

Using ShearBan® to Offload Shear on the Diabetic Foot

This white paper discusses:

- The importance of shear in the etiology of diabetic foot ulcers
- The principles of shear offloading at locations of high shear loads
- Offloading shear – using traditional methods
- Offloading shear – using ShearBan®

Executive Summary

ShearBan® is a patented interface material used by clinicians and footwear specialists to prevent and treat diabetic foot ulcers. ShearBan® works by offloading shear forces at areas of concern targeted by practitioners. ShearBan® complements current pressure offloading techniques.

Two mechanical forces – pressure and shear – cause cumulative trauma to the skin of the foot from repetitive loading. That cumulative trauma is evidenced by erythema, blisters, calluses, and ulcers. Of the two mechanical forces causing cumulative trauma to the foot, shear is the most damaging. This has been recognized by leading experts on the diabetic foot and human skin.

ShearBan® is a patented product designed to offload shear forces transmitted to human skin and tissue. It does this by reducing friction at high-risk areas on the skin and support devices such as footwear, orthotic, and prosthetic devices. J. Martin Carlson, CPO, MS (Engr.), and the product development team at Tamarack® Habilitation Technologies have spent over a decade developing, testing and refining ShearBan®. Testing has shown that ShearBan® can reduce shear forces by as much as 50%.

Along with this white paper, the following publications are available:

- Carlson JM, Friction management for neuropathic foot problems, 13th ISPO World Congress and ORTHOPAEDIE + REHA-TECHNIK 2010, Leipzig Germany, Congress Lecture 3827, May 10-15, 2010.
- Kuffel C, Clinical Considerations and Decisions for Protecting the Neuropathic Foot from Friction, 13th ISPO World Congress and ORTHOPAEDIE + REHA-TECHNIK 2010, Leipzig Germany, Congress Lecture 3827, May 10-15, 2010.
- Payette MJ, Technical Aspects of Friction Management, 13th ISPO World Congress and ORTHOPAEDIE + REHA-TECHNIK 2010, Leipzig Germany, Congress Lecture 3827, May 10-15, 2010.
- Carlson JM, Functional Limitations from Pain Caused by Repetitive Loading on the Skin: A Review and Discussion for Practitioners, with New Data for Limiting Friction Loads, J Prosth & Orthot, 2006;18: 93-103.
- ShearBan® Product Guide – practical information on the use of ShearBan® in footwear, orthoses, and prostheses.

Other information is available from www.tamarackhti.com.

The Importance of Shear in the Etiology of Diabetic Foot Ulcers

These observations refer to the significance of shear (or friction) in causing trauma to the diabetic foot.

A substantial amount of research on human subjects has also been done on the causes of mechanical trauma to non-diabetic feet.

This research is fully consistent with the observation that friction or shear is the governing cause of trauma.

Leading clinical and research experts have long recognized the importance of friction and shear in causing trauma to the diabetic foot:

Paul W. Brand, MD, is perhaps the best known expert to have studied and treated the diabetic foot. Dr. Brand's research and clinical work led to the insight that it is primarily the lack of sensation coupled with mechanical forces that cause damage to the diabetic foot. Dr. Brand said this about those mechanical forces:

"There are two types of force which occur on the sole of the foot, one is vertical force at right angles to the foot, which causes direct pressure on the tissues. The other is horizontal force, or shear stress, which is parallel to the surface of the foot and occurs in association with acceleration and deceleration. Of the two forces shear stress is more damaging than pressure."

Brand PW, Neuropathic Ulceration, reprinted in The Star, National Hansen's Disease Center, May-June, 1983.

David Armstrong, DPM, PhD, is a professor of surgery at the University of Arizona College of Medicine. He has authored hundreds of journal articles on the diabetic foot. With regard to shear, Dr. Armstrong stated:

"It's the equivalent of podiatric dark matter: we believe it's important but we can't measure it well. In fact, shear stress is probably more important than vertical stress because it occurs twice per step instead of once."

Quoted in Groner C, Shear madness: beyond plantar pressure, Lower Extremity Review 2010.

Cleveland Clinic researchers have examined the effects of shear forces on the diabetic foot and have attempted to measure it in various ways. The Cleveland Clinic researchers made these observations in a recent article:

"Diabetic foot ulcers are known to have a biomechanical etiology. Among the mechanical factors that cause foot lesions, shear stresses have been either neglected or underestimated... Plantar shear is known to be a factor in callus formation and has previously been associated with higher ulcer incidence. During gait, shear stresses are induced with twice the frequency of pressure."

