Continuing Medical Education

Pressure Reduction and Off-Loading the Diabetic Foot

Steps to take to reduce pressure stress.

Objectives

1) To know the risk factors for diabetic foot ulceration and why it is important to unload the diabetic foot.

2) To be familiar with the different off-loading modalities for healing diabetic foot ulcers, including: footwear, insoles, foot orthoses, prefabricated walking braces, total contact cast, Charcot Restraint Orthotic Walker (CROW) Orthosis, and PTB orthosis.

3) To know the indications for each of the different off-loading strategies above.

4) To know the advantages and disadvantages of each of the different off-loading strategies above.

5) To have some familiarity with the latest research in off-loading the diabetic foot.

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*Following this article, an answer sheet and full set of instructions are provided (p. 114).—**Editor***

By Ellen Sobel, D.P.M., Ph.D. and Steven J. Levitz, D.P.M.

Over 40 years ago, Bauman[1] concluded that healing trophic ulceration in anaesthetic feet in leprosy patients largely depended on the even distribution of pressure over the sole of the foot. It has now been well established that pressure reduction (off-loading) is critical for the healing of plantar ulcers in the neuropathic diabetic foot. Off-loading is also crucial for the patient with acute Charcot foot for healing and maintenance.

The reason that off-loading is so important is that 85 percent of lower extremity amputations in people with diabetes mellitus are preceded by a foot ulcer.[2] Therefore, by healing the diabetic foot ulcer, lower extremity amputations can be prevented. A large study of male veterans showed

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that the most common causal pathway to lower extremity amputation began with repetitive micro-trauma, leading to an ulcer that failed to heal.[2]

People with diabetes mellitus have been found to have high plantar foot pressures on weight bearing most commonly under the metatarsal heads. High peak plantar pressures are a great risk factor in the development of a foot ulcer and correlate with the sites of ulceration.[3,4] A number of factors are associated with high plantar pressure and risks for ulceration in people with diabetes. These include: peripheral neuropathy,[5-7] foot deformities such as hammer toes and bunions,[8,9] hyperkeratosis[10,11] limited joint mobility (Figure 1A/1B)[12-15] and history of foot ulceration.[16-18]

Although peripheral neuropathy is the single greatest risk factor for foot ulceration,[19] two or more of the risk factors above generally produce a synergistic effect in the production of a foot ulcer. For example, diabetic individuals with neuropathy and foot deformities such as hammer toes, hallux valgus, or Charcot foot are twice as likely to develop foot ulcers as those with neuropathy alone.[9] Diabetic neuropathic patients with high plantar pressures are more likely to develop a foot ulcer than diabetics with peripheral neuropathy, and normal plantar pressure.[17]

A large study of male veterans showed that the most common causal pathway to lower extremity amputation began with repetitive micro-trauma, leading to an ulcer that failed to heal.

High plantar pressures occur in people with rheumatoid arthritis which are equal to those in people with diabetes mellitus, but foot ulcers do not occur in individuals with rheumatoid arthritis, suggesting that high plantar weight-bearing pressures may be a necessary but not sufficient condition for a foot ulcer to form.[20]

There are other threats to ulcer healing in the diabetic foot beside high plantar pressures. For example, peripheral vascular disease is the most important factor related to outcome of foot ulcer healing.[21] A transcutaneous oxygen tension of greater than 30 mm Hg (normal 55 mm Hg) is necessary for a diabetic foot ulcer to heal.[22] Control of blood glucose is known to delay the onset of peripheral neuropathy[23-25] and poor glucose control has been associated with recurrence of diabetic ulcers.[26-27] Finally, thoroughly debrided ulcers have been shown to heal faster than non-debrided ulcers.[28]

There have recently been a large variety of off-loading modalities designed to reduce weight bearing pressure on the diabetic foot. This article will discuss all of the off-loading devices that are currently used to reduce pressure and heal diabetic ulcers and ac-

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Figure 1A: 64 year old male with neuropathic foot and hallux limitus.

Figure 1B: Same patient. Neuropathic ulcer under the base of the hallux, one of the most common sites of ulceration in the neuropathic foot. Limitation of passive extension of the great toe contributes to the risk of ulceration in this patient.

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commodate and off-load the diabetic foot. However, emphasis is placed on footwear, insoles/foot orthoses and the prefabricated walking brace, since they are used the most in primary care centers.

The goal of off-loading therapy is to keep the patient ambulatory while reducing weight-bearing pressure on the foot.[29] Guzman and associates[20] reviewed the various pressure removing treatment modalities and reported that a good pressure reduction modality must be: effective in removing pressure from the ulcer site at all times, be able to be applied to all types of patients, cause no secondary lesions or complications, easy to don and doff, encourage good patient compliance, allow optimal pursuit of other treatment goals and be cost effective. The above criteria should be kept in mind as the off-loading devices are reviewed in detail. Most off-loading techniques require between four and twelve weeks for the ulcer to heal.[28,29]

Foot Wear

About half of diabetic patients with preexisting peripheral neuropathy have a footwear-related pivotal event leading to their eventual limb amputation.[31] Shoes reduce plantar weight bearing pressure by increasing the weight-bearing surface area (Figure 2),[32] reduce callus formation and are critically important in prevention, healing, and avoiding recurrence of ulcers in the diabetic foot.[33] Peak

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Figure 2: Four different shoe soles demonstrate variability in surface area of the sole of the shoe.

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weight-bearing foot pressures were found to be lower when walking in a shoe than when walking barefoot.[34] Adding a soft cushioned insert to the shoe decreases weight-bearing pressure still further. In one study the addition of a dual density plastazote/PPT and viscoelastic insoles provided significant reduction in mean peak pressure with all shoe types tested including added-depth shoes, running shoes and SAS comfort shoes.[35] The incidence of foot ulcers was reduced from 72 percent to only 15 percent in patients with diabetic foot syndrome wearing molded shoes with rocker soles and 10mm thick insoles for 25 months.[36] In one study eight out of 17 open lesions were closed in less than two months using therapeutic footwear and custom foot orthoses.[37]

Patients with a healed diabetic ulcer are frequently placed in special footwear to prevent the ulcer from recurring. The use of therapeutic shoes has been shown to be effective in preventing recurrence in diabetic patients with previous ulceration. In three studies which measured the relapse rate in patients placed in therapeutic shoes after an ulcer healed, the recurrence rate ranged from

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Figure 3: Extradepth shoe (P.W. Minor & Son, Batavia, NY) with enough room for insert. Shoe has blucher closure, wedge heel, stiff counter, and high wide toe box.

