophy (overuse), tissue damage, fibrosis/scar tissue, and loss of bone density. This dysfunctional norm can only be reversed through rehabilitative therapies (conditioning) that retrain the optimal musculoskeletal function.

These concepts are not new to medical science. They are the foundation of most current rehabilitative and sports performance programs. The question is: How do they apply to the feet – the musculoskeletal structures that are comprised of nearly one-third of the bones in the human body?

2.0 Foot Function Norms

Eighty-five percent of Americans will see a medical professional for some type of foot-related pathology at some point in their lifetime, according to the American Orthopedic Foot and Ankle Society. In staggering contrast, habitually barefoot populations develop virtually no debilitating foot-related problems [10, 11, 12].

"All writers who have reported their observations of barefooted people agree that the untrammeled feet of natural men are free from the disabilities commonly noted among shod people – hallux valgus, bunions, hammer toes, and painful feet."

Stewart SF. Footgear—Its History, Uses and Abuses, Clinical Orthopaedics and Related Research, 88, 1972

"In unshod communities the foot muscles get freedom for exercise and the joints remain supple. This is why functional disorders of the foot are so rarely seen in such people."

"I sometimes like to look upon closed shoes as braces ...which takes up the work of muscles causing them to atrophy from disuse and make the joints stiff."

Sethi PK. The Foot and Footwear. Prosthetics and Orthotics International, Vol. 1, 1977

The structure of the foot and its biomechanical function have been commonly referred to in medical journals, studies, and in consumer publications as being of poor design and function, therefore susceptible to injury [13, 14]. Another common statement is that most foot dysfunctions and resulting pathologies are hereditary. These two myths have been perpetuated within the medical community simply by their repeated exposure in these mediums, not withstanding the fact that there are very few scientific studies to support these hypotheses – in fact, an abundance of research demonstrates otherwise [15, 16, 17].

There is much debate about what constitutes normal foot function and how "NORMS" are determined. It is important to note that the currently accepted "NORMS," as defined in most medical literature, were derived from studies on foot function and gait conducted mainly on sample populations that have worn shoes since childhood. For the most part, these NORMS have been one of the "tools" used to identify the causes of various pathologies and have traditionally formed the foundation of associated treatment options. Furthermore, they have played an integral role in the development of footwear designs and orthotic devices.

Significantly, the NORMS derived from studies on predominantly unshod populations show drastically different trends with respect to foot function [9, 14]. The difference between NORMS derived from shod vs. unshod populations is similar to comparing function and range-of-motion between:

- a limb that has been immobilized by a splint or cast for several years, and
- a limb that has experienced unfettered movement over the same period of time.

It is obvious, even to a lay person, that the chronically restricted limb would be weaker and exhibit joint stiffness with an associated limited range-of-motion. Additionally, the restricted limb would be incapable of many of the tasks that would be easily managed by an unfettered limb.

Therefore NORMS, with respect to foot function and upon which the efficacy of standard therapeutic practice is based, are themselves biased. As a result, the accuracy and applicability of a majority of current foot care research is questionable [15, 16, 17, 18, 19, 20, 21, 22, 23].

For example, most text books, journals, and studies refer to the terms "pronation" (a composite of dorsiflexion, eversion, and abduction) and "supination" (a composite of plantarflexion, inversion, and adduction) when describing foot function NORMS. The foot's weight bearing or stance phase of motion is most commonly described as consisting of pronation in early stance in association with lowering of the medial longitudinal arch, followed by a progressive supination in association with raising of the arch [24, 25, 26, 27]. The foot has been described as behaving much like a twisted plate, in that the arch rises or lowers according to counter motions of the rearfoot and forefoot segments [26,28, 29]. According to Hunt, et al., "...these commonly defined NORMS are largely speculative, as they are based on the application of static experiments or unquantified observations. Furthermore, they have been applied to the motion of foot segments and bones, although no data yet exists to provide a description of typical inter-bone motion during walking" [26].

Lundberg and colleagues' series of in vivo, quasi-static experiments investigating inter-bone motion provide new insights into weight bearing foot function. For example, they found that between 10% and 41% of total foot plantarflexion occurred in the bones of the medial longitudinal arch, and that the talonavicular joint contributed the most [30, 31, 32]. In addition, they found that frontal plane motion occurred primarily at the talonavicular joint, rather than at the talocalcaneal joint [30, 31, 32] as commonly reported. These findings suggest that the midfoot region would contribute more to the overall foot motion during walking than is commonly believed, and should therefore be a focus of research into normal foot function [26].

To better understand foot function, we must first examine how the feet should *ideally* function from a biomechanical/neuromuscular perspective. Once this is clearly understood, the negative environmental influences that lead to a disproportionate number of pathologies in the shod population can be examined in context. Preventative measures can then be developed and new, more effective treatment options can be implemented.

3.0 Lower Limb - Musculoskeletal Mechanics

During natural healthy foot function, optimal neuromuscular function (and related musculoskeletal mechanics/alignment), is ideally a dynamic response to activity levels and terrain. That is, the muscles of the foot should optimally align the bones to most effectively manage the forces generated during varying activities and terrain. Thus, the dynamic stable arch system would provide a capable foundation for the lower limbs and body (kinetic chain) while promoting optimal neuromusculoskeletal alignment/function/performance and little or no degenerative stress throughout.


Figure 1

From a strictly mechanical perspective, the lower limb structure can be considered to be comprised of: a ball and socket joint at the hip; a simple hinge joint at the knee; and the foot and ankle functioning similar to a universal joint that provides an effective interface with the ground. However, closer examination of the skeletal structure of the foot and ankle suggests that, with appropriate muscle contractions, the bones of the foot are capable of aligning to form a dome-like configuration that can act similar to a socket moving around an imaginary ball (Figure 1).

It is widely accepted that the shape of the interlocking bones, ligament strength, and plantar fascia maintain the transverse, medial longitudinal, and lateral longitudinal arches of the foot [27, 33, 34, 35]. This established viewpoint, while technically correct, overstates the role that bone shape and ligament strength play in maintaining optimal structural integrity of the foot. For example, if we isolate the bones of the foot from the muscle, tendons, ligaments, etc., and view the structure

The foot, "a masterpiece of engineering."

Leonardo da Vinci.

from a physics perspective, it becomes clear that the relative alignment and positioning of the bones are the primary determining factors in its structural capabilities [26, 27, 34, 36, 37].

The bones of different people exhibit considerable anatomical variation. They vary according to age, sex, physical characteristics (body habitus), health, diet, race, and Bones are vital living organs and will change considerably with age." [35]. Bones are also in a constant state of change through cellular regeneration (remodeling) or functional adaptation [38]. Functional adaptation in bone is remodeling of structure, geometry, and mechanical properties in response to altered loading [38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50]. The environmental forces of pressure and tension result in surface (external) and internal bone remodeling as the structure attempts to produce the same maximum normal stress (in brittle material: outer shell) or shear stress (in ductile material: spongy inner core) throughout the body for a specific load [46]. Although the adult skeleton is less versatile than that of maturing children, it is still capable of responding in an adaptive manner to strain and stress [6].

Therefore, regardless of age or genetic predisposition, the relative shape and strength of bone is significantly influenced by the pressures and tensions of bone-to-bone contact, their geometric alignment, and muscular forces. These dynamics are often ignored when investigating and defining the foot's structural function, pathologies, and treatment methods.

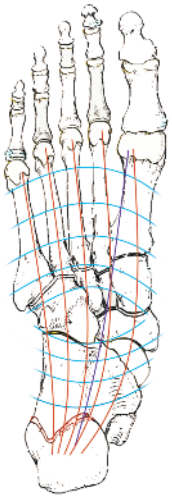


Figure 2

3.1 Theoretical Ideal Structural Physics Model of the Foot

As Wolfe identified in his "law of bone transformation" (1884): "...there is a perfect mathematical correspondence between the structure of cancellous bone in the proximal femur and Culmann's trajectories" [50]. This principle (i.e., cancellous bone patterns directly follow the lines of force that act upon that bone) is obviously applicable to every bone, not just the proximal femur. In fact, this is fundamental to the understanding of the mathematical relationship (mechanical physics) of the bones and the forces involved as a means to developing an ideal mechanical model for foot function. In essence, bone structure, bone shape, and bone alignment must **ALL** correlate with the forces that will be required to fit the "dome-like" foot functions suggested by Figure 1.

Within the medical community, the foot is commonly described as consisting of the medial longitudinal, lateral longitudinal, and transverse arches [35, 51]. From a physics perspective, this view is inordinately simplified and ignores the complexity of the structure as a whole. The structural physics of the foot more accurately demonstrate a series of intersecting arches that run medially to laterally and posteriorly to anteriorly from the calcaneus to the metatarsal heads (Figure 2). To better understand both the simplicity and complexity of this arch system, it is important to identify the dynamics of a single arch and its intrinsic relationship within a system of arches.

In the foot, the structural mechanics of a single arch (Figure 3) are determined by its components:

- the material composition of the arch: interlocking bone structure and ligaments – their relative strengths (tensile, compressive, etc.) and elasticity, and
- a tie beam: soft tissue, i.e., tendons, muscles, fascia, etc., – their relative strengths (tensile and elastic).

Within the material composition of any given arch structure, there exists a central "keystone" about which opposing forces must equalize as a means of maintaining the arch integrity. When force is applied to an arch structure, the stronger and more stable the material composition, the lower the degree of tensile (or pulling) force produced on the tie beam.

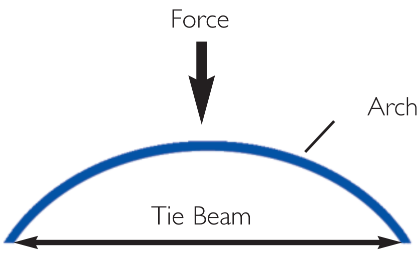


Figure 3

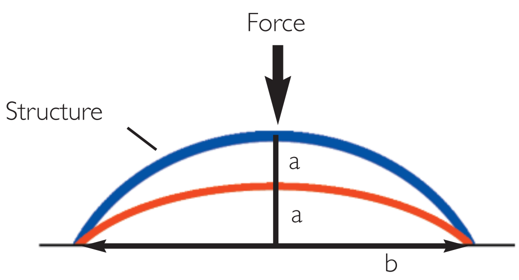


Figure 4

When comparing arches of identical composition with equivalent tie beam lengths, a higher arch is stronger and more stable and therefore generates less tensile stress (pulling force) on the tie beam (Figure 4). The blue arch is twice as high (2a) as the red arch (a), therefore the relative traction (tensile) force of the blue arch is "a/2a" (or one half of the applied vertical Force at the arch apex). Mathematically, if the tie beam length was 10 units and the height of the red arch was 2.5 units vs. 5 units for the blue arch, then the relative horizontal (tensile) stress component on the red arch tie beam would be 10/2.5 or 4 vs. 10/5 or 2 for the blue arch.

When this formula is applied to a single arch structure as seen in an individual foot with a fixed arch length (along the curve of the arch structure), it is clear that there is a direct relationship between a higher arch structure and a shorter tie beam (Figure 5).

"A normal arch is very important... ...very little muscular activity is necessary to support the body"

Subotnick SI. The Flat Foot. The Physician and Sports Medicine. 9(78): p.85, August 1981

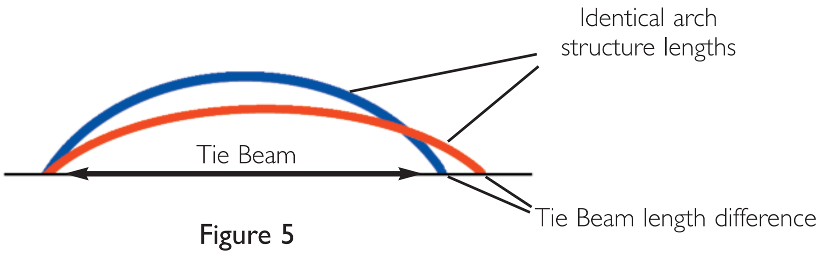


Figure 5

Despite their identical arch structure and tie beam components, the blue arch structure is not only proportionally stronger than the red arch structure (due to the increased height) – its strength is further accentuated by a decrease in its tie beam length. The increase in height combined with a decrease in tie beam length is reflected in a significantly decreased tensile (pulling) force on the tie beam.

When combined in a multi-arch system, such as the foot, these singular arch dynamics work synergistically to maximize relative strength and stability while greatly minimizing stress, and are more effective collectively than individually.

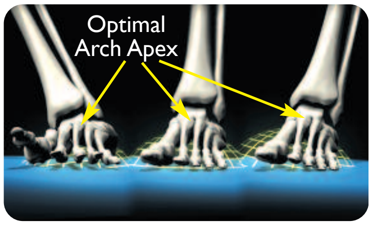


Figure 6

Therefore, from a physics perspective, the most inherently sound structural mechanics would be achieved if the bones of the foot could interlock and maintain the multi-arch functional dynamics of a *dome* shape. Such a dynamic could manage greater loads with minimal contribution from, or stress on, the ligaments and extrinsic/intrinsic musculature. The interlocking bones' dome shape would function much like a socket, capable of rotating around an imaginary ball (Figures 1 & 6). The dome's level of functional stability would be determined by the "Ideal" or "Optimal Arch Apex" height necessary to most effectively maintain structural integrity in the interlocking bones as they manage the forces generated throughout three-dimensional activity.

Furthermore, the location of the "Optimal Arch Apex" would ideally correlate to the location of the "conceptual" arch keystone for optimal force management.

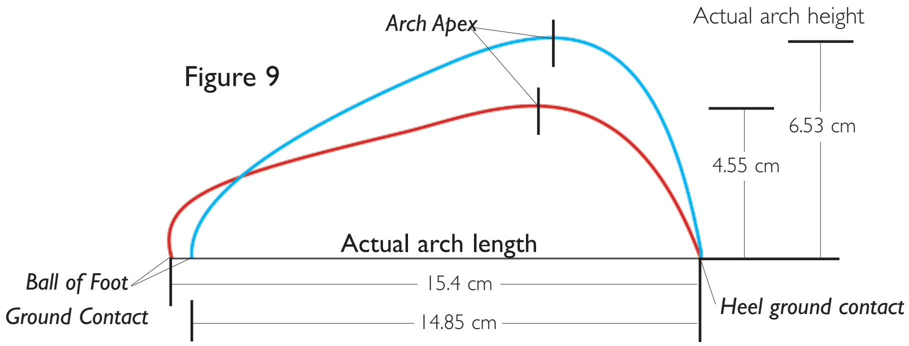
The relative positioning of the midfoot joints (re: the Optimal Arch Apex) is significant to the degree and pattern of forefoot segment motion, which in turn is indicative of the foot's stability [7, 19, 26, 27].

As is evident from the x-rays, the foot is capable of this functional dome-like alignment (Figures 7 and 8). Both x-rays are of the same subject's right foot during full weight bearing. Traditional analysis of the subject's foot indicated typical hypermobility that in a relaxed stance (Figure 7) would be inclined to excessively pronate (as commonly described). The x-ray in Figure 8 was taken approximately ten minutes after the x-ray in Figure 7, with the great toe dorsiflexed (minimal effort).

Figure 7

Figure 8

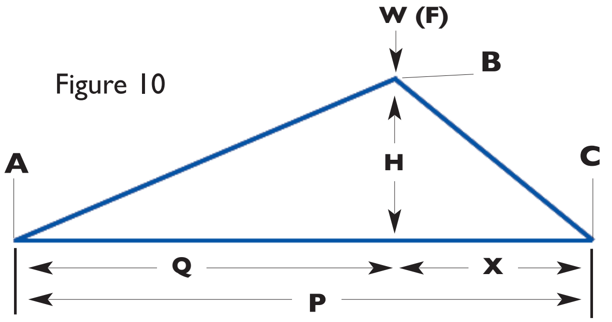
Figure 9



The structural integrity of the arch system is determined by the arc that is created through the structure's center of mass. Figure 9 illustrates the actual differences in arch length and height. The length of the blue arch in Figure 8 is only 3.25% shorter than the red arch in Figure 7, with a relative 43% increase in height.

Figures 10 and 11 illustrate the geometry and mathematical equations for measuring: (a) the relative strength or vertical Force (F) capabilities of the arch, and (b) the

Figure 10



A = ball of foot ground contact
B = arch apex
C = heel ground contact

a) <u>Relative arch strength</u>

F = THP/QX

T = tensile strength of tie beam (100 ft. lbs.)
F = **W**

b) <u>Relative tie beam tension</u>

T = W(Q/H) (X/P)

W = weight (170 lbs.)

<u>Foot in Figure 7 (red arch):</u>

a) F = (100 x 4.55 x 15.4)/(10.8 x 4.6)
F = 141.0

b) T = (170) (10.8/4.55) (4.6/15.4)
T = 120.5

<u>Foot in Figure 8 (blue arch):</u>

a) F = (100 x 6.53 x 14.85)/(10.45 x 4.4)
F = 210.9

b) T = (170) (10.45/6.53) (4.4/14.85)
T = 80.5

Figure 11

Tension (T) in the tie beam during the single support phase, up to the point where the heel leaves the ground.

Consequently, the foot's structural alignment (single arch) in Figure 8 is capable of managing 50% (i.e., 210.9 vs. 141.0) greater weight or vertical force while generating 34.8% (i.e., 80.5 vs. 120.5) less tension on the tie beam as determined by the equation for calculating plantar tension) [52].

Throughout the kinetic chain, the integrity of the foot's structural alignment plays a significant role in managing the forces and stresses generated during gait [27, 34, 53, 54]. It is clear that an ideal, dome-like structural alignment in the foot is possible, and that there is an inverse relationship between the structural integrity of the foot and the muscular effort required to facilitate and manage its relative alignment. The *more* structurally sound the arch, the *less* muscular effort is required to manage alignment.

In addition, it is clear that the relative geometry of the bone-to-bone contact is significantly different (Figure 7 compared to 8). Over time, habitual alignment in either scenario would result in bone remodeling in response to the forces and stresses generated. This dynamic will be more fully explored in Section 4.2.1, Unhealthy Bone Remodeling.

3.2 The Foot - Neuromuscular Function and Ideal Mechanical Physics During the Gait Cycle

3.2.1 Overview

The musculature of the foot is comprised of both extrinsic and intrinsic muscle groups. These muscle groups play varying and complementary roles relative to the alignment and stabilization of bone structure, in propulsion, in the management of forces during standing and gait, and in other non-gait related tasks, such as grasping, climbing trees, etc. As with any other muscles in the body, the muscles of the foot are influenced by both nociceptive and proprioceptive stimuli and can be positively or negatively conditioned by training or environmental influences [5, 8, 9, 13, 33, 56, 57].

"... the high arch foot is a better shock absorber with regards to the low back level than the low arch foot."

Ogon M, Alekesiev A, Pope M, Wimmer C, Saltzman C. Does Height Affect Impact Loading at the Lower Back in Running? Foot and Ankle International 20(4): p. 263, April 1999

As indicated earlier, ideally during natural healthy foot function, optimal neuromuscular function and related skeletal alignment is a dynamic (protective) reflex response to activity levels and terrain. That is, the muscles of the foot act to optimally align the bones to most effectively manage the forces generated during varying activities and terrain, prior to each step's ground contact. For example, while running, nociceptive and proprioceptive stimuli trigger reflex muscle activations to proactively create a higher (mechanically stronger) and more stable arch system than when walking. Thus, the protective reflex activated dynamic stable arch system provides a capable foundation for the lower limbs and body (kinetic chain) while promoting optimal musculoskeletal alignment/function and little or no degenerative stress throughout. {Please see Section 3.2.3 Neurologic Mechanisms (Somatosensory Feedback) for more information on nociceptive and proprioceptive mechanisms.}

An excellent example of neuromuscular conditioning potential can be found in individuals who have lost their arms, yet developed the foot dexterity to the extent that their feet function as "hands." Since they are capable of performing many complex tasks with finesse and precision, there is no reason that the neuromuscular function of the feet cannot be conditioned to achieve ideal, dynamic domed, structural alignment, as described in the previous Section.

It is virtually impossible to quantify the role of specific muscles throughout such a multiplicity of activities. However, throughout the gait cycle, we can examine the relative roles (primary and supporting) that they are ideally capable of performing, from a mechanical perspective.

The extrinsic muscles of the foot are comprised of the extensors (originating in the lateral aspect of the shin), the flexors (originating in the posterior side of the lower leg) – both groups are connected to the foot via long tendons – and the ankle plantar flexors (calf muscles). The intrinsic muscles of the foot (located primarily in the plantar region of the foot) are comprised of flexors, adductors, and abductors.

From an ideal mechanical perspective, the following muscles are grouped according to their gait-related roles (see Figures 12 to16):

PRIOR TO WEIGHT BEARING

- Alignment of the foot and ankle structure: **via active extrinsics** – **extensor hallucis longus & digitorum longus**, tibialis anterior, and peroneus longus [a.k.a. fibularis longus] (Group A),
- Stabilization of the foot and ankle structure: via active Group A (re – foot), active **peroneus brevis [a.k.a. fibularis brevis] and tibialis posterior (Group B)** (re – ankle), in concert with passive extrinsics – **flexors hall. long. & brev. and digitorum longus (Group C)**, and passive intrinsics - quadratus plantea and flexors dig. brev. & min., and lumbricals (Group D)

DURING WEIGHT BEARING

- Stabilization of the foot and ankle structure: **via active** Group A **and peroneus brevis [a.k.a. fibularis brevis] with passive to active** Group B, Group C, **and** abductors hallucis and digitorum minimi, adductor hallucis and the interossei (Group E), in addition to the plantar fascia (Group F)

PROPULSION

- Stabilization of the foot structure: via active Groups B, C, D, and E and active to passive Group A and **peroneus brevis [a.k.a. fibularis brevis]**
- Propulsion: via active Group B and active extrinsics – gastrocnemius and soleus.

Figure 12

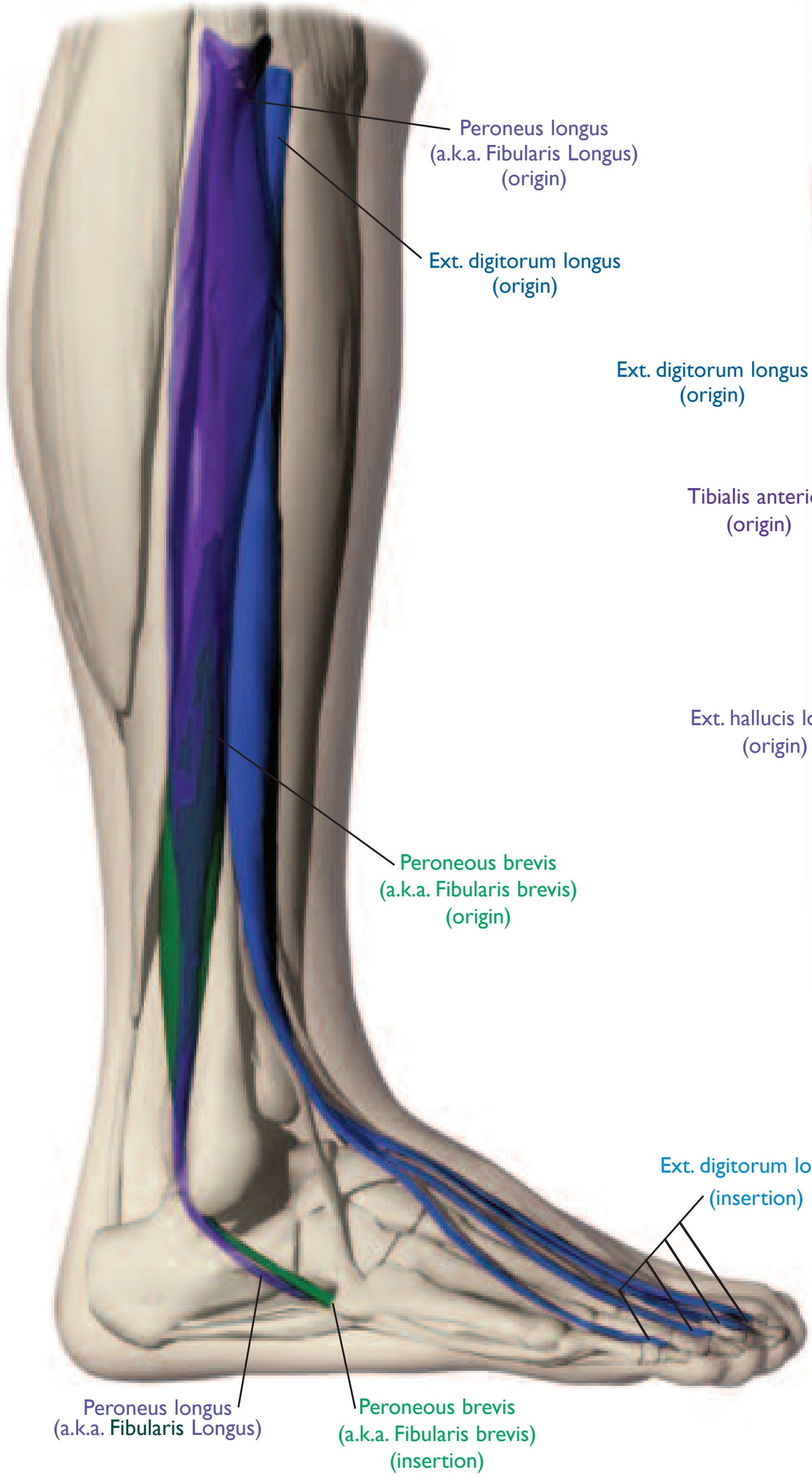


Figure 13

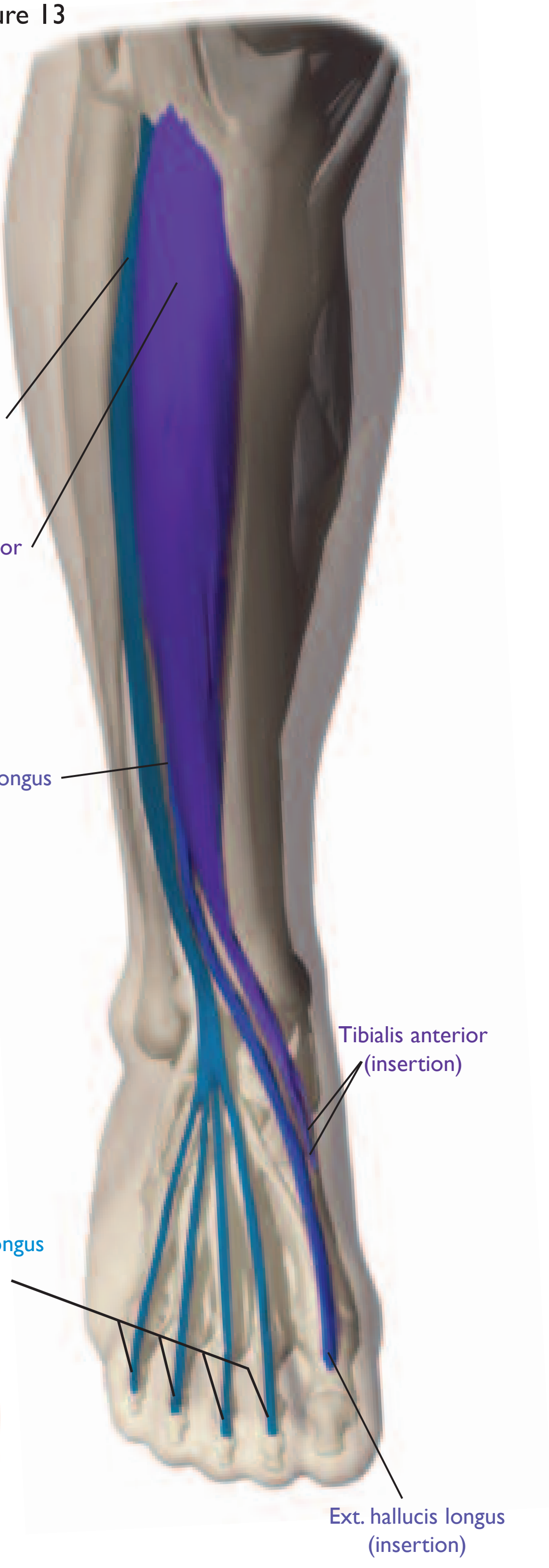


Figure 14

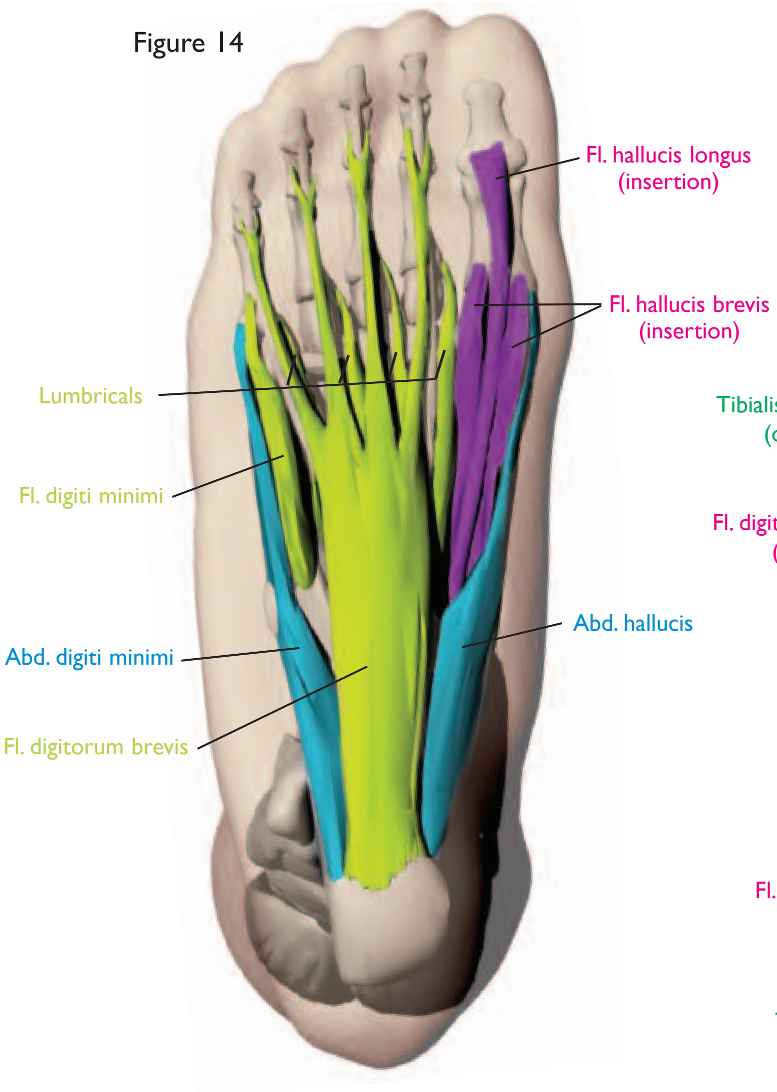
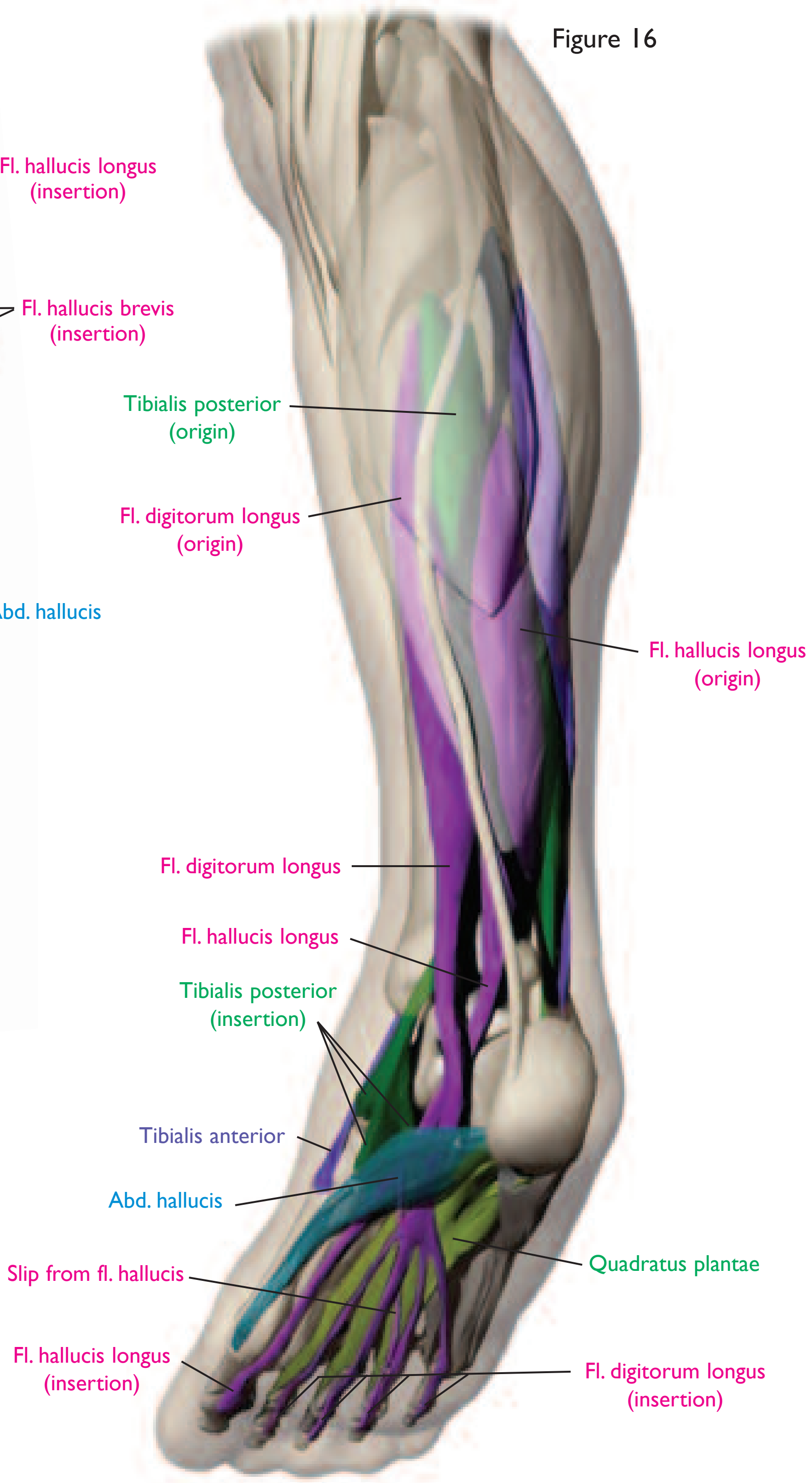


Figure 15

Figure 16



3.2.2 Ideal Neuromuscular Mechanics

Figure 17

If the foot's supporting musculature aligned and stabilized its interlocking bones into a functionally dynamic dome shape *prior* to weight bearing, the structure would be inherently strong and resilient. This would provide the most stable and stress free foundation for the rest of the body, requiring the lowest degree of muscular effort during the weight bearing and propulsion phases of gait [19]. This alignment and stabilization process is exhibited in barefoot gait, [14, 35, 58] and is easily achieved during the swing phase as the foot moves from the muscle-firing sequences of propulsion to the extensor muscle-firing sequences of dorsiflexion (Figure 17).

