Nonremovable, Windowed, Fiberglass Cast Boot in the Treatment of Diabetic Plantar Ulcers

Efficacy, safety, and compliance

Georges Ha Van, MD[1]
Hubert Siney, MD[2]
Agnes Hartmann-Heurtier, MD[1]
Sophie Jacqueminet, MD[1]
Françoise Greau[1]
André Grimaldi, MD[1]

OBJECTIVE — To compare the efficacy, safety, and compliance of a nonremovable fiberglass cast boot and off-loading shoes in the treatment of diabetic plantar ulcers.

RESEARCH DESIGN AND METHODS — Patients (n = 93) with noninfected, nonischemic plantar ulcers were included in this prospective nonrandomized study. Treatment used a nonremovable fiberglass cast boot for longer standing and deeper ulcers (n = 42) and a half shoe or heel-relief shoe for other ulcers (n = 51). We evaluated off-loading therapy, compliance, and complications in both groups.

RESULTS — The healing rate was significantly higher with the cast boot than with the off-loading shoe (81 vs. 70%, P = 0.017), with healing times of 68.6 ± 35.1 vs. 134.2 ± 133.0 days, respectively, and hazard ratio 1.68 (95% CI 1.04–2.70); complete compliance with treatment was 98 vs. 10% (P = 0.001), respectively. Secondary osteomyelitis developed in 3 patients in the cast boot group and 13 patients in the off-loading shoe group (P = 0.026).

CONCLUSIONS — A nonremovable fiberglass cast boot was effective in healing diabetic plantar ulcers and in decreasing the risk of secondary osteomyelitis. The cast boot forced compliance with off-loading, thus promoting healing.

Diabetes Care 26:2848–2852, 2003

Delayed healing of diabetic plantar ulcers is caused primarily by inadequate or inappropriate wound off-loading. It has been suggested that "untreated ulcer" may be a better term than "recalcitrant ulcer" when off-loading is suboptimal (1).

Neuropathy is the main cause of plantar ulcers in patients with diabetes. The wounds develop in insensitive areas subjected to excessive pressure (2). The loss of sensation in the foot results in diagnostic and therapeutic delays and is a major obstacle to compliance with treatments, particularly off-loading. Suboptimal off-loading is associated with an increased risk of wound infection. The infection can spread to the soft tissues, causing cellulitis of the foot, or to the underlying bone. Cellulitis and osteomyelitis can occur concomitantly; both complications greatly increase the risk of amputation.

Clinical studies have established that off-loading by a total contact cast (TCC) is the reference standard in the treatment of noninfected, nonischemic plantar ulcers related to diabetic neuropathy (3–9). Healing rates varied from 73 to 100% and mean time to healing from 37 to 65 days. The casts were closed and changed entirely every 5–7 days. In studies of other off-loading modalities, time to healing was 3.6 months with insoles (10), 90 days with a fiberglass boot (Scotchcast) (11), 56–70 days with half shoes, with 78% compliance as assessed during a telephone interview (12,13), and 10 months with a heat-molded bivalve orthosis (14).

Two randomized clinical trials (15,16) comparing off-loading devices have been published. In the earlier study (15), the healing rate was 90% with a mean time to healing of 42 days in the TCC group compared with only 32% and 65 days, respectively, in the control group treated with plastazote shoe inserts. Significantly fewer infections occurred in the TCC group (0 vs. 26%). Amputation was required in two control subjects and in none of the TCC patients. The second study (16) is a recent comparison of TCCs, removable cast walkers, and half shoes. Healing rates were 89.5, 65.0, and 58.3%, respectively, and the difference between TCC and the other two modalities was significant. Patients were significantly less active in the TCC group (600 daily steps) than in the removable cast walker group (767 daily steps) or the half-shoe group (1,461 daily steps).