Figure 4: APEX Ambulator (APEX Industries, South Hackensack, N.J.).

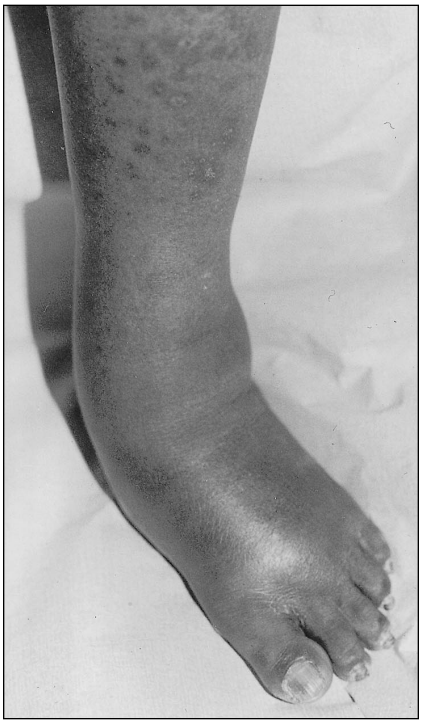

Figure 5A: Patient with acute Lisfranc fracture dislocation as a first sign of charcot neuropathic arthropathy.

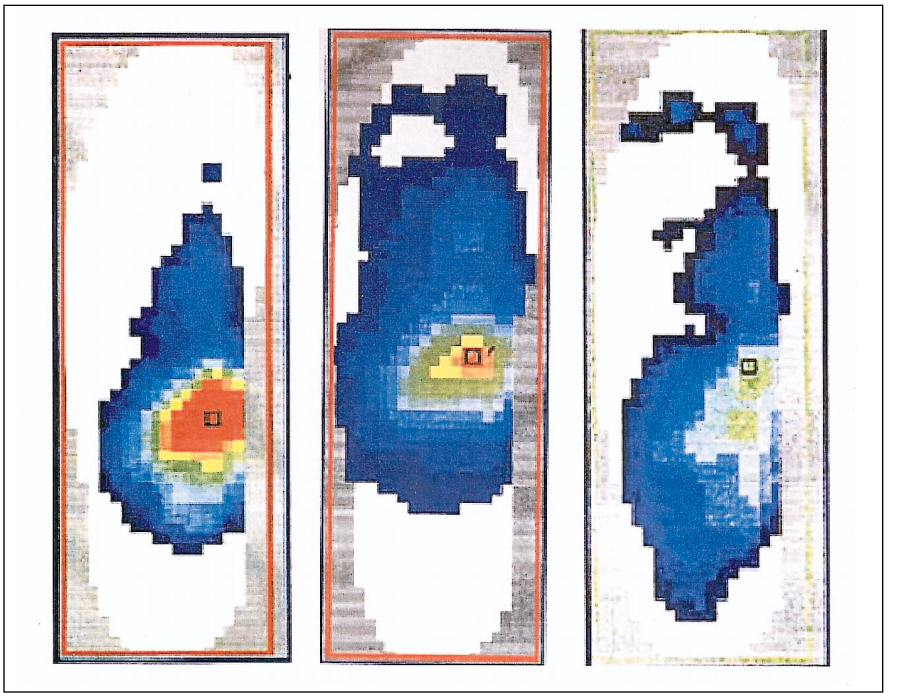

Figure 5B: Fscan analysis taken about six months later. Left: Patient walking with Equalizer Below Knee Walking Brace. Center: Patient walking with molded shoe. Right: Patient walking with Apex Ambulator shoe, shows greatest pressure reduction at Lisfrac joint area.

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26 percent to 42 percent in patients who continued to wear their therapeutic footwear versus 58 percent to 87 percent when patients wore their own shoes.[36,38,39]

In those who did have an ulcer recurrence, it tended to occur earlier in those who did not wear therapeutic shoes (3 months in those not wearing special shoes versus 9 months in those wearing therapeutic shoes).[39] The type of therapeutic shoe worn (custom molded versus added-depth) did not affect the recurrence rate of ulcers.[36,38] It is important that patients wear the shoes all of the time. In one study patients wearing their prescribed shoes more than 60 percent of the time reduced the ulcer relapse rate by greater than 50 percent compared to patients who wore their prescribed shoes for less time.[40]

Foot ulcers do not occur in individuals with rheumatoid arthritis, suggesting that high plantar weight-bearing pressures may be a necessary but not sufficient condition for a foot ulcer to form.

Conversely, the shoe may cause an ulcer mostly on the toes and the dorsum of the foot when the shoe is too tight. The most common cause of minor trauma to the diabetic foot is from poorly fitting shoes.[1,41,42] Shoe selection for the diabetic foot depends on the presence of peripheral neuropathy, foot deformity, and history of ulceration.[32] Patients with insensate feet are more likely to be unaware of foreign bodies in the sole of the shoe or adjust properly to poor walking surfaces and may require accommodative additional insoles in the shoe. Foot deformity such as rigid hammer digits, requires the roominess of an added-depth shoe with a high toe box. Generally a multilaminated insole will only fit into an added-depth shoe.