When examining the muscle-firing sequences of the lower leg extensors during the gait cycle, EMG analysis shows a co-contraction of the peroneus longus (a.k.a. fibularis longus) and tibialis anterior, prior to heel strike [59, 60, 61]. Coupling this information with their respective origins and insertions, these opposing contractions cause a transverse pulling or cinching action that essentially aligns the bones of the foot's midtarsal region into a dome-like position with an ideal (maximum) transverse arch apex height (Figure 18). This is further supported by the fact that the main actions of the tibialis anterior are dorsiflexion and inversion, while the main actions of the peroneus longus (a.k.a. fibularis longus) are dorsiflexion and eversion [34, 35].

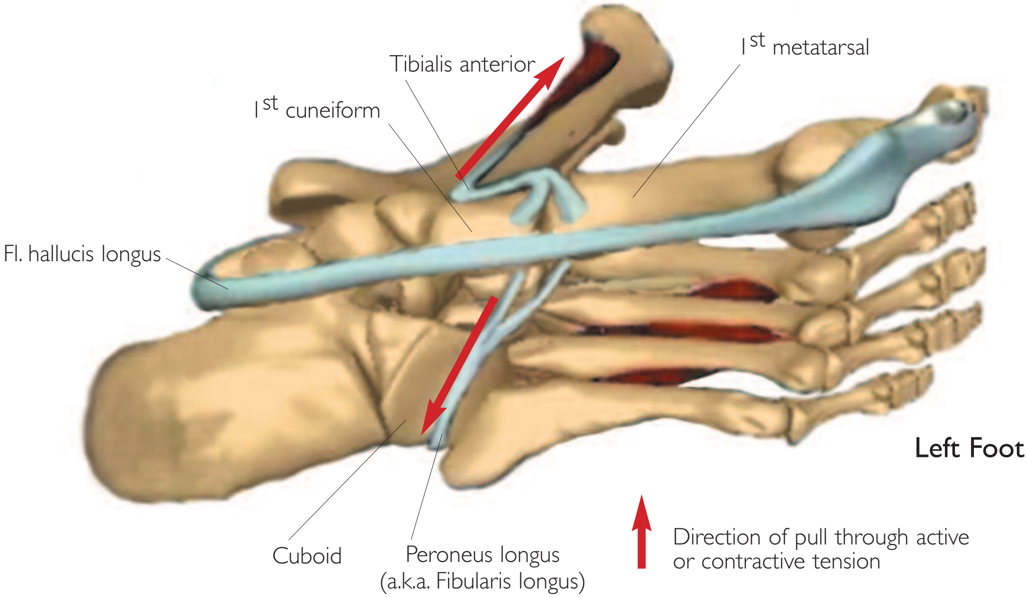
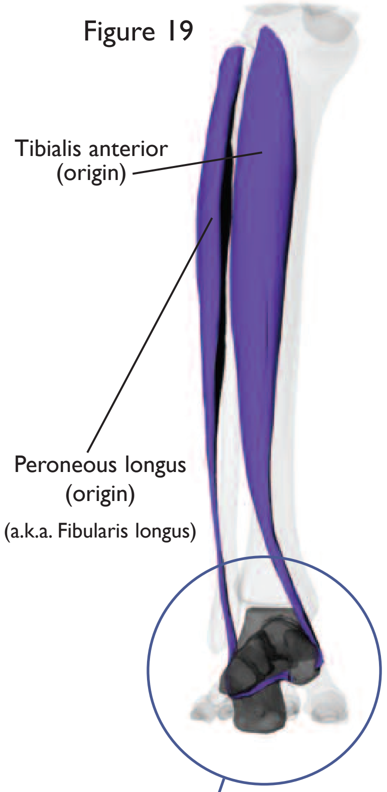


Figure 18 Active or contractive tension on peroneus longus (a.k.a fibularis longus) creates a pulley effect around the cuboid, cinching the cuboid, 1st cuneiform and 1st metatarsal together.

The cinching action of the peroneus longus (a.k.a. fibularis longus) tendon around the cuboid is essential to the control of the transverse arch's feature of stability with adaptability. This process, with the antagonistic activity of the tibialis anterior, establishes the 1st metatarsal/1st cuneiform joint, not only as the "conceptual" transverse arch keystone, but as the foundation of the entire kinetic chain, regardless of activity levels and terrain.

Figure 19



Note: Many medical texts state that the action of the peroneous longus (a.k.a. fibularis longus) everts and plantar flexes the foot or ankle, or the foot at the ankle. However, these are inaccurate descriptions of what should optimally occur during gait-related activities. The following is a more accurate description of how the peroneous longus (a.k.a. fibularis longus) functions in concert with the tibialis anterior.

The origins of both muscles are located adjacent to each other: the tibialis anterior at the upper two thirds of the lateral surface of the tibia, and the peroneous longus (a.k.a. fibularis longus) at the upper two thirds of the lateral surface of the fibula. Their muscle bodies connect to their insertions via long tendons. The tibialis anterior tendon transverses across the ankle to its insertion at the medial/plantar surfaces of the 1st cuniform and base of the 1st metatarsal. The peroneous longus (a.k.a. fibularis longus) tendon extends down, behind the lateral malleolus, underneath the trochlear process of the calcaneus through the peroneal sulcus of the cuboid to its insertion at the plantar/lateral surfaces of the 1st cuniform and base of the 1st metatarsal (Figures 19 and 20).

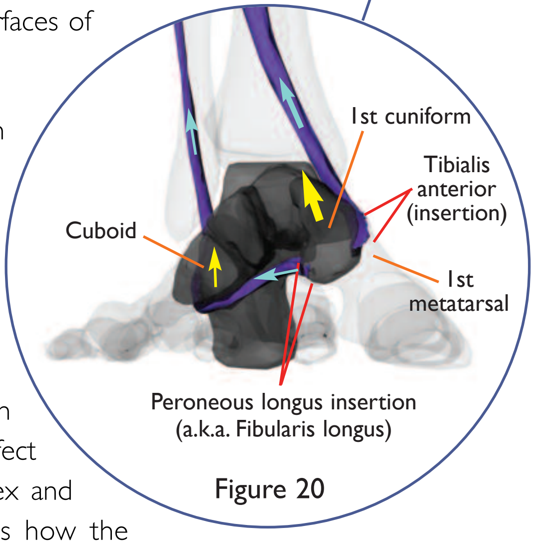
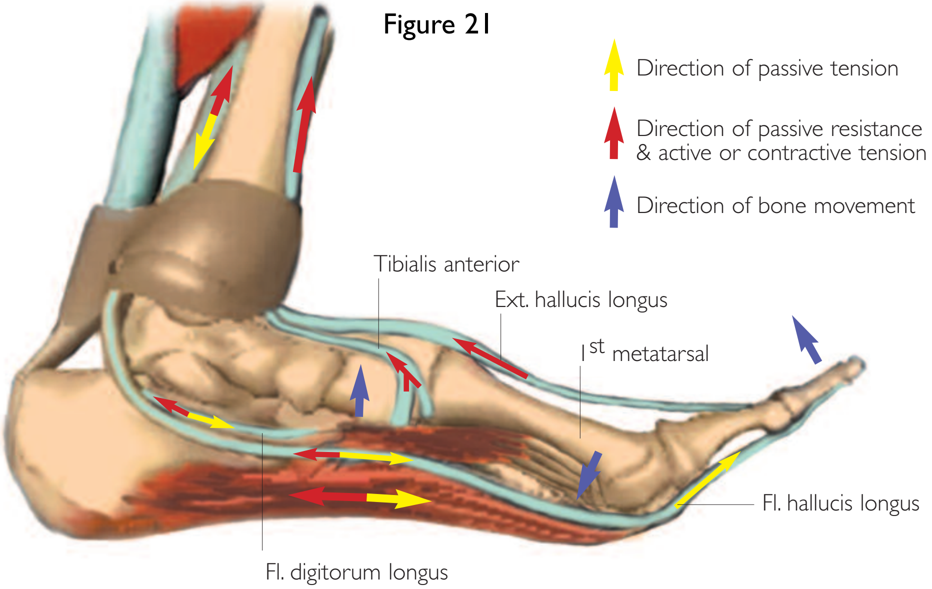


Figure 20

The tibialis anterior and peroneous longus (a.k.a. fibularis longus) are both functionally antagonistic and synergistic. During gait-related activities both should fire at the same time to create a dynamic sling mechanism that stabilizes the midfoot. The larger tibialis anterior's greater contractive forces will cause the 1st cuneiform and base of the 1st metatarsal to rise (dorsiflex), invert, and become dynamically fixed. In other words, their dorsiflexion and inversion cannot be overpowered by simultaneous firing of the smaller peroneous longus (a.k.a. fibularis longus) which can only create sufficient tension on its tendon to create a pulley-like effect on the cuboid, causing the lateral aspect of the mid foot to dorsiflex and transversally cinch the bones of the midfoot. Figure 20 illustrates how the simultaneous and synergistically antagonistic tension (illustrated by the blue arrows) created by the peroneous longus (a.k.a. fibularis longus) and tibialis anterior create the dynamic sling mechanism that stabilizes the midfoot by cinching the cuboid, the1st cuneiform, and 1st metatarsal together, while at the same time dorsiflexing the cuboid and 1st cuneiform, and 1st metatarsal junction (joint) (illustrated by the yellow arrows).

Inversion and eversion of the foot is controlled by the relative contractive forces of the tibialis anterior and peroneous longus (a.k.a. fibularis longus) as a means of maintaining the optimal forefoot and heel orientation with the ground – while the midfoot is stabilized.

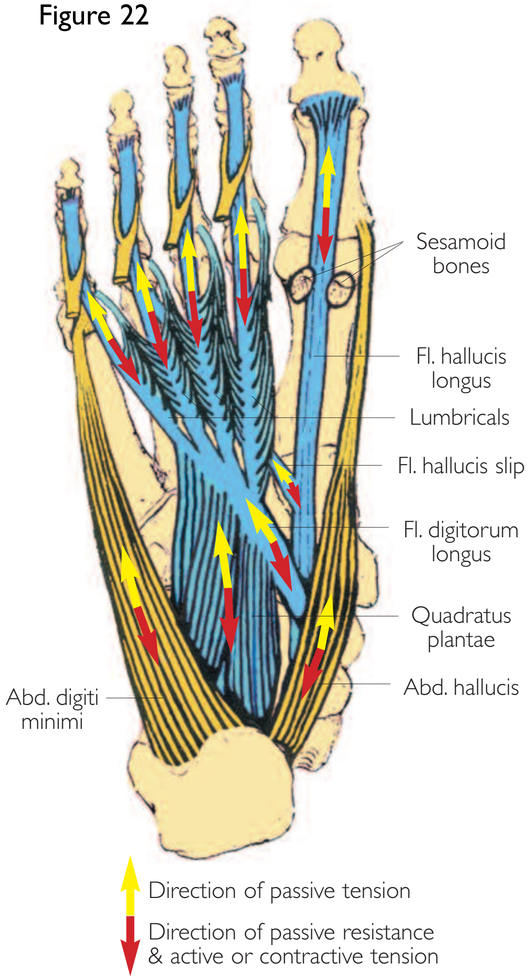
Figure 21



The function of the interosseous muscles (i.e., adduction of the 3rd to 5th toes toward the 2nd toe, and abduction of the 2nd to 4th toes) establishes the 2nd metatarsal as the longitudinal axis of the foot's dome-like functional configuration.

Another important contribution to the dome-like alignment and ideal longitudinal arch apex in the pre-contact phase is contraction of the extensor hallucis longus; this results in the "Windlass Effect" (dorsiflexion of the great toe and plantarflexion of the first metatarsal) (Figure 21) [62, 63, 64, 65, 66]. In addition, simultaneous contraction of the extensor digitorum longus causes dorsiflexion of the corresponding digits, and plantarflexion of the related metatarsals. The "Windlass Effect" is further enhanced, regarding the 2nd to 5th digits, by passive to active tension within the lumbricals which (via their dorsal insertion points) also contribute to dorsiflexion of the interphalangeal joints.

Figure 22



As the digits dorsiflex, the mechanical dynamic that causes plantarflexion of the metatarsals corresponds to a passive tension or preloading of the following:

- the tendons of flexors hallucis longus (and slip) and digitorum longus, muscle body of quadratus plantae and the lumbricals – the second layer muscles (Figure 22)
- abductor hallucis, flexor digitorum brevis, and abductor digiti minimi – the intrinsic 1st layer muscles, and
- the plantar fascia.

The opposing active tension created between the extrinsic extensors and 1st & 2nd layer muscles cinches the interlocking bones into a dynamic dome-like structure that is capable of handling enormous force with minimal muscular contribution (Figures 23 & 24). The pre-loaded intrinsic 1st & 2nd layer muscles and plantar fascia provide a resilient tie beam of optimal tensile strength [65] (Figure 24).

Figure 23

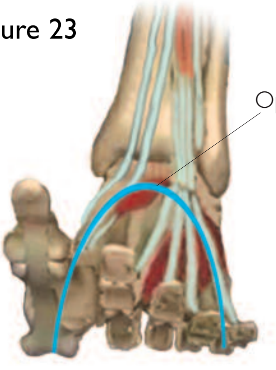
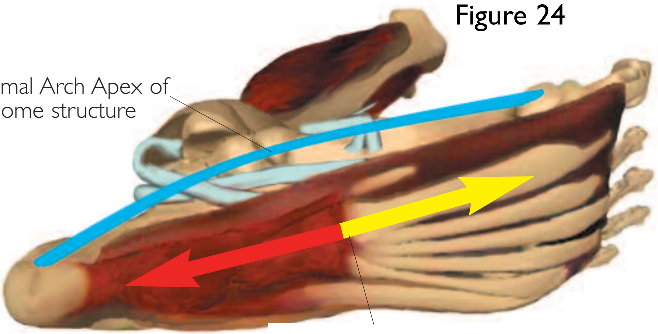


Figure 24



Additionally, the great toe and the sesamoid bones play a significant role in this stabilization and locking process [65]. As the great toe dorsiflexes, the sesamoids move forward and up around the first metatarsal head, maximizing the tension on the flexor hallucis longus (Figure 25). The synergistic effects of these dynamics are significantly greater than their individual additive benefits and create the structure's Ideal or Optimal Arch Apex – the arch system mechanics that are capable of effectively and efficiently managing the greatest loads with the lowest degree of unhealthy stress. The arch system's contribution to load management has been demonstrated mathematically in earlier work by Henning, et. al. [67].

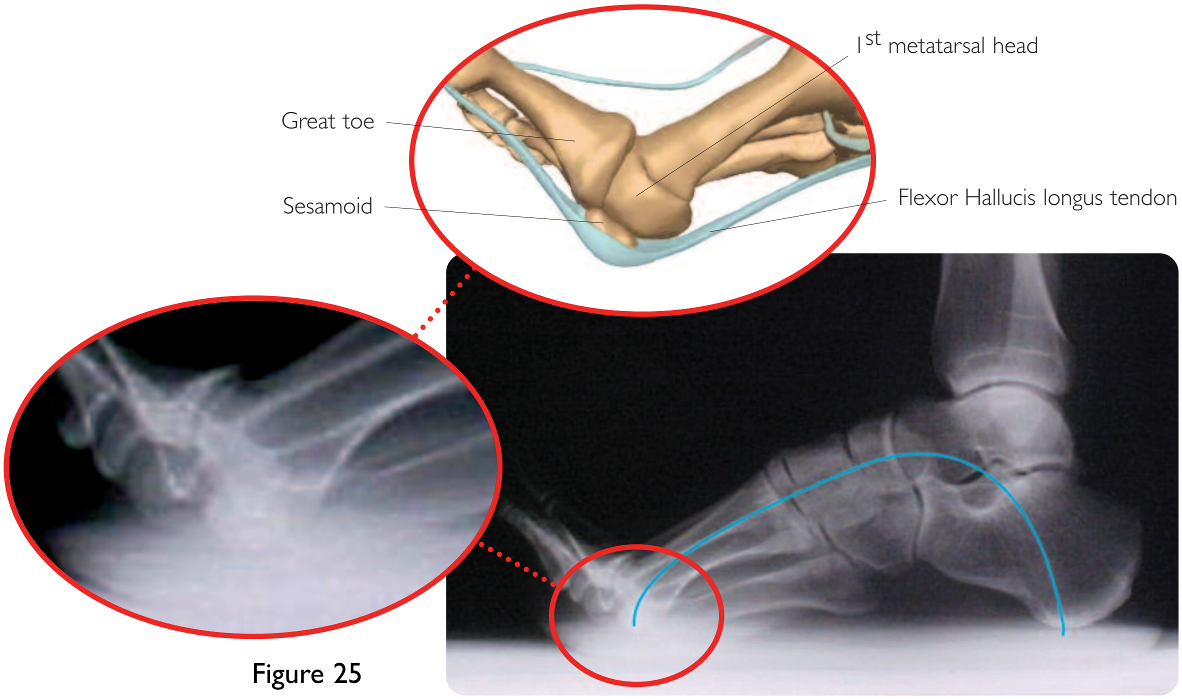


Figure 25

3.2.3 Neurologic Mechanisms (Somatosensory Feedback)

To appreciate the importance of somatosensory feedback in the creation of optimal function and alignment and in the prevention of injury, an understanding of the following neurophysiological concepts is required (Figure 26).

Musculoskeletal Feedback Loop

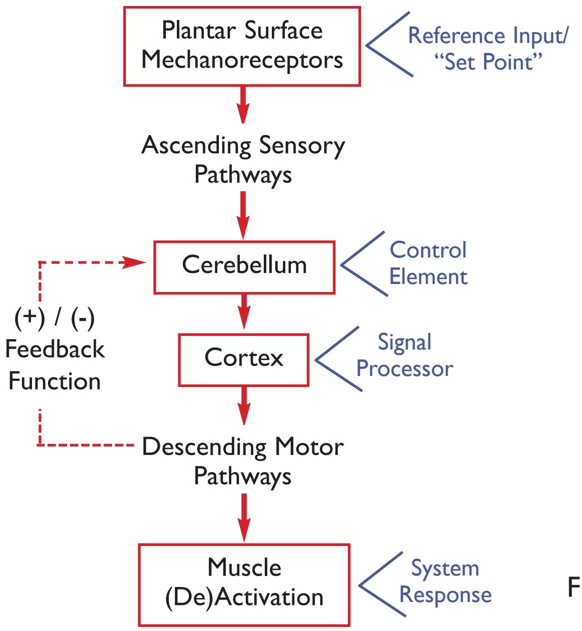


Figure 26

Neurologically speaking, the cortex decides what the body will do and the cerebellum decides how it will do it. In the absence of ascending sensory input (via external stimuli) the cerebellum becomes inefficient at influencing the cortical descending pathways.

Specifically, from a musculoskeletal perspective, nociceptive and proprioceptive stimuli play a central role in providing information input to the physiologic loop that controls and influences bodily movement. In addition, nociceptive and proprioceptive sensory receptors play an important role in the body's natural reflex response to protect it from harm [i.e., pulling your hand away when touching a hot object (Nociceptive Withdrawal Reflex) or reaching out with your hands and arms to catch yourself in a fall (Proprioceptive Reflex)].

Nociceptive neuroreceptors are a peripheral nerve organ or mechanism for the reception and transmission of painful or injurious stimuli. Mechanical nociceptors (mechanoreceptors) respond to small discrete displacements, to directionally applied force (shearing), and to low intensity repetitive force (vibration). Mechanoreceptors have a relatively low threshold. Nociceptive sensory input activates reflex muscle activity relative to pain or excessive mechanical pressure caused by potentially damaging external stimulus [14, 70].

"The barefoot walker receives a continuous stream of information about the ground and about his relationship to it, while a shod foot sleeps inside an unchanging environment. Sensations that are not listened to become decayed and atrophy."

Platte B. San Francisco Chronicle Interview
with Dr. P.W. Brand. Medical Research.
www.unshod.org/pfbc/pfmedresearch.html: 1976

Proprioceptive neuroreceptors are one of a variety of sensory end organs (such as the muscle spindle and Golgi tendon organ) in muscles, tendons, and joint capsules. Proprioceptive sensory input provides feedback solely on the status of the body internally (indicates whether the body is moving with required effort, as well as where the various parts of the body are located in relation to each other). Further, proprioception is a key component in muscle memory and hand-eye coordination, and training can improve this sense. Proprioceptive muscle activity can be influenced by both nociceptive stimuli and the body's interaction with the three dimensional environment.

Neurologic learning allows us to master new skills or improve old ones.

Neurologic impairments can occur due to habituation, desensitization, or adaptation. This can happen when conscious sensory impressions disappear, just as a scent can disappear from awareness over time. One practical advantage of this is that unnoticed actions or sensations are still functionally active in the background while the individual moves on to other concerns. However, external environmental influences that inhibit sensory input or impair musculoskeletal movement can, over time, result in the desensitization, adaptation, and habituation of poor proprioceptive function which continues without conscious awareness.

Neurologic sense can be sharpened by removing the external environmental influences that inhibit sensory input, habituate or impair musculoskeletal movement. By introducing activities that sharpen and condition, it is possible to train optimal neuromuscular function. In sports, this is often called training with "Proper Technique."

Training with "poor technique" conditions inefficient neuromuscular function (poor structural alignment and mis-timed and unbalanced muscle use). Inefficient mechanics increase both degenerative stresses and the risk of injury.

On the other hand, "Proper Technique" conditions efficient neuromusculoskeletal mechanics (optimal structural alignment and optimally timed and balanced muscle use). Efficient mechanics increase the healthy stresses that safely strengthen the structure, significantly decrease or eliminate degenerative stress, reduce the risk of injury, and enhance performance capabilities.

The plantar and palmar epithelia share the unique characteristic of an extremely high density of nociceptors/mechanoreceptors. The plantar surface of the foot is highly sensitive and it is common knowledge that noxious plantar skin sensation contributes to intrinsic foot muscular activation [9, 68]. One common example of a nociceptive reflex mechanism is the involuntary muscular response known as the Babinski Reflex. Research data supports the notion that somatosensory plantar feedback plays a central role in safe and effective locomotion and has demonstrated a relationship between increased arch height and barefoot activity; the greatest increases were found in subjects who performed barefoot activities outdoors [13, 69].

> *"...sensory-induced behavior associated with the physical interaction of the plantar surface with the ground (in the unshod), or the footwear and underlying surface (in shod), is considered unimportant to the traditional thesis. This omission is astounding because logically, the plantar surface, being a highly sensitive layer, would produce significant sensations in either state, and it is common knowledge that noxious plantar skin sensation can easily induce avoidance behavior..."*

Robbins SE, Hanna AM, Gouw GJ. Overload Protection: Avoidance Response to Heavy Plantar Surface Loading. Medicine and Science in Sports and Exercise 20(1): p. 85, February 1988.

From a mechanical perspective, increased arch height can only be achieved by the muscle-firing sequences described earlier or by contractions of the foot's intrinsic first layer musculature, which is accompanied by curling of the toes. However, the latter provides no benefit during the gait cycle (prior to, or at weight bearing) since the resulting structural alignment effectively prohibits natural gait. It is logical to assume that the foot's nociceptive/proprioceptive feedback mechanisms play an integral role (as a protective reflex catalyst) in stimulating the necessary muscle-firing sequences that contribute to the foot's ideal structural mechanics, prior to heel strike [9, 13].

Therefore, the digits' degree of dorsiflexion and resulting variable (dynamic) Optimal Arch Apex are precipitated by the body's natural nociceptive/proprioceptive response to terrain and activity levels. The greater the demands, the greater the dorsiflexion, and the higher the arch apex must rise to effectively manage the increased loads.

The fine motor control, of which the opposing, intrinsic muscle groups (i.e., the abductors vs the adductors, in harmony with the flexors vs the extrinsic extensors) are capable during active gait, confers the following features to the foot's dynamic dome-like alignment:

1. adaptable relative rigidity
2. adaptable distal transverse arch width
3. adaptable ground contact angles of the 2nd to 5th metatarsal heads and thus,
4. the ability to "fine tune" the dome's size and position, which ensures optimal shock management and the most ideal propulsion leverage through the 1st ray.

All of these features are reflexively maintained in response to nociceptive and proprioceptive stimuli to both protect from, and react to, the environment and the loads generated (i.e., varying terrain and activity demands), while optimizing propulsion.

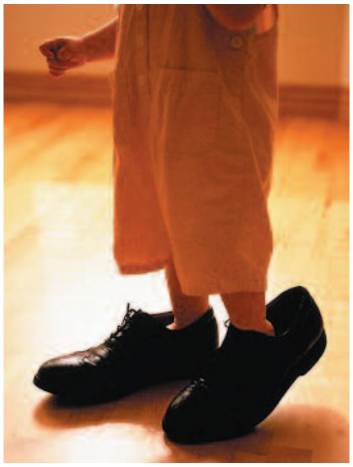
Ideal propulsion, from the weight bearing phase to the toe-off phase of gait requires:

1. a rigid (1st class) lever (i.e., the 1st ray)
2. the vector of force for foot plantarflexion to fall perpendicular to the point of ground contact (the 1st metatarsal head).

Optimal mechanics suggests that a rigid propulsive lever is created and maintained by:

- the Windlass Effect concurrent with the cinched up mid-tarsal region (with both of these actions initiated by the proprioceptive reflex catalyst), while
- the perpendicular vector of the plantarflexion force is provided by the adaptive fine motor control of the intrinsic foot muscles after an antagonistic balance has been achieved between the flexor hallucis longus and the extensor hallucis longus muscles.

This biomechanical efficiency decreases the incidence of stress and fatigue-related injuries at the muscle, tendon, and ligament junctions throughout the kinetic chain.



"...the arch develops during the first decade of life..."

"... shoes increase the frequency of flat feet (studies from India suggest that shoes actually cause flat feet)..."

Dr. James G. Wright, Assistant Professor, Department of Surgery, University of Toronto Faculty. The Hospital for Sick Children. Foot and Ankle Symposium Co-sponsored by the Canadian Orthopaedic Association and the Department of Surgery, Orthopaedic Division University of Toronto, held at Sunnybrook Hospital, April 1996

3.2.4 Schematic Model of Ideal, Dome-like Foot Function in Gait

The human foot, in a gross generalization, is capable of two categories of function:

1. gait-related and
2. non gait-related.

The second category includes activities such as tree climbing, swimming, and acting as ersatz hands for individuals who lack hands. It is primarily the adaptability of the intrinsic muscles that convey such versatility.

Alternatively, during gait-related activity, the foot must serve the seemingly disparate functions of propulsion (requiring rigidity), and balance (requiring supple adaptability). The features of foot function, as discussed in previous sections, indicate that this apparent contradiction is not only present but elegantly utilized within the unshod population. This capacity is essentially "switched-on" via somatosensory stimuli received by the plantar surface mechanoreceptors. The following is a schematic model of ideal foot function (as deduced from the information thus far presented) that accomplishes these roles (Figure 27).

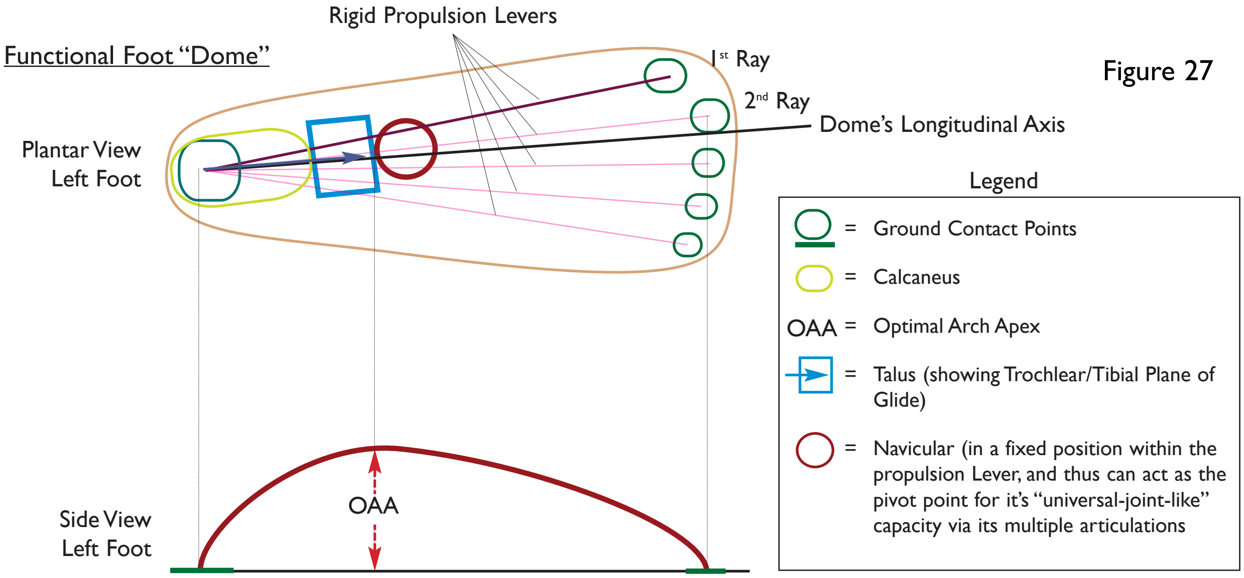


Figure 27

The following table delineates the specific role(s) played by each component of the foot in the creation of the above model.

PART	ROLE
CALCANEUS	1. Weight bearing ground contact at heel strike; 2. Posterior end of rigid propulsion lever; 3. Posterior end of dome-like functional configuration; 4. Posterior sulcus acts as pulley for flexor hallucis longus tendon, which establishes the line of pull for the flexor hallucis longus that establishes the longitudinal axis of the propulsion lever; 5. Articulates with talus in lever formation; 6. Articulates with cuboid for mid-foot cinching; 7. Round inferior surface for efficient ground contact adaptability.

PART	ROLE
TALUS	1. Articulates with calcaneus + navicular in rigid lever formation; 2. Articulates with cuboid for mid-foot cinching; 3. Controls plane of tibial glide over the trochlea – creating the ideal axis for the rigid propulsion lever.
NAVICULAR	1. Keystone of longitudinal arch/point of Optimal Arch Apex; 2. Articulates with talus and 1st cuneiform in rigid lever formation; 3. Articulates with 2nd + 3rd cuneiforms and cuboid to enable ground contact + activity level adaptability.
1ST CUNEIFORM	1. Articulates with navicular + 1st metatarsal in rigid lever formation; 2. Acts as the base of the kinetic chain via insertions of tib. ant. + per long (a.k.a. fib long) and thus is part of the keystone of the transverse arch.
1ST METATARSAL	1. Articulates with navicular + 1st phalange in rigid lever formation; 2. Acts as the base of the kinetic chain via insertions of tib. ant. + per long (a.k.a. fib long) and thus, is part of the keystone of the transverse arch; 3. Plantarflexes in creation of the Windlass Effect; 4. Primary weight bearing ground contact for propulsion at the anterior end of rigid propulsion lever; 5. Antero-medial end of dome-like functional configuration.
SESAMOIDS	1. Increase leverage of flexor hallucis longus 2. Lock 1st phalange in dorsiflexion to maintain the Windlass Effect throughout weight bearing.
2ND CUNEIFORM	1. Articulates with navicular, 1st cuneiform, 3rd cuneiform, and 2nd metatarsal to enable ground contact + activity level adaptability.
3RD CUNEIFORM	1. Articulates with navicular, 2nd cuneiform, 3rd metatarsal, and cuboid to enable ground contact + activity level adaptability.
2ND – 5TH METATARSALS	1. All articulations, at their bases, enable ground contact + activity level adaptability; 2. Secondary weight bearing ground contact at their heads contributes to balance and adaptability; 3. Plantarflex during the Windlass Effect and are secondary propulsion levers; 4. Anterior end of dome-like configuration.
PHALANGES	1. Articulate with heads of metatarsals and are dorsiflexed to create the Windlass Effect; 2. Can plantarflex to aid propulsion and/or ground adaptability.

PART	ROLE
FLEXOR HALLUCIS LONGUS	1. This powerful muscle, originating at the posterior aspect of the fibula below the deep fascia of the calf, with its tendon pathway around the posterior calcaneal sulcus + its plantar insertion at the 1st metatarsal head indicates the ideal axis for the rigid propulsion lever; 2. Its active-passive tension, in opposition to but "in line" with the extensor hallucis longus activity, creates the 1st ray Windlass Effect.
EXTENSOR HALLUCIS LONGUS	1. This thin muscle, originating from the middle two quarters of the anterior surface of the fibula and the adjacent interosseous membrane and inserting via tendon at the base of the distal phalanx of the big toe, creates the 1st ray Windlass Effect via antagonistic balance with tension of flexor hallucis longus; 2. Creates the rigidity of the propulsion lever; 3. Shifts the sesamoids into their "locked" position, ensuring lever rigidity.
TIBIALIS ANTERIOR	1. This fleshy muscle, originating at the lateral condyle and upper two thirds of the lateral surface of the tibia, becomes tendonous at the lower third of the lower leg. It inserts medially and under the surface of the 1st cuneiform and at the base of the 1st metatarsal. 2. Cinches the mid-tarsal region into an Optimal Arch Apex, in conjunction with the peroneus longus; 3. Secondarily, the cinching effect adds rigidity to the propulsion lever; 3. Its activity establishes the base of the kinetic chain, with the per. long (a.k.a. fib. long.).
PERONEUS LONGUS (a.k.a Fibularis Longus)	1. This long muscle, originating along the lateral edge of the head and proximal shaft of the fibula, descends along the lateral edge of the leg to approximately half way between the knee and ankle where it tapers to form a long tendon that loops under the cuboid and inserts laterally under the surface of the 1st cuniform and at the base of the 1st metatarsal. 2. Cinches the mid-tarsal region into an Optimal Arch Apex in conjunction with and antagonisitic to the tibialis anterior; 3. Secondarily, the cinching effect adds rigidity to the propulsive lever; 4. Its activity establishes the base of the kinetic chain with the tib. ant.
INTRINSIC FOOT MUSCLES	1. Theses are smalll muscles that orginate and insert within the foot. 2. Create adaptable relative rigidity of foot; 3. Create adaptable distal transverse arch width; 4. Create adaptable ground contact angles of 2nd-5th metatarsal heads; 5. Create the ability to "fine tune" the dome's size and position, which ensures the most ideal propulsion leverage through the 1st ray.