Other off-loading modalities are bed rest and use of crutches or a wheelchair. Because patients do not easily perceive the benefits of these modalities, they have little motivation to accept the stringent discipline they require. The objective of this study was to compare the efficacy and safety of off-loading by a shoe with that of a nonremovable fiberglass cast boot (with a window cut over the ulcer and a double-incorporated heel) left in place until complete healing or treatment failure. We sought to determine whether a patient

From the [1]Department of Diabetology and Metabolism, Pitié-Salpêtrière Teaching Hospital, Paris, France; and the [2]Computer Sciences Department, Saint-Vincent-de-Paul Teaching Hospital, Paris, France.

Address correspondence and reprint requests to Georges Ha Van, MD, Service de Diabétologie Métabolisme Pr Grimaldi, Groupe Hospitalier Pitié-Salpétrière, 47-83 Boulevard de l'Hôpital, 75013 Paris, France. E-mail: ghavan@club-internet.fr.

Received for publication 13 June 2002 and accepted in revised form 16 July 2003.

Abbreviations: ABI, ankle-brachial index; TCC, total contact cast.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Figure 1—*Ulcer of the midfoot treated with a cast boot.*

with a diabetic neuropathic ulcer could wear a fiberglass cast boot until complete healing without opening the cast and whether the healing rate would be faster by forced compliance than by more conventional off-loading treatment.

RESEARCH DESIGN AND METHODS

— This prospective nonrandomized study was conducted from 1 January 1994 to 7 July 2000. From 1 January 1994 to 15 April 2000, 93 patients with a single plantar ulcer were included, 42 in the cast boot group and 51 in the shoe group. Data were collected prospectively using a standardized clinical report form. The date of study inclusion was defined as the date of off-loading initiation with either of the two methods under study (cast boot or off-loading shoe). The date of ulcer development was recorded as the date the patient reported noticing the ulcer for the first time.

Patients were eligible if they had diabetic neuropathy and a grade 1A plantar ulcer in the San Antonio classification (17) with no clinical or radiological evidence of infection or osteomyelitis and without severe peripheral arterial disease. No ulcer went to bone or tendon. Diabetic neuropathy was defined as insensitivity to the 10-g Semmes-Weinstein 5.07 monofilament (18) at the plantar aspects of the toes and metatarsal heads. The ulcers were located at the plantar aspect of the fore-, mid-, or hindfoot. The following characteristics were noted for each ulcer: location, duration, maximum depth measured using a sterile metallic probe, and greatest length and width measured using a ruler graduated at 1-mm intervals and placed on sterile tracing paper applied over the wound.

Exclusion criteria were severe peripheral arterial disease, osteomyelitis, and cellulitis. We included patients with moderate peripheral arterial disease in the two groups. Moderate peripheral arterial disease was defined as the presence of at least one of the following criteria: no posterior tibial and/or pedal pulsations by palpation with arterial lesions by Doppler ultrasound (but at least one of the three major leg arteries was detectable up to the foot), transcutaneous oxygen tension ($TcPO_2$) between 20 and 30 mmHg, ankle-brachial index (ABI) between 0.5 and 0.9, history of revascularization and no ischemic trophic disorders, and no necrosis or gangrene. We considered an ABI >1.15 as unreliable. Peripheral arterial disease was considered severe if there was critical ischemia or a wound with gangrene or necrosis, TcPO2 <20 mmHg or failure of arterial doppler ultrasonography to detect a major leg artery, and severe arterial lesions by arteriography. Osteomyelitis was defined as contact with bone upon probing an inflammatory ulcer with a blunt-tipped metal probe or as radiographic evidence of bony erosion or joint involvement deep to the ulcer. The definition of cellulitis was infection of the subcutaneous tissue with local evidence of inflammation.

Off-loading of the ulcer was provided to all patients. Two methods were used to achieve off-loading. Patients with an ulcer of >6 months' duration with failure of off-loading shoe treatment, those with a midfoot ulcer and Charcot neuroarthropathy, and those who declined to wear an off-loading shoe were treated with a below-knee nonremovable fiberglass cast boot in which a window was cut at the site of the ulcer (cast boot group) (Fig. 1). In the shoe group, we included patients with an ulcer of <6 months' duration without Charcot foot or who refused the cast boot treatment (shoe group). The type of shoe was selected according to the location of the ulcer. Written and oral detailed explanations on treatment with the cast boot or the off-loading shoe were provided, and patient oral consent was obtained before inclusion in one group.