Medicare reimburses patients with diabetes mellitus with peripheral neuropathy for one pair of therapeutic shoes, shoe modifications, and three pairs of dual density accommodative inserts.[43] Shoe modifications include: rocker soles, metatarsal bars, wedges, flared heels, velcro closures, and toe fillers.[43] However, the Medicare Shoe Bill is grossly underutilized because of the difficult access and only .6 percent of beneficiaries meeting the Medicare inclusion criteria

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had a therapeutic footwear claim in 1995.[44]

The shoe for the diabetic foot with peripheral neuropathy, moderate forefoot deformities, and a healing or healed ulcer should be laced with blucher closure to provide maximum adjustability.[45] An added-depth shoe with wide high toe box, soft leather upper, cushioned rubber crepe sole and removable insoles is preferred (Figure 3). A low wedged sole offers greater support and stability and has a greater sole surface area for pressure reduction than a separate heel and toe. The heel should be no higher than one inch. There should be 3/8 to 5/8 inch in length beyond the longest toe and the end of the shoe.[46,47] Shoes older than two years tend to lose their shock absorption.[34]

Medicare regulations stipulate that the depth inlay shoe must have a minimum of 3/16 inch additional depth through the shoe when removable insoles are taken out of the shoe.[43] Standard dual density insoles for the extra-depth shoe consist of medium pink plastazote 2 and firm white plastazote 3. The Extra-depth shoe (P.W. Minor & Son, Batavia, NY) is one of the most commonly prescribed shoes for the foot pathology associated with the diabetic foot (Figure 3). Extra-depth shoes combined with padded stockings were found to reduce in-shoe foot pressures in diabetic patients at risk for foot ulceration when compared to their own footwear.[48] SAS comfort shoes (SAS Shoemakers, San Antonio TX) have recently been found to be as effective in pressure reduction as the extra depth shoe or running shoes.[35]

The APEX Ambulator (South Hackensack, NJ) shoe includes an insole made of blue ethyvinylacetate (EVA), antishock-Apex pink plastazote top and thermoformed urethane (Figure 4). The APEX Ambulator shoe was the most effective off-loading device as demonstrated by F-scan analysis for a patient with Charcot arthropathy with LisFranc fracture dislocation at the authors' institution (Figure 5A/B).

Molded shoes have a place in the treatment of the diabetic foot especially when the deformity is severe, such as in Charcot foot or even in severe hammer toe and hallux valgus. The MABAL molded therapeutic shoe and custom insole served as the primary unloading device healing 21 of 23 two-centimeters-square ulcers under the metatarsals and hallux with a mean healing time of thirty-four days.[49]

Running shoes also have been found to be effective in reducing the size of plantar calluses in diabetics[50] as well as a reduction of 30 percent in forefoot pressure.[51]

IPOS Postoperative Half Shoe/Healing Sandal

The IPOS postoperative shoe was originally designed to take all pressure off the forefoot for use after surgery.[52,43] The shoe has a 10 dorsiflexory wedge and the heel is elevated four centimeters to avoid any forefoot contact with the ground when walking (Figure 6). The shoe cannot be worn by individuals with ankle equinus or used for bilateral ulcers. Half shoes were shown to

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TABLE 1
MATERIALS USED FOR SHOE INSERTS IN DIABETIC INDIVIDUALS

PLASTAZOTE (Apex Foot Products, South Hackensack, N.J.)
Closed cell cross linked irradiated polyethylene foam with nitrogen gas. Durometer Medium=20; firm=35; Rigid=69 (Skin=20). Thermomolding and pressure holding. Will deform to contours of foot.
PPT (Langer Biomechanics Group, Inc., Deer Park, NY),
Open cell urethane foam. About 20 durometers. Smooth on one side. Abraded on other side. Covered with nylon or synthetic suede. Thermosetting.
SPENCO (Spenco Medical Corp., Waco, Tx)
Neoprene rubber foam with enclosed nitrogen gas with nylon covering. Has three way stretch. Decreases shock and shear. Thermosetting.
PELITE (Durr-Fillauer Medical Inc., Chattanooga, TN),
Cross-linked copolymer of polyethylene and EVA. Comes in 4 durometers. Thermomolding.
SORBOTHANE (Sorbothane, Inc., Kent, OH)
Non cellular polyurethane visco-elastic polymer. Thermosetting

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heal ulcers faster and be associated with fewer serious infections than patients treated with standard wound care therapy.[52]

In a retrospective review of patients with Wagner grade 1 and 2 neuropathic forefoot ulceration, 77 percent of patients healed their ulcers with an IPOS postoperative half shoe and wore prescription inserts and extra-depth shoes at a mean of 8 weeks follow-up. However, complications consisting mostly of imbalance, falls, bone and joint pain and new ulcerations occurred in 38 percent of patients.[52] In another study a customized healing sandal with a 25 degree rigid forefoot rocker significantly reduced forefoot pressure as compared to prescription added depth shoes.[54]

In one study the addition of a dual density plastazote/PPT and viscoelastic insoles provided significant reduction in mean peak pressure with all shoe types tested including extra-depth shoes, running shoes and SAS comfort shoes.

Insoles

Insoles are an important effective treatment for neuropathic ulcers and markedly help the shoe in pressure reduction. In one large study 88 percent of ulcers were fully healed by soft inserts and corrective foot wear within the eighteen-month study period.[55] The type of materials, thickness, and shape are all important. Shoe inserts for the diabetic patient are most commonly soft and accommodative with good cushioning. The insert must be of an appropriate thickness and the greater the thickness the better the pressure reduction.[36]

Figure 6: IPOS Postoperative Half Shoe.

The main pressure dispersing material used for shoe inserts in individuals with diabetic foot problems is plastazote (Apex Foot Products, South Hackensack, N.J), a closed-cell polyethylene foam available in three color-coded grades of density. It can be heated to 280° F and molded directly to the patient's foot. The main shock absorbing materials are PPT (Langer Biomechanics Group, Inc., Deer Park, NY), an open-cell urethane foam and Spenco (Spenco Medical Corp., Waco, TX), a neoprene rubber foam with nylon covering (Table 1).

Medium plastazote (plastazote 1; pink plastazote) fatigues very rapidly in both compression and shear corresponding clinically to the phenomenon of "bottoming out." For the insensitive foot using plastazote, the force of walking will dissipate through compression of the insert rather than through breakdown of the plantar skin. This is a function of the easy compression of the material.[56] However, due to its extreme loss of thickness upon loading,

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plastazote works best when combined with other materials (Figure 7). Plastazote is generally laminated as the top layer against the skin with PPT or Spenco on the bottom for shock absorption. A 1/4 inch medium plastazote insert used in a sedentary diabetic individual is estimated to last eight weeks.[56]

PPT and Spenco inserts were not found to be reduced in pressure relief after being worn for one month.[57] When plastazote and Poron are used together they provide excellent cushioning, self accommodation and shock attenuation.