3.2.5 Ideal Gait Mechanics

As already described, natural healthy foot function and ideal gait mechanics should demonstrate optimal neuromusculoskeletal function (timing of muscle firing and alignment) throughout the kinetic chain as a dynamic response to activity levels and terrain. That is, subtle variable stimuli to the sole of the foot produces:

- nociceptive reflex activations of the foot and ankle related muscles,
- proprioceptive reflex activations in the muscles throughout the lower limb, hip, and back kinetic chain.

Together they optimally align the bones to most effectively manage the forces generated during varying activities and terrain – while promoting optimal neuromusculoskeletal function and little or no degenerative stress. Nociceptive and proprioceptive sensory stimuli of the first step, and/or optimal proprioceptive conditioning, triggers a protective reflex response during the swing phase of gait prior to the second step ground contact. This continuous, step by step, nociceptive/proprioceptive reflex activity results in the pre-ground contact cinching of the foot and ankle's interlocking bones to:

1. form a strong yet adaptable dome-like shape in the foot (i.e., Optimal Arch Apex), and
2. lock the foot and ankle to inhibit eversion or inversion at ground contact (i.e., stabilize the subtalar region for optimal mechanical positioning through the knee and hip in line with the Arch Apex).

The reflexive pre-ground contact musculoskeletal cinching is a dynamic response to activity levels and terrain. Functioning in this ideal manner, the foot's musculoskeletal structure is capable of providing optimal structural integrity, alignment, and shock management throughout multi-directional ground contact, weight bearing, and toe off, while forming a spring-loaded rigid lever when in propulsion mode.

When the ankle is locked against eversion and inversion at heel contact, the roundness of the heel initiates a smooth, stress-free transition that naturally aligns the forefoot to the ground. This is consistent in multi-directional activity through varying angles of impact. The pivot point for this movement is located in the calcaneus' mass, centered at the radius of the curve created by the fleshy surface of the heel (Figures 28 & 29).

Figure 28

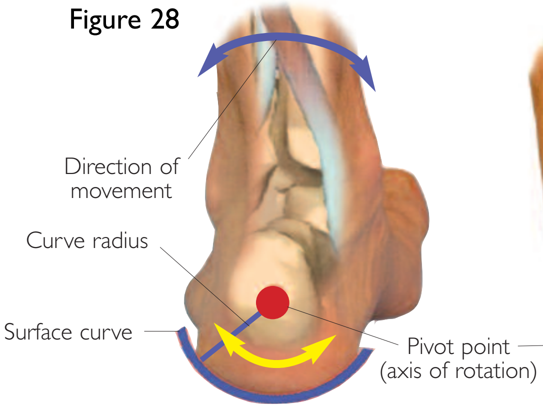
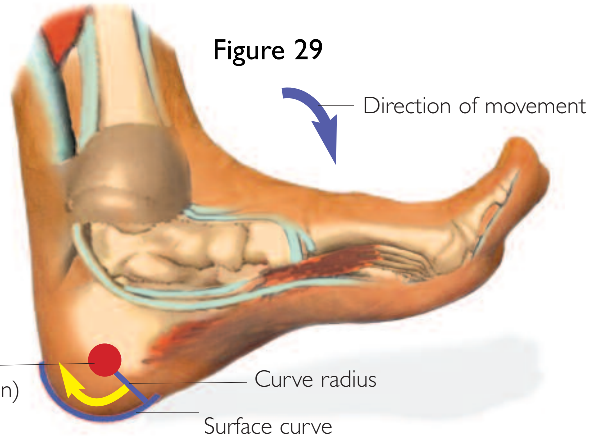


Figure 29



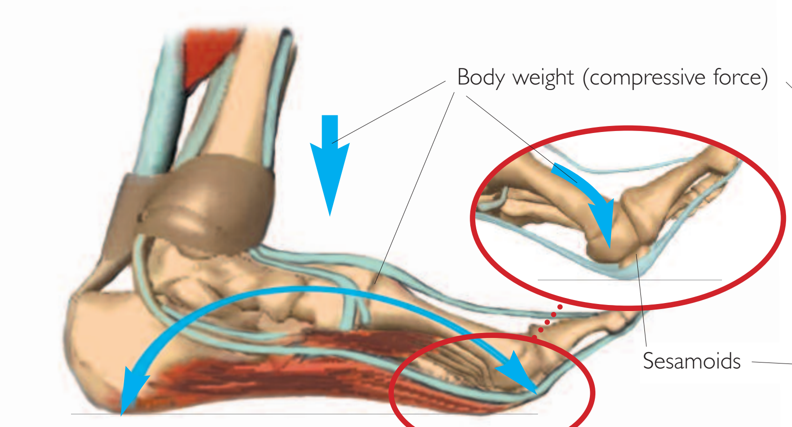


Figure 30

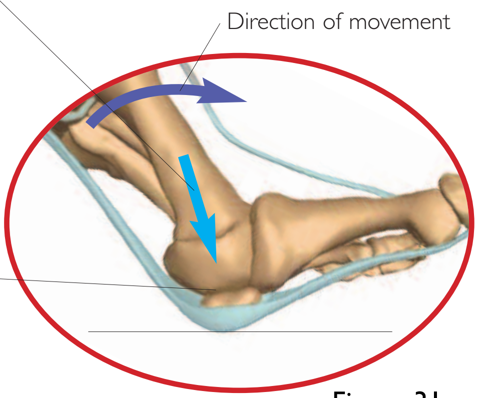


Figure 31

Once the forefoot contacts the ground, the compressive force created by the body's weight restricts the sesamoids from moving backward, effectively locking the structure into a functional dome shape (Figure 30).

As the foot moves into the propulsion phase of gait and the extensors ease their contractions, the "locked" sesamoids ensure that the domed arch structure maintains the greatest dynamic stability (i.e., rigid lever) (Figure 31).

Sub-talar neutral (the mechanical relationship between the talus and navicular) is often considered the "key" to "proper" structural alignment in the foot. Contrary to the conventional view, this mechanical relationship is dynamic rather than static in nature. That is, the relative positioning of the "subtalar joint" is determined by the nociceptive and proprioceptive reflex muscle activations (or lack thereof) in response to activity levels and terrain.

While the extrinsic musculature of the foot plays the predominant role in the alignment and maintenance of the arch system's optimal structural integrity, the intrinsic musculature of the foot plays only a minimal role, therefore, it is used more effectively in the fine-tuning of balance and ground interface interaction.

Functioning as described, the optimal structural integrity of the foot's domed arch system is maintained throughout the weight bearing and propulsion phases of a wide range of three-dimensional movements, facilitating superior natural shock management throughout.

When the interlocking bones of the feet are optimally aligned and stabilized, the longitudinal axis of the rigid 1st ray propulsion lever parallels the tibia/trochlea axis of glide, thus ensuring a torsion-free, strictly frontal plane of knee motion (thus fulfilling the ideal as set out in Figure 1). Just as significantly, this ideal alignment

> *"The non-neutral foot allows for instability, and the muscles work out of phase and inefficiently to maintain balance ."*

Subotnick SI. The Flat Foot. The Physician and Sports Medicine 9(78): p. 85, August 1981

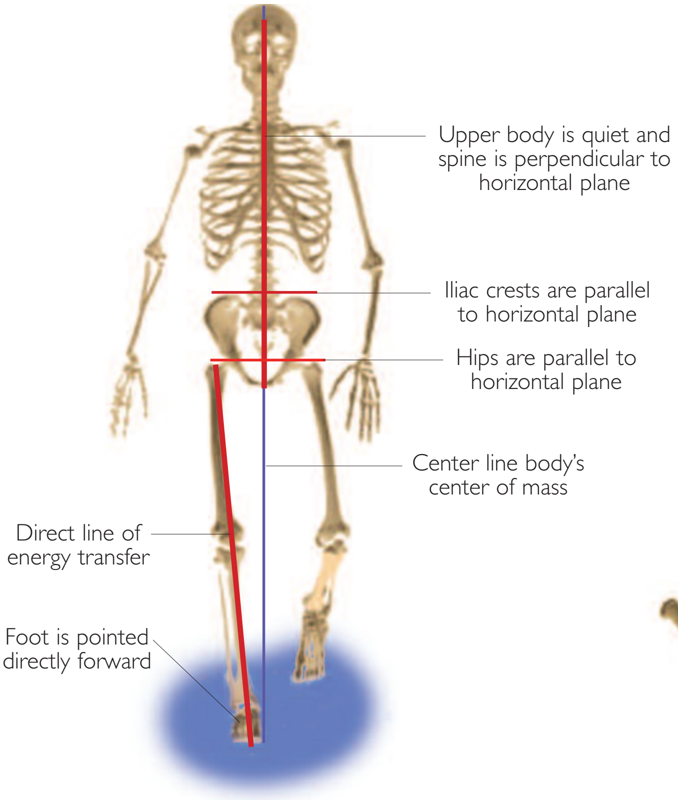


Figure 32

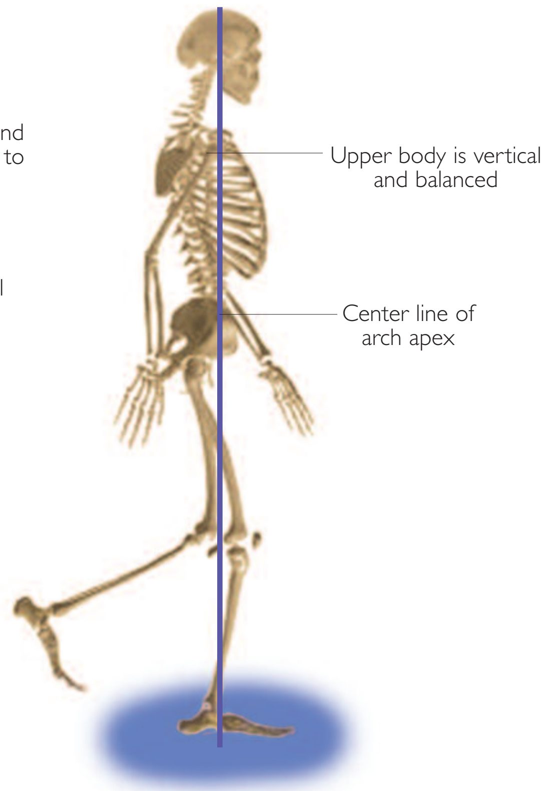


Figure 33

is capable of being maintained regardless of terrain or activity levels via the round nature of the inferior calcaneus surface and the adaptable nature of the intrinsic foot musculature. The feet thus provide an extremely effective, stress-free platform for the rest of the body. Consequently, the entire kinetic chain's musculoskeletal structure demonstrates:

- optimal energy efficiency,
- a greater capacity to safely manage increased activity levels,
- little or no degenerative stress, and
- a significantly reduced propensity to injury.

Ideally, the consequence of a stable dome-like arch system is that the foot points directly forward through weight bearing and there is a direct line of force through the arch apex, the center of the knee, and at a midpoint between the greater trochanter and lesser trochanter of the femur (Figure 32). The hips and iliac crests are parallel and the spine is perpendicular to a horizontal plane. Viewed from the side, the upper body remains balanced and vertical as the body's center of mass moves over the arch apex (Figure 33).

4.0 Footwear's Relationship to Lower Limb Biomechanics and Resulting Pathologies

It is commonly accepted that poor foot biomechanics play a significant role in the development of pathologies such as metatarsalgia, plantar fasciitis, hallux valgus, heel spurs, neuromas, Achilles tendonitis, shin splints, patello-femoral problems, hip and back pain, etc. It is often argued that genetics play a leading role in dysfunctional foot biomechanics, yet little science exists to support this hypothesis. However, abundant scientific evidence points to "footwear" as the leading cause of foot dysfunction and the majority of associated foot-related pathologies [13, 14, 58, 71, 72, 73, 74, 75, 76, 77, 78].

It is more likely that foot pathology trends in families are the result of footwear buying patterns as opposed to genetic predisposition. From an early age, children's footwear is selected by parents whose own choices closely reflect their socio-economic values. Considering the rate (and amount) of bone development throughout childhood, along with the bone remodeling principles previously identified, it would seem obvious that footwear environments would impact significantly on structural development. An abundance of research indicates that children's feet are negatively affected by footwear by the age of six and that optimum foot development occurs in the barefoot environment [72, 74].

Furthermore, studies on predominantly shod populations that present some type of foot-related pathology have demonstrated a reversal of symptoms through increased barefoot activity [11, 76]. It has also been widely reported that predominantly unshod populations develop a paradoxically low incidence of foot-related problems and that there is a direct relationship between related pathologies proportionate to footwear use – to a level equal to habitually shod populations [10, 11, 12, 17, 80].

Most conventional footwear designs affect the feet much like a cast or splint would affect an arm or leg. Specifically, the chronic restrictions imposed by footwear account for muscle atrophy, loss of bone mass, less than ideal bone geometry (through remodeling), and joint stiffness. Wearing shoes can actually weaken the feet and legs, increasing their susceptibility to injury [9, 13, 14, 17, 35, 71, 81, 82].

Shoes isolate the soles of the feet from the subtle varied stimulus required for optimal neuromuscular function throughout the lower limb/hip/back kinetic chain. This dampened nociceptive stimulus impairs the timing and intensity of optimal proprioceptive muscle activity throughout the kinetic chain, effectively destabilizing its dynamic load-bearing and propulsion capabilities (i.e., the dynamic mechanical capabilities – alignment and muscle efficiencies – are impaired). This dynamic instability results in degenerative stresses in the muscles and at joints that cause or contribute to various "arthritic-like" problems (pathologies) in the feet, legs, hips, and back.

Aside from improper sizing, the numerous footwear design characteristics (Figures 34 & 35) and their contribution to poor foot function are:

◆ **Cause:** rigid soles • cushioning properties (underfoot) • arch supports

Effect: dampens the varied sensory stimulus (to the sole of the foot) needed to trigger the proper muscle function that aligns the bones for optimal dynamic stability. Both nociceptive and proprioceptive reflex musculoskeletal activity are inhibited.

◆ **Cause:** restrictive toe box height/width and/or rigid soles that prevent dorsiflexion of great toe • restrictions over arch area (by design or via tight lacing) that prevent optimal arch apex height • narrow width through metatarsal area

Effect: act like a brace on the feet by restricting the natural dynamic nature of the foot (i.e., full foot mobility involving the natural raising of the arch and dorsiflexion of the toes) that is necessary to effectively manage varying loads (impact stresses), and terrain changes. Rigid soles inhibit natural walking and running dynamics and increase the forces the foot must manage. Shallow rigid toe boxes restrict the natural toe movement required to form a strong stable arch. Tight lacing inhibits natural raising of the arch in response to increased loads, causing the foot to flatten (promoting inefficient bone alignment and structural instability), which weakens the restricted muscles and causes others to fatigue from overwork. Enclosed footwear with rigid soles and tight lacing will condition "poor" proprioceptive reflex muscle activity.

◆ **Cause:** wide or flared heels or midsoles • rigid soles or midsoles • stiff uppers

Effect: increases lever arm mechanics and accelerate forces during gait – premature plantarflexion and excessive pronation

◆ **Cause:** increased heel height

Effect: inhibits balanced stance and equal distribution of weight during walking or standing – poor structural alignment through feet and entire kinetic chain.

Figure 34

Figure 35

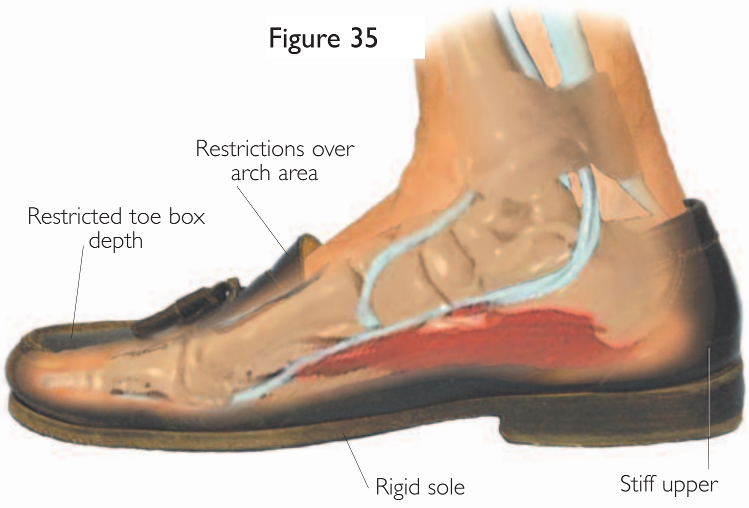


Figure 36

Each of these design characteristics impose singular negative effects on lower limb, hip, and back neuromuscular function; in combination, their negative effects are magnified significantly. It is apparent that the majority of footwear on the market today features a number of these characteristics, many of which are ironically promoted as beneficial for the user. In all instances, damaging degenerative stresses increase relative to the amount of cushioning, support, and restrictiveness of the footwear.

4.1 Lack of Nociceptive and Proprioceptive Sensory Feedback

A shoe that is rigid and supportive or one that features abundant cushioning (Figures 34, 35, & 36) greatly diminishes the subtle varied sensory feedback required for optimal "natural" nociceptive and proprioceptive reflex muscle-firing sequences that stabilize the arch [82]. According to Robbins, "Wearers of expensive running shoes that are promoted as having additional features that protect (e.g., more cushioning, 'pronation correction,' etc.), are injured significantly more frequently than runners employing inexpensive shoes." [80].

Footwear in general, specifically the modern running shoe, substantially diminishes sensory feedback but does not diminish injury-inducing impact – a dangerous situation [11, 55, 65, 68].

Supportive cushioning features are widely promoted as essential for safety when walking or running to mitigate chronic overload on the lower extremities due to modern man's purported inherent fragility. However, this supposition is inconsistent with reports that indicate habitually unshod humans are not subject to chronic overloading when running and are virtually free of foot-related pathologies [9,10,11]. Considerable research indicates that the lower extremities of predominantly barefoot populations are inherently durable and that chronic overloading is a consequence of wearing footwear [9,10, 65, 66, 80, 81].

Figure 37

Figure 38

Figure 39

Figure 40

Over time, the impaired neuromuscular activity becomes "static" as it is conditioned or trained via desensitization, habituation, and adaptation, hence the body is no longer capable of effectively responding to the ever changing environment. In other words, the unhealthy (degenerative) stress-generating neuromuscular function becomes a conditioned response (i.e., the dysfunctional "norm") and the major contributing factor to the majority of foot-related pathologies. Common symptoms include pain, stiffness, and swelling in joints and other supporting structures of the body, such as muscles, tendons, ligaments, and bones, along with muscle atrophy (underuse), muscle hypertrophy (overuse), tissue damage, fibrosis/scar tissue, and loss of bone density. This dysfunctional norm can only be reversed through rehabilitative therapies (conditioning) that retrain the optimal proprioceptive muscle activity.

"Technique" training is neuromuscular training and this conditioning concept is the foundation of most modern sport training. That is, "Proper Technique" is fundamental for conditioning optimal neuromusculoskeletal function. It promotes little or no degenerative stress, reduces risk of injury, and enhances performance capabilities. On the other hand, "Poor Technique" conditions less than optimal neuromusculoskeletal function, increases degenerative stress, increases risk of injury, and hampers performance capabilities.

Studies on barefoot populations indicate that the intrinsic properties of a biomechanically sound foot, unfettered by the constrictions of footwear, can effectively manage the forces and stresses generated during the most rigorous activities on the hardest surfaces [9, 11, 14, 68]. Man-made cushioning and motion control designs pale in comparison.

4.2 Restrictions in Structural Alignment

Footwear for women that features narrow pointed toe boxes and high heels has generated ample criticism from foot care professionals. It is commonly understood that improper footwear (by design or size) contributes to a host of foot pathologies, yet opinions are conflicting about what constitutes appropriate footwear and the effect it actually has on the foot's structure and the dynamics of gait [83].

4.2.1 *Maladaptive Bone Remodeling*

The ancient Chinese custom of foot binding and the use of Lotus shoes (Figure 34) is an excellent example of how negative environmental influences can restructure the foot. Chinese foot-binding spanned over a thousand years – many millions of women endured this extremely painful process. It was banned in 1911, yet continued until the New China was founded in 1949. This wide-spread practice has caused severe life-long disability for millions of elderly women [84].

Figure 41

Figure 42

Figure 43

In early childhood, a girl's feet were bound with meters of cloth to inhibit growth so that they would resemble the most desired "three inch golden lotus" – a size no larger than 10 centimeters, or 3.9 inches [85] (Figure 37). The practice would cause the soles of their feet to bend in extreme concavity (Figures 38 & 39).

A bandage, ten feet long and two inches wide, was wrapped tightly around each foot, forcing the four small toes under the soles. This made the feet narrower and at the same time shortened them because it forced the big toe and the heel closer together, bowing the arches. The bandages were tightened each day and the girl's feet were put into progressively smaller and smaller sized shoes (Figure 40). The entire process usually took about two years, after which, the feet were rendered essentially "dead" and utterly useless.

As the practice waned, some girls' feet were released soon after their initial binding, leaving less severe deformities. However, the legacy of foot binding is that the deformities linger on as a common cause of disability in elderly Chinese women [84, 86].

Similar deformities are also common in today's modern society (Figures 41, 42 & 43).The environmental influences of the toe box design characteristics clearly demonstrate the negative physiological impact of restrictive footwear (Figure 41). Not only does footwear impede healthy optimal neuromuscular function; it actually contributes to maladaptive bone remodeling [87, 88] (Figure 43).

As implied by Wolfe's Law, bone is living tissue and is consistently undergoing cellular regeneration and, as such, possesses the ability to change and adapt [44, 89, 90]. In fact, bone constantly changes in response to many varied influences; some of which are mechanical, others are hormonal, some are genetic, etc. [3, 38, 43, 44, 49, 89, 90, 91].

Casting an arm or leg ensures that the bones are "at rest" and protected from mechanical stresses. In the absence of normal "healthy" stress, even normal bones remodel, becoming weaker (exhibiting reduced bone mass) [49, 91]. Immediately upon removal of the cast, the weakened bones are more prone to fracture but will respond to the resumption of moderate "healthy" mechanical stress by reversing the process – building greater density and strength.

Even though bone is in a constant state of change, it requires time to adapt to environmental influences. With increased activity and exercise, bones hypertrophy (become thicker and stronger) to more effectively manage new levels of stress without the risk of fracturing [3, 43, 45, 50, 89, 92].

There is an optimum range of "healthy" stress for maximum strength – when understressed or overstressed, bone can actually weaken. Stress is generated through repetitive or constant tension and/or pressure and may exert a healthy or unhealthy "degenerative" influence depending on the mechanical action it generates, coupled with the inherent characteristics of the bone.

For example, unhealthy repetitive stress can be demonstrated in the formation of heel spurs at the insertion of the plantar fascia to the calcaneus. In this case, the bone remodels toward the source of repetitive tension as a means of mitigating the stress (Figure 42). Bunions and "pump bumps" provide similar examples of how unhealthy repetitive stress affects bone (Figure 43). Healthy repetitive stress that is generated through moderate exercise, such as running or lifting weights, helps build and maintain bone density.

It is clear that mechanical factors are the one constant in this remodeling process and act on bone in concert with hormonal, metabolic, and genetic influences. Therefore, understanding neuromusculoskeletal mechanical physics and its effects on the skeletal structure's remodeling process is essential to understanding the cause of related pathologies and their prevention and treatment.

These concepts, while relatively new to foot care, are widely accepted in other medical disciplines and are regularly integrated into treatment methodologies. For example, orthodontists use braces on individuals of all ages to remodel the bone anchoring the teeth (alveolus socket in the alveolar process). Constant pressure is exerted on the bone through the roots of the braced teeth by rubber bands connected to the braces. These mechanics cause the teeth to act as lever arms, with the bone remodeling *away* from the constant pressure. Once the braces have been removed, the new alignment is maintained through a diversity of forces (healthy stresses generated through chewing) that sustain the integrity and density of the bone. Failure to maintain this healthy stress can result in loss of bone mass and a subsequent loosening of the teeth, as witnessed in those who are unable to chew solid food.

> *"The inescapable conclusion is that footwear use is ultimately responsible for ankle injury."*
>
> Robbins SE, Waked E, Rappel R. Taping Improves Proprioception Before and After Exercise in Young Men. British Journal of Sports Medicine 29(4): p. 242, 1995

These dynamics (the alveolus' remodeling in reaction to braces) are demonstrated in bone throughout the body as it responds to the forces exerted by muscle tension and the related mechanics of structural alignment.

A Stanford University study examined how loads applied to the calcaneus influence the bony architecture [67]. The study's findings suggest that there is a strong relationship between bone structure and loading history. Mechanically favorable bone remodeling has also been documented on other areas of the body [38, 93, 94, 95], with demonstrated changes in bone shape geometry at bone-to-bone contact.

4.2.2 Unhealthy Neuromusculoskeletal Mechanics

The most damaging footwear design characteristics are those that inhibit subtle variable sensory input to the soles of the feet, those that prevent structural integrity of the domed arch dynamic and, those that increase the forces and stresses on the musculoskeletal structure.

In addition to dampening subtle varied sensory feedback, rigid soles and restrictive toe box areas exert the most damaging influence by inhibiting dorsiflexion of the toes, which is necessary for alignment and stabilization of the strong, functional dome-like dynamic of the interlocking bones in the foot and ankle. Chronic interruption of this dome-like dynamic can actually condition improper muscle-firing sequences and result in either compensatory overuse or a failure to fire at all. The dynamic is further hampered by restrictions over the arch area that prevent the formation of the optimal arch apex, which is necessary for efficiently managing specific loads. These restrictions may be inherent to the footwear design, and may result from improper shoe size or from overtight lacing. These dampening and restrictive influences negatively impact all types of developed foot function, however in slightly different ways.

A rigid high arch is structurally capable of managing greater loads initially, but without appropriate muscular activity to maintain the arch systems' domed integrity the arch system suddenly fails mechanically when loads exceed its structural capacity. This results in more "acute-like" degenerative stresses and a diminished capacity to effectively manage "shock."

A hypermobile or flat foot is structurally capable of managing lesser loads. In both instances, its load bearing capacity is notably diminished without appropriate muscular activity to maintain the arch systems' domed integrity. A functional arch system is either not present (flat) or fails immediately (hypermobile) at forefoot/ground contact and results in more "chronic-like" degenerative stresses and compensatory muscle imbalances throughout the closed kinetic chain.

X-rays graphically illustrate the limitations of structural alignment between the fully mobile unshod right foot (Figure 44) and the restricted shod right foot (Figure 45) during full weight bearing. The x-rays are of the same subject, taken approximately 10 minutes apart.

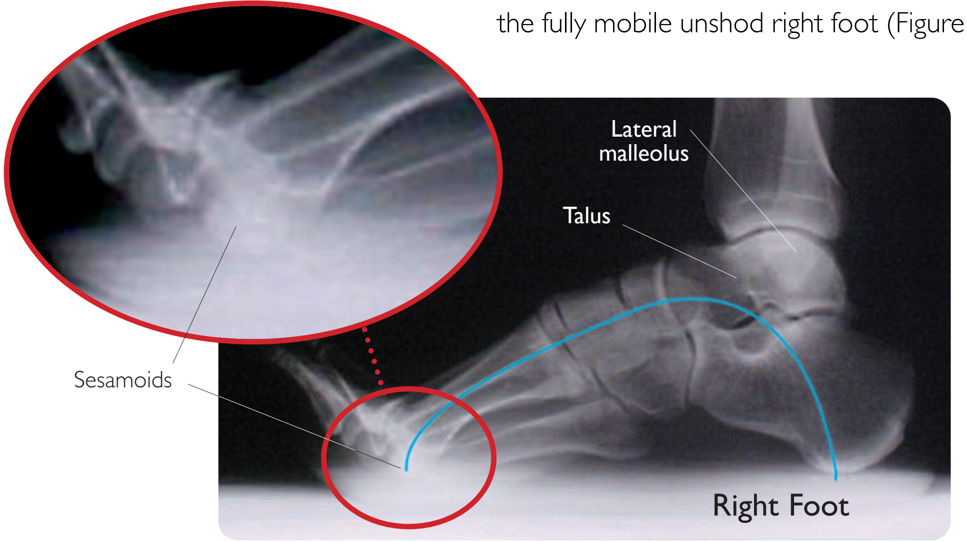


Figure 44

Note the differences in the relative positioning and alignment of the interlocking bones. In the unrestricted foot with the great toe dorsiflexed, the interlocking bones are cinched tightly together, forming a stable dome-like dynamic (Figure 44). The metatarsals are plantarflexed relative to the midfoot, the midfoot is inverted and plantarflexed relative to the rearfoot, and the talus and calcaneus are dorsiflexed and inverted.

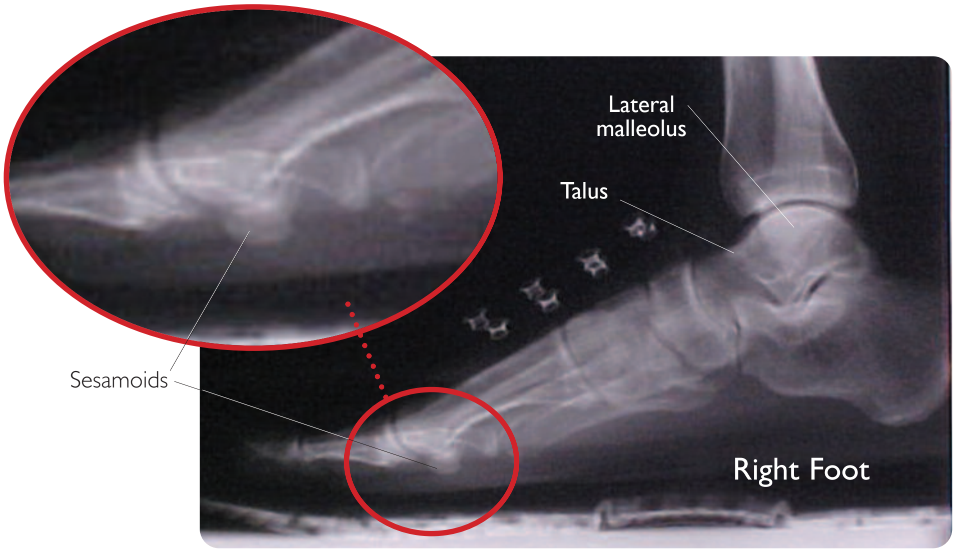


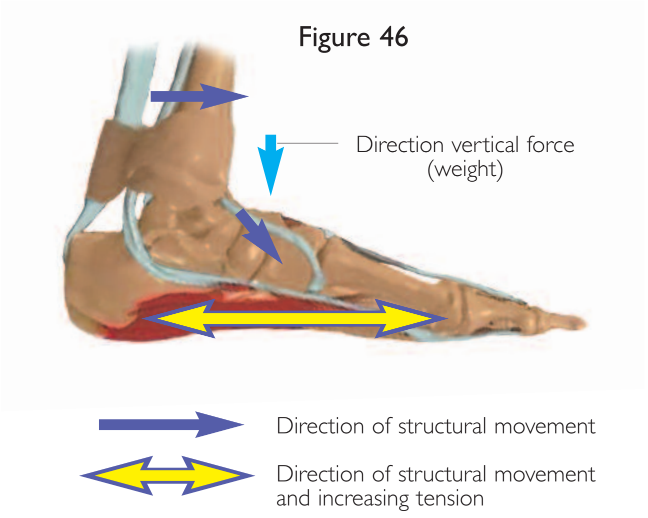
Figure 45

When the great toe is restricted and unable to dorsiflex, or when restrictions or lacing prevent raising of the mid-foot, the interlocking bones are unable to achieve this stable dynamic (Figure 45). Instead they are loosely aligned and demonstrate poor structural integrity. The metatarsals are dorsiflexed relative to the midfoot, the midfoot is dorsiflexed and everted relative to the rearfoot, and the talus and calcaneus are plantarflexed and everted. The sesamoids remain *behind* the 1st metatarsal head, which prevents them from locking the structure throughout the weight bearing and propulsion phases of gait. Upon weight bearing, this positioning can actually restrict dorsiflexion of the great toe – an action that is necessary for effective dynamics through the propulsion phase of gait.

Note also the relative position of the lateral malleolus to the talus and the degree of medial tibial rotation demonstrated in Figure 45 when compared to the relative positioning in Figure 44. From a physics perspective, the alignment, structural integrity, and height of the foot's arch system corresponds directly to the degree of tibial rotation and inefficient alignment at the knee.

As the foot moves from heel strike to full weight bearing, loads increase over the arch area in response to varying activity levels. When running, loads can reach up to 2.5 times body weight [53, 96, 97]. As these loads increase, the unlocked arch system progressively destabilizes, losing its structural integrity and strength, collapsing the arch system, and accelerating tension on the tie beam (intrinsic first and second layer muscles and plantar fascia) (Figure 46). These accelerating horizontal forces can stress the integrity of the tie beam components beyond their tensile or elastic capabilities, leading to plantar fasciitis or "heel spurs" [51].

Figure 46



In addition, the relative geometry of compressive forces through the arch system generates stresses that will affect adaptive bone remodeling. In external (shape) and internal (density) bone remodeling, the rate of change at a location is a function of surface strain, stress, or strain energy at that point [50].

The mechanical physics of the high stable arch system (Figures 44 & 47), by necessity, means that the compressive forces generated by the body's weight are evenly distributed at bone-to-bone articulations, most particularly through the midfoot as it articulates with the forefoot and rearfoot. A consistently smooth tendon/muscle pull facilitates healthier bone stress/remodeling vs. inconsistent/jerking/jarring actions that may cause unhealthy stress/remodeling at the tendon-bone junction. These balanced forces promote optimal bone shape and geometry during the ongoing process of remodeling.

