For those with diabetes the aspect of the loss of a limb may always be in the back of the mind. The loss of peripheral nerve transmission has profound effects in 3 areas;

1) Loss of muscle control and contribution (Motor Nerves)
2) Loss of perception of environmental stimuli. (Sensory Nerves)
3) Loss of involuntary systems (Autonomic)

The possible effects of any one of these, and more notably, the interplay of all three, predispose a person with diabetes to potential limb loss through the creation of lesions which may manifest themselves into more serious issues.

The sequence of events maybe something as simple as this:

1) Blister develops
2) Blister progresses to open sore
3) Open sore becomes infected and becomes gangrenous.
4) Foot amputation is required

As diabetic peripheral neuropathy progresses, various nerves are affected. These damaged nerves can cause problems that encourage development of ulcers. For example:

- Deformities (such as bunions or hammertoes) resulting from motor neuropathy may cause shoes to rub against toes, creating a sore. The numbness caused by sensory neuropathy can make the patient unaware that this is happening.
- Because of numbness, a patient may not realize that he or she has stepped on a small object and cut the skin.
- Cracked skin caused by autonomic neuropathy, combined with sensory neuropathy’s numbness and problems associated with motor neuropathy can lead to developing a sore.

**Symptoms**

Depending on the type(s) of nerves involved, one or more symptoms may be present in diabetic peripheral neuropathy.

**For sensory neuropathy:**

- Numbness or tingling in the feet
- Pain or discomfort in the feet or legs, including prickly, sharp pain or burning feet

**For motor neuropathy:**

- Muscle weakness and loss of muscle tone in the feet and lower legs
- Loss of balance
- Changes in foot shape that can lead to areas of increased pressure

**For autonomic neuropathy:**
Diabetes: Exercise Implications, Footwear and Barefoot Science.

Whether it is Type 1 or Type 2 diabetes there is overwhelming support for the notion that exercise is beneficial for those with diabetes. Why not? Exercise has been shown to be good for everyone; however those with diabetes can receive additional benefits.

For those with diabetes exercise has been shown to encourage the body to use the insulin already existing in it, which helps to reduce the blood glucose levels. Some with diabetes may also exhibit an “insulin resistance” meaning that although the body is still producing insulin it is not as effective in reducing the blood glucose levels as it could be. Generally this is linked to an increased body fat content and a reduced muscle mass content. Decreasing your body fat and increasing your muscle mass enhances the body’s ability to use the insulin it has in reducing blood glucose levels. A logical way to decrease body fat and increase muscle mass is through exercise.

The secret in all of this is in simply doing the exercise. For many people the lifestyle and morphology that is associated with diabetes relates is typical of that being sedentary and overweight. The introduction of, and compliance to, an exercise program is often difficult due to pain and discomfort. Very often this starts at the ground up, since the foot-ground interface is the first point of contact for the body. As expressed previously there are also additional considerations if there is a presence of diabetic peripheral neuropathy.

Traditionally attempts to address issues at this foot-ground interface have been based on artificially cushioning the foot or bracing the foot, and in the case of those with diabetes reducing pressure hotspots. All of these have seen limited success. Helping intervene at an early stage through the encouragement of motor, sensory and autonomic neuron involvement may have profound preventative effects.

The Barefoot Science Foot Strengthening System finally is able to offer to the person with diabetes a perfectly logical and natural way to get people introduced back into exercise. The benefits to those with diabetes are above those of traditional insole products. The exercise of the muscles of the foot and the sensory enhancement may save the feet of many with diabetes; in addition there are the overall benefits of exercise to the rest of the body and the impact on the overall diabetic condition.

By using the body’s own sensory perception and bio-feedback, Barefoot Science naturally and gradually introduces a muscle activation stimulus to the sole of the foot which subconsciously begins a series of muscle contractions which begins to strengthen the foot. The benefit of the repeated exposure to this is the gradual and natural strengthening of the foot’s supporting musculature. Stronger muscles and increased blood flow to the extremities assists in the lowering of the blood sugar levels and the continuous simulation of the nerves and circulatory systems of the extremities may decrease the onset and magnitude of neuropathy in the distal portions of the leg.

In pre-clinical trials using the Barefoot Science insoles it was shown that using the products increases the structural integrity of the foot, and in addition there was a lessening of pressure hot spots beneath the foot. For those with diabetes the reduction of these pressure points is key in that it reduces the likelihood of lesions and friction related damage to the skin, which often goes unnoticed and develops into much more serious problems.
Accumulative Pressure: during gait with standard shoe insole.

Accumulative Pressure: during gait with Barefoot Science Foot Strengthening insole.