Plastazote, latex foam, PPT, Spenco, ortho felt, and molo have all been demonstrated to decrease plantar pressure; however, plastazote and Spenco resulted in the greatest reduction in pressure in one study[58] although others have found no difference in pressure reduction properties of plastazote, Spenco, and PPT, but did find significant plantar pressure reduction of these materials as compared to no insole.[59]

Although plastazote insoles are consistently found to lower plantar pressure, modifying the insoles with metatarsal pads and medial longitudinal arch pads did not improve on pressure reduction in diabetic patients with and without hallux amputations.[60]

Extra-depth shoes combined with padded stockings were found to reduce in-shoe foot pressures in diabetic patients at risk for foot ulceration when compared to their own footwear.

In a study testing the effectiveness of insoles to heal ulcers, 37 out of 38 diabetic patients with foot ulcers healed after using a specially-constructed insole for an average of 3.6 months.[61] In this study a temporary insole was dispensed for the patient to walk with for the first two weeks and subsequently a modified insole was manufactured from imprints in a plastazote model.[61] The pressure under the ulcer was redistributed by redirecting it more proximally by excavating the insole under the ulcerated area.[61]

Recently a rocker insole (Langer Biomechanics, Deer Park, New York) has been found to be effective for the treatment of metatarsal head ulceration.[62] The rocker insole works to alleviate forefoot pressure like the rocker-bottom, with the advantage that

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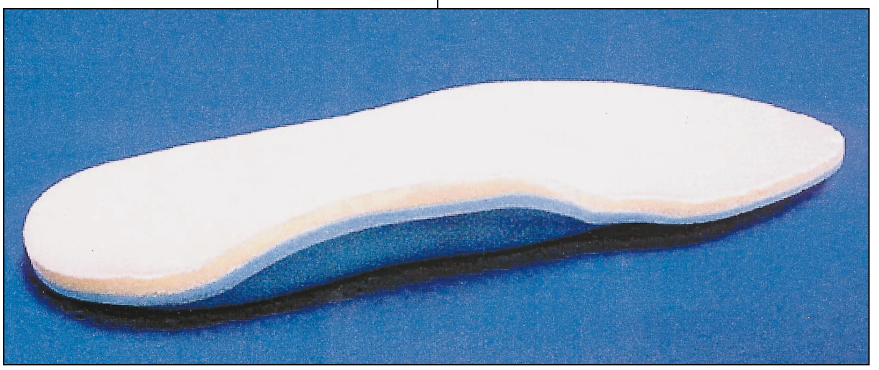

Figure 7: Prefabricated molded insole shows laminations of medium pink plastazote with blue PPT sole.

Figure 8: Custom foot orthosis for people with diabetes mellitus. (LBG, Biomechanics, Deer Park, New York).

Figure 9A: DH-Pressure Relief Walker (Royce Medical Co., Camarillo, CA).

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the patient is not exposed to the likelihood of tripping in a rocker bottom sole.

Custom Foot Orthoses

Custom foot orthoses seem to work better than insoles in pressure reduction and ulcer healing and the mechanism at least in some cases seems to be by increasing surface area (Figure 8). In one study seven diabetic patients with foot ulcers or past histories of foot ulcers, plantar pressures were reduced 56 percent in patients wearing custom foot orthoses and there was a corresponding 63 percent increase in contact area suggesting a more even pressure distribution in the custom foot orthoses.[63] Custom foot orthoses were found to reduce plantar pressure in diabetic patients with a pronated foot type.[64]

The reduction of forefoot pressure with the custom foot orthoses was thought to have been achieved partly by redistribution of the load into the midfoot area.

Custom foot orthoses have been shown to reduce forefoot peak plantar pressure more effectively than flat inserts.[65] The custom foot orthoses in this study were fabricated with a rigid plastazote shell, a PPT middle layer and a soft plastazote top cover with a thickness of 19 mm in the forefoot area. The flat PPT insoles were 6 mm thick. The reduction of forefoot pressure with the custom foot orthoses was thought to have been achieved partly by redistribution of the load into the midfoot area as well as the increased cushioning from the thickness of the custom foot orthoses. Although foot orthoses for diabetics tend to be soft and accommodative, rigid orthoses have also been found to reduce plantar pressures in the insensitive foot.[66] After 12 months of treatment with rigid foot orthoses, diabetic patients showed a significant reduction in callosities.[67]

The custom foot orthosis for diabetic patients with foot deformities must redirect pressure away from the high pressure callused metatarsal heads and support the arch in the hyperpronated foot. The prescription generally consists of a medium plastazote top cover, a PPT dispersion pad and a thin polyethylene thermoplastic, or rigid plastazote shell for arch support.

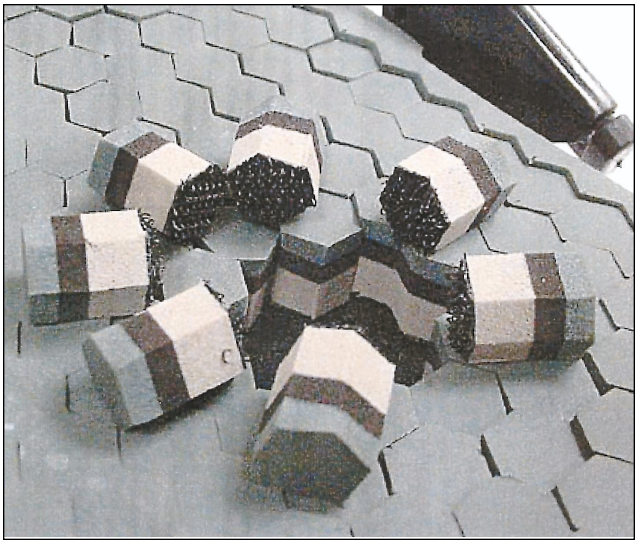

Figure 9B: Hexagonal Plugs of the DH-Pressure Relief Walker should be left in place.