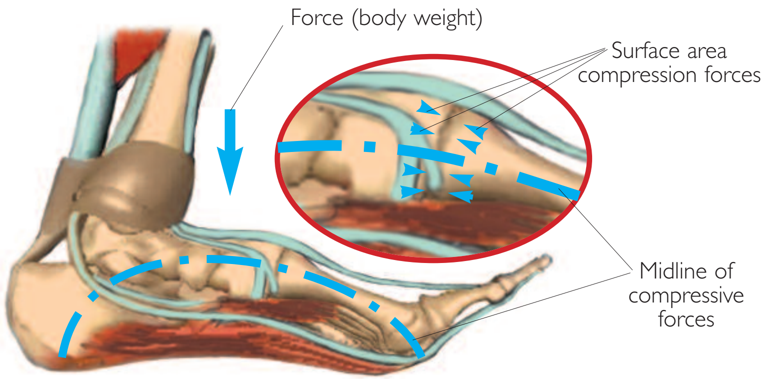


Figure 47

The mechanical physics of the unstable collapsing arch system subject the dorsal surface area of the bone-to-bone articulations in the midfoot to greater compressive forces (Figure 46 & 48). These forces are also seen in the relative articulations between the midfoot and the fore- and rearfoot. When standing, these forces are constant but increase progressively as the arch collapses due to fatigue, footwear restrictions (such as tight lacing), or the increased loads generated during gait.

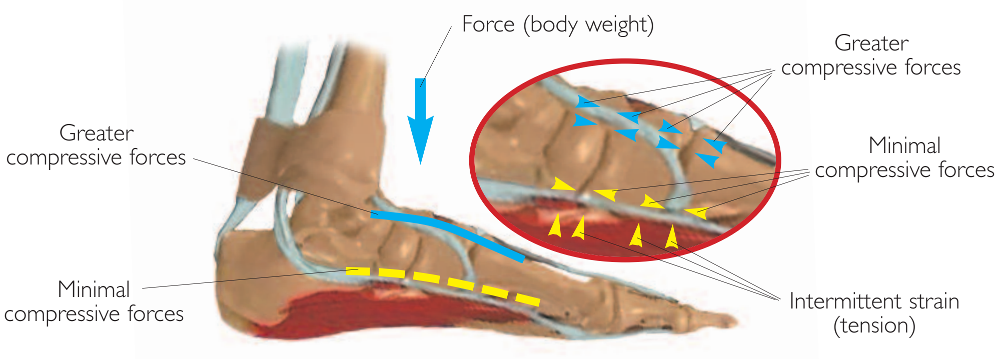


Figure 48

The plantar surface area of the corresponding bone-to-bone articulations is subject to a much lower degree of compressive force and greater tensile force at the insertion points of ligaments and muscle. These tensile stresses tend to be intermittent and accelerating in nature, and increase significantly as the arch system collapses under increasing loads. Unbalanced stresses promote poor bone shape and geometry as the bone remodels in an attempt to equalize the stress throughout the structure [50, 89]. The bone remodels *away* from the constant compressive forces on the dorsal surface areas of the bone-to-bone articulation and *toward* the intermittent tensile stresses on tendon and ligament attachment points in the plantar region, until these forces are balanced throughout the structure [50].

With the great toe unable to dorsiflex, the foot follows a number of dysfunctional paths, depending upon activity and predilection (pes planus or pes cavus). Pes planus individuals typically excessively "pronate" and pes cavus individuals typically excessively "supinate." Two of the most common pes planus [54, 65, 98, 99] dysfunctional mechanisms are detailed below:

1) In normal walking gait, at heel contact, the foot and leg are abducted excessively (Figure 49). As the body's center of mass moves forward over the foot, the foot's arch system collapses as the forefoot and midfoot increasingly dorsiflex, while the rearfoot plantarflexes and everts. The tibia and knee rotate medially (adduct) as a result. Through propulsion and toe off, the abducted foot and adducting leg cause a diagonal rolling about and over the medial side of the first metatarsal head. The propulsion stride directs the body's mass medially and forward, relative to the foot's positioning.

Figure 49 **Normal Gait**

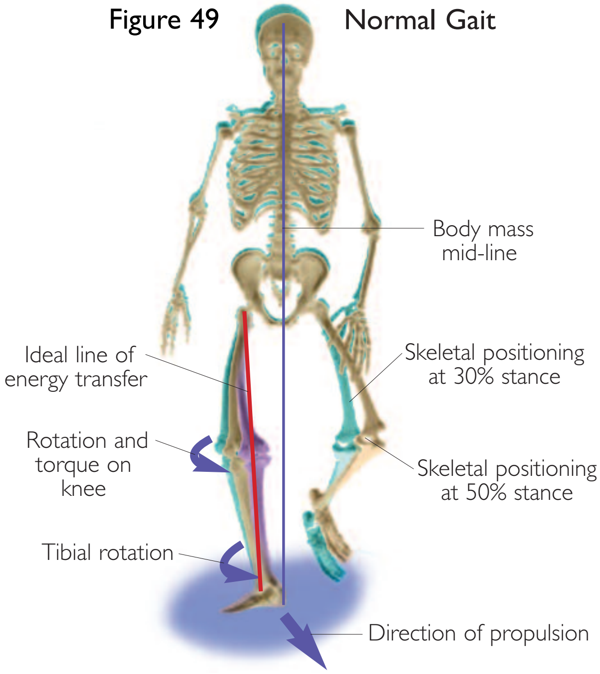


Figure 50 **Lateral Cutting Gait**

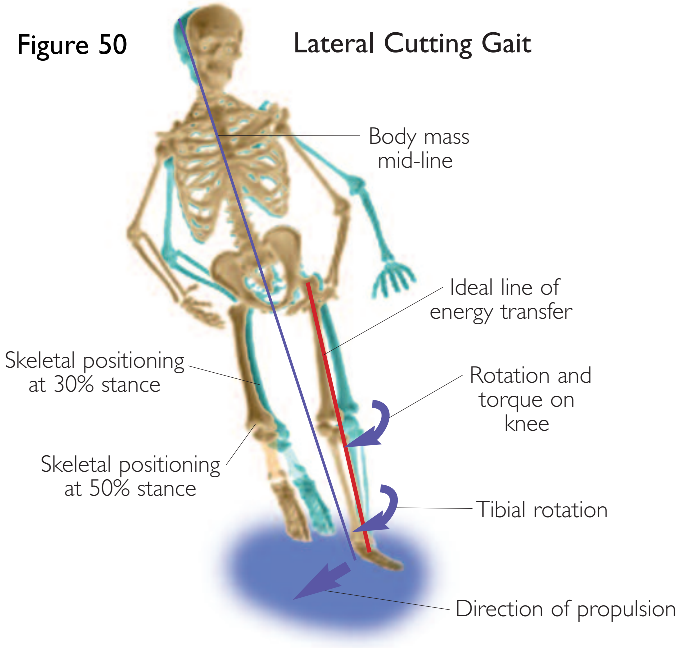
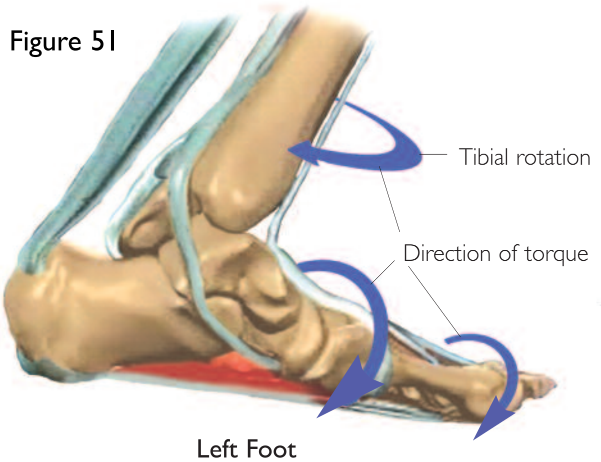


Figure 51

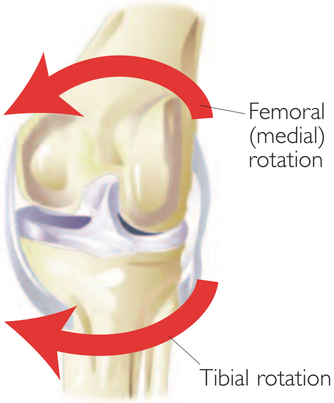


Left Foot

2) During lateral cutting movements, at contact, the foot is abducted slightly but is more in line with the body (Figure 50). At initial ground contact, the knee is abducted slightly but is predominantly pointing forward. As the force generated by the body's center of mass is absorbed by the lower limb, the foot's arch system collapses, as described above, causing a progressive acceleration of medial tibial rotation and adduction at the knee. These accelerating collapsing and torsional forces are maximized as propulsion is initiated. This produces an inefficient propulsion stride because of the poor foot and knee alignment and results in significant energy loss.

In both instances, tremendous torsional stresses are generated on the joint of the first metatarsal head and great toe (Figure 51). These stresses contribute directly to pathologies such as hallux valgus and turf toe. In addition, the foot generates a tremendous amount of torque and friction within the shoe and, depending on the shoe design, these stresses often result in excessive calluses, bunions, bunionettes, metatarsalgia, Morton's Neuroma, and "pump bumps" at the heel. Accelerating torsional stresses are also generated at the knee, contributing to ligament and cartilage damage, chondromalacia, patello-femoral syndrome, illiotibial band syndrome (ITBS), etc., (Figure 52).

Figure 52

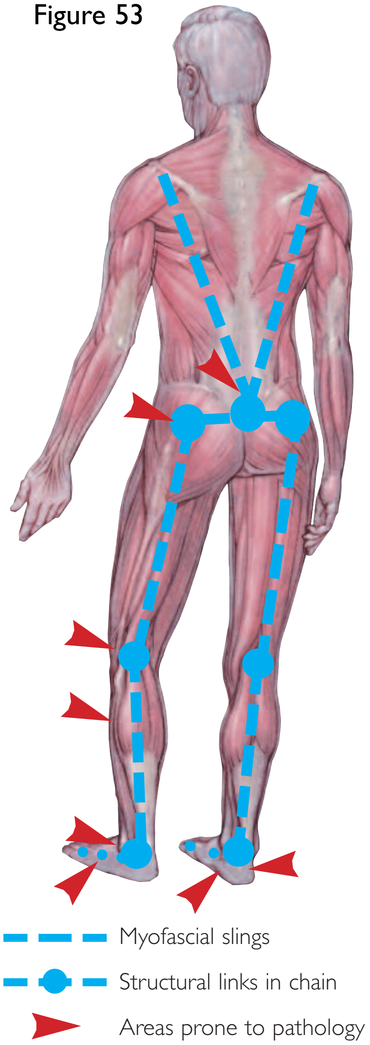


Left Knee

Individuals exhibiting pes cavus feet typically demonstrate less mid-foot flexibility and excessively supinate, invert, and toe-in through heel strike to toe off, thus rolling off the 4th and 5th metatarsal heads during propulsion. During normal walking gait, at heel contact, the foot and leg are abducted excessively. As the body's center of mass moves forward over the foot, through heel strike, full weight bearing, propulsion, and toe off, the abducted foot and abducting leg cause a diagonal rolling about and over the lateral side of the 4th and 5th metatarsal heads. The propulsion stride is inefficient, directing the body's mass laterally and forward, relative to the foot's positioning, generating tremendous torsional stresses on the 4th and 5th metatarsal heads.

While the high rigid arch is structurally capable of managing greater loads than the hypermobile foot, when its load bearing capacity is exceeded (without appropriate nociceptive and proprioceptive muscle activity), the structural integrity fails more acutely, resulting in more traumatic (sudden) degenerative stress. In addition, the foot generates a tremendous amount of torque and friction within the shoe. Depending on the shoe design, these stresses often result in excessive calluses, bunions, bunionettes, and metatarsalgia. Accelerating torsional stresses are also generated at the knee, contributing to ligament and cartilage damage, chondromalacia, patello-femoral syndrome, etc.

Figure 53



The Kinetic Chain

Regardless of foot type, habitual use of footwear that dampens somatosensory stimulus and/or creates a restrictive environment will condition improper (maladapted) muscle-firing sequences throughout the supporting musculature of the lower limb, hip, and back. Muscles will cease to fire completely or fire at inappropriate intervals [14]. This can lead to muscle atrophy (from lack of use) or hypertrophy (from overwork) and to muscles becoming easily fatigued [9]. Pathologies, such as plantar fasciitis, heel spurs, or shin splints typically develop when these dynamics are present.

When the foot's supporting musculature fails to provide structural stabilization, the resulting inefficient alignment negatively affects the mechanical geometry of the smaller and deeper levels of intrinsic musculature. Poor mechanical geometry leads to compensatory and inefficient (over-worked) muscle function, increased stress, and fatigue. These smaller muscles are best suited for fine motor control and dexterity. They are not able to effectively manage the forces generated by an unstable and poorly aligned structure.

As the unstable structure enters first into the weight bearing then propulsion phase of gait, the poorly aligned and unlocked bones are unable to effectively manage the forces and stress generated. These forces/stresses magnify as they migrate up through the musculoskeletal structure and can lead to chronic or acute pathologies at the sites of the weakest links in the kinetic chain, depending on activity levels (Figure 53). Conditions such as Achilles tendonitis, patellofemoral syndrome, knee, hip, and back problems are commonly associated with these poor structural dynamics [100].

Unfortunately, the stresses generated by poor structural dynamics are further exacerbated by footwear design characteristics – some of which were engineered to stabilize the unstable foot.

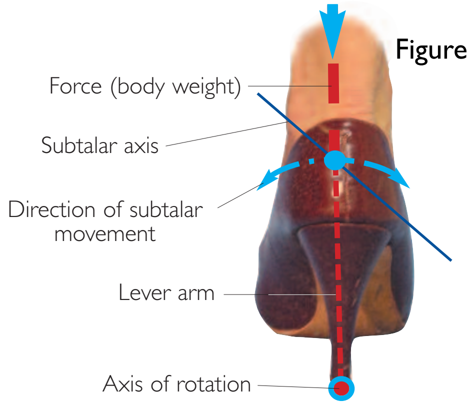
4.3 Increased Lever Arm Mechanics (Heel Height and Width)

It is commonly accepted that high heels negatively affect balance and posture, not only while walking, but while standing as well. It is also commonly accepted that there is a relationship between the height of the heel and its negative effects on the body [73, 101]. What isn't generally understood, however, is how heel height, regardless of footwear type, affects mechanical physics while standing, walking, or participating in any other gait-related activity.

Figure 54

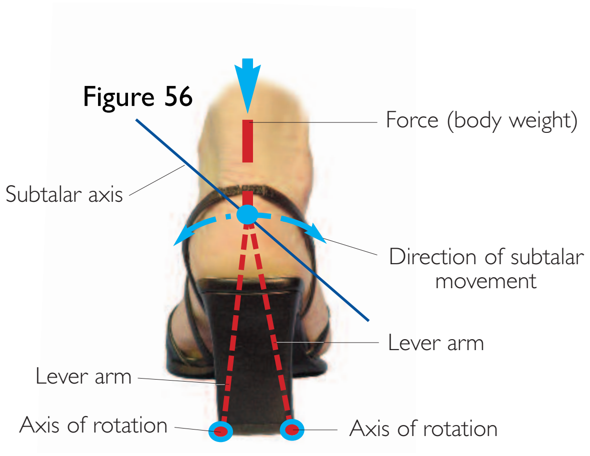
There is a corresponding relationship between heel height and the transfer of increased weight to the metatarsal heads during weight bearing (Figure 54). In order to keep from falling forward, the body attempts to compensate

Figure 55



Right foot

Figure 56



Right foot

by shifting upper body mass further back – arching the lower back and altering the mechanics at the hips. The associated muscles are then forced to compensate, increasing stress to these areas.

Heel height also dictates the degree of transverse lever arm forces that are generated through the midfoot and at the ankle. A narrow pointed heel will create a single pivot point at ground contact, centered under the calcaneus (Figure 55). As the body's weight shifts away from midline balance, movement increases about the subtalar joint, and stress is generated either medially or laterally at the ankle, depending on the direction of movement (Figure 55). Heels with wider bases provide a more stable platform while standing, but create two pivot points that increase the lever arm forces about the midfoot and ankle during gait (Figure 56).

Many shoe manufacturers incorporate designs that attempt to stabilize the foot (motion control) and reduce shock (thicker midsoles) during the gait cycle (Figure 57). Unfortunately, at best, these design characteristics function one-dimensionally when standing or when straight-line walking on a horizontally flat surface.

Figure 57

These design characteristics actually accelerate the negative forces generated by the unstable structure during gait over uneven terrain or in multi-directional activities, as described above. Increasing degrees of heel height and heel flare create pivot points (axes of rotation) and lever/moment arms that dramatically increase the speed of pronation and plantarflexion (of the shoe and foot) [73, 102, 103]. In fact, heel height and the degree of posterior heel flare directly correspond to the speed and degree of acceleration that starts at heel strike and continues through to weight bearing forefoot contact. This significantly increases the load at midstance on the arch system, particularly on the mid- and forefoot [103].

For the unshod foot, with a given amount of force (i.e., gait momentum and body weight), the speed at which the centers of mass – for each of the arch apex and metatarsal heads – rotate about the pivot point is directly proportional to their distance from the pivot point. This is clearly a fixed variable for a given unshod foot, but, when considering the shod foot, the pivot location changes from the calcaneus' center of mass to the shoe/ground interface. This increases the distance between the pivot point and the center of mass for each of the arch apex and the metatarsal heads. As a result, footwear magnifies the vertical and horizontal forces that are generated during weight bearing [103] (Figures 58 - 60). Furthermore, the shod foot, when compared to the bare foot:

1. strikes the ground sooner,
2. strikes the ground further from the body's center of mass,
3. has a greater plantar surface angle, and
4. has a greater angle of lower leg to contact surface, at heel strike.

As either heel height or posterior flare increases, the vector forces become correspondingly greater as their distance from the axis of rotation increases. At full weight bearing, the accelerating vertical forces are directed forward over the forefoot/midfoot rather than being centered over the arch apex (forefoot/midfoot/rearfoot). In addition, both the calcaneus' and foot's center of mass

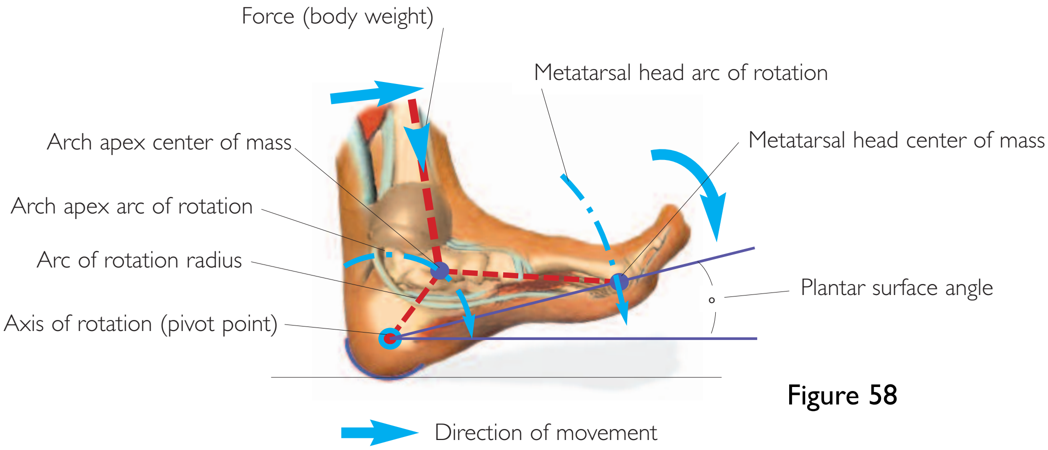


Figure 58

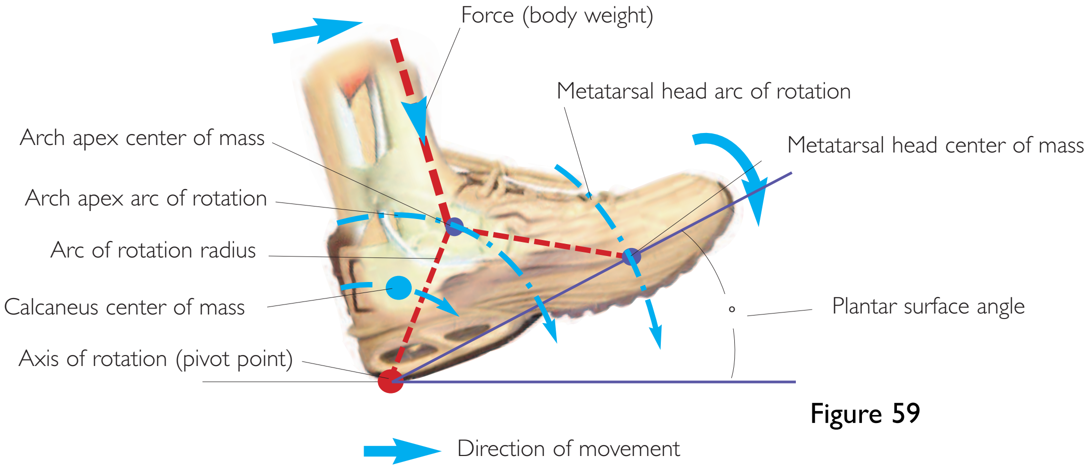
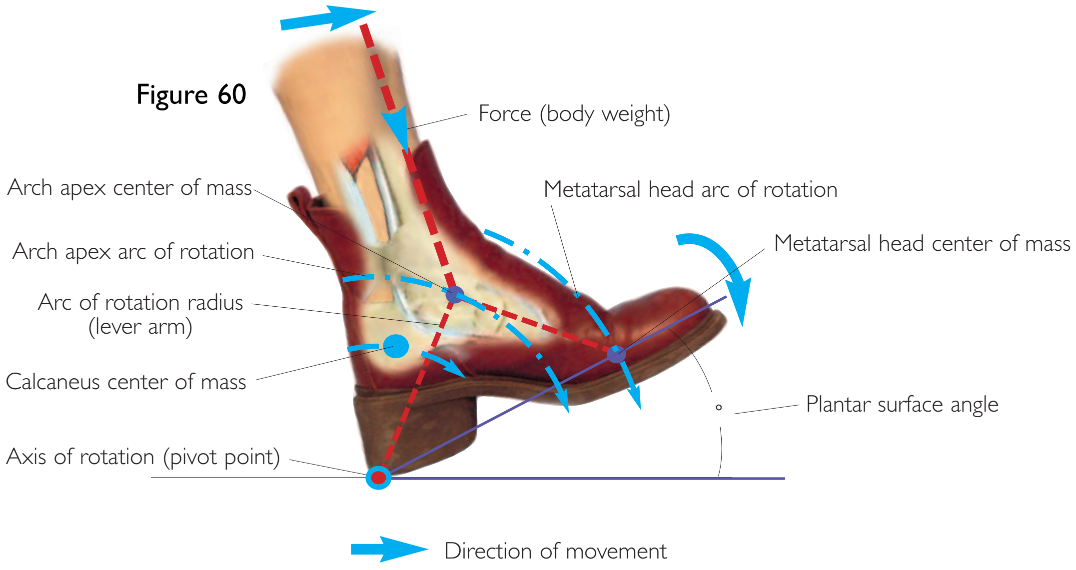


Figure 59

gain velocity as they rotate about the axis, generating horizontal momentum upon weight bearing contact. This leads to friction on the plantar surfaces of the heel and forefoot that can contribute to excessive calluses.

Heel counters, heel height, and degree of heel flare (width) directly correspond to the acceleration and velocities of pronation and eversion at lateral heel strike, and to supination and inversion at medial heel strike [97, 103, 104]. These accelerating velocities produce structural load increases of up to 400% [105]. Increases in midsole thickness and flare are also directly related to the acceleration and velocity of both forefoot eversion at lateral forefoot strike, and forefoot inversion at medial forefoot strike [104].

Figure 60



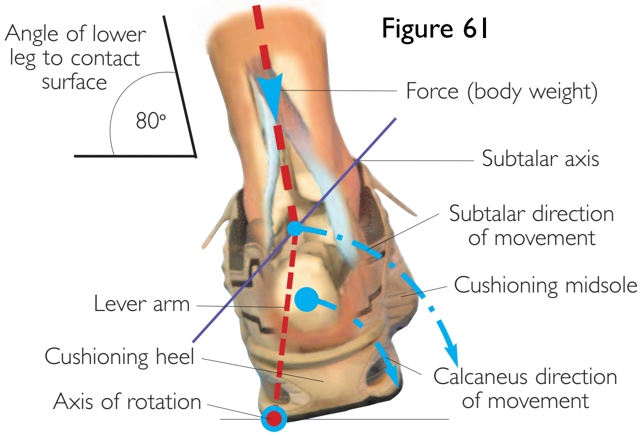


Figure 61

Left foot heel strike

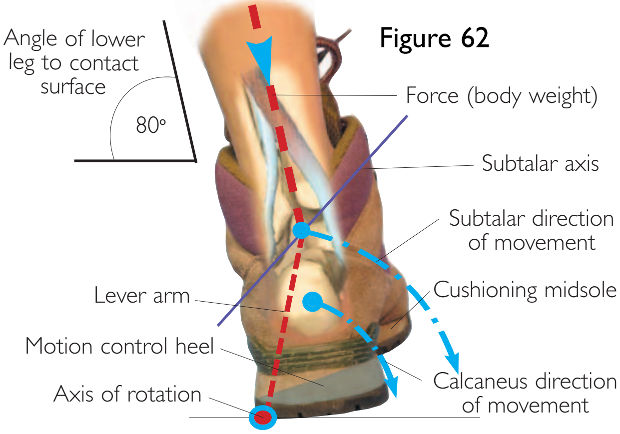


Figure 62

Left foot heel strike

Regardless of shoe midsole type, during normal shod gait on a predominantly flat surface, the lateral rear area of the heel first contacts the ground and creates a pivot point, or axis of rotation, about which the rest of the foot moves until the forefoot attains maximum weight bearing contact (Figures 61 & 62) [104]. This creates a lever or "moment" arm, whose length determines the acceleration and velocity of pronation – proportionally increasing the vertical and horizontal forces (stresses) on the forefoot. These accelerating dynamics are not present in barefoot gait.

During normal barefoot gait on a predominantly flat surface, the heel contacts the ground later in the swing phase, reducing the angle of lower leg to contact surface and making contact closer to the body's center of mass. Heel contact is slightly lateral to the calcaneus' center of mass (axis of rotation). The curvature of its plantar surface facilitates a smooth roll about the axis of rotation, allowing an efficient transition to and alignment of, the forefoot parallel to the ground at full weight bearing contact (Figure 63).

This naturally efficient dynamic is demonstrated while walking or running barefoot on varied terrain and in multi-directional (i.e., lateral sideways cutting) movements (Figure 64). Upon initial forefoot ground contact on varied terrain or during multi-directional movement, the forefoot proprioceptively aligns itself parallel to the surface area prior to contact [105]. This alignment produces the lowest torsional and torque forces through the subtalar joint, throughout the foot and up through the kinetic chain.

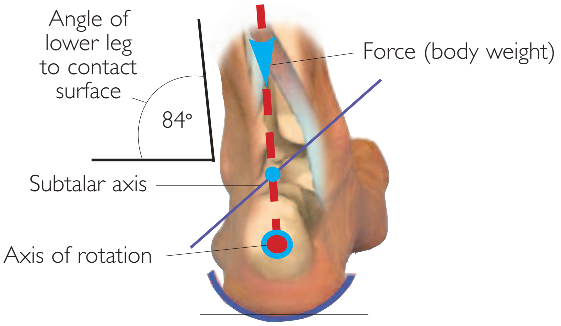
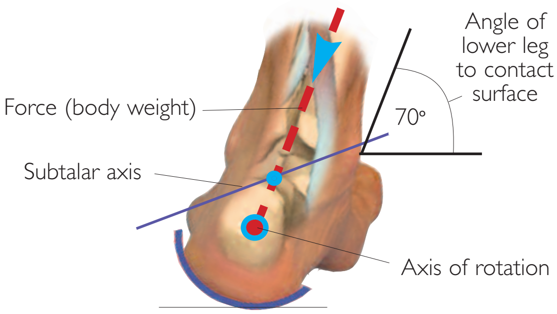


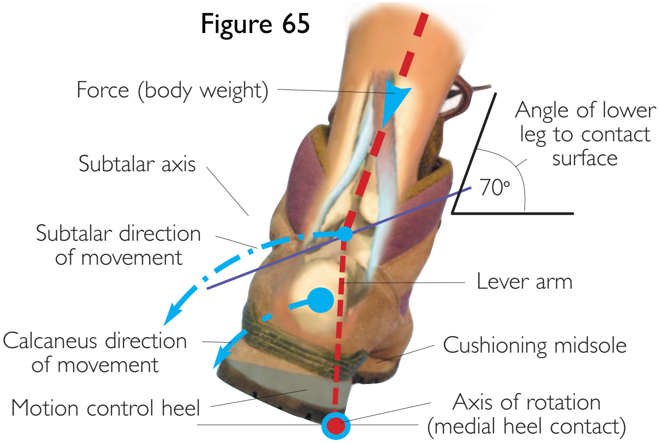
Figure 63 Left Foot



Left Foot **Figure 64**

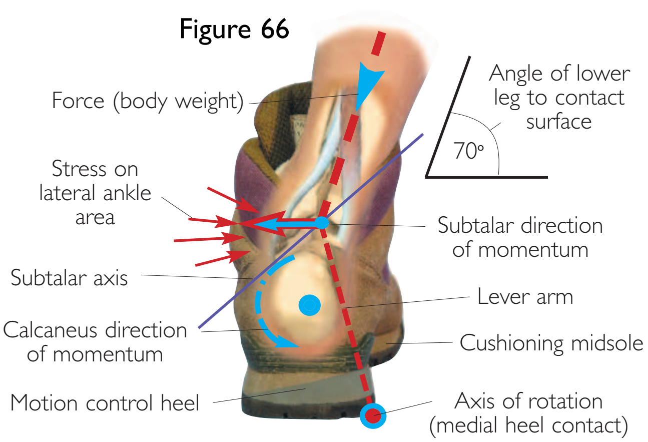
The barefoot condition also provides superior natural lateral stability during sideward cutting movements and during multi-directional activities, when compared to the shod condition [103] (Figure 64). Shoes increase the lever arm length and, consequently, increase the movement around the subtalar joint [103] (Figures 65 & 67). Given similar angles, torsion is increased from contact to full weight bearing, which is equivalent to an inversion movement of the rearfoot relative to the forefoot [103]. The degree of stress on the ligaments of the lateral aspect of the foot and ankle is directly proportional to the velocity of inversion (Figures 66 & 68). Heel counters are designed to stabilize the shoe relative to the heel to ensure that they follow the same motion. Unfortunately, by locking the heel in place (forcing it to follow the movement of the shoe), heel counters contribute to the forces generated by heel height and width.

Figure 65



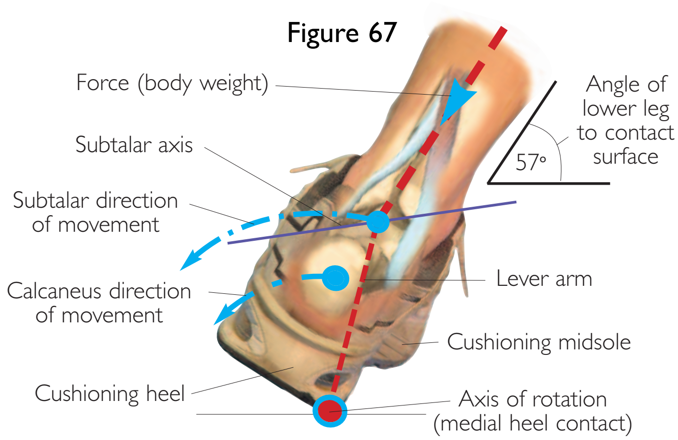
Left foot at ground contact

Figure 66



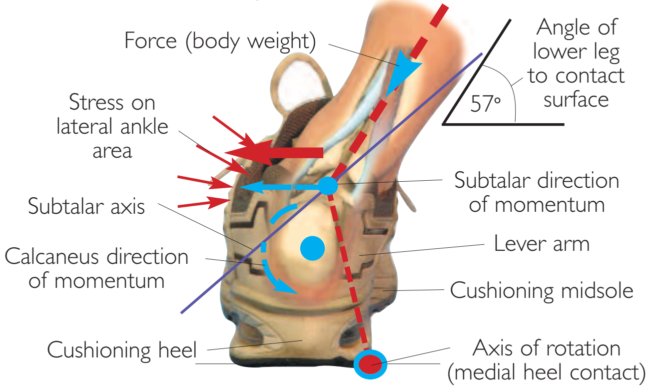
Left foot at full weight bearing

Figure 67



Left foot at ground contact

Figure 68



Left foot at full weight bearing

From a mechanical perspective, the effects of varying footwear characteristics (midsole and heel height/flare) are synergistic in their resultant accelerating velocities of plantarflexion, pronation, supination, inversion, and eversion. In varying combinations (due to design geometry), they impact significantly on structural loads, magnify the horizontal tie beam and torsional stresses throughout the foot and ankle, and negatively affect structural integrity [104]. These design geometries directly influence the location and degree of poor structural alignment and the relative increase in degenerative stress at the joints throughout the kinetic chain, particularly the knees, hips, and lower back. Clearly, footwear design characteristics play a major role in the development and exacerbation of musculoskeletal pathologies throughout the gait-related kinetic chain [14, 58, 83, 87, 88, 101, 106].

5.0 Conventional Treatments for Foot-Related Pathologies

"...current treatment of foot disorders is limited..."

Dr. Roger A. Mann, Associate Clinical Professor, Department of Surgery, University of California at San Francisco. Foot and Ankle Symposium Co-sponsored by the Canadian Orthopaedic Association and the Department of Surgery, Orthopaedic Division, University of Toronto, held at Sunnybrook Hospital, April 1996

The most common treatments for the host of pathologies that result from poor foot biomechanics focus on cushioning, supporting, or bracing the foot and ankle – often in combination. While exercise and rehabilitation programs are sometimes recommended, the focus is usually on the flexors as opposed to the extensors and compliance is usually poor. More aggressive treatments, such as surgical intervention, may be necessary in certain instances when other treatment methods prove unsuccessful, however, surgical intervention is beyond the scope of this monograph and will not be addressed.

5.1 Cushioning

Cushioning treatment options include foam, gel, felt-based insole products, and footwear that incorporates cushioning midsoles. Cushioning often presents a "comfortable" feeling initially, but it provides a false sense of security by offering benefits that are superficial at best. In reality, cushioning spreads the ground contact forces to the sole of the foot over a wider surface area – optimal subtle varied stimulus becomes an attenuated uniform stimulus.

"...consistent use of (shock absorbing) orthotic inserts did not prevent lower limb pain among healthy soldiers in basic training..."

