

# Plantar pressure and shear stress reduction shoe and insole for diabetic foot ulceration

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## Background

The American Diabetes Association reports that 20.8 million people or 7% of the United States population have diabetes. Many people first become aware that they have diabetes when they develop one of its major complications such as blindness, heart disease, stroke, peripheral vascular disease, and numbness or neuropathy in the feet. A high blood sugar level also affects the body's immune system and causes delayed wound healing.

Diabetic foot complications are the most common cause of non-traumatic lower extremity amputations in the United States. The risk of lower extremity amputation is 15 to 46 times higher in diabetics than in normal persons, and the majority of diabetic foot complications begin with the formation of skin ulcers on the bottom of the foot.

One of the main causes of diabetic ulceration is the increase in plantar pressure on the bottom of the foot, especially the forefoot and the heel area. Foot deformities, which are common in diabetic patients, lead to focal areas of high pressure. When an abnormal focus of pressure is coupled with a lack of sensation, a foot ulcer can develop (Figure 1). Therefore, off-loading plantar foot pressure is an important component in treating diabetic foot ulcerations.

Figure 1. Plantar foot ulcer



## Description of current off-loading techniques

There are many off-loading techniques and devices available, each having specific applications according to the anatomic location of the wound. Off-loading devices made for non-ambulatory use include airflow mattresses, soft padding for the bed and wheelchair, and heel protectors such as the multipodus boot that suspends the limb to completely remove pressure from the problem area.

For ambulatory patients with plantar foot ulcerations, the ultimate off-loading device is a total contact cast, which acts to transfer weight away from the foot and redistributes the forces of weight bearing proximally onto the leg. A removable cast walker device performs much of the same off-loading as a total contact cast but is often more easily tolerated by the patient because it is removable for bathing and for daily wound care. Other off-loading but less ideal devices include a half-shoe (or so-called "wedge shoe"), a postoperative/surgical shoe with a soft accommodative padding layer. A randomized clinical study was conducted to compare the effectiveness of total contact casts, removable cast walkers, and half-shoes to heal neuropathic foot ulcerations in individuals with diabetes. The study reports that a significantly higher proportion of patients were healed in 12 weeks in the total contact cast group when compared with the two other modalities (89.5% vs 65%, and 58.3%).<sup>1</sup>

Figure 2. H-Fit shoe



## Description of the new diabetic healing shoe

The new diabetic healing shoes, H-Fit and T-Fit, (Sunrise FootWoRx, Fair Oaks, CA) are designed with a solid rocker bottom outsole, well padded inner liner, and infinite adjustment levels for shoe closure by using heavy duty Velcro fastener straps (Figures 2 and 3). The H-Fit shoe is designed for off-loading the typical diabetic foot ulcer. The T-Fit shoe is designed to off-loading plantar pressure in patients who already had a transmetatarsal amputation. The main innovative feature of the H-Fit and T-Fit shoe is a new insole design, which can significantly reduce the plantar pressure under the forefoot and heel.

This new insole is consisting of shock-absorbing and shear-reducing composite layers of Poron or soft EVA for the bottom layer, Plastazote or cushioned polymer gel for the middle layer, and a closed cell Neoprene top cover. These materials are commercially available in sheets.

Main shear stress reduction is accomplished by the middle layer because it has the elastic property to "slide" or "give" between the

Figure 3. T-Fit shoe



top and bottom layers when the direction of force is parallel or near parallel to the insole surface.

The main advantage and uniqueness of this new design, comparing to other existing insoles, are the evenly spaced holes throughout the insole. The holes will significantly reduce the direct plantar pressure and shear stress dynamically exerting on the plantar skin upon loading. When there is a focal point of pressure, the holes will be distorted or stretched to the direction of the pressure, which will also allow the insole material to distort or “give”, resulting in reduction of the peak plantar pressure and the associated shear stress. This will also eliminate any pressure transferring problems as encountered in other insoles. Removing the pressure will allow the insole material to return back to the original state.

Therefore, dynamic direct plantar pressure and shear stress can be significantly reduced by these holes.

This insole can also be used to off-load plantar pressure of a deformed foot, which has bony prominences because plantar fat pads atrophy in people with rheumatoid arthritis.