Total Contact Casting

The total contact cast is a well-molded, thinly padded below-knee cast that covers the entire foot. It can be fabricated of plastic or fiberglass with or without a walking heel and can be used to unweight ulcers on the plantar forefoot, midfoot or heel. The total contact cast unweights the foot by transferring pressure to the walls of the cast.[68] It is indicated for superficial plantar ulcers (i.e., Wagner grades I and II) in the presence of decreased or absent sensation.[69] The patient does not have to have diabetes mellitus. Neuropathic ulcers of virtually any etiology can be treated with a total contact cast. However, the patient must have adequate circulation and there must be no sign of infection. The total contact cast

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has been used on pedal ulcers in diabetic immunosuppressed patients after transplantation.[70] Hard-to-heal interphalangeal ulcers under the great toe have been treated with Keller arthroplasty in conjunction with total contact casting.[71]

Healing ulcers with the total contact cast is reported to occur on average 91 percent of the time (range 73 percent to 100 percent) and takes one to two months from the initial start of casting.[72]

Although the total contact cast remains the gold standard for off-loading the diabetic foot,[73] no significant differences were found in plantar pressure measurements between conventional short leg casts and total contact casts in healthy volunteers[74] nor in patients with Charcot midfoot collapse and rockerbottom deformity.[75] The complication rate for total contact casting ranges from 6 percent to 54 percent. The recurrence rate within the first four weeks after healing with total contact casting is between 35 percent and 57 percent.[76]

The likelihood of re-ulceration within the first six months after initial healing of a foot ulcer is so high that some consider healing successful only after six months of continuous skin closure.[77,78] The total contact cast may soon be replaced by the prefabricated walking brace as the most effective unweighting device for the diabetic foot (see below).

Prefabricated walking braces have been found to reduce plantar weight bearing pressure in healthy and diabetic subjects, but their effectiveness in actually healing diabetic ulcers in random clinical trials has not yet been demonstrated.

Prefabricated Below-Knee Walking Brace

Although the custom ankle-foot orthosis has been recommended for closing ulcers in the diabetic foot and preventing their recurrence,[79] the prefabricated below-knee walking braces, including the DH-Pressure Relief Walker (Royce Medical Co., Camarillo, CA) (Figure 9A/B).[80,81] Equalizer Premium Walker (Royce Medical Co., Camarillo, CA),[82] and Aircast Pneumatic Walker (Summit, NJ) (Figure 10),[83,84] formerly used for lower extremity trauma, have recently been found to be effective in reducing plantar pressure in the diabetic foot and have become very popular unweighting devices. Average peak forefoot pressures were reduced greater than 51 percent using the Equalizer Premium Walker and Aircast Walker.[82]

In contrast to the total contact cast these prefabricated walking braces are relatively easy to use, inexpensive, and allow easy access to the wound for dressing changes. The prefabricated walking brace provides the necessary

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Figure 10: Aircast Pneumatic Walker (Summit, New Jersey). This brace is most commonly compared to the Total Contact Cast because it hugs the foot and leg, maintaining total contact for reduction of edema and pressure.

Figure 11: Charcot Restraint Orthotic Walker (CROW) Orthosis.

Figure 12A: Patellar Tendon Bearing (PTB) Orthosis, plastic type, was designed to simulate the weight bearing of a PTB Prosthesis (shown on left).

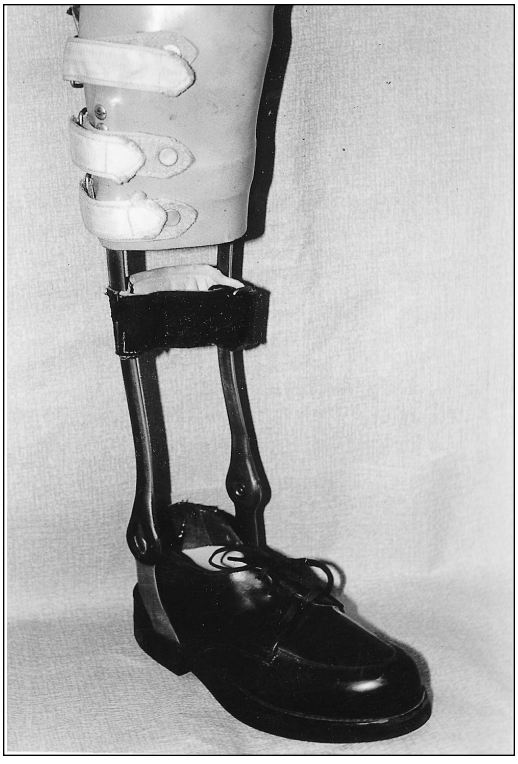

Figure 12B: PTB Orthosis, metal double upright type.

stability while allowing easy donning and doffing for physical therapy sessions, washing and sleeping. A rocker sole or ankle joints may be added to facilitate ambulation.[84] The prefabricated walking brace can be used for immobilization of the Charcot foot in diabetic patients.[85]

In one study the DH Pressure-Relief walker (Royce Medical Orthopaedics, Carmarillo, CA) (Figure 9) reduced plantar pressures under all the metatarsals and the great toe significantly better than several other off-loading devices tested and reduced forefoot pressure equally as well as the total contact cast.[80] In another study comparing the DH Pressure Relief Walker with the Total Contact Cast in the reduction of plantar pressure reduction, the DH Pressure Relief Walker reduced plantar forefoot pressure 85 percent from baseline as compared to 76 percent reduction in plantar pressure with a Total Contact Cast.[81]

The Aircast Pneumatic Walker, because of its air bladders in the rigid shell, has the advantage over other prefabricated below-knee walkers of a total contact fit to reduce edema and shear forces (Figure 10).[86] In a study comparing the Aircast Pneumatic Walker with the total contact cast, the Aircast Pneumatic Walker decreased peak plantar foot pressures to an equal or greater degree than the total contact cast in all tested locations of the forefoot, midfoot and hindfoot in 10 healthy male volunteers.[83]

Recently introduced is the new prefabricated walking brace, the Bledsoe Conformer Diabetic Boot (Bledsoe Brace Systems, Grand Prairie, TX) which has been reported to combine the pressure reduction features of the total contact cast with the comfort and ease of wear of a removable walking brace.

Although these prefabricated walking braces have been found to reduce plantar weight bearing pressure in healthy and diabetic subjects, their effectiveness in actually healing diabetic ulcers in random clinical trials has not yet been demonstrated.