Sherman RA, Karstetter KW, May H, Woerman AL. Prevention of Lower Limb Pain in Soldiers Using Shock-Absorbing Orthotic Inserts. Journal of the American Podiatric Medical Association, Volume 86, No. 3, March 1996

Cushioning products are purported to dissipate the vertical shock that results from chronic overloading, thereby reducing the stress to the foot. Contrary to common perceptions, cushioning products mitigate vertical shock by less than 10% at best [105, 107, 108]. Unfortunately, studies show that horizontal forces – rather than vertical forces – contribute most significantly to foot pathologies [107, 109, 110]. Research demonstrates that the control of initial pronation is of greater importance than shock absorption [7, 109, 110]. Studies indicate that cushioning the foot isolates the plantar surface from the sensory feedback it requires to induce its protective adaptations – essential for effectively managing the forces generated at impact [80, 108, 111, 112]. It has been demonstrated, in vivo, that impact remains unchanged whether the runner uses soft running shoes, hard running shoes, or is barefoot (without a barefoot adaptation period) [110, 113].

A study on U.S. Army trainees examined the prevention of lower limb pain using shock-absorbing orthotic inserts. The relatively large study tested the most effective shock absorbing insert (as per clinical comparison trials) [114, 115] and concluded that consistent use of this insert did not prevent lower limb pain among healthy soldiers in basic training and, in fact, suggested that the insert actually caused some injuries – the insert group (vs. the non-insert group) presented a slightly higher rate of several problems [114].

> *"Shock absorbing materials in the shoe are not required if subtalar joint function is normal."*
>
> Tiberio D. The Effect of Excessive Subtalar Joint Pronation on Patellofemoral Mechanics: A Theoretical Model. Journal of Orthopedic & Sports Physical Therapy 9(4): p. 160, 1987.

5.2 Support (Bracing)

5.2.1 Orthotics

Custom orthotics and similar products attempt to stabilize the subtalar joint by supporting the arch, claiming to "correct" the poor biomechanics of the foot [17, 18, 116, 117, 118, 119, 120]. This claim of correction is misleading. In reality, by their very nature, orthotics spread the ground contact forces to the sole of the foot over a wider surface area – optimal subtle varied stimulus becomes an attenuated uniform stimulus.

> *"We should have a clear body of evidence that orthoses actually work. Unfortunately we don't."*
>
> Hamill J, Derrick TR. Orthoses: Foot/Custom: The Mechanics of Foot Orthoses for Runners. Biomechanics: February 1996

Subtalar neutral position (the mechanical relationship between the talas and navicular) is often thought of as the "key" to "proper" structural alignment in the foot. Contrary to the conventional view, this mechanical relationship is dynamic in nature rather than static. That is, the relative positioning of the "subtalar joint" is determined by the nociceptive and proprioceptive reflex muscle activations (or lack thereof) in response to activity levels and terrain.

Aside from acute trauma, it is commonly accepted that most foot-related pathologies arise from unhealthy stresses generated by a biomechanically unsound structure that has been subjected to excessive repetitive activity.

Acute or chronic symptoms manifest as a result of varying levels of intensity. These symptoms impact at the most structurally unstable locations or the "weakest links" in the individual's kinetic chain relative to the repetitive activity. For example, poor structural mechanics, along with increased lever arm forces inherent in footwear design, promote excessive pronation that can lead to plantar fasciitis, shin splints, or knee problems [99]. All too often, excessive pronation is incorrectly identified as the cause of these problems when it has been demonstrated herein to be merely a clinical sign.

> *"...the results of a two-year prospective randomized national study on the treatment of heel pain. The study found inexpensive off-the-shelf shoe inserts to be more effective than plastic custom arch supports in the initial treatment of heel pain (plantar fasciitis)."*
>
> Glenn Pfeffer, M.D., San Francisco,
> Chairman of the AOFAS Heel Pain Study Group,
> American Orthopedic Foot and Ankle Society (AOFAS)
> 1996

Clearly, the real *cause* of the above noted foot-related problems is the foot's inability to align, stabilize, and lock the arch structure prior to heel strike, as influenced by restrictive footwear. These poor structural dynamics of the collapsing arch system are further exacerbated by rigid soles and by increased heel height and flare[103, 104]. It is also clear that

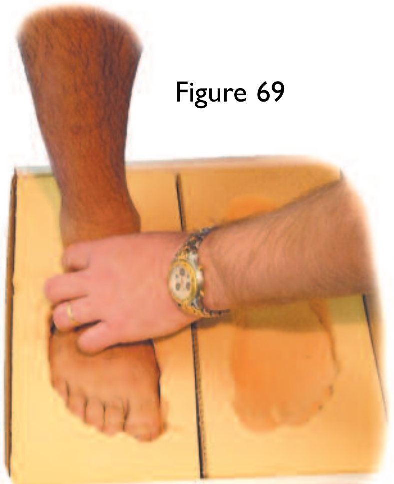


Figure 69

Figure 70

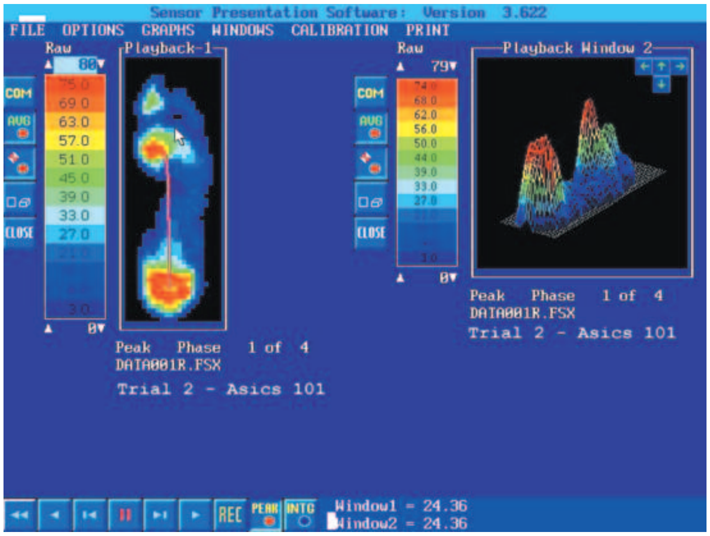
Figure 71

the relative positioning of the bones of the midfoot significantly affects the foot's ability to manage the forces generated by gait [26].

Orthotics "mask" symptoms by artificially supporting or bracing a dysfunctional structure (i.e., one that exhibits poor bone alignment), along with its inherent muscle imbalances, by simply introducing a new angle of ground interface to the foot [116].

A variety of "measuring processes" are used to develop orthotic prescriptions. Older methods involve taking a foam or plaster impression of the foot's plantar surface (Figure 69). "Corrective" posting angles for the rearfoot and forefoot are often dependent on the practitioner's expertise [117] (Figures 70). These methods are subjective at best.

Newer methods involve force plate measuring systems that produce recommended forefoot and rearfoot posting through comparison of database NORMS (Figures 71 & 72). Force plate measurement systems make inferences about foot shape through pressure distributions – measuring vertical forces on the foot's plantar surface through one step of the gait cycle, specifically heel strike to toe off. The final "custom" orthotic is usually chosen from a prefabricated inventory of varying sizes and postings (Figures 73 - 75). Unfortunately, this type of measurement system does not take into account the relative three-dimensional geometry of bone alignment, which has proven essential for normal foot function [26].



Peak Phase 1 of 4
DATA001R.FSX
Trial 2 - Asics 101

Peak Phase 1 of 4
DATA001R.FSX
Trial 2 - Asics 101

Window1 = 24.36
Window2 = 24.36

Figure 72

Figure 73

Figure 74

Initial ground interface angle

Figure 75

"Corrected" ground interface angle

In addition, impressions and measurements are commonly taken shortly after the patient removes his or her footwear. Poor structural alignment and inherent compensatory muscle imbalances resulting from the footwear are therefore reflected in the impressions and measurements.

The supportive bodies of the more state-of-the-art custom orthotics are manufactured from a rigid plastic or composite material; older technologies incorporate cork, foams, and leathers that are layered alone or in combination (Figure 73). There are a wide range of surface coverings available that include a variety of fabrics and leathers – some bonded to thin layers of foam. These materials insulate the foot's plantar surface from the sensory feedback required to induce protective adaptations necessary for healthy foot function.

Without the "corrective" postings, the orthotic body mirrors the casting impression of the dysfunctional structure (with its inherent compensatory imbalance) as it interacts with the ground – the initial ground interface angle (Figure 74). Varus or valgus wedges post the rearfoot and/or forefoot as a means to support or brace the arch (Figure 75). Contrary to claims of correcting biomechanical alignment commonly made by those who support orthotic use, the relative change in structural alignment is minimal [18, 25] (Figures 76 & 77). More accurately, the orthotic simply introduces a new ground interface angle to the plantar surface of the foot. And as noted above, by their very nature, orthotics spread the ground contact forces to the sole of the foot over a wider surface area – optimal subtle varied stimulus becomes attenuated uniform stimulus.

Figure 76

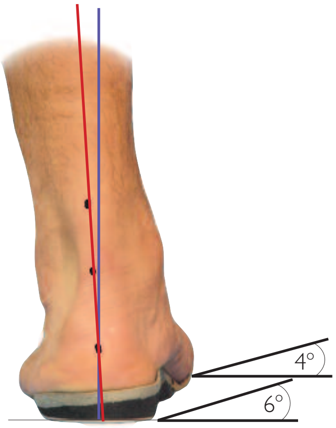


Figure 77

Figure 78 Right foot shod with orthotic

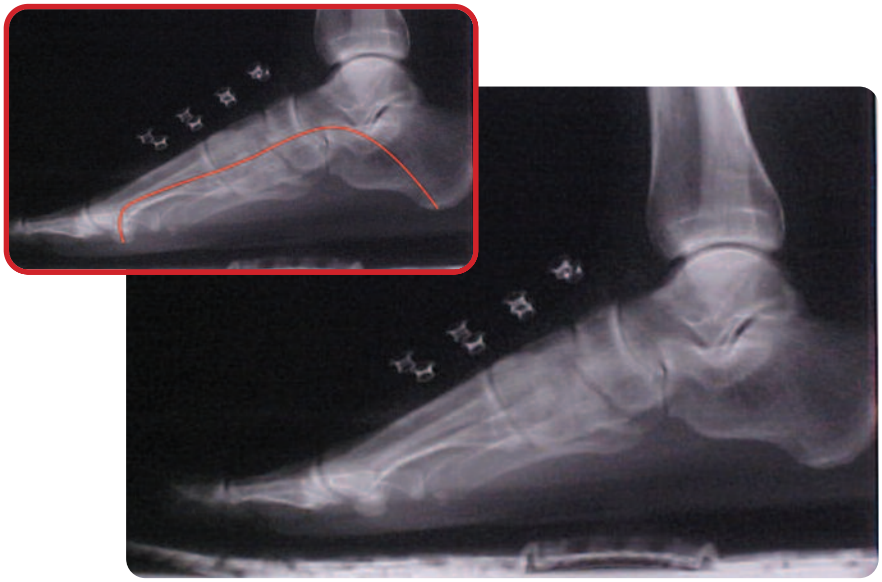


Figure 79 Right foot shod without orthotic

To clearly identify the effects of orthotics on structural alignment in the foot, x-rays were taken of three subjects' feet – with and without orthotics in their shoes. Figures 78 & 79 contain the x-rays for one individual. The x-rays were taken during full weight bearing and within a ten minute time period. The orthotics used were a commonly prescribed type – "corrective" postings for the forefoot and rearfoot ranged from 4-6 degrees. A medical professional had previously determined that all three subjects required orthotics. In every instance, the orthotics had little or no effect on the relative alignment or structural integrity of the interlocking bones, specifically in the midfoot – an area identified as significant to normal (healthy) foot function [26]. The only appreciable change observed in the relative alignment was strictly a result of the increased heel height (Figure 80). In all instances, the bones of the foot remained "unlocked," and functionally unstable.

Viewing the x-rays and comparing the arcs created by the arch structures' center of bone mass reveals little, if any, difference in their relative geometry (Figure 80. When the arcs are rotated and placed on a horizontal plane, they are virtually identical (Figure 81).

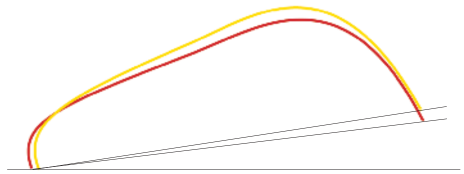


Figure 80

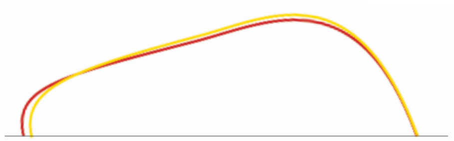


Figure 81

By bracing (supporting) the foot with "corrective" postings, the orthotic is purported to "force" the foot to follow a more biomechanically sound pattern of movement throughout the gait cycle.

The claims and benefits of foot orthotic therapy have generated controversy amongst researchers and foot care practitioners [1,18, 103, 106, 117, 121, 122, 123].

Researchers have gathered qualitative data from patient surveys to offer proof of orthotic efficacy [106]. Several quantitative studies have demonstrated that orthotics affect both the kinetics and kinematics of gait when used by pronated subjects. Unfortunately, repeating quantitative results has proven difficult, with many researchers unable to confirm the quantitative effects of orthotics or find significant variations in their effects [18, 106, 119, 120, 121].

From a mechanical perspective, orthotics simply cause a shift in the dynamics of repetitive movement by introducing a new angle of ground interface. The symptoms resulting from the old dynamic disappear and the problem seems to be corrected, but this effect is temporary. Unfortunately, over time or with increased activity levels at the new ground interface angle, the repetitive movement often results in the appearance of new symptoms at different locations. A repetitive cycle emerges as new orthotics are prescribed to compensate for ever-migrating symptoms and pathologies. Current practice is to recommend new orthotics approximately every two years, generally with increases in the forefoot and rearfoot postings.

A study on the effects of shoe insert construction (orthotics) found that the most common harder inserts allowed for more individual variation of foot and leg movement and did not force the foot into preset movement patterns [120]. The individual results showed substantial differences between subjects and, therefore, did not indicate a trend.

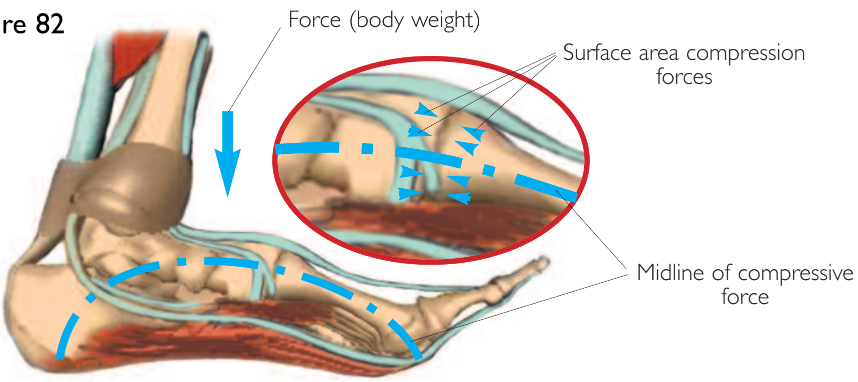
Medial wedges (postings) alter the angles of the weight bearing surface that affect tension on the plantar fascia [53, 123]. Medial wedges or postings are commonly incorporated into orthotics with a view that they will reduce this tension. Contrary to conventional teachings, an in vitro study found that medial wedges (postings) on the forefoot significantly increased the strain on the plantar aponeurosis; lateral wedges reduced the tension; and heel wedges had no significant effect [123].

From a bone remodeling perspective, orthotics change the manner in which forces are managed throughout the structure. In a foot with a dynamically controlled arch, the vertical forces generated by body weight

> *"No one method for measuring STJ neutral has been proven accurate and reproducible by different testers."*
>
> Miller M, McGuire J. Literature Reveals No Consensus on Subtalar Neutral. Biomechanics: p. 63, August 2000

result in horizontal compressive forces through the foot's arch system (Figure 82). By supporting the medial side of the foot, the orthotic manages the vertical loads in place of the arch system (Figure 83). The forces remain vertical throughout the bones of the foot's arch system and the structure remodels in response, leading to a weakened structure and an increased dependency on the artificial support [56].

Figure 82



Rearfoot posting of orthotics increases the relative lever arm forces associated with footwear heel height and width (Figures 83, 84 & 85). This proportionately increases the acceleration and velocities associated with plantarflexion, pronation, inversion, and eversion, and the loads on the structure [104]. Therefore, risk of lateral foot and ankle injury increases with orthotic use, particularly in side to side cutting movements, as the forces increase through the unlocked and misaligned structure.

There is no evidence that orthotics rehabilitate the neuromuscular functional dynamics of the foot, and thus, claims of correction have no actual scientific basis [119, 120]. It is important to note that in virtually all areas of musculoskeletal medicine, long-term bracing is not the recommended treatment of choice. Orthotics may be lucrative for those who are dispensing them, but from the user's perspective, it is clear that a more effective rehabilitative treatment and preventative methodology is preferred.

Figure 83

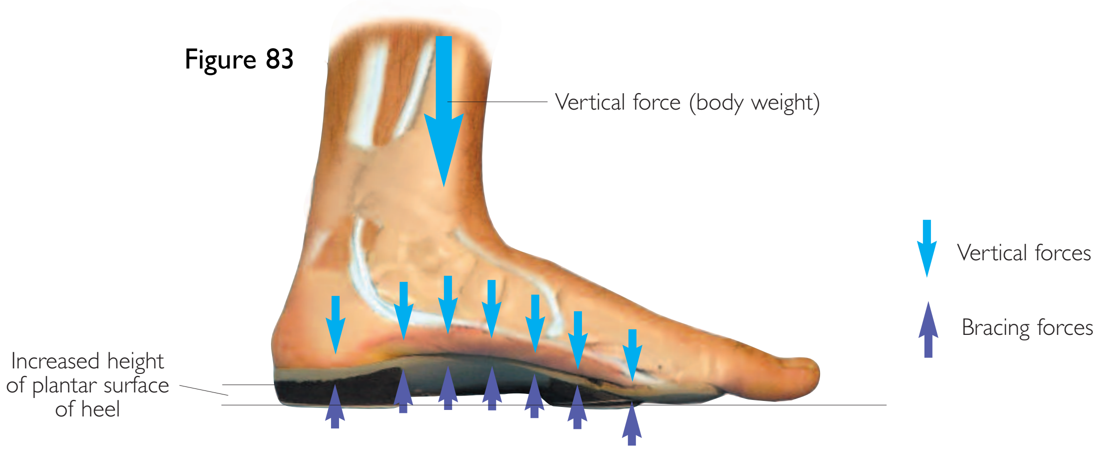
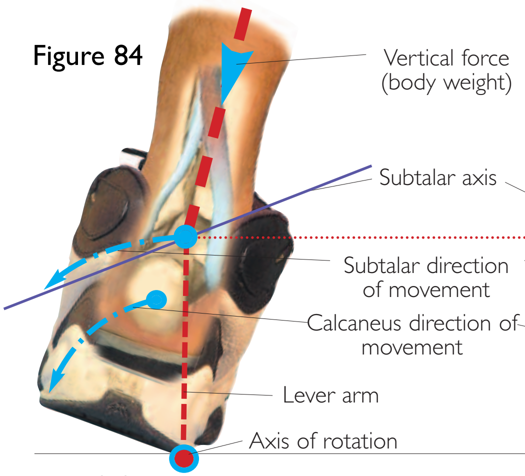
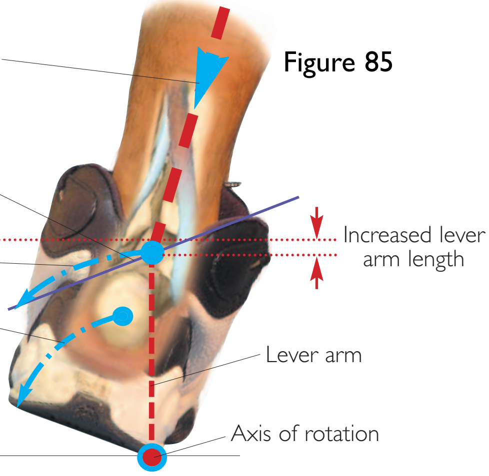


Figure 84



Left foot with orthotic

Figure 85



Left foot without orthotic

5.2.2 Taping and Ankle Braces

Foot and ankle taping or ankle braces are commonly used to support an injured area or to prevent injury from occurring (Figure 86). Ankle taping is commonly used by both professional and amateur athletes as a preventative measure.

As demonstrated, restrictions inherent in footwear design destabilize the structural integrity of the foot and ankle. In addition, athletic footwear manufacturers incorporate stabilization or motion control features in an attempt to stabilize the structure. Unfortunately, these design characteristics actually increase the stresses on the ankle. Ankle taping and braces are used in an attempt to protect the foot and ankle from these stresses, but conversely result in structural atrophy and an increased dependence on the artificial support.

Studies on external ankle supports (braces) suggest that they negatively affect balance [58, 124, 125, 126]. Athletes wearing them showed greater fluctuations in ground reaction force and touched down more frequently with the non-supporting foot. The researchers believed that posture control and balance were adversely affected by the supports due to restriction of normal ankle movement. They indicated that braces may provide a false sense of security and would not endorse them for prevention purposes, cautioning that, even during rehabilitation, they should not be used for prolonged periods [124, 125, 126].

While ankle taping improves foot position perception for people wearing athletic footwear, foot position awareness remains poor when compared to the barefoot condition – with taped and un-taped subjects wearing athletic footwear demonstrating 58.1% and 107.5% poorer foot position awareness respectively [58].

Figure 86

5.3 Exercise (Rehabilitation)

Exercise as a means of rehabilitation is a common therapy throughout musculoskeletal medicine. In fact, exercise, where appropriate, is usually the first treatment of choice, prior to more radical options, such as surgery. Many orthopedic surgeons recommend a regimen of exercise, both before and after surgery, as a means to speed recovery times. Mobility braces are commonly used after reconstructive ligament surgeries (i.e., at the knee) to reduce scar tissue formation and maintain mobility at the joint.

The most commonly recommended exercises for foot pathologies focus on rolling a ball or cylinder with the sole of the foot, plantarflexing the toes, or using the toes to grasp an object. These exercises may provide some benefit, but the muscular sequences involved have very little relevance to gait mechanics.

The most beneficial foot exercise would involve multi-directional barefoot activity on diversified terrain to enhance neuromuscular function and develop a balance of strength and flexibility throughout the lower limbs, hips, and back. However, this type of activity is impractical for most individuals [9, 14, 71].

Regardless of the exercises involved, the amount of time spent to achieve some positive benefit would be in direct proportion to the amount of time the person had been wearing restrictive footwear. While exercise is promising for most individuals, it is limited by time constraints, hence the typically poor compliance.

6.0 Foot Care Steps in a New Direction

The abundance of research, mechanical physics models, and quantitative evidence presented herein clearly demonstrates the negative environmental influences associated with footwear use and its correlation to poor foot function, increased stresses, and resulting pathologies. It is also clear that conventional theories and treatment methods are founded on erroneous assumptions regarding foot function – that the foot structure is inherently weak and as such, requires artificial support and cushioning.

In essence, footwear weakens the structure by impairing the foot's sensory response to the ground, while also restricting both movement and optimal structural alignment. These factors, alone or collectively, can lead to structural instability. Conventional treatment methods attempt to mitigate instability by incorporating additional restrictions through support/bracing or cushioning areas of peak pressure, but inadvertently create a never ending cycle and an ever-increasing dependence on the artificial support.

Conversely, research has demonstrated that the unfettered dynamic of barefoot gait, whether habitually unshod, or through increased barefoot activity, leads to optimal foot development, a significant reduction of structural loading, optimal stability, and the fewest incidences of pathologies [9, 11, 12, 13, 14, 127].

This should not be surprising given that the health benefits of exercise, which promotes a balance of strength and flexibility (full range of motion) in opposing muscle groups, is universally considered important for normal, if not optimal, musculoskeletal function. It is also widely accepted that the application of moderate exercise to a weakened (injured) area of the musculoskeletal system will lead to improved strength, mobility, and structural integrity of the affected area.

It would seem self-evident that these principles are equally applicable to the foot and lower limb.

Clearly, footwear provides protection from the elements and from hazardous environments, and for some individuals affords socio-economic status through fashion appeal or perceived athletic performance. "Going barefoot" is not a practical solution in today's modern world.

It follows that the development and incorporation of footwear design characteristics that facilitate the dynamics of barefoot gait should be a priority in the prevention and rehabilitation of foot-related pathologies. These characteristics can be separated into three different categories:

1) Introduction of subtle varied stimulus to facilitate the protective adaptive response necessary for optimal neuromuscular function, optimal structural alignment, and reduced stress.
2) Elimination of restrictions that inhibit dorsiflexion of the digits, allowing optimal structural alignment.
3) Midsole and outsole geometry and material properties that incorporate ground contact angles to promote rotational axes through the bone structures' center of mass.

Footwear incorporating these design characteristics would actually facilitate the development and maintenance of optimal stability and structural integrity of the foot's arch system. Regular use of such footwear would encourage optimal foot, leg, hip, and lower back health, optimal athletic performance, and would significantly reduce risk of injury and pathology.

"...the development of a prophylactic orthotic would be of great benefit in the prevention and treatment of foot disorders."

Dr. Roger A. Mann, Associate Clinical Professor, Department of Surgery, University of California at San Francisco. Foot and Ankle Symposium Co-sponsored by the Canadian Orthopaedic Association and the Department of Surgery, Orthopaedic Division, University of Toronto, held at Sunnybrook Hospital, April 1996

6.1 First Generation Arch Stimulus Insoles

Gardiner's initial arch stimulus insoles, developed in the 1990's, provided a revolutionary approach to not only rehabilitate the foot's dysfunctional structure, but to actually prevent problems from occurring in the first place. Sold as "Foot Strengthening System" insoles since 1998, they have been used by medical professionals, consumers, and professional athletes.

The Foot Strengthening System ("FSS") insoles were designed to facilitate the dynamics of barefoot gait while using conventional footwear and to overcome footwear-related design disadvantages by introducing a nociceptive/proprioceptive response stimulus to the sole of the foot's arch area.

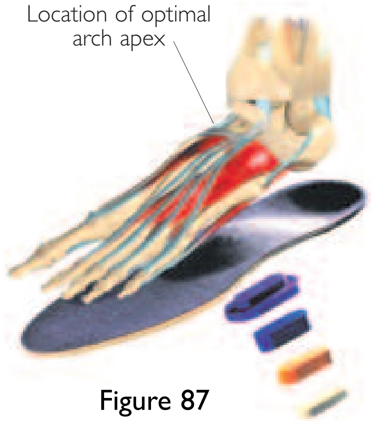


Figure 87

6.1.1 Foot Strengthening System Insoles ("FSS Insoles")

6.1.1.1 The Mechanical Physics

As identified in Section 4.2.2, Unhealthy Musculoskeletal Mechanics, the mechanical physics of the arch system dictate that, as the structure collapses, the vertical forces of body weight result in greater tensile loads on the plantar aponeurosis. With orthotics, vertical loads are borne by the orthotic rather than the skeletal structure (Section 5.2.1, Orthotics). This leads to an increase of degenerative stress and/or atrophy, and an increased dependence on the artificial support. In such instances, the body is naturally responding (via modeling or conditioning) to the inhibiting/restricting environmental influences of conventional footwear.

However, this modeling or conditioning process can also be used to advantage by incorporating into footwear/insole design a safe barefoot-like nociceptive/proprioceptive stimulus to the foot's sensitive plantar surface.

The FSS insoles were designed to take advantage of these mechanical dynamics by introducing stimulus to the sole of the foot, sufficient to create a nociceptive/proprioceptive (reflex) response, which safely initiates and retrains the muscle-firing sequences that align, stabilize, and lock the foot's interlocking bones. The shape and unique dome design (Figure 87) generates a gentle recoil pressure on the foot's sensitive plantar surface area at a location directly beneath the midfoot that corresponds to the Optimal Arch Apex (height) during weight bearing (Figures 88 & 89).

Figure 88

The FSS Insoles incorporate a series of resilient and progressively firmer/higher interchangeable inserts that act as nociceptive/proprioceptive catalysts to stimulate an involuntary adaptive sensory response (Figure 87).

Typically, the user starts with the softest/lowest insert and progresses steadily through to the highest/firmest insert as the structure adjusts to the stimulus. The degree of stimulus generated is inversely proportional to the structural integrity of the foot's arch system; the higher and more stable the arch, the less stimulus generated.

Figure 89

With an unstable arch structure, the FSS insoles produce a noticeable but not uncomfortable pressure (noxious stimulus) on the foot's plantar surface (activating the nociceptors/mechanoreceptors) (Figure 88). Due to the mechanical physics, the stimulus increases progressively as the arch system collapses (i.e., the forefoot and midfoot increasingly dorsiflex and evert while the rearfoot plantarflexes and everts). By the nature of their design and materials, the dome and insert flatten out with increased loads and, therefore, do not brace or support the foot, nor do they mechanically manage the vertical loads.

The shape, positioning, and resiliency of the dome and inserts allows the foot an uninhibited full range of motion through three-dimensional movement (regardless of terrain geography or activity – standing, walking, running, diagonal cutting movements, etc.). The dome's shape and positioning was designed to direct the stimulus to a precise and consistent location on the plantar surface. The dome's positioning was intended to ensure that an appropriate protective adaptation response is initiated regardless of activity (Figure 90).


Figure 90

The FSS insoles' stimulus affects the structure in two similar yet distinct ways: (1) when standing and (2) during gait.

1. When standing, as the arch system collapses, a constant increasing pressure is generated on the sensitive plantar surface (Figure 91). The involuntary neuromuscular response (i.e., withdrawal reflex) is to retract the midfoot up and away from the pressure, plantarflexing and inverting the forefoot and midfoot, while dorsiflexing and inverting the rearfoot (Figures 90 & 92). Every time the arch collapses, the foot is automatically "reminded" to stabilize itself, or "pull away" from the stimulus. Therefore, over time, the muscles are conditioned to attempt to maintain the Optimal Arch Apex necessary to effectively manage loads through the arch system. When standing for long periods, this repetitive action encourages the foot to "move," counteracting the lethargy propagated by footwear's restrictive nature and insulation from plantar surface stimulus.

2. During gait, the FSS insoles generate little or no pressure (noxious stimulus) while the foot is off the ground, however, as the arch system collapses upon weight bearing (Figure 91), the pressure (noxious stimulus) generated on the sensitive plantar surface increases proportionately to the intensity of activity. For instance, running will generate greater forces than walking. In these instances, the body's protective adaptive response to the noxious stimulus is an involuntary neuromuscular response (i.e., proprioceptive reflex) that attempts to pre-align the structure to its most stable position prior to weight bearing as a means to mitigate the intensity of the noxious stimulus (relative to the activity levels) (Figure 93). Therefore, a higher arch dynamic is triggered when running compared to walking. With each weight bearing step, the brain is "reminded" to pre-stabilize the feet to prevent the pressure from occurring. Over time, this conditions muscle-firing sequences that more closely resemble those that maintain the Optimal Arch Apex, prior to and during weight bearing.

Figure 91

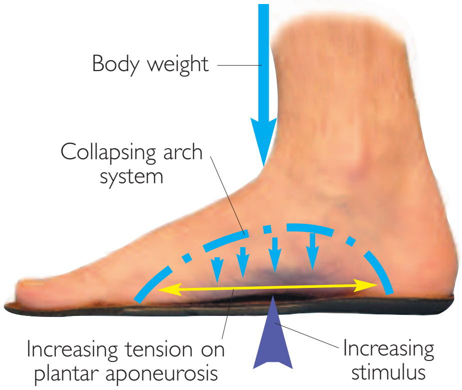
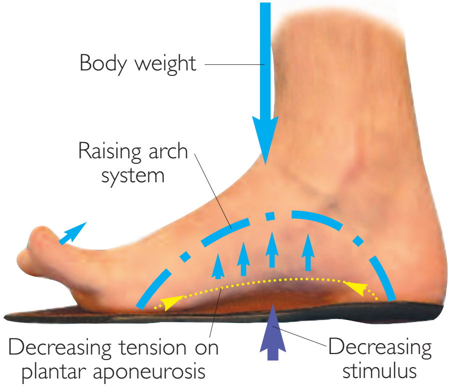


Figure 92



While standing or during gait, the nociceptive/proprioceptive reflex triggers contractions of the tibialis anterior, tibialis posterior, anterior extensors, and peroneals (a.k.a. fibularis) – the only muscles that can efficiently create

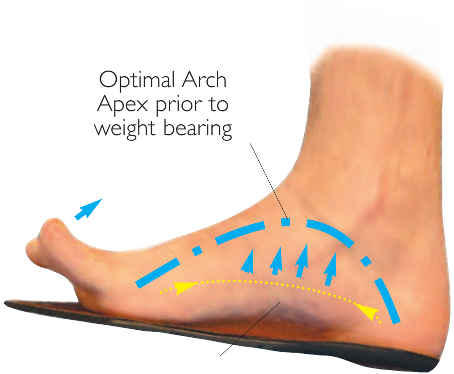


Figure 93

and stabilize the arch apex, and effectively raise the sensitive plantar surface area up and away from the noxious stimulus.

With sufficient ongoing use of the FSS insoles, the foot is safely and progressively conditioned to function similar to the function described in Section 3.2.2, Ideal Muscle Mechanics. Relative to the restrictiveness of the footwear that the insoles are used within, the following neuromuscular activity occurs:

- Contraction of the tibialis anterior, tibialis posterior, and peroneals (fibularis) attempt to raise the medial and lateral aspects of the arch system.
- Contraction of the peroneus (fibularis) longus "cinches" the midfoot transversely; while contraction of the extensor hallucis longus creates the "Windlass Effect"(i.e., dorsiflexion of the great toe and plantarflexion of the first metatarsal).
- The remaining extensors dorsiflex the associated digits and plantarflex the metatarsals.

These muscle-firing sequences attempt to align the interlocking bones of the foot into the most structurally sound dome-like dynamic or Optimal Arch Apex (Figures 90, 92 & 93). The intrinsic musculature of the foot then fulfills its primary role as a means of fine-tuning both balance and the structure's interaction with the ground.

With optimal muscle-firing, the foot and kinetic chain are now capable of functioning as described in Section 3.2.5, Ideal Gait Mechanics, with optimal structural integrity and alignment maintained up throughout the body through a wide range of three-dimensional movements. As a result, the entire structure demonstrates a greater mechanical ability to safely manage greater loads, is more energy efficient, demonstrates enhanced natural shock management, and is capable of superior performance with the lowest risk of injury.

Through the continuous stimulation of neuromuscular responses, the FSS Insoles attempt to counteract the restrictive environmental influences of most footwear that lead to muscle atrophy and structural instability. However, excessively rigid or restrictive footwear can, to a relative degree, impede optimal structural alignment and mechanical function. Optimal results are achieved with soft flexible footwear that allow uninhibited dorsiflexion of the great toes and raising of the optimal arch apex.