8 week progressive analysis of foot surface area associated with Barefoot Science insole use.
Barefoot Science: Potential Diabetes Related Pilot Studies.

1) Measure of Latency between Motor Nerve Stimulation and Muscle Activation.
   - Although this is a reasonable method for measuring and monitoring nerve response time and thus neuropathy, it is more applicable to large muscles and those in exterior compartments. This may not be a usable technique for the intrinsic of the foot but because BFS also encourages proper and increased active firing of the longer muscles extrinsic to, but influencing, the foot like Tib. Ant and Per. Long. This maybe a reasonable method of testing the influence of BFS on nerve intervention with the foot.
   - We need some assistance in determining what normal neuropathic deterioration would be to have a prospective type study done. For the time being it would be logical to assume that if we took the latency period at Day 0 and used that as a baseline, then if the affected muscles were truly being exercised on a sub-conscious level through the use of BFS at week 12 the latency period should be decreased.
   - If this observation can be made it may be safe to assume that the same affects would be shown at the level of the more minute intrinsic plantar muscles if there was a way to measure it.

2) Measure of blood supply strength at distal site (Doppler Ultrasound):
   - The goal here is to measure the prevention of blood flow impairment to the periphery and/or measure the improvement in blood flow.
• It is the common belief that accompanying diabetic neuropathy is PVD, or peripheral vascular disease. The degradation of muscle recruitment at the foot negatively affects blood flow and thus has a negative effect in the delivery of nutrients to the skin surface and to affected injury sites.

• Under the assumption that changes in the strength of the Posterior Tibialis pulse or the Dorsalis pedis arterial pulse are both indicative of changes in blood supply to the foot, we would analyze the strength of the pulse at week 0 and then again periodically over a study duration up to week 12 to observe a hypothesized increase in pulse.

3) Under Foot Pressure Distribution:

• A key preventative measure in those with diabetic neuropathy relates to the prevention of blisters. Blisters are indicator of stress to the dermis and most notably as a result of friction. The exact mechanism causing the causing the friction has both a compressive and shearing force component. The reduction in either of these can be an indicator to the reduction of blisters.

• High frequency repetition of blister formation at any one location can also be regarded as a precursor to the formation of a callus at that location. For those with diabetic neuropathy the inability of the autonomic nervous system and sensory nervous system to function optimally can result in the blister formation to manifest itself as a more dramatic complication.

• Underfoot pressure mapping systems such as those provided by companies like TekScan and Novel can be used to successfully measure under foot vertical pressure. Mapping of in-shoe center of pressure movement can also be used to deduce the amount of shearing force.

• Through the use of BFS the reduction in either the compressive force (pressure) of the deviation of the CoF from the ideal should be assumed to be a logical indicator of the reduction of the forces typically attributed to blister formation.

• The use of film based force transducers on the medial and lateral aspects of the foot in the regions of the medial forefoot, lateral forefoot, medial calcaneus and lateral calcaneus can also be used as an indicator for the amount of shearing occurring at the level of the dermis. Through the use of BFS the reduction in these shearing forces can be logically associated with a reduction in the blister causing mechanisms.

4) Peripheral Neuropathy and Motor Control /Balance

• Peripheral neuropathy logically has a negative effect on the proprioceptive ability of the body to sense the orientation, position and required stabilization of the foot for normal and effective gait.

• Under the assumption that BFS is having a positive effect on the strength of the muscles key to the foot’s stabilization as well as enhancing the integration of the peripheral nerves there should be a noticeable increase in the ability to maintain balance during standing and during gait.

• Under foot center of pressure mapping and measures of postural sway could be used as indicators of balance. Changes in these measures at day 0 and further at week 12, after using the BFS insoles could be attributed to the use of the insoles.

• Of note, is that in addition to the implications to those with diabetic complications is the overall benefit to those of the geriatric population. This population represents a growing percentage of our overall demographic as well as is a leading cohort experiencing falls resulting in an enormous cost to health care systems.

5) Reductions in Underfoot Surface Area.

• In this repeat of our earlier pilot study, in shoe pressure and surface area mapping would be used to monitor reductions in plantar surface area that accompany the use of the BFS insole.

• Loss of muscle tone and strength is cited as a symptom of motor neuron degradation. If in the diabetic population the sue of the BFS insole can be shown to result in a recued plantar surface area, and if this can be shown to occur in a period as short as 12-16 weeks, then it is far to attribute the change in plantar surface to an increasing in the muscle strength and tightening of the connective tissue.
• If muscle atrophy is seen a precursor to other more serious diabetic complications we can conclude that the onset and possible severity of these complications maybe reduced.