Crow Orthosis

For patients with Charcot foot too deformed to fit into an added-depth shoe, the Charcot Restraint Orthotic Walker (CROW) may be indicated (Figure 11). The CROW orthosis is a rigid, custom full-foot enclosure ankle-foot orthosis[87] which provides immobilization and protection during the prolonged healing of diabetic neuroarthropathy. The orthosis is constructed with a total posterior and anterior shell which includes the foot so that a patient does not need to wear a shoe with the brace as would be necessary with a regular plastic AFO or PTBO. Eighteen patients rated their CROW orthosis as good to excellent and none reported significant activity restrictions while wearing the orthosis and all patients believed that their life style was markedly improved.[87] The total contact bi-valved, rocker-bottom-sole ankle-foot orthosis was shown to be effective in controlling the complications in 14

The felted-foam padding with an aperture for the ulcer is directly applied to the full length of the plantar aspect of the foot. The felted foam padding works well as additional padding in the prefabricated walking brace.

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individuals with Charcot foot.[88] In a more recent report, all patients wearing the CROW orthosis noted varying measures of improvement in symptoms and function at an average 12-month follow-up.[89]

Patellar Tendon Bearing Orthosis

The Patellar Tendon Bearing Orthosis (PTBO) is one of the original orthoses for unweighting the rearfoot and the leg.[90,91] It has a pretibial component in which the patient rests his upper leg and knee when ambulating (Figure 12A/B). Patients are trained to walk by sinking their weight into the pretibial shell and the weight is transferred down the uprights to the floor, bypassing the leg and the rearfoot. When patients walk properly with the PTB and a cane, it has been found to reduce weight bearing on the leg and rearfoot up to sixty percent.[92]

The PTB was originally indicated for patients with fractures of the leg and rearfoot, and to unweight a painful diabetic Charcot rearfoot.[90] It has been used to unweight patients with painful chopart joint amputations.[93]

More recently, a study of 10 healthy subjects showed the PTB orthosis was significantly more effective in reducing plantar pressure than walking with a cast shoe.[94] The PTBO has also recently been found to be successful as an adjunctive treatment in patients with significant lower-limb ischaemia and tissue loss complicated by neuropathy.[95] Eight patients with lower-limb ischaemia and neuropathy had ulcer healing wearing the PTBO within five months.[96]

Patients are able to walk with the PTBO while the ulcer is healing and once the ulcer has healed the brace can be used prophylactically. The PTBO has the advantage over total contact casting of being removable and is easier to maintain.[96] It comes in metal and plastic varieties and must have a solid ankle and rigid anterior shell closure to work properly.[97-99]

It is also helpful to have a heel-shoe clearance of 3/8 inch to one inch and a rocker sole.[100] The advantage of the metal double upright variety is that patients with diabetes with neuropathy, who are most likely to use this orthosis, may not be able to tolerate a plastic orthosis directly against the skin even if the orthosis is lined with pelite or plastazote foam.[96]

Felt and Foam Total Contact Padding

Foam and felt padding is a technique used to off-load ulcers on the plantar and marginal aspect of the foot.[30] One-quarter inch foam with single-sided adhesive positioned on the plantar aspect of the foot is combined with one-quarter inch felt. The felted-foam padding with an aperture for the ulcer is directly applied to the full length of the plantar as-

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TABLE 2
SUMMARY OF METHODS OF OFF-LOADING THE DIABETIC FOOT

Off-Loading Modality	Comments/Advantages/Disadvantages
Complete Bed Rest	Compliance is difficult
Assistive Device	Canes/Crutches
Total Contact Cast	Gold Standard of Off-loading Modalities Can be constructed of plaster or fiberglass. Indications: Neuropathic ulcers from any cause/Wagner Grade 1 & 2 ulcers which are not infected; Circulation must be good. Ulcer may occur anywhere on the plantar aspect including: forefoot, midfoot, or rearfoot, however most effective in healing forefoot ulcers. Cast should be changed usually weekly. Effective in healing 80% of neuropathic ulcers Wagner Grade 1 & 2 within two months. Advantages—Efficient off-loading; Total patient compliance; Controls edema. Disadvantages—Expensive, hard to use, cannot be tolerated by many patients.
Walking Brace	Prefabricated. DH Pressure Relief (Royce Medical Co.,Camarillo, CA) Aircast Pneumatic Walker (Aircast, Summit, New Jersey) Has been shown in pressure reduction Studies with in-shoe pressure reduction Measurements to be as effective in reducing plantar pressure as the Total Contact Cast. Advantages—Inexpensive, easy to use, offers easy access to the wound, can be used with infected wounds, has been shown to reduce pressure effectively with in-shoe pressure measurement systems; Good for patients who cannot tolerate a cast. Disadvantages—Patients may have a tendency to not be compliant and not wear the walking brace.

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pect of the foot. The felted foam padding works well as additional padding in the prefabricated walking brace. Contraindications include interdigital or dorsal ulcers, severely atrophic plantar skin, acute tinea pedis, and adhesive sensitivity. See Table 2 for a summary of the off-loading devices. ■

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TABLE 2 *(CONTINUED)*
SUMMARY OF METHODS OF OFF-LOADING THE DIABETIC FOOT

Off-Loading Modality	Kinds/Advantages/Disadvantages
Half-Shoe	OrthoWedge Healing Shoe (Darco International, Inc. Huntington, WV) Has a 10˚ dorsiflexory wedge. Patient must have good ankle dorsiflexion range of motion. Good for ulcers under the hallux and lesser digits. Cannot be used bilaterally. Complications include balance problems and falling. Advantages—Easy to use, inexpensive, provides total unloading of the forefoot, easy access to the wound. Disadvantages—Cannot be used for patients with ankle equinus. Tendency to create instability and patients may fall, this may especially be a problem in the elderly.
Insoles	Should be multidensity, soft, full foot Plastazote/PPT Combination with plastazote against the skin for dispersion of pressure and PPT closest to ground for cushioning and shock absorption.
Shoe Wear	Extradepth shoes with plastazote insoles form the standard of care for the basic pressure reduction for the diabetic foot. A rocker bottom sole may be helpful in reducing pressure from the metatarsal heads. Molded shoes may be necessary for diabetic patients with severe charcot foot deformity.
Custom Foot Orthosis	Should be accommodative and soft.
Patellar Tendon Bearing (PTB) Orthosis	Unweights the rearfoot Can effectively reduce rearfoot pressure up to 60% when used with a cane. Must be constructed with a solid ankle and a stable pretibial shell. Can be made of plastic or metal. Disadvantages—Not a comfortable brace. Patients must use a cane and be taught to walk in a new way sinking their upper leg into the brace in order for maximal unweighting of the rearfoot to occur.