6.1.1.2 Testing

The FSS insoles have undergone extensive testing, with quantitative and qualitative data acquired.

6.1.1.2.1 Changes in Foot Length

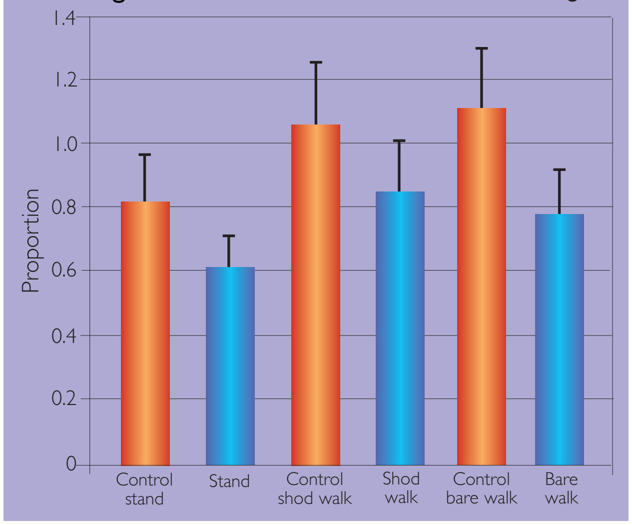
A six week pilot study on the effects of the FSS insole prototypes, conducted at the University of Huddersfield in the UK, concluded that the technology appears to be affecting foot shape and, therefore, may affect foot function. A slight reduction in foot length, along with a shortening of the medial, lateral, and transverse arches, and reductions in the valgus index were observed in the test group. The results only show trends as opposed to statistical significance due to the small sample numbers and lack of a control group [129]. The observations were similar to those found in a study on increased barefoot activity in the habitually shod.

6.1.1.2.2 Changes in Plantar Surface Area Due to Proprioceptive Response

An eight week study on the effects of the FSS insoles on weight bearing plantar surface area reinforced the Huddersfield findings. Test subjects consisted of a control group and an experimental group. All experimental group subjects used the FSS insoles in their regular footwear over the duration of the study [130]. F-Scan weight bearing surface area measurements were taken of all subjects prior to their use of the System and changes in both groups were monitored every two weeks over the duration of the study. Three tests were conducted on both test groups: static unshod standing, dynamic unshod walking, and dynamic shod walking. The test subjects did not use the FSS insoles in their footwear during the measurement process. Data was collected for two experiments: Experiment One assessed the relative plantar surface change over the duration of the study between the experimental group and control group, and Experiment Two measured the proportional plantar surface area change in the experimental group over time.

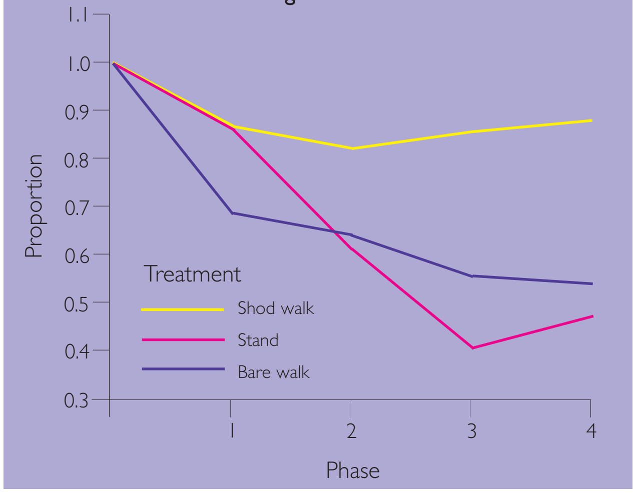
Experiment One results: A significant difference between the test and control groups was observed for the barefoot walking condition. After eight weeks, the test group showed an average 15% decrease in plantar surface area, while the control group did not change. No significant differences were observed among the test and control group for the standing and the shod walking conditions, however, a general trend was observed, indicating a decrease in surface area over time for the standing (averaged 11%) and shod walking conditions (averaged 10%) (Figure 94).

Figure 94 Relative Plantar Surface Area Change



Experiment Two results: An interaction was observed between treatment type and phase. Both standing and barefoot walking showed a marked decrease in plantar surface area over time, while shod walking decreased only slightly (Figure 95).

Figure 95 Proportional Plantar Surface Area Change Over Time



The smaller decrease of plantar surface area observed in the unshod standing results vs. the unshod walking results is attributed to the reduced loads while standing (lower proprioceptive stimulus) and the increased loads while walking (greater proprioceptive stimulus). In the shod walking condition, the initial decrease, followed by a leveling off, is attributed to the constricting effect of footwear.

The study concluded that the decrease in weight bearing plantar surface area was attributed to an anatomical restructuring of the foot in response to the gradual biofeedback created by the FSS insoles. It also concluded that the insoles stimulated the foot's supporting musculature to fire in sequences that were similar to those attained in barefoot gait.

Although the limitations of F-Scan measurement protocols prevented plantar surface area measurements while the FSS insoles were in use, the above noted studies clearly demonstrate a relationship between the insoles' use and a decrease in weight bearing plantar surface area and foot length, over time. As identified in Section 3.2.2, Ideal Structural Mechanics, a reduction of arch (tie beam) length corresponds to an increase in arch height in the same foot. In addition, there is a direct relationship between the length and height of a foot's arch system and the structure's load bearing capabilities. During weight bearing gait, a decrease in arch (tie beam) length can only be achieved by the muscle-firing sequences that raise the midfoot and create the Windlass Effect [64, 65, 66]. These sequences involve: contraction of the tibialis anterior and peroneus (fibularis) brevis, which raises the medial and lateral aspects of the arch system; contraction of the peroneus (fibularis) longus, which "cinches" the mid-foot transversely; and contraction of the extensor hallucis longus, which creates the "Windlass Effect"(dorsiflexion of the great toe and plantarflexion of the first metatarsal) (Section 3.2.4, Ideal Gait Mechanics).

6.1.1.2.3 Motion Capture Gait Analysis

Two motion capture studies were undertaken to determine FSS insoles' effect on the foot's structural mechanics.

6.1.1.2.3.1 Study One

The test protocol involved videotaping the medial sides of both subjects' bare feet prior to the start of the study, then every two weeks thereafter, over an eight week period. A digital video camera was set one meter away from and perpendicular to a reference mark placed on the ground, indicating exact positioning of the medial side of the foot. Once in position, all subjects were asked to raise their great toe as high as possible during stationary full weight bearing. The subjects then made a number of walking passes (with full weight bearing contact on or near the reference mark) through the camera's viewing range (Figure 96).

The test group subjects consisted of twelve police officers that walked for the majority of their eight hour shifts. During work hours they wore regulation footwear (same style and design). All subjects used the FSS insoles in all their footwear over an eight week study period and made no other changes in their regular activities.

Figure 96

At the end of the study, the video data was analyzed in freeze frame (30 frames per second). Angular measurements were taken on the degree of great toe dorsiflexion, frame by frame:

- during full weight bearing (maximum possible while standing),
- at heel strike (walking gait),
- immediately prior to forefoot contact (walking gait), and
- at toe off (walking gait).

The averaged results indicate substantial increases in great toe dorsiflexion over the duration of the study (Figure 97). Great toe dorsiflexion increased by 26.45% for maximum weight bearing (while standing), 34.29% at heel strike, 51.43% at pre-forefoot contact, and 15.9% at toe off. These results clearly indicate that the FSS insoles made a significant beneficial impact on the muscle-firing sequences required to stabilize the foot structure prior to full weight bearing.

6.1.1.2.3.2 Study Two

Motion capture analysis was undertaken to determine the FSS insoles' effect on structural mechanics during their actual use. Data was collected using the protocols outlined in Study One (above) to determine angles of great toe dorsiflexion for the barefoot condition during the walking gait cycle. This information was then used as a baseline for data collected during repetitive gait cycles using a strain gauge (timing and degree of great toe dorsiflexion) and magnetic positioning sensors (relative joint alignment positioning).

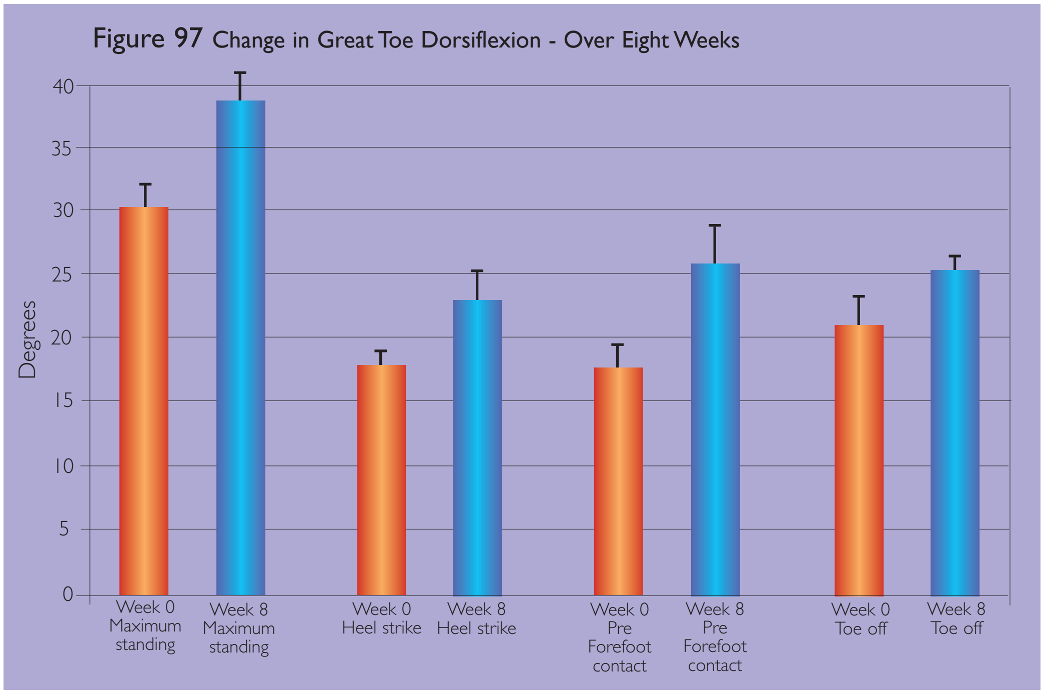
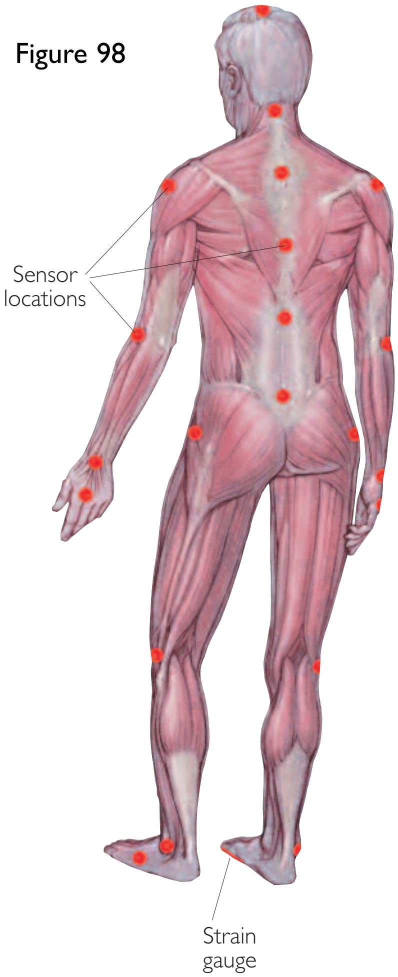


Figure 97 Change in Great Toe Dorsiflexion - Over Eight Weeks

The study monitored the musculoskeletal function and alignment of three test subjects who had used the FSS insoles for at least two months and one control subject with no previous orthotic or shoe insert experience. The control subject was a 26-year-old male who demonstrated "normal" foot function with no history of foot problems. The demographics of the test group were as follows:

- Subject One: male, age 37, presented a rigid pes cavus (high arched) foot with a history of foot-related pathologies including hallux limitus (FSS insole use: Level 6-7).
- Subject Two: male, age 47, presented a hypermobile normal foot with a history of foot-related pathologies including excessive callousing, bunionette, ankle sprains, and knee problems (two minimal incision surgeries for medial meniscus, MCL & ACL repairs, and one complete ACL reconstruction) (FSS insole use: Level 6-7).

Figure 98



- Subject Three: male, age 26, presented an inflexible pes planus (flat) foot with a history of repeated ankle sprains (FSS insole use: Level 3).

All subjects were fit, in good health, and participated in regular athletic activities and the test subjects had been free of injury since using the insoles.

Each subject was fitted with magnetic positioning sensors at each joint and a strain gauge underneath the first metatarsal and great toe (Figure 98). The sensors' 3D positioning (motion capture) was monitored through a sensory field (8' x 8' x 8') created by an overhead sensory grid. The strain gauge measured timing and degree of dorsiflexion of the great toe. Each subject undertook a number of activities: walking, running, and diagonal cutting movements through the sensory field; and walking and running (jog and sprint) on a treadmill. The test group first performed these activities barefoot, then in at least two types of regular footwear (casual and athletic), first without, then with the FSS insoles. In both instances, the control subject performed the activities barefoot, and then shod, without the insoles.

The data for the three test subjects was collected in three classifications: barefoot gait, regular shod gait without the FSS insoles, and shod gait with the insoles. The control subject's data was also classified in the same manner, but without the insoles. The motion capture data from the sensors was digitized, time code synchronized, and line graphed.

During barefoot gait, all subjects demonstrated a significant degree of nociceptive/proprioceptive dorsiflexion of the great toe that began during the swing phase and increased at heel strike to maximum, immediately prior to forefoot contact (Figure 99 & 100). The degree of nociceptive/proprioceptive dorsiflexion prior to forefoot contact was directly proportionate to the activity levels. Progressively greater degrees of nociceptive/proprioceptive great toe dorsiflexion were observed between walking, a light jog, and a brisk jog. The highest degree of great toe dorsiflexion occurred at toe off in the barefoot condition.

During regular shod gait (walking or running), all subjects demonstrated no appreciable nociceptive/proprioceptive great toe dorsiflexion prior to heel or forefoot contact (Figures 101 & 102).

During shod gait with the FSS insoles, the test subjects demonstrated a significant degree of nociceptive/proprioceptive great toe dorsiflexion during all activities (Figures 103 & 104). The timing and trends of great toe dorsiflexion mirrored those observed during barefoot gait (Figures 99 & 100).

Footwear design characteristics (restrictions of toe box depth and midsole/outsole rigidity) contributed to a 10 degree reduction in great toe dorsiflexion immediately prior to forefoot contact and toe off when compared to the barefoot condition.

Figure 99 Great Toe Dorsiflexion (Subject Two)
Barefoot gait (walking)

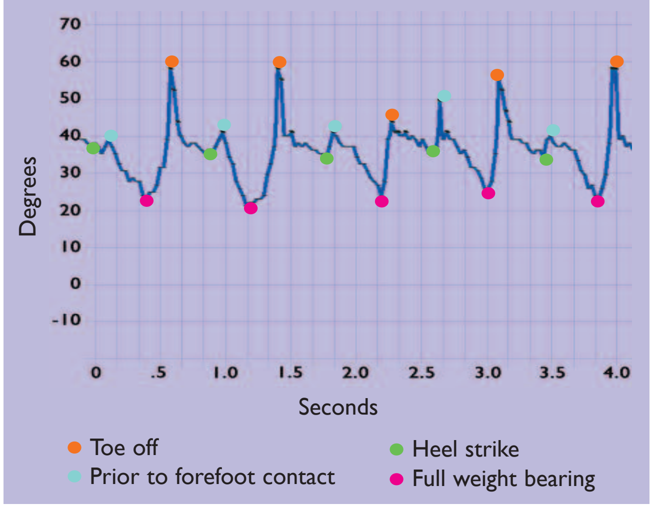


Figure 100 Great Toe Dorsiflexion (Subject Two)
Barefoot gait (jogging)

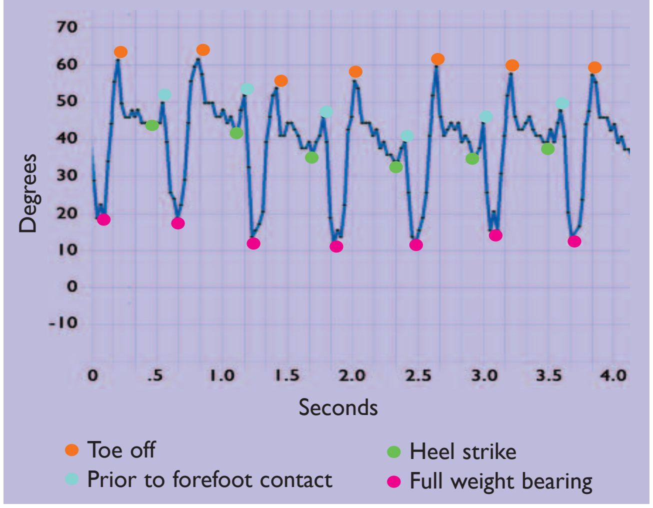


Figure 101 Great Toe Dorsiflexion (Subject Two)
Shod gait (walking)

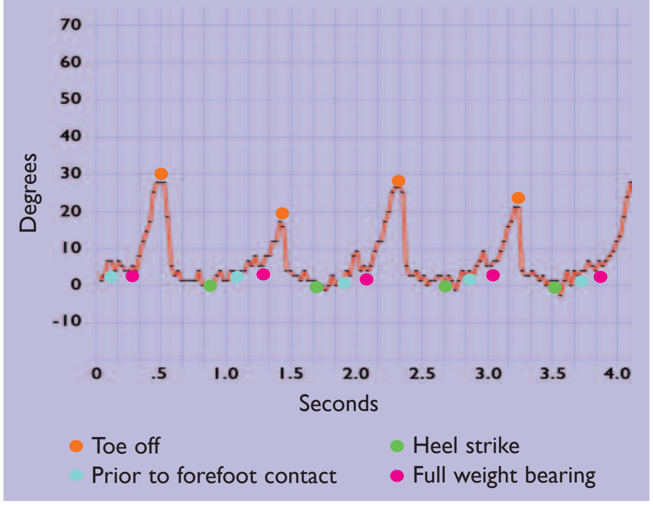


Figure 102 Great Toe Dorsiflexion (Subject Two)
Shod gait (jogging)

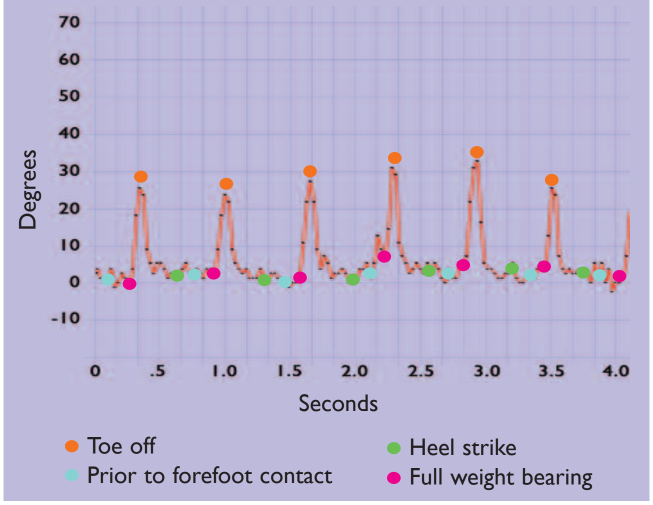


Figure 103 Great Toe Dorsiflexion (Subject Two)
Shod gait w/Foot Strengthening System (walking)

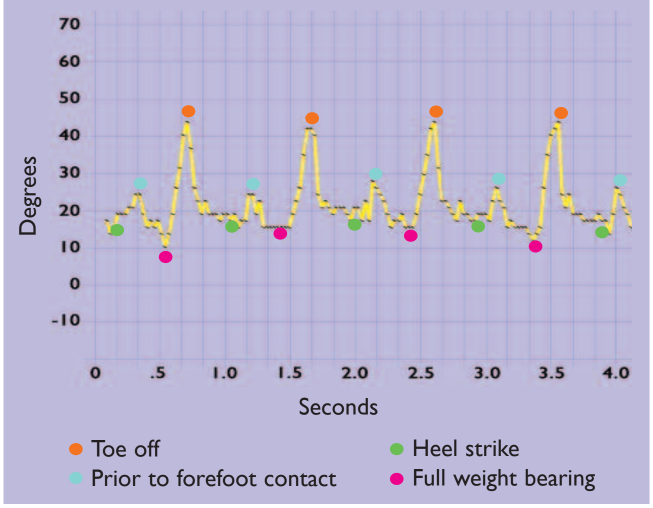
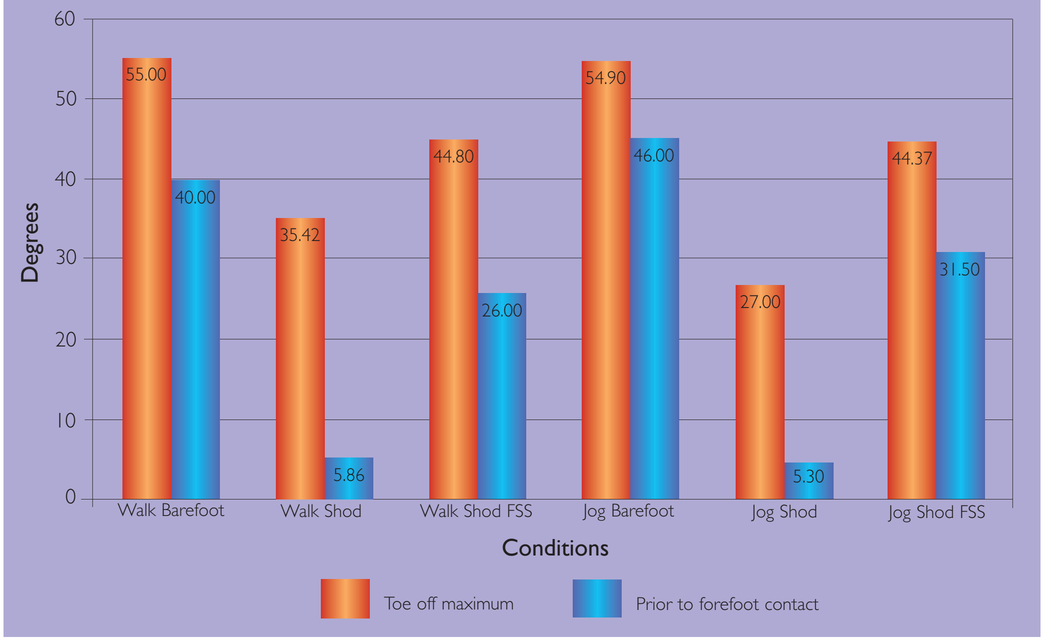


Figure 104 Great Toe Dorsiflexion (Subject Two)
Shod gait w/Foot Strengthening System (jogging)

Figure 105 Average Degree of Great Toe Dorsiflexion (Subject two) While Walking and Jogging per Condition



The study results clearly demonstrate that, during barefoot gait, adaptive (i.e., protective) nociceptive/proprioceptive muscle-firing sequences (re: dorsiflexion of the great toe) occur in corresponding degrees in response to activity levels. The results also indicate that footwear inhibits these natural proprioceptive adaptive (i.e., protective) muscle-firing sequences, which are required for optimal structural alignment and stability (Figure 105). It was also clearly demonstrated that, regardless of foot type, the FSS insoles stimulated these necessary nociceptive/proprioceptive muscle-firing sequences in the same footwear that had previously prevented them. These observations, while remarkable, suggest that the FSS insoles' results could be further improved with footwear designed to facilitate the great toe's dorsiflexion and the formation of the Optimal Arch Apex.

The motion capture data was used in the development of an animated 3D skeletal model of the human body (Figures 100 to 109: still captures of animation sequences). This animated skeletal model demonstrates the relative structural alignment during various movements. The viewer is able to isolate areas of interest by being able to enlarge their view of a specific joint movement, or can observe the model as a whole in "real time" slow motion and freeze frame throughout the animation sequences. An infinite number of camera (viewing) angles is possible.

The variances in structural alignment and function, relative to the degree of dorsiflexion of the great toe during ground contact, are clearly demonstrated in Figures 106 to 109. These freeze frame images illustrate comparative skeletal alignment during jogging and side-to-side diagonal cutting movements (at the identical point in time during the gait cycle) while shod with the FSS insoles and while shod without the FSS insoles.

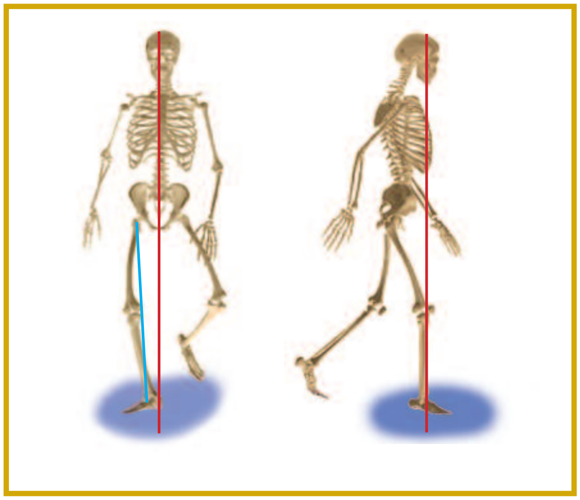


Figure 106 Shod gait without FSS insoles (jogging)

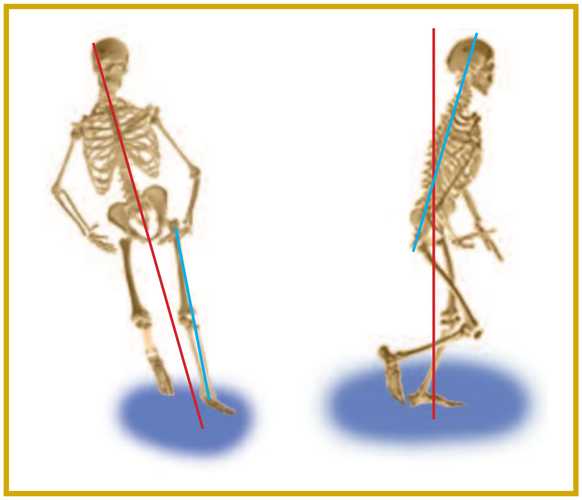


Figure 107 Shod gait without FSS insoles (diagonal cutting movements)

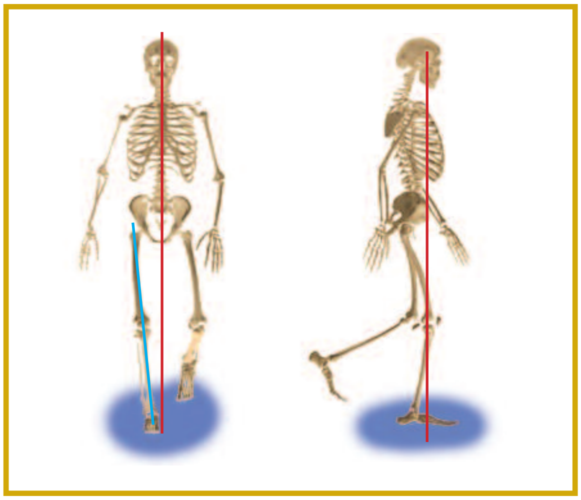


Figure 108 Shod gait with FSS insoles (jogging)

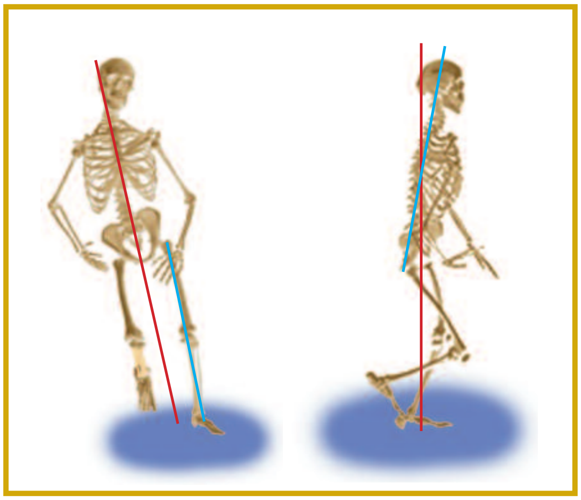


Figure 109 Shod gait with FSS insoles (diagonal cutting movements)

A direct relationship is demonstrated throughout the gait cycle between the degree of great toe dorsiflexion and the efficiency of alignment at the ankle and knee. A higher degree of great toe dorsiflexion, prior to forefoot contact, corresponded to an increased efficiency in structural alignment. As identified earlier, optimized alignment correlates to increased stability and less degenerative stress throughout the kinetic chain.

6.1.1.2.4 Structural Relationship Between Arch Length and Height

Photographic measurement and x-ray protocols were developed to determine the changes in structural alignment due to increased dorsiflexion of the great toe and the mechanical relationship between reduced foot length and arch height. These protocols were also used in identifying and comparing the relative structural changes caused by footwear, orthotics, and other insole products.

A pilot study was undertaken to examine the relationship between arch height and length relative to dorsiflexion of the great toe during full weight bearing. The study consisted of twelve subjects that had used the FSS insoles for at least two months (to allow for a soft tissue adaptation period). The subjects presented foot types in the following proportions: three flat (inflexible, pes planus), seven normal (two hypermobile), and two high arch (rigid, pes cavus). Reference points were marked on the subjects' skin surface, and relative distances were measured between points. Arch length and height were measured externally, both with the foot relaxed, and with the great toe dorsiflexed. The averaged results show a 2.88% decrease in arch length with the great toes dorsiflexed.

A fixed camera position was used to take multi-angle photographs of structural positioning changes in the subjects' feet and lower legs during full weight bearing (Figures 110 & 111).

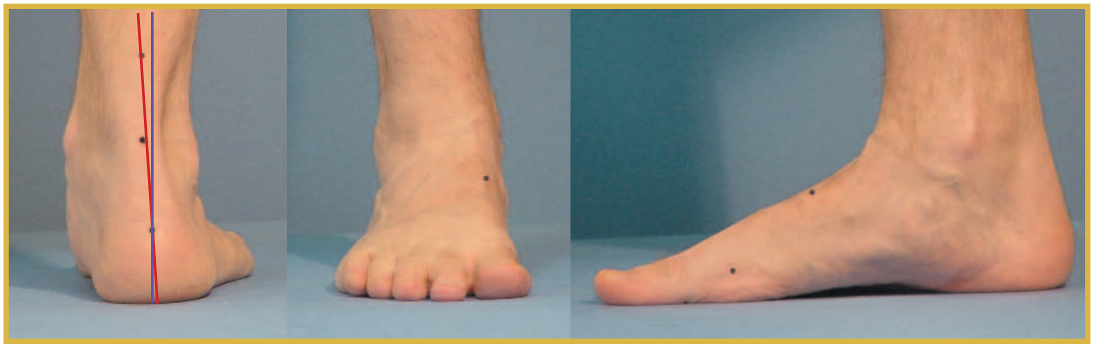


Figure 110 Relaxed – Subject Two

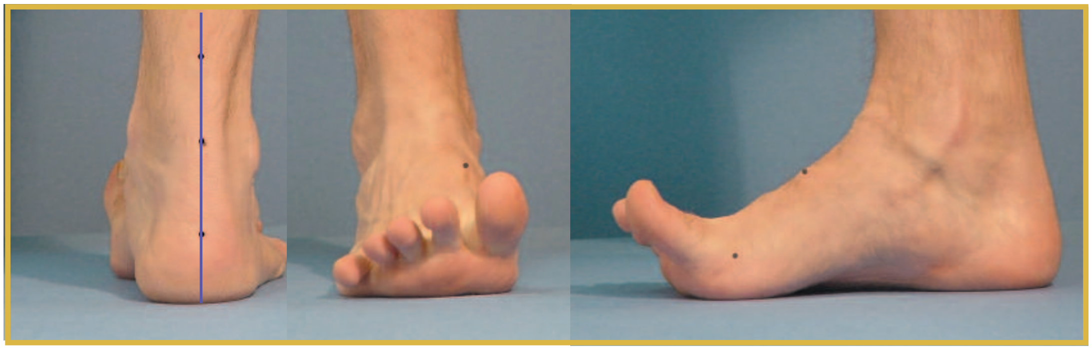


Figure 111 Great toe dorsiflexed – Subject Two

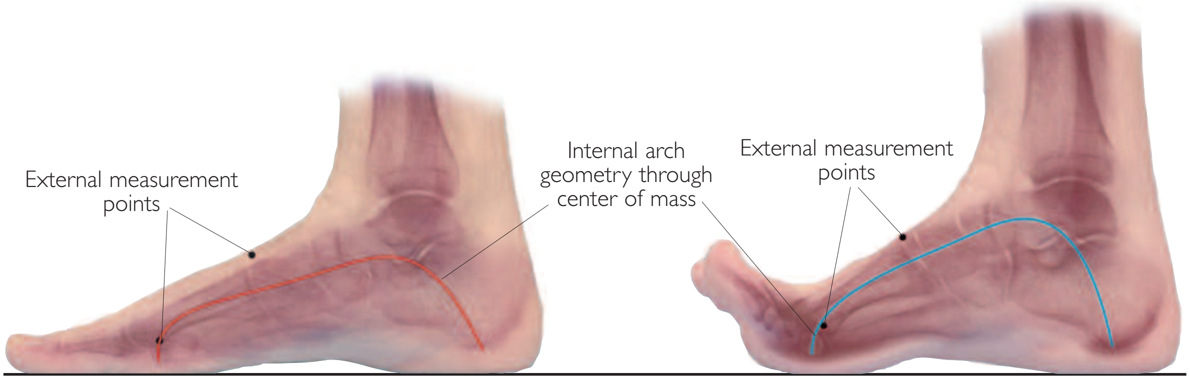


Figure 112 Arches created through center of mass (Subject Two)

In all instances, alignment improved when the great toes were dorsiflexed as evidenced below.