Yavuz M, Tajaddini A, Botek G, Davis BL. Temporal characteristics of plantar shear distribution: Relevance to diabetic patients, J Biomech. 2008; 41(3): 556–559.

There is agreement among experts that shear and friction are a primary cause of trauma to the diabetic foot.

The next section discusses how to deal with the problem of shear by offloading it.

P.F.D. Naylor, M.A., M.D., the British dermatologist conducted ground-breaking human studies in the 1950s on the response of skin to rubbing (i.e., friction). As Dr. Naylor states:

“Friction applied to the skin may cause either of two main types of reaction. Firstly, if the friction is small in amount but frequently repeated the skin may react by becoming thicker... Secondly, larger amounts of friction may cause the skin to react by the formation of a blister.”

Naylor PFD, Experimental Friction Blisters, British Jnl Dermatology, 1955;55:327-342.

Researchers associated with the United States Military, such as the epidemiologist Joseph Knapik, have done extensive research on human subjects on the causes of skin trauma such as blisters. A Review article summarized the cause of trauma to the foot this way:

“Blisters occur frequently especially in vigorously active populations. Studies using repetitive rubbing techniques show that blisters result from frictional forces that mechanically separate epidermal cells at the level of the stratum spinosum.”

Knapik JJ, Reynolds KL, Duplantis KL, Jones BH. Friction blisters. Pathophysiology, prevention and treatment. Sports Med. 1995 Sep;20(3):136-47.

J. Martin Carlson, CPO, MS (Engr.), founder of Tamarack Habilitation Technologies, has extensive clinic experience with both pressure sores and diabetic foot ulcers. He has also had extensive experience working with different techniques and materials for offloading pressure and shear. He summarized the research literature this way:

“The research literature clearly indicates that the shear (friction) component of the contact loading is the direct culprit. Pressure is not the direct cause of repetitive loading skin trauma (hot spots, blisters, abrasions, and ulcers). Pressure is a factor that enables the friction/shear to reach traumatic levels.”

Carlson JM, Functional Limitations from Pain Caused by Repetitive Loading on the Skin: A Review and Discussion for Practitioners, with New Data for Limiting Friction Loads, J Prosth & Orthot,2006;18: 93-103.

The Principles of Shear Offloading at High-Risk Locations

Shear offloading should generally be done at the same locations where pressure offloading is done: at sites with previous ulceration; callusing, and deformities.

These sites should be relatively easy for the practitioner to identify since they are the same ones where pressure offloading is traditionally done.

How can friction and shear forces be offloaded?

Friction and shear, like pressure, cannot be eliminated from the foot of the ambulatory person. In fact, friction is necessary for efficient gait (otherwise the foot would slide around inside the footwear). Thus, friction and shear, like pressure, need to be managed and relief needs to be targeted to high risk locations.

The first step in offloading shear involves identification of areas of high potential shear on the foot. Those areas of high potential shear fit into three categories. These three categories are ones where pressure offloading has traditionally been done.

- **Areas of previous ulceration are at a high risk for re-ulceration:**

Murray and colleagues found that the relative risk of an ulcer developing at a site of previous ulceration was 57 compared to a relative risk of 5 for an area of elevated pressure. Murray HJ, Young MJ, Hollis S, Boulton AJ. The association between callus formation, high pressures and neuropathy in diabetic foot ulceration. *Diabet Med.* 1996 Nov;13(11):979-82.

- **Areas of callusing are at high risk for ulceration or reulceration:**

Callus formation precedes ulcer formation in over 82% of patients with diabetic foot ulcers (Sage et al. 2001). Murray and co-workers reported callus formation to be “highly predictive” of diabetic ulcer generation, second only to previous ulceration (Murray et al. 1996).

- **Areas of deformities may be high risk:**

Hammer/claw toes, prominent metatarsal heads, or Charcot deformities are locations of likely ulceration. Apelqvist J, Bakker K, van Houtum WH, Schaper NC, Practical guidelines on the management and prevention of the diabetic foot, based upon the International Consensus on the Diabetic Foot (2007) Prepared by the International Working Group on the Diabetic Foot, *Diabetes Metab Res Rev* 2008; 24(Suppl 1): S181–S187.