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TABLE 2 *(CONTINUED)*
SUMMARY OF METHODS OF OFF-LOADING THE DIABETIC FOOT

Off-Loading Modality	Kinds/Advantages/Disadvantages
Felted Foam Dressing	Consists of foam-felt dispersive padding over the ulcer. Has been shown to be effective in helping to heal ulcers and is used at a variety of centers. Advantages—Effective, easy to use, Inexpensive Disadvantages—Cannot be used with sensitive skin which is common in patients with diabetes mellitus
CROW Orthosis	Charcot Restraint Orthotic Walker Consists of a bivalved (total contact) AFO which can be worn directly without a shoe. For the very deformed foot. Advantages: Good stability and provides mobility for a very deformed foot which would not be able to fit into a store bought shoe.

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EXAMINATION

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See answer sheet on page 115.

1) What percentage of lower extremity amputations is preceded by a foot ulcer in diabetic people?
   A) 85 percent
   B) About 50 percent
   C) 15 percent
   D) Impossible to tell

2) The most common pathway leading to lower extremity amputation in people with diabetes was found to be:
   A) Neuropathy—Infection—Ulceration
   B) Neuropathy—Peripheral Vascular Disease—Gangrene
   C) Repetitive Microtrauma—Neuropathy—Infection
   D) Repetitive Microtrauma—Ulceration—Failure to Heal

3) Where is the most common site of ulceration in the diabetic foot?
   A) Midfoot
   B) Heel
   C) Metatarsal heads
   D) All of these

4) Approximately how long should it take for an ulcer to heal using an unloading device?
   A) 2 weeks-4 weeks
   B) 4 weeks to 12 weeks
   C) Up to 6 months is normal
   D) Can not tell

5) What can be concluded about the role of shoewear in off-loading the diabetic foot?
   A) Shoewear is important after the primary unloading device is used, but can never be used as a primary unloading device.
   B) Molded shoes have been found to be more effective in reducing plantar weight-bearing pressure than added-depth shoes.
   C) Therapeutic shoes have been found to be highly effective in preventing ulcer recurrence.
   D) Therapeutic shoes in people with diabetes work mostly by providing good arch support.

6) In order to get the maximum benefit from the insole for the diabetic foot:
   A) The insole should be laminated with plastazote/PPT/Spenco combinations with plastazote closest to the skin and worn with therapeutic shoes.
   B) The insole should be as thin and light weight as possible.
   C) If the insole is made particularly well, therapeutic footwear will not improve upon the effects of wearing the insoles alone.
   D) Custom molded shoes do not require an insole.

7) In studies comparing the effectiveness of prefabricated insoles with custom foot orthoses for the diabetic foot:
   A) Prefabricated insoles reduce plantar foot pressure more than custom foot orthoses.
   B) Custom foot orthoses reduce plantar foot pressure more than prefabricated insoles.
   C) Prefabricated insoles and custom foot orthoses reduce plantar weight bearing pressure equally well.
   D) It is not known whether custom foot orthoses or prefabricated foot orthoses work equally well in reducing plantar foot pressure in the diabetic foot.

8) What has been shown regarding the prefabricated walking braces such as the DH Pressure-Relief Walker and the Pneumatic AirCast Walker?
   A) The prefabricated walking braces are ineffective in off-loading diabetic foot ulcers.
   B) The prefabricated walking braces are effective in reducing pressure and off-loading the diabetic foot, but have not been shown to actually heal ulcers in diabetic patients in clinical studies.
   C) The prefabricated walking braces are effective in reducing pressure and off-loading the diabetic foot, and have recently been shown to actually heal ulcers in diabetic patients in clinical studies.
   D) The prefabricated walking braces are not effective off-loading devices, but they have been effective in healing ulcers anyway.

9) A contraindication for total contact casting is:
   A) Severe neuropathy
   B) Wagner grade 1 and 2 ulcers
   C) Immunosuppression
   D) Minor infection

10) How does the pressure reduction capacity of the prefabricated walking brace compare with the total contact cast?
   A) Prefabricated walking brace reduces pressure as well or better than the total contact cast.
   B) Total contact cast reduces pressure greater than the prefabricated walking braces.
   C) It is unknown whether prefabricated walking braces reduce pressure greater than the total contact cast.
   D) Neither the prefabricated walking brace or the total contact cast reduce pressure very well.

11) The PTB orthosis can be said to:
   A) Totally unweight the forefoot.
   B) Totally unweight the rearfoot.
   C) Unweight the rearfoot 60 percent and also the leg.
   D) Unweight the rearfoot 60 percent, and also the leg, and should be worn with a cane.

12) For patients with a deformed Charcot foot who cannot fit into an added-depth shoe, a good unweighting choice would be:
   A) Running shoe with custom foot orthosis
   B) Crow Orthosis
   C) Custom molded shoes
   D) Crow Orthosis or Custom molded shoes

13) The prefabricated walking brace was originally used for:
   A) Post-operative surgical brace
   B) Diabetic foot ulcers
   C) Lower extremity trauma
   D) Infection

14) How is insole thickness related to pressure reduction for unloading the diabetic foot?
   A) The thicker the insole the greater the pressure reduction.

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Continuing Medical Education

EXAMINATION

(cont'd)

B) The thinner the insole the greater the pressure reduction.
C) There is no relationship between thickness of the insole and pressure reduction.
D) The insole material is more important than the thickness of the insole.

15) How is the IPOS dorsiflexory half shoe used in the off-loading of diabetic foot ulcers?
A) It should not be used because it is ineffective.
B) Used for ulcers under the forefoot.
C) Used for ulcers under the heel.
D) Used for ulcers anywhere under the plantar aspect of the foot as long as it is unilateral and the patient has adequate dorsiflexion.

