by Hienvu Nguyen, DPM

Diabetic shoe and insole stress reduction for ulcer care

The American Diabetes Association reports that 20.8 million people, or 7% of the U.S. population, have diabetes. Many people first become aware that they have the disease when they develop one of its major complications such as blindness, heart disease, stroke, peripheral vascular disease, and numbness or neuropathy in the feet. The high blood sugar levels associated with diabetes also affect the body's immune system and slow wound healing.

Complications of diabetic foot problems are the most common cause of nontraumatic lower extremity amputations in the U.S. The risk of lower extremity amputation is 15 to 46 times higher in people with diabetes than in those without the disease, 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 ulcers is alterations in pressure on the plantar surface of the foot, especially the forefoot and heel areas. Foot deformities, which are common in patients with diabetes, lead to focal areas of high pressure. When an abnormal focus of pressure is coupled with lack of sensation, a foot ulcer can develop. Therefore, offloading plantar foot pressure is an important component in the treatment of diabetic foot ulcerations.

Current offloading techniques

There are many offloading techniques and devices available, each having specific applications according to the anatomic location of the wound. Offloading devices made for nonambulatory use include airflow mattresses, soft padding for beds and wheelchairs, 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 offloading device is the total contact cast, which acts to transfer weight away from the foot and redistributes weight-bearing forces proximally to the leg. A removable cast walker device achieves much of the same offloading as a total contact cast but is often more easily tolerated by the patient because it is removable for bathing and daily wound care. Another, less ideal, offloading device is a half-shoe (or so-called wedge shoe), a postoperative/surgical shoe with a layer of soft, accommodative padding. A randomized clinical study compared the effectiveness of total contact casts, removable cast walkers, and half-shoes to heal neuropathic foot ulcerations

Without proper offloading, ulcers such as this one may heal more slowly, possibly putting the patient's limb at risk.

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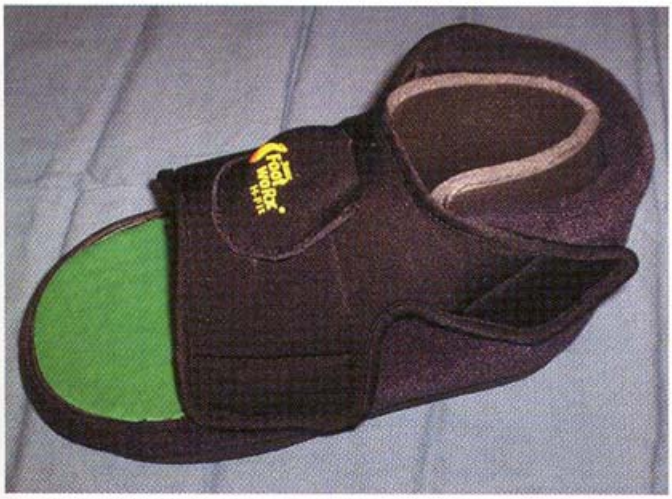

The round-toed H-fit shoe is designed to offload the pressure on diabetic ulcers.

in diabetic patients and found that a significantly higher percentage of patients (89.5%) were healed in 12 weeks in the total contact cast group than with the two other modalities (65% and 58.3%, respectively).[1]

A new diabetic healing shoe

Introduced in August 2005, 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 via heavy-duty Velcro straps. The H-fit is designed for offloading the typical diabetic foot ulcer. The T-Fit is designed to offload plantar pressure in patients who have had a transmetatarsal amputation. The main innovative feature of the H-fit and T-fit shoes is a new insole design that can significantly reduce plantar pressure under the forefoot and heel. The shoes retail for $150 and are not reimbursable by Medicare.

This insole consists of a bottom layer of shock-absorbing and shear-reducing composite layers of Poron or soft EVA, a middle layer of plastazote or cushioned polymer gel, and a closed-cell neoprene topcover. These materials are commercially available in sheets.