Three subjects were selected, from the group of twelve, for a series of foot x-rays – one from each of the following foot types:

- **High Arch** – Subject One: rigid, pes cavus
- **Normal** – Subject Two: hypermobile
- **Flat** – Subject Three: inflexible, pes planus

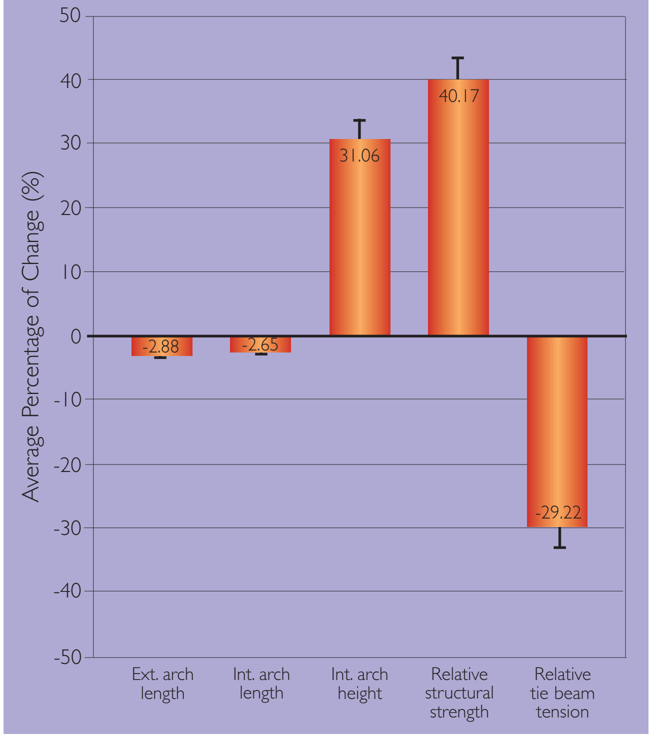
Images were taken of their feet when relaxed, and with the great toe dorsiflexed – barefoot and shod – with and without the FSS insoles. X-rays were also taken of their feet, barefoot and shod, with and without custom orthotics and other insole devices.

To determine the relative structural positioning mechanics from the reference point measurements, the x-ray and photographic images of the medial side of the foot were digitized, combined, and scaled to actual size using Adobe Photoshop software (Figure 112). Accurate internal structural measurements were then taken of the skeletal arch geometry (through the center of bone mass) and were compared to the external arch height and length measurements.

The data for the three x-ray test subjects was averaged into percentiles of internal and external structural change and factored into data collected from each of the foot type groups (Figure 113). The averaged results indicated that for each 1% decrease in arch length, the internal arch height correspondingly increased by 10.78%. The internal structural geometry changes of the x-ray group were also averaged into the Relative Arch Strength and Relative Tie Beam Tension equations (see Section 3.1, Theoretical Ideal Structural Physics Model of the Foot). The results indicate a 1.2% increase in arch strength for every 1% increase in internal arch height.

Given the same loads, with the great toe dorsiflexed, the test group's structural geometry averaged a 40.17% increase in relative arch strength, and tension in the plantar fascia decreased by 29.22%.

Figure 113 Average Arch Length and Height Changes in Relation to Relative Foot Structure Strength



The structural alignment of the three x-ray subjects' arches through center of bone mass (Figure 114) were compared for four conditions:

1) Barefoot – with the great toe dorsiflexed
2) Shod – regular footwear only
3) Shod – with the great toe dorsiflexed, via the FSS insoles (as per Study Two 6.1.1.2.3.2)
4) Shod – with a custom orthotic (posted to four degrees at rearfoot and six degrees at forefoot)

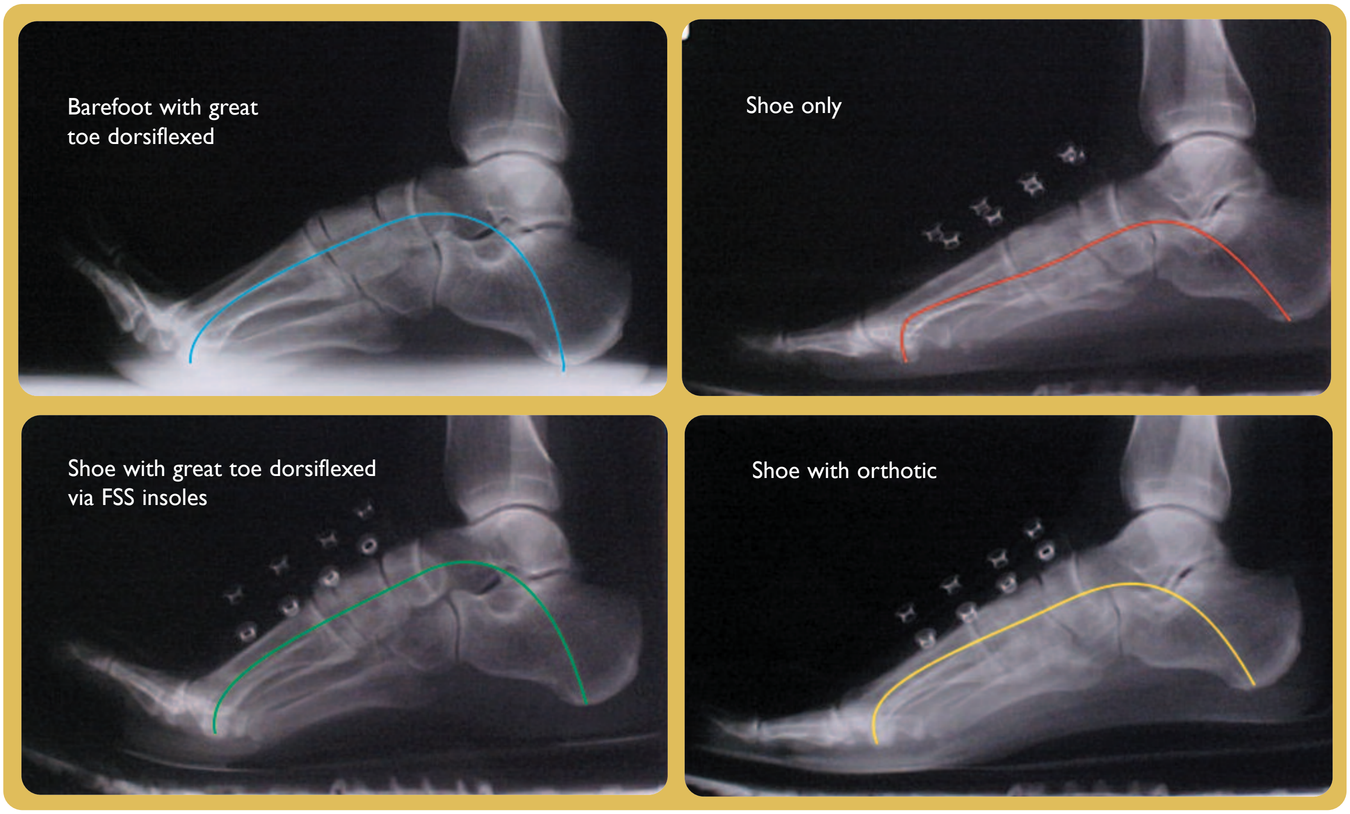


Figure 114 Subject Two - Right Foot

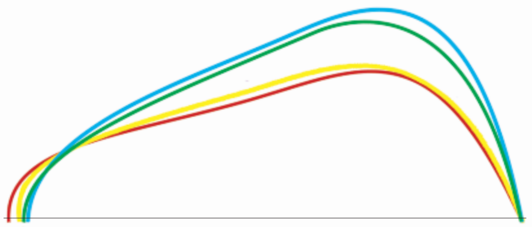


Figure 115

The resulting arch profiles were then grouped (Figure 115) and their geometric measurements entered into the Relative Arch Strength and Relative Tie Beam Tension equations (see Section 3.1, Theoretical Ideal Structural Physics Model of the Foot). The percentage of change demonstrated in each condition, compared to the regular shod condition, is reflected in the accompanying graphs (Figures 116, 117 & 122).

Subject One (rigid pes cavus foot) demonstrated the lowest degree of change in all conditions (Figure 113). The "barefoot - with the great toe dorsiflexed" condition demonstrated an improvement in relative structural strength of 15.03%, and tie beam tension was reduced by 13.06%. The "shod – with the FSS insoles" condition demonstrated an improvement in relative structural strength of 8.07%, and tie beam tension was reduced by 8.94%.

In identical footwear, this condition demonstrated a 4.2 times greater improvement in structural alignment, 2.72 times greater structural strength, and 3.1 times less tie beam tension when compared to the "shod - with custom orthotics" condition, which demonstrated structural alignment changes (arch height increases) of 1.88%, structural strength increases of only 2.97%, and tie beam tension decreases of 2.88%.

Subject Two (normal hypermobile foot) demonstrated the greatest degree of change in the "barefoot – with the great toe dorsiflexed" and "shod – with the FSS insoles" conditions (Figure 117).

The "barefoot – great toe dorsiflexed" condition's relative structural strength improved by 57% and tie beam tension was reduced by 36.31%. The "shod – with the FSS insoles" condition's structural strength improved by 50.5% and tie beam tension was reduced by 33.6%. In identical footwear, this condition demonstrated a 6.6 times greater improvement in structural alignment (arch height), 6.7 times greater structural strength, and 4.8 times less tie beam tension, when compared to the "shod – with custom orthotics" condition, which demonstrated structural alignment (arch height) improvements of 5.56%, structural strength increases of only 7.55%, and tie beam tension decreases of 7.02%.

Subject Three (inflexible pes planus foot) did not demonstrate a functional arch geometry through center of bone mass in either the relaxed barefoot or shod conditions (Figure 118).

Figure 116 Arch Length, Height, Tension, and Force % Change Relationships by Condition (Subject One - rigid pes cavus foot)

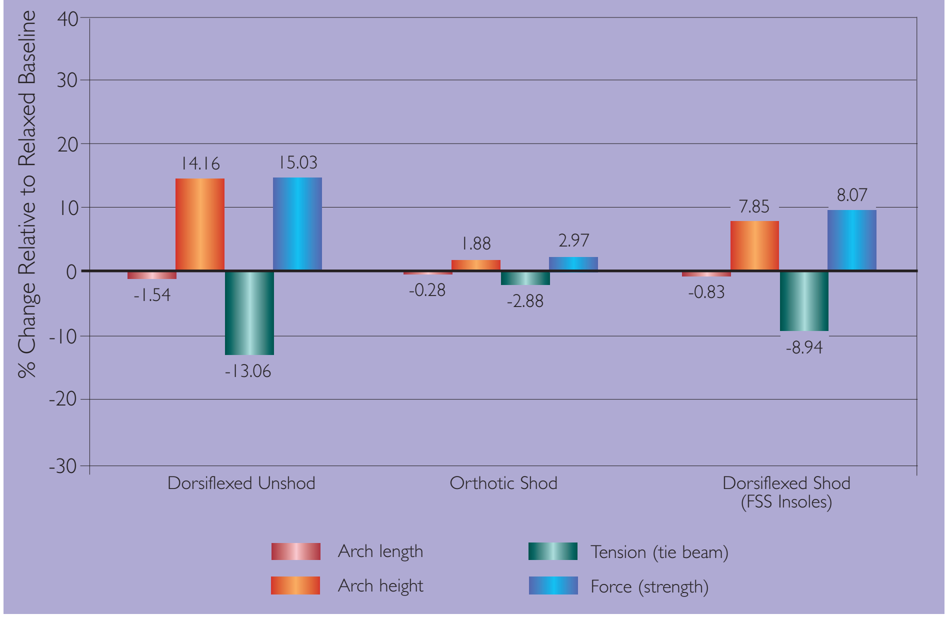
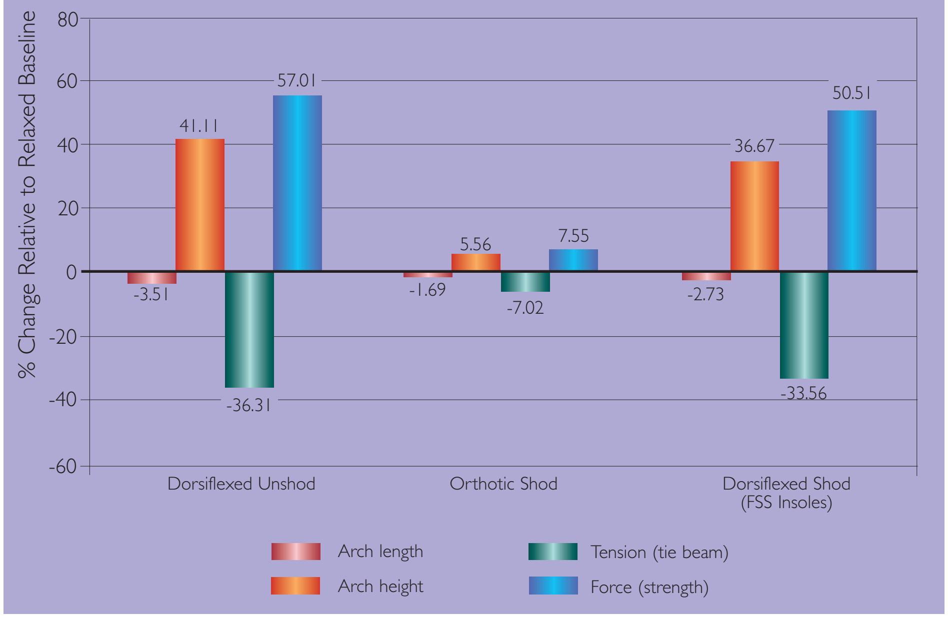


Figure 117 Arch Length, Height, Tension, and Force % Change Relationships by Condition (Subject Two - normal hypermobile foot)



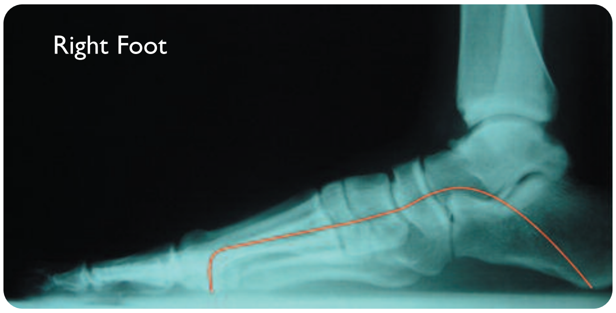


Figure 118 Subject Three (07/2001)

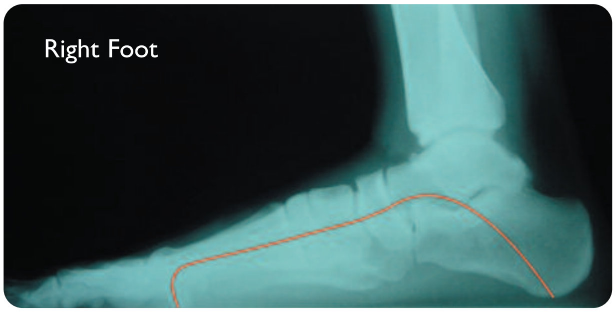


Figure 119 Subject Three (02/2002)

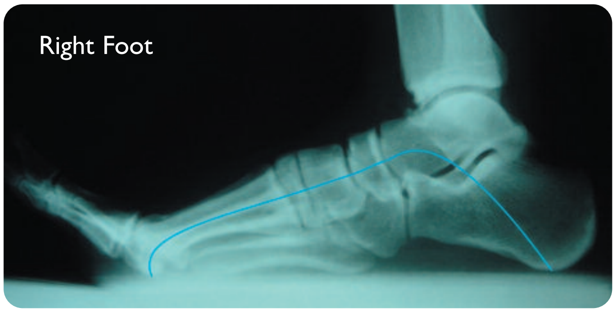


Figure 120 Subject Three (07/2001)

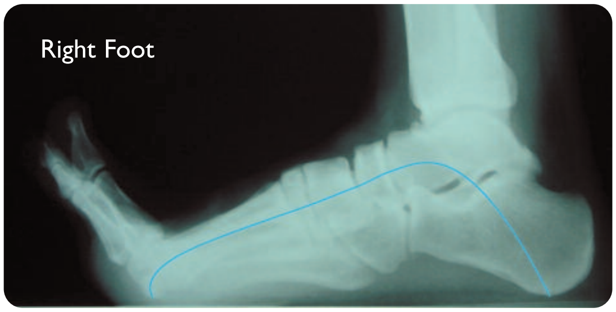


Figure 121 Subject Three (02/2002)

In order to compare structural strength and tie beam tension changes, a stable arch was assumed and relative geometric measurements were taken and incorporated into the Relative Strength and Tie Beam Tension equations (Figure 122). With this considered, the "barefoot – great toe dorsiflexed" condition's relative structural strength improved by 21.75% and tie beam tension was reduced by 17.86%. The "shod – with the FSS insoles" condition's structural strength improved by 15.22% and tie beam tension was reduced by 13.21%. In identical footwear, this condition demonstrated a 1.6 times greater improvement in structural alignment (arch height), 2.23 times greater structural strength, and 2 times less tie beam tension when compared to the "shod – with custom orthotics" condition, which demonstrated structural alignment improvements (arch height) of 6.14%, structural strength increases of 6.82%, and tie beam tension decreases of 6.38%.

Subject Three had used the FSS insoles for the least amount of time and was still progressing though the Insoles' insert stages, therefore, follow-up x-rays and measurements were taken approximately six months later (Figures 119 & 121).

These later x-rays, when compared to those initially taken, clearly illustrate improved structural alignment and mobility. The structural alignment in the later weight bearing unshod condition (Figure 119) reflects an improved functional arch geometry (note 5th metatarsal and cuboid positioning). Great toe dorsiflexion improved from 33° (Figure 120) to 71° (Figure 121).

New structural geometry measurements were taken and incorporated into the Relative Strength and Tie Beam Tension equations. Significant improvements in structural strength, and reduced tie beam tension, are demonstrated (Figure 123). The "barefoot – great toe dorsiflexed" condition's relative structural strength improved to 35% and tie beam tension was reduced by an additional 8.17%, to a total reduction of 26.03%. The "shod – with the FSS insoles" condition's structural alignment (arch height) improved from 10% to 17.05%, structural strength improved from 15.22% to 21.16%, and tie beam tension was further reduced to 17.47%. In identical footwear, this new condition demonstrated a 2.8

times improvement in structural alignment (arch height), 3.1 times greater structural strength, and 2.7 times less tie beam tension when compared to the "shod – with custom orthotics" condition.

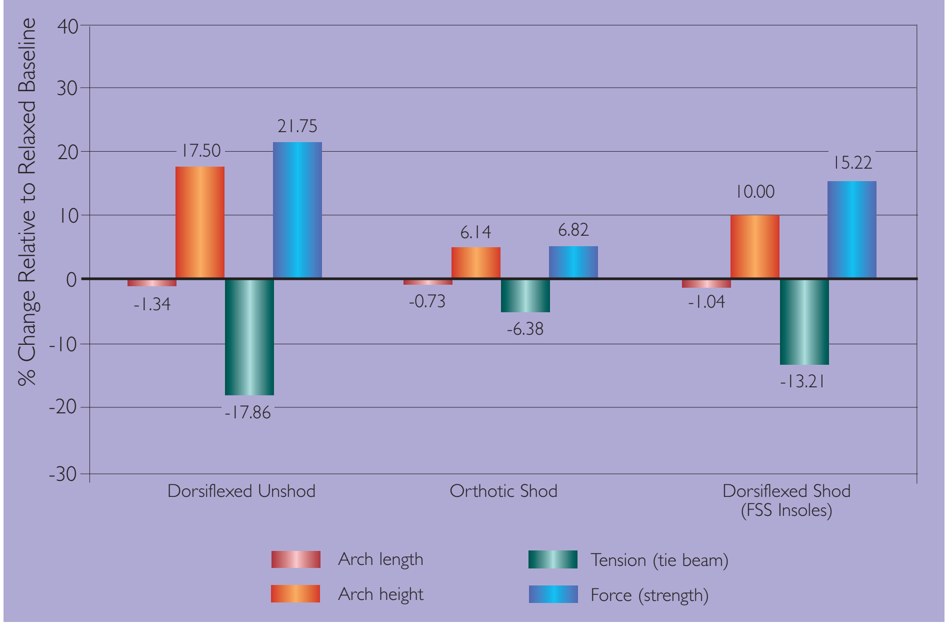


Figure 122 Arch Length, Height, Tension, and Force % Change Relationships by Condition (Subject Three - inflexible pes planus foot)(07/2001)

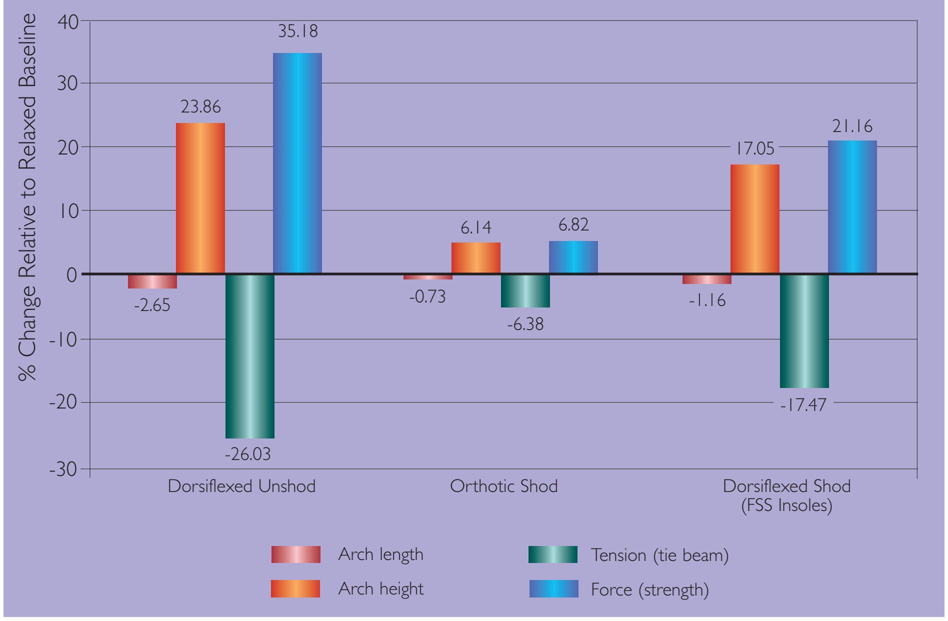


Figure 123 Arch Length, Height, Tension and Force % Change Relationships by Condition (Subject Three - inflexible pes planus foot)(02/2002)

The above six studies clearly demonstrate a relationship between the use of the FSS insoles in footwear, and the nociceptive/proprioceptive muscle activation necessary to optimally align and stabilize the foot, prior to and during weight bearing ground contact. It is also clear that this muscle activation is a natural adaptive response to activity levels during barefoot gait, and is virtually eliminated during regular footwear use.

It has also been demonstrated that pre-forefoot contact muscle activation significantly improves the foot's structural alignment and strength, which dramatically reduces the damaging horizontal (tie beam) forces (tensions). In footwear, this improved muscle activation and structural stability increases circulation to the muscles of the foot and improves the balance of strength and flexibility – all of which are necessary for optimal foot health.

In addition, the foot's improved structural alignment and functional dynamics clearly demonstrate the greatest degree of benefical change (when compared to orthotics) in structural alignment through the lower leg. There is a significant improvement in structural efficiency (performance) and a reduction of unhealthy stress in the muscles and at joints. This data provides compelling evidence that the benefits of the FSS insoles are vastly superior to those of conventional orthotics.

6.1.1.2.5 The FSS Insoles' Effect on Foot and Back Pain (Study One)

In a 12 week pilot study conducted for Scholl PLC, a test group of sixty-five foot and back pain sufferers used a developmental prototype of an earlier FSS insole in their regular footwear. Their results were compared to those of a control group, consisting of twenty-two foot and back pain sufferers, who were not users of any insole or orthotic product. A Mankoski Pain Scale questionnaire was used to monitor both groups bi-weekly. All subjects' lifestyles required that footwear be worn in an accumulated weight bearing manner for a minimum of six, but not more than nine, hours per day. All subjects were asked to maintain their regular pre-study lifestyle. Neither group used any pain medication during the test period. The study results indicated that the insole users demonstrated a significant reduction of intensity, duration, and frequency of foot and back pain, while the control group demonstrated an increase of intensity, duration, and frequency of foot and back pain (Figures 124 & 125).

Figure 124 Degree of Back Pain Normalized

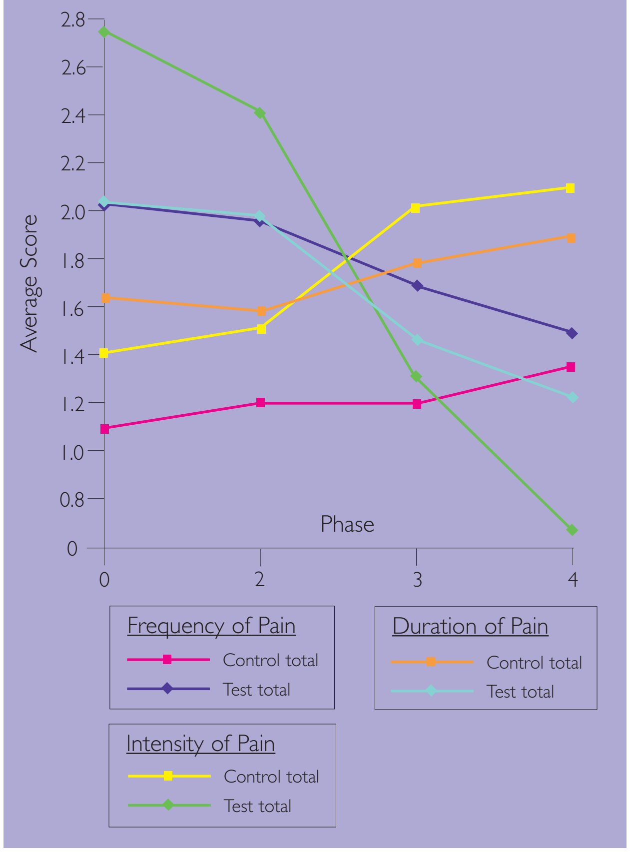
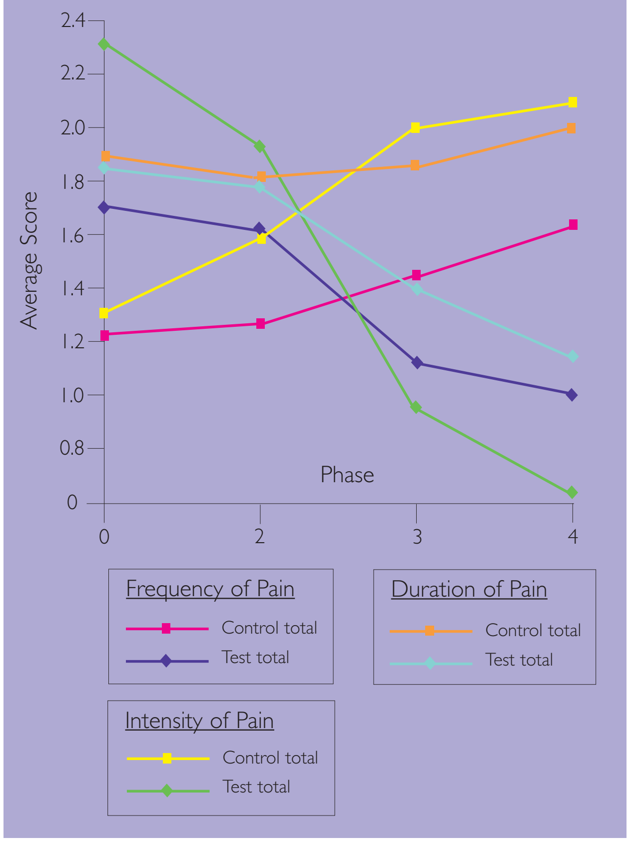


Figure 125 Degree of Foot Pain Normalized



6.1.1.2.6 The FSS Insoles' Effect on Foot and Back Pain (Study Two)

A five week study was conducted on the Emergence Room staff at a large urban hospital to evaluate the effect of the FSS insoles on musculoskeletal pain. The study participants consisted of forty-seven nurses, administrative, and medical staff. The test group used the FSS insoles in their regular footwear during their shifts at the hospital. 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 FSS insoles.

When data were analyzed using repeated measurement with a random coefficient regression model, which provides more accurate assessment of the trend, there were clinically and statistically significant declines in pain scores for all the body parts including: upper back , ankles, legs and hips, as well as significant declines for "tiredness" for all body parts. There was also a significant decline in general fatigue (p<.05). Between the baseline and the end of the study, 75% of participants had a decline in foot tiredness, 75% in foot pain and 70.8% in general fatigue. Satisfaction with the product was high, with 90.3% of users reporting they a "great" or "good" experience with the FSS insoles.

The study concluded that the FSS insoles can significantly reduce many types of musculoskeletal pain and fatigue in a working environment involving long periods of weight bearing activity (Figures 126 & 127).

> *"The experimental changes of shortening of the medial arch and load redistribution to the digits can only be explained by an activation of this normally inactive musculature associated with increased barefoot weight-bearing activity.*
>
> *The data clearly demonstrates that the normally shod foot is capable of rehabilitation of foot musculature."*
>
> Robbins SE, Gouw JG, Hanna AM. Running Related Injury Prevention Through Innate Impact-Moderating Behaviour. Medicine and Science in Sports and Exercise 21(2): p. 1390, 1987 (American College of Sports Medicine).

Figure 126 Pain Scores For Participants

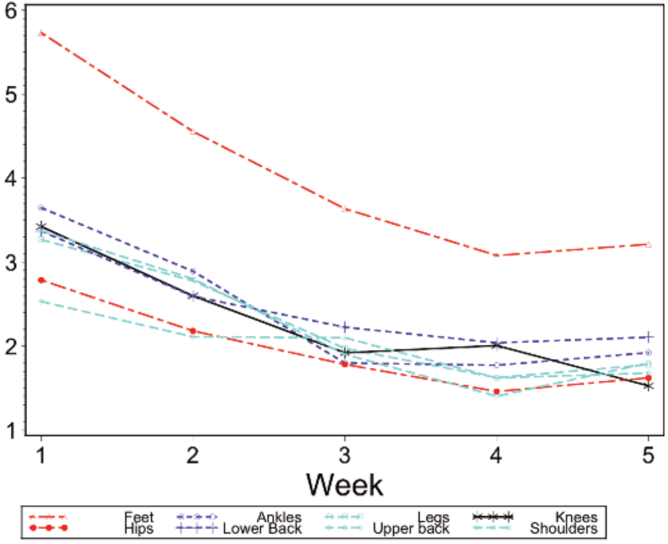
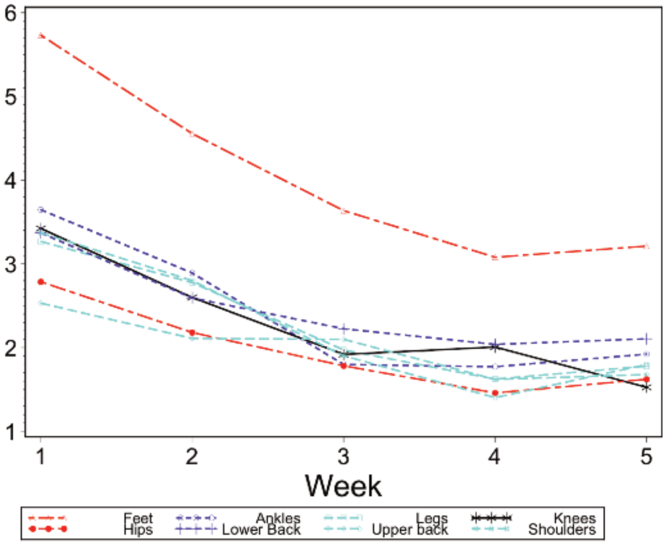


Figure 127 Tiredness Scores For Participants



6.1.1.2.7 The FSS Insoles' Effect on Lower Limb Muscle Activity

Clinicians used an eight channel sEMG testing system to identify muscle activity as a means to help develop therapy and exercise programs for their patients. Their analysis indicated a whole body pattern or *bias* in the motor system unassociated with the area of injury or pathology. While the data indicated that the body was compensating and adjusting around injuries or weaknesses, another pattern was showing up in every instance. This other pattern was also observed in those who were not presenting injury or pathology. The clinicians concluded that the pattern appeared to operate "normally" beneath (or in the background of) issues typically evaluated. They further identified the pattern as a normal self-defensive central nervous system bias steering muscle use at the deepest level. And that this bias is so consistent that resulting overuse or underuse of various muscles always produces the same list of predictable dysfunctions [132].

The clinicians tested the effects of the FSS insoles on the bodies of people they had already studied to identify areas of interest and observe exactly what the insoles were changing. In every case where no FSS insoles had been used prior to testing, hamstring and gluteal function showed increases in amplitude after as little as five minutes' use with the FSS Insoles (Figure 128).

Figure 128 Hamstring and Gluteal Function Amplitude

After six weeks, there was a much more robust contraction pattern across all monitored muscles – with symmetrical contraction of hamstring and paraspinals (Figures 129 & 130). In every case, there was a leveling and posterior shift of the pelvis that the clinicians presumed was related to an increased hamstring role. A reduced forward head was also observed. Further observations included:

- Improved muscle load distribution (evidence of improved participation of all necessary muscles);
- Decreased asymmetrical inefficiency (evidence of shift toward L/R balance in amplitude);
- Reduced fatigue (evidence of delayed onset);
- Decreased pelvic torsion + improved pelvic level = core stability; and
- Increased performance (reported in all cases).