Traditional Techniques to Manage Shear

In theory there are a variety of ways to make a contact surface – footwear, orthosis, etc. – more slippery.

Many solutions have been tried in the past. However, each presents challenges.

Once an area of concern on the foot has been identified, how is it managed? The solution is grounded in the research conducted by P.F.D. Naylor in the 1950s. Naylor found that “the coefficient of friction between skin and the rubbing agent affects the number of rubs which the epidermis can withstand before it ruptures” (Naylor October, 1955). By lowering the coefficient of friction (COF) between the epidermis and contact surfaces, the epidermis can withstand more rubs.

The COF of a surface in contact with the skin can be lowered by making the interface between the skin and the contact surface more slippery.

Lubrication

Lubricating agents have been used to increase the slipperiness of the materials in an interface in order to reduce friction and shear forces. These include oils, silicone, and powders. In studies, the agents initially decreased the COF of the interface with the skin but, once the lubricants were absorbed or worn away, COF levels spiked (Knapik et al 1995). Therefore lubricating agents ultimately can be very counterproductive.

Moleskin

Materials such as moleskin have been used for a long time. The benefit of moleskin, however, is a tactile illusion. The COF of moleskin when paired with a cotton sock is extremely high (Carlson JM 2006).

Socks

Socks can be made of materials that provide some relief from shear. However, the relief is not targeted. Friction is not always bad and, in fact, is necessary for efficient ambulation. Socks and insoles that reduce friction over larger areas may also reduce gait efficiency because the entire foot can slip slightly with each step (Cooper 1995). Moreover, the effect may be to transfer loading to non-plantar skin which is less suitable than plantar skin at handling gait-related loading.

What has been needed therefore is a material that provides:

- substantial reductions in COF;
- to targeted locations;
- throughout the gait cycle;
- through a high number of cycles; and
- under differing environmental conditions.

Shear Offloading with ShearBan®



ShearBan® has several features and benefits:

Conclusion

ShearBan® is a patented patch with three principal layers: a low friction outer surface made of specially formulated polytetrafluoroethylene (PTFE), textile backing, and pressure sensitive adhesive. Based on extensive research and testing, Tamarack selected a particular formulation of PTFE that is supple, durable, and very slippery. In addition, Tamarack uses special propriety techniques to bond the PTFE to the textile backing.

ShearBan® comes in a variety of forms: small ovals or large rectangles that can be cut to size. ShearBan® is applied to the inside surfaces of footwear or other pieces of equipment at the contact point where calluses, blisters, and ultimately ulcers have formed or might form – reducing shear forces by as much as 50% (Carlson 2006).

Orthotists and prosthetists have used ShearBan® for years to prevent hotspots on the residual limbs of amputees or a point of rubbing between an orthosis and an extremity. Professional and extreme athletes have long used ShearBan's sister product ENGO® to manage friction blisters. Now, increasingly, healthcare professionals are using ShearBan® to prevent and manage diabetic foot ulcers.

Features of ShearBan® Patch	Benefits of ShearBan® Patch
Ultra-low friction surface	<ul style="list-style-type: none"> • Neutralizes shear – the primary cause of calluses and foot ulcers – by forming a low COF interface • Maintains low COF in moist conditions
Thin	<ul style="list-style-type: none"> • Does not interfere with foot function • Does not interfere with pressure relief modalities • Does not interfere with footwear fit
Supple	<ul style="list-style-type: none"> • Conforms to contours or depressions • Easy to work with
Applies to footwear, not skin	<ul style="list-style-type: none"> • Reduces skin irritation • Works well with variety of wound dressings & treatment modalities • Long-lasting durability
Peel backing and apply	<ul style="list-style-type: none"> • Easy to use
Different forms (ovals/sheets)	<ul style="list-style-type: none"> • Ovals offer convenience • Sheets allow customization of patch
Durability	<ul style="list-style-type: none"> • Multi-week (most often longer) protection

Shear is increasingly recognized as the mechanical force most directly implicated in causing diabetic foot ulcers. ShearBan® is a patented interface material used by clinicians and footwear specialists to prevent and treat diabetic foot ulcers. ShearBan® works by offloading shear forces at areas of concern targeted by practitioners. ShearBan® complements current pressure offloading techniques. It can reduce friction and shear by as much as 50%.