Another unique feature of the H- and T-Fit shoes is the enclosed pedometer. With the pedometer, physician can effectively measure the compliance of the patients – whether they are using the healing shoes as instructed or not. It can also be used as a device to tell the patient to limit his/her walking after the pedometer has reached a certain number of steps.

## Peak plantar pressure of various insoles

We conducted a preliminary study to determine the plantar pressure under the medial forefoot and under the heel using:

- Plain surgical shoe;
- Laminated insole with 1/4” pink Plastazote and 1/8” PPT. This is the **normal insole material** for diabetic shoe; and
- Laminated insole with 1/4” soft EVA for the bottom layer, 1/4” pink Plastazote for the middle layer, and 1/8” Spenco for the top layer. One has no hole and another one has 3/16” holes drilled through all layers of the insole and are evenly spaced at 1/2”.

The plantar pressures were measured using the F-Scan in-shoe pressure measurement system (TekScan, South Boston, MA). The test was performed on a treadmill at a walking speed of 1.5 mph with a female subject weights 135 lb and wearing a surgical shoe with and without the insoles above. Data were collected and tabulated as follows:

Plain surgical shoe	Pressure
Pressure under medial forefoot	15 psi (10.35 N/cm <sup>2</sup> )
Pressure under heel	20 psi (13.8 N/cm <sup>2</sup> )

### Insole with PPT and pink Plastazote and surgical shoe

Number 1 insole	Without holes
Pressure under medial forefoot	14 psi (9.66 N/cm <sup>2</sup> )
Pressure under heel	18 psi (12.42 N/cm <sup>2</sup> )

### Insole with 1/4” soft EVA for the bottom layer, 1/4” pink Plastazote for the middle layer, and 1/8” Spenco for the top layer, and surgical shoe

Number 2 insole	Without holes	With holes
Pressure under medial forefoot	13 psi (8.98 N/cm <sup>2</sup> )	<b>10 psi (6.9 N/cm<sup>2</sup>)</b>
Pressure under heel	17 psi (11.73 N/cm <sup>2</sup> )	<b>15 psi (10.35 N/cm<sup>2</sup>)</b>

As indicated in the tables above, the peak plantar pressure was further reduced by using insoles with evenly spaced holes.

A similar study conducted by Lavery LA and cohorts in “Reducing dynamic foot pressures in high-risk diabetic subjects with foot ulcerations” reports mean peak pressure for ulcers under the 1st metatarsal heads (medial forefoot) for the Total Contact Cast, DH Pressure Relief Walker (Royce Medical, Camarillo, CA), Aircast Pneumatic Diabetic Walker (Aircast, Summit, NJ), and Extra Depth Shoe as 7 N/cm<sup>2</sup>, 8 N/cm<sup>2</sup>, 12.3 N/cm<sup>2</sup>, and 39.5 N/cm<sup>2</sup> respectively.<sup>2</sup>

Another study conducted by Armstrong DG and cohorts in “Total contact casts and removable cast walkers” reports peak plantar heel pressure for the Total Contact Cast, DH Pressure Relief Walker Aircast Pneumatic Diabetic Walker, and PW Minor Extra Depth Shoe (PW Minor and Son, Batavia, NY) as 18 N/cm<sup>2</sup>, 19 N/cm<sup>2</sup>, 20 N/cm<sup>2</sup>, and 25 N/cm<sup>2</sup> respectively.<sup>3</sup>

## Conclusion

Comparing to the above studies for peak plantar pressure under the medial forefoot and the plantar heel, there is no substantial difference between the new innovative diabetic insole and the total contact cast, which is a gold standard for off-loading diabetic foot ulceration, to off-load the medial forefoot (6.9 N/cm<sup>2</sup> vs 7 N/cm<sup>2</sup>). However, the new insole is much better to off-load the plantar heel pressure (10.35 N/cm<sup>2</sup> vs 18 N/cm<sup>2</sup>). The new H-Fit and T-Fit shoes are more comfortable than a total contact cast. Furthermore, patient could remove it to facilitate wound dressing change.

Clearly, there are definite benefits of using the H-Fit and T-Fit shoes to off-load diabetic foot ulcerations. It is also cost effective. We are actively using both of the shoes in our clinic to off-load the diabetic foot ulcers. Additional clinical studies to further evaluate the benefit of the shoes are in the planning.

### References

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