Figure 129 sEMG Testing Pre FSS Insoles

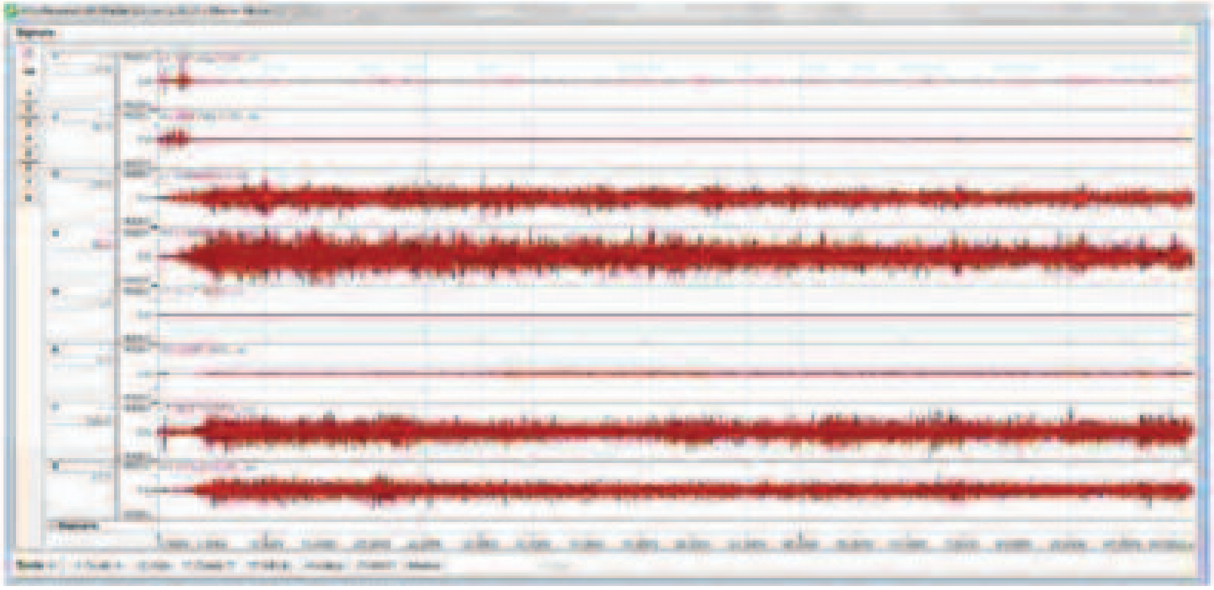
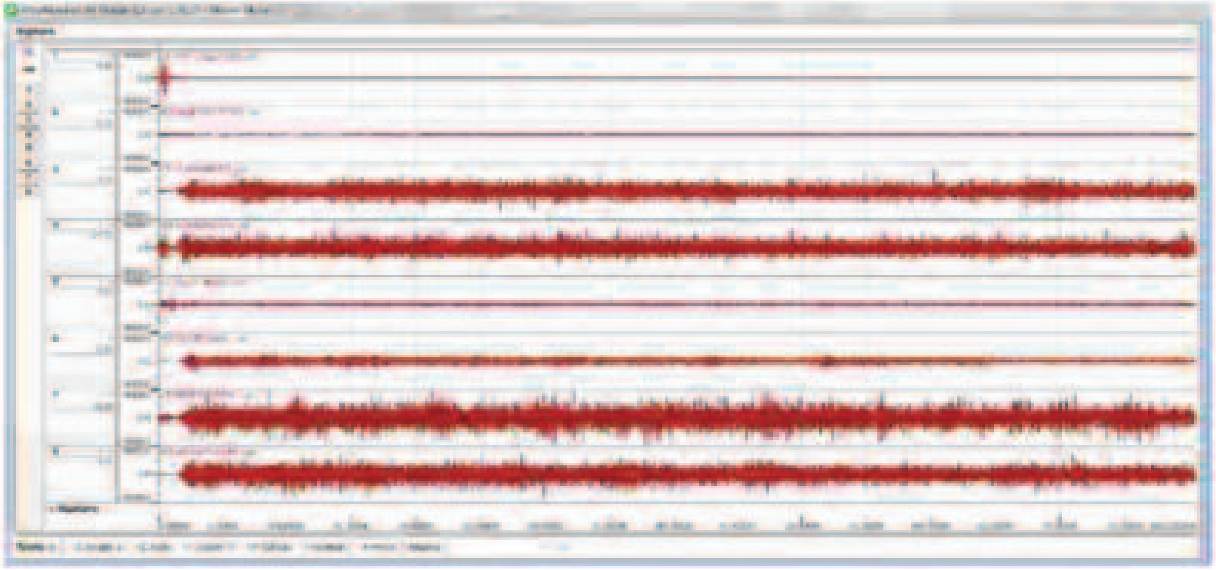


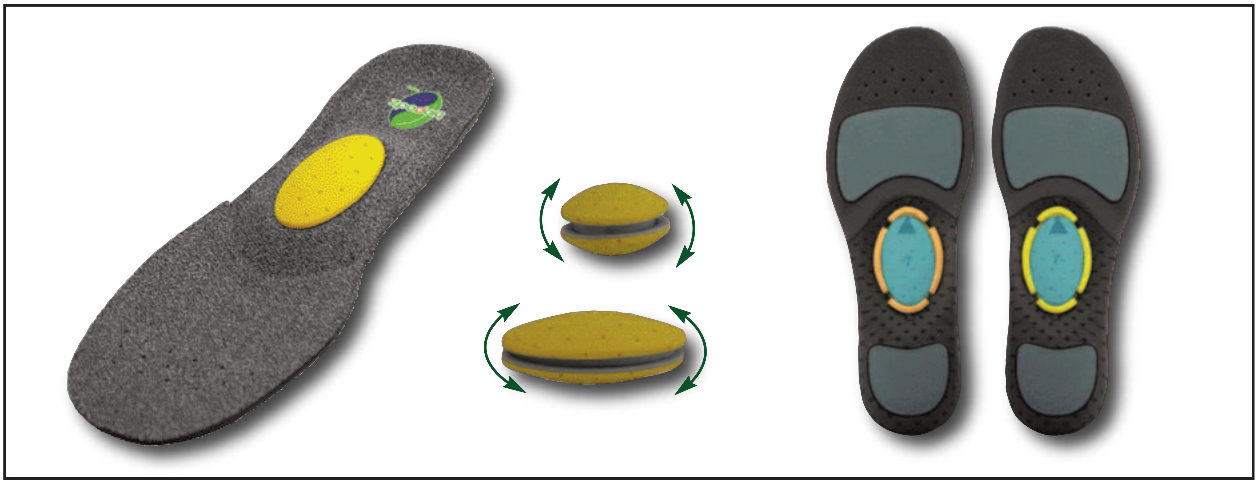
Figure 130 sEMG Testing With FSS Insoles After 6 Weeks



6.1.2 Additional Clinical Observations

The above noted studies and research findings validate the FSS insoles' efficacy and underlying scientific principles, and clearly demonstrate a superior treatment methodology when compared to cushioning and supportive insole and orthotic products. However, after over 16 years of clinical use and tens of thousands of pairs dispensed, it has been observed that, over time, the body habituates to the insoles' stimulus resulting in a loss of neuromuscular benefit. While the remaining benefits still greatly exceeded those provided by supportive orthotic and cushioning soles, Biopods Inc. ("Biopods") undertook additional research to identify the reasons for the loss of benefit and to find a viable solution.

Figure 131 Prototype Insoles With Osculating Stimulus Mechanisms



Biopods' first observation was that the FSS insoles' EVA foam insole body and EVA foam inserts compacted significantly over the first few months of use. It was also observed that this compaction significantly lessened or eliminated the foam's rebound resiliency, which led to the insole's dome becoming more of a static supporting feature rather than the intended dynamic stimulus mechanism. This caused a reduction of the centralized stimulus by spreading the loading forces over the totality of the sole of the foot's surface area. It was thought that the resulting loss of centralized dynamic stimulus could be overcome by employing a series of progressively firmer osculating stimulus mechanisms (Figure 131).

Figure 132

It was also proposed that, by allowing the apex of the stimulus mechanism to maintain contact with the sole of the foot – centralized at the Arch Apex {as described in section 6.1.1.1 The Mechanical Physics} (Figure 132), a more effective stimulus would be produced. However, when historical users of the FSS insoles tested the prototype insoles with the osculating stimulus mechanisms, the results were surprising. When the stimulus was always focused at the same location on the soles of their feet, their bodies habituated to the stimulus more rapidly. Eventually their bodies failed to effectively respond reflexively to it.

Following the aforementioned revelations, a wide variety of alternative designs and materials were developed and tested. Through this process Biopods identified the following:

- their bodies' positive response to the FSS insoles' progressive inserts was the result of sufficient stimulus variation over the first several months of use;
- this positive response was due more to the users changing the inserts every week, than to the centralized stimulus location;
- once people progressed through the insert levels and settled on a final insert, their bodies habituated to that stimulus over the next 4-6 weeks, depending on use;
- their bodies responded better to subtle varied stimulus than to more constant aggressive stimulus; and
- their brains became constantly alert to subtle varied stimulus and tuned out the repetitively consistent and constant stimulus.

6.2 *Biopods Variable Reflex Technologies™ ("VRT®")*

Biopods' research and testing resulted in the development of proprietary patent-pending "Biopods®" Variable Reflex Technologies ("VRT") that are based on the neuromuscular rehabilitative principles detailed herein. Biopods VRT insole and footwear products rehabilitate and prevent foot-related maladaptive neuromuscular function and are designed to facilitate the optimal neuromuscular dynamics of barefoot gait. Biopods VRT products overcome the disadvantages of the FSS Insoles and current footwear design by introducing:

- subtle varied nociceptive/proprioceptive response stimulus to the soles of the feet – Biopods Stimsoles®,
- midsole and upper design characteristics that promote dorsiflexion of the digits and optimal arch apex height – Biopods sandal and footwear products, and
- midsole and outsole geometries and characteristics featuring ground contact angles that promote rotational axes through the bone structure's center of mass, thus a reduction of acceleration and velocities – Biopods sandal and footwear products.

Figure 133

6.2.1 *Biopods Stimsoles®*

Biopods Stimsoles take advantage of the body's innate neuromuscular dynamics by introducing the subtle varied stimulus to the soles of the feet that is required to:

- activate an optimal a neuromuscular "protective reflex" response throughout the feet, legs, hips, and lower back;
- safely initiate and retrain the muscle-firing sequences that optimally align, stabilize, and lock the foot's interlocking bones; and
- optimally align and stabilize the bones throughout the lower limb, hip, and lower back.

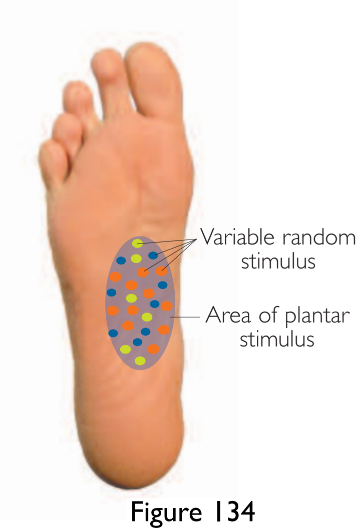


Figure 134

The geometry and dynamic resiliency properties of the Stimsoles' unique VRT Pod design (Figure 133) generates subtle varied recoil pressure on the foot's sensitive plantar surface during weight bearing. This varied subtle stimulus is randomly located at varying points beneath the midfoot, in the area that corresponds to the Optimal Arch Apex (Figures 133, 134 & 135). The Pod material's exceptional dynamic rebound properties also create progressive levels of varying stimulus intensity (Figure 135). This optimal, subtle, varied nociceptive/proprioceptive stimulus facilitates an involuntary adaptive sensory response throughout the lower limb kinetic, chain as {as described in section 6.1.1.1 The Mechanical Physics}.

Figure 135

Three different Pod heights provide three corresponding levels of stimulus. Typically, when initially using Biopods Stimsoles, the optimal Pods VRT level is determined first by the stimulus most suitable for specific foot types (Figures 136 & 137). The VRT 300 Pods provide the most aggressive stimulus (best for higher intensity running related activities in loose fitting flexible footwear). The VRT 100 Pods provide the least aggressive stimulus (best for standing or lower intensity activities and for tight fitting footwear). Lower stimulus intensities are also prefered for activities such as skiing, skating, cycling, etc. The VRT 200 Pods provide a moderate stimulus (best suited for everyday use in loose fitting flexible footwear).

Over time, regardless of the Pods used, the stimulus intensity will increase subtly as the insole body's EVA foam compacts slightly (about 1mm) around the Pods, which do not compact. This subtle increase allows the body to gradually adjust to the new neuromuscular dynamics.

Figure 136 Mobile Foot Types – The toes and arches ARE able to rise easily

Activity Intensity	 Flat Foot	 Normal Arch	 High Arch
Low	VRT 100/200	VRT 100/200	VRT 100
Moderate	VRT 200	VRT 200	VRT 100/200
High	VRT 200/300	VRT 200/300	VRT 200
	Recommended Pod Level		

Figure 137 Imobile Foot Types – The toes and arches are NOT able to rise easily

Activity Intensity	 Flat Foot	 Normal Arch	 High Arch
Low	VRT 200	VRT 100	VRT 100
Moderate	VRT 200	VRT 200	VRT 100
High	VRT 200/300	VRT 200/300	VRT 100/200
	Recommended Pod Level		

The Pods produce occasionally noticeable but not uncomfortable randomly located subtle pressure points (noxious stimulus) on the foot's plantar surface (activating the nociceptors/mechanoreceptors). Due to the mechanical physics, the stimulus at these random locations progressively increases and decreases as the foot adapts to, and manages, the forces generated throughout the ground contact gait cycle (heel strike to toe off). When the arch structure is unstable, stimulus levels increase as the arch system collapses (i.e., the forefoot and midfoot increasingly dorsiflex and evert while the rearfoot plantarflexes and everts) (Figure 138). The body innately attempts to mitigate the noxious stimulus by triggering a "protective" reflex response during the next step's pre-ground contact swing phase (Figure 139). This reflex response ensures appropriate protective muscle activity in initiated throughout the lower limb kinetic chain prior to ground contact, involving the feet, ankles, knees, legs, hips and lower back. Consequently, during ground contact, the lower limb's closed kinetic chain is capable of safely and efficiently managing the forces generated, regardless of the activity (Figure 140).

The Pods' shape, positioning, resiliency and dynamic capabilities allows the foot an uninhibited full range of motion through three-dimensional movement (regardless of terrain geography or activity – standing, walking, running, diagonal cutting movements, etc.). In addition, by design, and significantly, the Pods flatten out with increased loads and, therefore, do not artificially brace or support the foot, nor do they mechanically manage the vertical loads.

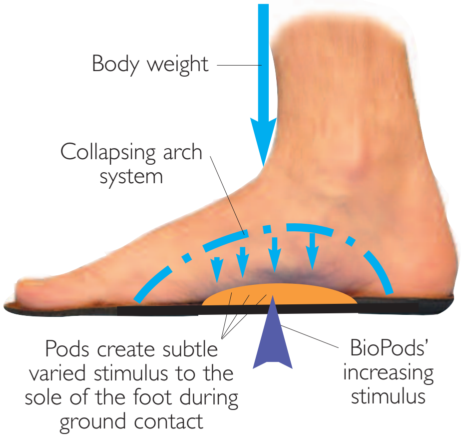
6.2.1.1 Clinical Observations

Medical professionals who have cumulatively dispensed hundreds of pairs of orthotics, thousands of pairs of FSS Insoles, and several hundred of pairs of Biopods Stimsoles in their practices have provided the following observations [133].

For most, when first introduced to the concept of a therapeutic foot stimulation insole (in contrast with the status quo/supportive insole that was part of their education and is still a part of the vast majority of MSK-practitioners' education), it was a very "hard sell."

At first, many found the concept of rehabilitating the feet rather than simply supporting them attractive but difficult to grasp. In essence, they had to "unlearn" what they believed they knew about feet, and replace that knowledge with a truly functional model of foot function. The first step in this new education was accepting that (rather oddly when considered objectively) feet have historically been the only part of the body NOT actually rehabilitated. The second step was

Figure 138



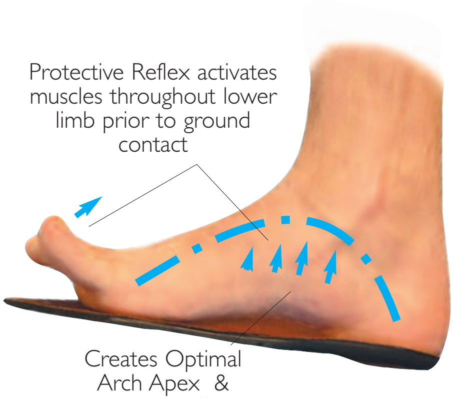
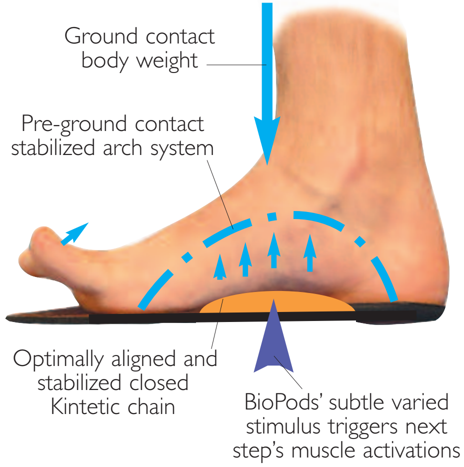


Figure 139

Figure 140



to learn to visualize and appreciate the elegance and efficiency of the unshod foot. The "Aha!" moment typically occurred when they realized that the muscular activity that provides adaptive, functional bone alignment (commonly referred to as "the arch") is modulated by the nervous system, in response to an ever changing field of stimuli, deep within the plantar surface of the foot – just as every other physiological system of the body is. Once this concept was grasped, integrating the FSS insoles into their practices made sense. After observing the benefits that their patients experienced, the FSS insoles became indispensable.

Compared to their experiences with custom orthotics, the first generation FSS Insoles proved to be immensely effective and have been used by medical professionals around the globe since 1998.

As these same practitioners began using next generation Biopods Stimsoles, it became apparent that patients who converted from FSS Insoles to Biopods Stimsoles demonstrated a significant improvement in neuromuscular function. It also became apparent that the original FSS insoles' ability to provide stimulation diminished as the product's EVA foam materials compacted with use. This caused them to become more supportive over time. It appears that the current Biopods Stimsoles' design has achieved a capacity for delivering enduring "pure" variable stimulation to the unshod foot. Clinical results have certainly been more rapid and imply that an almost "perfect" stimulus is being provided to the feet.

The most significant barrier found by practitioners who made use of the first FSS insoles, before transitioning to the Biopods Stimsoles, is that the FSS insole users have correlated their positive results (i.e., pain relief) with a notable "feel" of firmness under their feet. When such a patient has used the FSS insoles for a prolonged period of time, the Biopods Stimsoles practitioner realizes a transition must be made away from the FSS insole's "packed out" and more supportive role to the more efficient stimulus role of the Biopods Stimsoles.

Once the practitioner convinces the patient that, while they will not "feel" much of anything under their feet with the Biopods Stimsoles, they will receive a more effective stimulus than with FSS insoles. Typically, within about one week of using Biopods Stimsoles, the patient will have accepted and actually embraced the improvement.

These patient/practitioner interactions strongly reinforced that:

- FSS insoles have been too supportive (made more so when packed out), and
- Biopods Stimsoles provide virtually "pure" stimulus (with the least support possible thus far) without conscious awareness of superficial sensory input or presence.

Further to these principles, practitioners who administered FSS insoles to their patients observed that a modest number of patients (approximately 2–3%) were unable to tolerate the FSS insoles under their feet. Such individuals experienced intolerable pain when attempting to use the FSS insoles and could be divided into those:

- with extreme advanced scar tissue in the feet, often multi-site and
- who were fibromyalgia sufferers.

Fibromyalgia patients now have Biopods Stimsoles, which are far better tolerated. They offer much-needed relief to the additional pain source and full-body ***mis***-alignment. This should be observed as a "coup" within the fibromyalgia realm.

To provide full-body alignment benefit to patients with severe scar tissue within their feet, much treatment has often been needed to enable: 1) the Biopods' stimulus to work pain-free, and 2) improvement of the full musculoskeletal functional alignment. In other words, the feet must be able to tolerate the Biopods Stimsoles' stimulus without transmitting pain signals from the feet themselves.

The practitioners who have been using the FSS insoles (and now Biopods Stimsoles) for their patients have observed another subgroup of patients (approximately 2–3%), perhaps best described as "hard reactors." The observation has been positive (i.e., superior pain reduction and functional improvement, when compared to custom orthotics, but not to the point of improvement expected as observed for the majority of users). The underlying issues comprise two subgroups:

1. neurologically comprised (i.e., peripheral neuropathy, MS, ALS, etc.,) and
2. hallux compromised (i.e., hallux rigidus, surgically fused hallux, congenitially fused hallux, advanced degenerative arthritis, and accute gout episodes).

This is not to imply these conditions represent contra-indications for Biopods Stimsoles use, but to understand these user's limitations. Their net functional results have still been notably beneficial, compared to custom orthotics.

6.2.1.2 Soft Tissue Adaptation Phase & Supplementary Treatments

When using Biopods Stimsoles for the first time, the body's neuromuscular systems will undergo a Soft Tissue Adaptation Phase as the feet, legs, hips, and back respond to the new inshoe stimulus. For most patients, as is consistent with any neuromuscular muscle training, the Soft Tissue Adaptation Phase takes approximately 6-8 weeks, but can take longer for those sufferers noted below.

It has also been observed that the Soft Tissue Adjustment Period can vary according to age, activity levels, footwear design, and the percentage of weight bearing time per day that the Biopods Stimsoles are used. Children typically respond faster than adults, though no age is too advanced – seniors in their 70's and 80's have also experienced remarkable results. Generally, the more time people spend on their feet, the more active they are, the more accommodating their footwear, and the more frequently they use the Biopods Stimsoles, the faster their Adjustment Period will be {see Section 6.1.2, Biopods Stimsoles Appropriate Footwear for Healthy Feet}.

During the Soft Tissue Adjustment Period, most individuals will experience transient episodic twinges, tightness, or fatigue in unforeseen regions virtually anywhere within the lower limb kinetic chain – these should be considered to be a normal adaptation toward that individuals' ideal musculoskeletal alignment. However, during this period, if an individual experiences the onset of "new" pain that lingers, it is considered to be a manifestation of latent historical scar tissue (i.e., fibrosis).

Thus, while the majority of patients progress with Biopods Stimsoles without the need for any additional treatment, a small percentage will require specific therapy. In most instances, these patients will have had:

- either a traumatic event,
- or, far more commonly, maladapted tissue (ligament, tendon, muscle, even bone), as a result of their previous misaligned state that manifested as sites of non-symptomatic micro trauma injury over their lifetime, resulting in fibrotic scar tissue adhesions.

As a more "optimized neuromuscular function" and body alignment are restored throughout the feet, legs, hips, and back, symptoms relating to these previously injured tissues may temporarily prevent initial or progressive use of Biopods Stimsoles until the injured site(s) are effectively treated (Figure 141).

Most commonly, these symptoms arise from tension on the scar tissue and fibrosis formed during the old injury's healing process while the structure was poorly aligned. In effect, the scar tissue and fibrosis prevent the structure from achieving optimal alignment. In virtually all cases, these sites can be effectively treated through the modern methods of physiotherapy or soft tissue mobilization (to break down the scar tissue and fibrosis), such as ultrasound, deep tissue massage, A.R.T. (Active Release Technique), or Graston Technique, as appropriate.

Figure 141 Sites of Historical Injury Requiring Additional Treatment and Appropriate Remedies

Common Symptomatic and Non-symptomatic Sites	Recommended Treatments
• Plantar fascia damage and scar tissue	- deep massage, ultrasound, electrotherapy
• Lateral ankle ligament fibrosis/old sprain	- ultrasound, manipulation of talus, calcaneus, & navicular
• Peroneal (Fibularis) muscle and tendon fibrosis/old strain	- ultrasound, electrotherapy, cuboid, navicular & talus manipulation
• "Shin splints" micro tear and fibrosis of muscle fibers	- ultrasound, electrotherapy
• Peripatellar fascial fibrosis	- ultrasound, electrotherapy
• Fibrosis of erector spinales insertion at iliac crests	- ultrasound, electrotherapy & spinal manipulation
• Gluteal muscle insertion/IT band fibrosis	- ultrasound, electrotherapy, & massage
• Fibrosis of deep calf region (tibialis posterior and flexor hallucis longus bellies)	- ultrasound, electrotherapy & manipulation of calcaneus and midfoot regions

Please Note:

1. Biopods Stimsoles do not treat pre-existing, damaged tissue such as scar tissue or fibrosis that has been caused by trauma or maladaptation-related degenerative stresses from poor foot mechanics and function.
2. Individuals who suffer with neuropathy, chronic myofascial pain, fibromyalgia, neurologic disorders (i.e., MS, ALS, foot drop, etc.) and multiple sites of pre-existing tissue damage may expect longer or more difficult adaptation to the Biopods Stimsoles' corrective stimulus.
3. Individuals who have hallux rigidus, congenitally or surgically fused hallux, a severe degenerative arthritis of the hallux – in essence blocking the creation of the Windlass Effect – will have an unfortunate difficulty reaching the optimal corrections of lower limb adjustment, achievable by the vast majority of the other Biopods Stimsole users.

6.2.1.1.2 Biopods Stimsoles Diagnostic, Rehabilitative, and Preventative Use

There are a host of environmental influences (footwear, activity levels, etc.,) that can cause, contribute to, or exacerbate the maladapted neuromuscular function that leads to a multitude of foot-related pathologies. From a diagnostic perspective, the mitigation of unhealthy environmental influences and related symptoms would logically provide the best opportunity to identify the more critical pathologies. Biopods Stimsoles provide the practitioner with a practical tool during the assessment process. Not only do Biopods Stimsoles demonstrate improved patient compliance, they also promote increased awareness of the environmental influences (footwear types, lacing, etc.) that contribute to their symptoms.

Positive results, i.e., reduction or elimination of symptoms, most often indicate that continued use of Biopods Stimsoles will fully address (rehabilitate) the problem. However, it is possible that some patients have developed sufficient inelastic scar tissue or fibrosis to cause mobility and/or muscle elasticity "sticking points." In some instances, these sticking points may initially be non-presenting and only reveal themselves during the Biopods Stimsoles' Soft Tissue Adjustment Phase. In these instances, Biopods Stimsoles can be utilized as a diagnostic tool to assist the medical professional with the identification of the non-presenting areas. These now-presenting symptoms can then be addressed as outlined in Section 6.2.1.2, Soft Tissue Adaptation Phase & Supplementary Treatments.

A small number of patients will not initially respond positively to Biopods Stimsoles due to the magnitude of preexisting scar tissue and fibrosis. However, once these areas have been identified, they are easily addressed with more aggressive (and costly) soft tissue mobilization treatment methods. Once the fibrotic tissue has been sufficiently addressed, Biopods Stimsoles can be effectively used to rehabilitate neuromuscular function, as described herein.

Significant research has been presented herein providing compelling evidence that footwear use is the leading cause of the majority of foot-related pathologies. Furthermore, research indicates that footwear use has a negative impact on foot development through bone remodeling. The preventative use of Biopods Stimsoles can counteract the negative environmental influences of footwear – promoting healthier foot function and optimal remodeling dynamics. While these benefits are available to all ages, they could be greatest for children in their formative growth years.

6.2.1.1.3 Biopods Stimsoles and Safety

Regardless of the Biopods Stimsoles' Pods stimulus level used, no patients have reported any injury related to their use. This is most likely due to the fact that the Pods cannot exert mechanical forces of sufficient magnitude to cause injury to the musculoskeletal structures. Individuals who are too sensitive to the plantar stimulus simply reduce the Pods stimulus level or discontinue use. Using Biopods Stimsoles in restrictive footwear, including shoes with lacing that is too tight, has resulted in patients experiencing the following discomfort:

- over-stimulation (irritation) of the plantar surface, and/or
- muscle cramping as muscles overwork, and/or
- lactic acid build-up as muscles overwork.

These symptoms are similar to those presented by individuals who exercise too vigorously after an extended period of inactivity, and are easily mitigated by loosening the shoe or selecting a less aggressive Pods stimulus level. The discomforts are most often experienced by those who start out with a more aggressive Pods stimulus level, thinking that they can short-cut the adjustment period. Patients who follow the directions that accompany the Biopods Stimsoles rarely present any of these discomforts.

6.2.1.2 Biopods and Performance Enhancement

In addition to providing patients who present with sports-related injuries excellent rehabilitative and preventative benefits, athletes using BioPods Stimsoles have also experienced significant improvements in performance.

> *"As my shin splints healed, with the help of BioPods insoles, and I returned to intense training, I immediately attained new personal bests in the 200 and 400 meter sprints."*
>
> Garfield Bailey Jr. (National level track athlete)

Performance Enhancement Hypothesis

As presented in Section 4.0, Footwear's Relationship to Lower Limb Biomechanics and Resulting Pathologies, current footwear designs negatively impact optimal neuromuscular function and related structural alignment from a mechanical perspective. The resulting inefficiencies lead to compensatory muscle imbalances (overuse and underuse). In other words, inefficient neuromuscular function results in:

- a skeletal structure that is poorly aligned,
- dissipated or lost muscular energy due to poor mechanical geometry, and
- a greater muscular effort required to obtain a desired performance level.

Not only do muscles work longer and harder to achieve performance levels, a significant amount of muscular energy must also be used to attempt to create and maintain optimal structural alignment – this energy is not available for performance.

Therefore, optimal neuromuscular function not only results in less unhealthy stress, but a significantly greater degree of muscular energy becomes available that can be applied more directly and efficiently to achieving higher levels of performance. Given equal outputs of muscular energy, optimal neuromuscular function equates to a more stable structure (better mechanical geometry), greater functional robustness (agility, speed, and strength), and lower oxygen consumption, than when exhibiting poor (inefficient) neuromuscular function.

From an athletic perspective, there are two primary footwear and foot neuromuscular functional dynamics that must be considered:

- Static function – the foot doesn't follow the typical mechanical patterns of gait. Static function is demonstrated in sports, such as skiing, skating, cycling, rowing, etc.
- Dynamic function – the foot follows the typical mechanical patterns of gait. Dynamic function is demonstrated in sports, such as football, track and field, soccer, basketball, baseball, etc., or in activities, such as walking.

In both instances, optimal neuromuscular function contributes to improved performance although it is achieved in slightly different ways.

Performance Enhancement Observations

During static function, the foot's adaptive proprioceptive behaviors are not as prevalent due to the immobilizing effect of the boot or skate or the fixed foot positioning common to cycling or rowing. Optimal neuromuscular function and related structural alignment is best conditioned outside these sports in dynamic function activities and then maintained (stabilized) in the static environment. During static function sports, Biopods Stimsoles are more effective at maintaining, rather than creating, optimal neuromuscular function and related structural stability.

Using Biopods Stimsoles during dynamic function sports best facilitates or creates optimal neuromuscular function and related structural alignment. In this dynamic, Biopods Stimsoles function much like an exercise program – to retrain and maintain optimal neuromuscular mechanics throughout the feet, legs, hips, and lower back. The best results are achieved when Biopods Stimsoles are used in all footwear and not only during athletic activities. Elite athletes may wish to use Biopods Stimsoles exclusively in their every day footwear prior to high levels of competitive use to allow the neuromuscular mechanics to adapt – usually not longer than one month. After this adjustment period, Biopods Stimsoles should be used at all times and in all footwear for optimal benefits.

6.2.1.3 Proper Usage

Biopods Stimsoles must sit on a flat surface regardless of footwear type and all arch supports and contoured insoles must be removed. Biopods Stimsoles must be used exclusively and consistently throughout the day for optimum benefits. Using Biopods Stimsoles in some shoes while using a rigid orthotic in others is not recommended and should be avoided.

Biopods Stimsoles will provide benefit in virtually all footwear with heel heights of 1.5 inches or less, however, the greatest benefit is realized when they are used in footwear that is soft and flexible with minimal restrictions over the arch area. Ideally, footwear should also provide adequate toe box depth and feature minimal heel flare and height. In all instances, lacing should be loose (just enough to keep the shoe on).

When used in conventional footwear, only 25% to 75% of Biopods Stimsoles' optimal benefits are achieved due to the design characteristics described in 4.1.2, Restrictions in Structural Alignment. Although even benefits of 25% are considerably greater than those of existing treatment methods {See Section 6.1.2, Biopods Appropriate Footwear for Healthy Feet}.

6.2.1.3.1 Biopods Stimsoles Are Customizable To Accommodate Different Footwear

Biopods Stimsoles' VRT technology is currently incorporated into a variety of modifiable insole designs and will soon be integrated directly into footwear design. Biopods Stimsoles trimmed to 3/4 length (with the forefoot area removed) work best in shoes without removable insoles (i.e., dress shoes), while the full length Biopods Stimsoles work best in shoes with removable insoles (i.e., athletic shoes), as a replacement.

6.2.1.3.2 Biopods Stimsoles' Stimulus Progression

After selecting the appropriate Biopods Stimsole size and Pods VRT level for their foot type, footwear type, and activity, the user simply trims the Biopods Stimsoles to fit their shoes. With use, the Biopods Stimsoles' EVA foam insole body will begin to compact slightly over time (approximately 1mm) while the proprietary Pod material does not. As the EVA foam gradually compacts, the Pod's stimulus intensity will increase slightly in unison. This gradual and most often imperceptible increase in stimulus allows the body's neuromuscular system to safely adapt during the Soft Tissue Adjustment Period.

6.2.1.3.3 Biopods Stimsoles' Stimulus and Footwear Type

Regardless of footwear type, Biopods Stimsoles must sit on a flat surface – all arch supports and contoured insoles must be removed from the shoe. Footwear characteristics, such as restrictions over the great toe and arch area will affect not only the Soft Tissue Adjustment Period but also the comfort relative to the Pod's level of VRT stimulus. For example, the Soft Tissue Adjustment Period can be prolonged if footwear restrictions over the arch and toes prevent the arch and toes from raising in response to the stimulus. The inability to raise the arch can also create an uncomfortable or irritating pressure from the Pods if the

Pod's stimulus level is too aggressive. In some instances, these restrictions may cause cramping as the muscles overwork in an attempt to lift the structure away from the pressure, footwear and the least aggressive Pod stimulus level (VRT 100) in more restrictive footwear. The user should use the Pod stimulus level that they find comfortable in their respective footwear.

6.2.1.3.4 Biopods Stimsoles' Stimulus and Activity Levels

The user may find that varying activity levels also require different Pod stimulus levels. For example, standing generates significantly less force on the foot's arch system than walking or running. Consequently, someone who spends a considerable amount of time standing will require less stimulus to initiate an appropriate neuromuscular reflex response. In this case, the least aggressive Pod stimulus level (VRT 100) may be preferred. Again, the user should select the Biopods Stimsoles with the Pod stimulus level that they find comfortable for each activity.

6.2.1.3.5 Biopods Stimsoles' Appropriate Footwear for Healthy Feet

While the Biopods Stimsoles will provide benefit (up to 25-75% of optimal) in most footwear, choosing complementary footwear will optimize the results and promote the healthiest foot function.

The softer and more flexible the shoe, the better. This includes uppers, midsoles, and outsoles. Stiffer shoes cause greater friction between the shoe and the foot by resisting the foot's natural movement.

It is most important that the great toe be able to dorsiflex in the shoe. This can be facilitated by footwear with a deep toe box, soft flexible material over the toe box, a pliable midsole and outsole, or a combination of the above.

The shoe should not be tight or snug on the foot and should allow the arch to rise without restriction. Each pair of Biopods Stimsoles comes with a Lacing Guide to assist the user in identifying optimal lacing tension. Ideally, even when laced, the shoe should be able to be easily removed and placed back on the foot. This is particularly true for athletic footwear where greater Optimal Arch Apexes are required.

A rounded heel is the most beneficial – flared heels should be avoided. Lower heel and midsole heights are recommended as they significantly reduce the unhealthy stresses to the foot, ankle, and knee.

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