16) In general how should the pegged hexagons be used with the DH Pressure Relief Walker?
A) They should be removed exactly where the ulcer is for dispersion.
B) They should be removed a little wider than the diameter of the ulcer to avoid the edge effect.
C) They should be removed a little narrower than the diameter of the ulcer.
D) They should not be removed.

17) All of the following are risk factors for foot ulcers EXCEPT:
A) Neuropathy
B) Reduced passive joint range of motion
C) Foot deformity such as hammer toes and bunions
D) Abnormally reduced plantar foot pressures

18) The felted foam dressing should NOT be used:
A) On plantar foot ulcers in patients with severe neuropathy
B) In elderly patients
C) On sensitive skin
D) With prefabricated walking braces

19) The gold standard for unweighting the diabetic foot is:
A) In-depth inlay shoes and dual density insoles
B) Dorsiflexory wedge half shoe
C) Prefabricated walking brace
D) Total Contact Cast

20) What is the relationship between high plantar pressures and plantar foot ulcers in people with diabetes mellitus?
A) High plantar pressure is a necessary but not sufficient condition for a foot ulcer to develop.
B) High plantar pressure is a necessary and sufficient condition for a foot ulcer to develop.
C) There is no relationship between high plantar pressures and the development of plantar foot ulcers.
D) There is an inverse relationship between high plantar pressures and the development of plantar foot ulcers.

See answer sheet on page 115.

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Enrollment/Testing Information and Answer Sheet

Note: If you are mailing your answer sheet, you must complete all info. on the front and back of this page and mail with your check to: ***Podiatry Management*, P.O. Box 490, East Islip, NY 11730.** Credit cards may be used only if you are faxing or phoning in your test answers.

TESTING, GRADING AND PAYMENT INSTRUCTIONS

(1) Each participant achieving a passing grade of 70% or higher on any examination will receive an official computer form stating the number of CE credits earned. This form should be safeguarded and may be used as documentation of credits earned.

(2) Participants receiving a failing grade on any exam will be notified and permitted to take one re-examination at no extra cost.

(3) All answers should be recorded on the answer form below. For each question, decide which choice is the best answer, and circle the letter representing your choice.

(4) Complete all other information on the front and back of this page.

(5) Choose one out of the 3 options for testgrading: mail-in, fax, or phone. To select the type of service that best suits your needs, please read the following section, "Test Grading Options".

TEST GRADING OPTIONS

Mail-In Grading

To receive your CME certificate, complete all information and mail with your check to:

Podiatry Management
P.O. Box 490, East Islip, NY 11730

There is **no charge** for the mail-in service if you have already enrolled in the annual exam CPME program, and we receive this exam during your current enrollment period. If you are not enrolled, please send $15.00 per exam, or $99 to cover all 10 exams (thus saving $51 over the cost of 10 individual exam fees).

Facsimile Grading

To receive your CPME certificate, complete all information and fax 24 hours a day to 1-631-563-1907. Your CPME certificate will be dated and mailed within 48 hours. This service is available for $2.50 per exam if you are currently enrolled in the annual 10-exam CPME program (and this exam falls within your enrollment period), and can be charged to your Visa, MasterCard, or American Express.

If you are *not* enrolled in the annual 10-exam CPME program, the fee is $17.50 per exam.

Phone-In Grading

You may also complete your exam by using the toll-free service. Call 1-800-232-4422 from 10 a.m. to 5 p.m. EST, Monday through Friday. Your CPME certificate will be dated the same day you call and mailed within 48 hours. There is a $2.50 charge for this service if you are currently enrolled in the annual 10-exam CPME program (and this exam falls within your enrollment period), and this fee can be charged to your Visa, Mastercard, or American Express. If you are not currently enrolled, the fee is $17.50 per exam. When you call, please have ready:

1. Program number (Month and Year)
2. The answers to the test
3. Your social security number
4. Credit card information

In the event you require additional CPME information, please contact PMS, Inc., at **1-631-563-1604**.

ENROLLMENT FORM & ANSWER SHEET

Please print clearly...Certificate will be issued from information below.

Name _____ Soc. Sec. #_____
Please Print: FIRST MI LAST

Address_____

City_____State_____Zip_____

Charge to: _____Visa _____ MasterCard _____ American Express

Card #_____Exp. Date_____

Note: Credit card payment may be used for fax or phone-in grading only.

Signature_____Soc. Sec.#_____Daytime Phone_____

State License(s)_____Is this a new address? Yes_____ No_____

Check one: _____ I am currently enrolled. (If faxing or phoning in your answer form please note that $2.50 will be charged to your credit card.)

_____ I am not enrolled. Enclosed is a $15.00 check payable to Podiatry Management Magazine for each exam submitted. (plus $2.50 for each exam if submitting by fax or phone).

_____ I am not enrolled and I wish to enroll for 10 courses at $99.00 (thus saving me $51 over the cost of 10 individual exam fees). I understand there will be an additional fee of $2.50 for any exam I wish to submit via fax or phone.

Over, please

ENROLLMENT FORM & ANSWER SHEET (cont'd)

EXAM #2/2001
Pressure Reduction and Off-Loading the Diabetic Foot
(Sobel & Levitz)

Circle:

1.	A	B	C	D	11.	A	B	C	D
2.	A	B	C	D	12.	A	B	C	D
3.	A	B	C	D	13.	A	B	C	D
4.	A	B	C	D	14.	A	B	C	D
5.	A	B	C	D	15.	A	B	C	D
6.	A	B	C	D	16.	A	B	C	D
7.	A	B	C	D	17.	A	B	C	D
8.	A	B	C	D	18.	A	B	C	D
9.	A	B	C	D	19.	A	B	C	D
10.	A	B	C	D	20.	A	B	C	D

LESSON EVALUATION

Please indicate the date you completed this exam

_____

How much time did it take you to complete the lesson?

_____ hours _____minutes

How well did this lesson achieve its educational objectives?

_____Very well _____Well

_____Somewhat _____Not at all

What overall grade would you assign this lesson?

A B C D

Degree_____

Additional comments and suggestions for future exams:

_____

_____

_____

_____

_____

_____