All fiberglass cast boots were made by the same two operators with extreme care, according to strictly defined rules. The foot was padded using four Soffban bandages (Smith and Nephew) 15 cm in width and 2.7 m in length. Bony prominences were padded by five bandage layers. The bandages were covered by a water-repellent stockinette. A 1-cm layer of cotton was placed beneath the plantar arch. Additional padding by three layers of bandage was used at the proximal and distal parts of the cast boot to protect the skin from the sharp edges of the fiberglass. Either Dynacast (Smith and Nephew) or Scotchcast (3M) fiberglass was used, with bands measuring 10, 7.5, and 5 cm. The toes were left free. A double rubber heel was placed at the plantar aspect of the cast boot opposite the site of fore- or hindfoot ulcers or on either side of midfoot ulcers. A window was cut in the cast boot at the ulcer site to allow daily wound assessment and care. The rubber heels were sufficiently high to ensure full protection of the ulcer from pressure and friction during walking. The total time needed to fashion the cast boot ranged from 60 to 90 min. The fiberglass cast boot was worn without opening until complete ulcer healing or until an event occurred that required emergency treatment for intolerance, arterial or venous thrombosis, ulcer formation, or secondary osteomyelitis.

Two types of off-loading shoes were used. For ulcers under the forefoot or toes, we chose the Barouk half shoe, which has a heel 6 cm in height extending from the posterior edge of the foot to the midfoot and stretches under the forefoot by means of a platform that remains a distance from the ground and supports a

Table 1—*Clinical characteristics of patients at recruitment*

Characteristic	Cast boot	Off-loading shoe	*P*
n	42	51	—
Age (years)	58 ± 11	62 ± 7	NS
Men	38 (90.5)	40 (78.4)	NS
Type 1 diabetes	6 (14.3)	12 (23.5)	NS
Diabetes duration (years)	17 ± 11	15 ± 10	NS
BMI (kg/m^2)	28.55 ± 3.42	29.06 ± 4.76	NS
Retinopathy	31 (74)	37 (73)	NS
Peripheral arterial disease	23 (55)	22 (43)	NS
Neuropathy	42 (100)	49 (96)	NS
HbA_{1c} (%)	7.85 ± 2.7	8.18 ± 1.6	NS
Creatinine (μmol/l)	119 ± 205	163 ± 200	NS
Ulcer length (mm)	20.43 ± 12.06	15.61 ± 12.31	NS
Ulcer width (mm)	13.8 ± 7.71	10.21 ± 9.12	0.045
Ulcer depth (mm)	5.42 ± 5.35	3.37 ± 3.16	0.03
Ulcer duration >6 months	20 (48)	9 (18)	0.002
Ulcer duration (days)	395 ± 560	134 ± 272	0.0078
Ulcer under the forefoot	35 (83)	49 (96)	—
Ulcer under the midfoot (Charcot deformity)	4 (10)	0	0.0439
Ulcer under the hindfoot	3 (7)	2 (4)	—

Data are means ± SD or *n* (%).

shaft. The Sanital heel-relief shoe was used in patients with ulcers under the hindfoot. This shoe places the foot in 20° equinus and has a Sanital plastazote insole with a posterior opening that leaves the posterior and plantar aspects of the heel unsupported. Each patient in the shoe group received a detailed prescription corresponding to the type of shoe that was recommended. Strong emphasis was put on the absolute necessity for the patient to use the shoe consistently during standing or ambulation at all times, even if for only a few seconds. Patients in both groups were advised to use crutches, particularly during the initial period of acclimatization to the off-loading device.

All patients received daily local care delivered at home by a nurse. The ulcer was cleansed with saline and then covered with a gauze square saturated with petroleum jelly. Antibiotics were not given during the treatment. Employed patients were asked to stop work.