Shear stress reduction is accomplished by the middle layer, since it has the elastic property to "slide" or "give" between the 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 design, compared to existing insoles, comes from the holes evenly spaced throughout the insole. These holes significantly reduce the direct plantar pressure and shear stress dynamically exerted on the skin of the plantar surface upon loading. When there is a focal point of pressure, the holes distort or stretch in the direction of the pressure, which also allows the insole material to distort, or "give," resulting in reduced peak plantar pressure and associated shear stress. This material distortion also eliminates pressure transfer problems that are sometimes encountered with other insoles. Therefore, dynamic direct plantar pressure and shear stress can

The square-toed T-Fit shoe is designed to offload plantar pressure in transmetatarsal amputation patients. (Shoe has an H-Fit strap for demonstration.)

be significantly reduced by these holes. Removing the pressure allows the insole material to return to its original state.

This insole can also be used to offload plantar pressure from feet with bony prominences due to plantar fat pad atrophy in people with rheumatoid arthritis.

Another feature of the H- and T-fit shoes is the enclosed pedometer. With the pedometer, practitioners can effectively measure patients' compliance—whether they are using the healing shoes as instructed or not. It can also be used to limit patients' walking, say after the pedometer has reached a certain number of steps. The pedometer is set when the shoe is dispensed; the number of steps are reviewed and recorded every time the patient returns to the clinic. The typical number of steps recorded has been around 2500 per day for patients with diabetic foot ulceration.

Peak plantar pressure of various insoles

To determine plantar pressure under the medial forefoot and heel, we conducted a preliminary study using a plain surgical shoe, a surgical shoe with a laminated insole of 1/4-inch pink plastazote and 1/8-inch PPT (this is the normal insole material for diabetic shoes), and a surgical shoe with an insole of a 1/4-inch soft EVA bottom layer, a 1/4-inch pink plastazote middle layer, and an 1/8-inch Spenco top layer, all laminated together. The first insole was solid and the other had 3/16-inch holes, evenly spaced 1/2-inch apart, drilled through all layers of the insole.

Plantar pressures were measured using the F-Scan in-shoe pressure measurement system (TekScan, South Boston, MA). A 135-pound female subject walked on a treadmill at 1.5 mph under all three conditions. Data were collected and tabulated.

As indicated in the table on page 66, results with both insoles were lower than with the plain surgical shoe and the reduction was greatest for the insoles with holes.

PRESSURE MEASUREMENTS OF OFFLOADING FOOTWEAR OPTIONS (IN N/CM^2)

DEVICE	PRESSURE	
	MEDIAL FOREFOOT	HEEL
Plain surgical shoe	10.35	13.8
Insole #1 (without holes)	9.66	12.42
Insole #2		
Without holes	8.98	11.73
With holes	6.9	10.35

A similar study conducted by Lavery and colleagues[2] looked at the mean peak pressure of ulcers for six offloading treatments and found the total contact cast had the lowest mean peak pressure under the first metatarsal head (medial forefoot) and diabetic extra depth shoes had the highest. Mean peak pressure at that site for the shoes was more than five times higher than for the TCC. Pressure at that site in a surgical shoe with the new insole is only 3 N/cm^2 above that for the total contact cast.

A study by Armstrong and Stacpoole-Shea[3] reported on peak plantar pressure at the heel for four offloading treatments and found that though the total contact cast reduced pressure at the heel significantly more than the other modalities studied, pressure was not as low as that achieved with the new diabetic insole in a surgical shoe.

Conclusion

Comparing it to the above studies for peak plantar pressure under the medial forefoot and the plantar heel, there is not a substantial difference between this new diabetic insole and the total contact cast, which is the gold standard for diabetic foot ulceration offloading, to offload the medial forefoot. However, the insole is much more effective at offloading pressure at the plantar heel. The new H-fit and T-fit shoes are more comfortable than a total contact cast. Furthermore, patients can remove them to facilitate wound dressing changes. They are also cost-effective.

We are actively using both of the shoes in our clinic to offload diabetic foot ulcers. Additional clinical studies to further evaluate the benefit of the shoes are being planned.

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References are available online at www.biomech.com.