Follow-up for all patients was conducted at our Diabetic Foot Clinic at 2-week intervals for a clinical examination, monitoring of home care, and wound debridement. Additional visits occurred at the slightest suspicion of an emergency. Patients with complications were admitted. At each visit, osteomyelitis was sought by determining whether a sterile metal probe inserted into the ulcer made contact with bone. Healing was defined as complete epithelialization, with no drainage or sinus tract.

The treatment period stopped when healing was achieved or when treatment failed (complications or absence of healing at study end). Care was taken to record any adverse events that occurred during this treatment, such as wounds caused by the cast boot or off-loading shoe, secondary osteomyelitis, ischemia, cellulitis, and deep vein thrombosis. Compliance with the off-loading treatment was assessed at each 2-week visit by asking the patient to complete a brief questionnaire. The semiquantitative score on the questionnaire ranged from 0 (no use at all) to 3 (use as directed).

Statistics. Data were analyzed using the SAS software version 8 on a personal computer. Comparability of the two groups at study inclusion was evaluated using *t* tests (Mann-Whitney for nonnormal data) and χ^2 tests (Fisher's exact test for small samples). Kaplan-Meier curves were drawn to compare the healing rates for the two treatment groups. The Cox model was used to test whether the healing rate differed between the treatment groups after accounting for other prognostic factors.

RESULTS — The characteristics of the patients in the cast boot and off-loading shoe treatment groups were different at inclusion for width and depth of the wound, ulcer duration, and ulcer site (Table 1). These data were tested in the Cox model with data that were almost significant (age and length of the ulcer). We included the patient's age in the analysis, which was the only factor other than treatment group that was statistically prognostic of healing. The healing rate was significantly higher with the cast boot than with the off-loading shoe (81 vs. 70%, respectively). The age-adjusted hazard ratio for healing in patients treated with a cast boot, as compared with the off-loading shoe, was 1.68 (95% CI 1.04–2.70, $P = 0.017$). The mean time to healing was 68.6 ± 35.1 days in the cast boot group compared with 134.2 ± 133.0 days in the off-loading shoe group, as seen in the healing rate curves (Fig. 2).

No patients were excluded from the study. As soon as a patient was included in the study, there were no changes in his

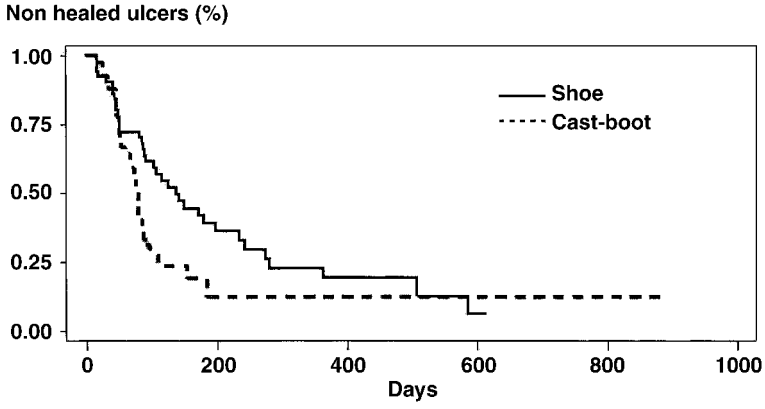

Figure 2—*Comparison of the treatments.*

Table 2—*Compliance with off-loading treatments*

Compliance	Cast boot	Shoe
Level 3: Use of the off-loading device whenever weight is borne on the foot.	41 (97.6)	5 (9.8)
Level 2: Use of the off-loading device during walking, except over short distance (e.g., to use the bathroom at night).	0	16 (31.3)
Level 1: Use of the off-loading device only for walking short distances during the day (or to use the bathroom at night), but no use outside the home, particularly when driving.	0	28 (55)
Level 0: Off-loading device removed by the patient or very rarely used.	1 (2.3)	2 (3.9)
Total	42	51

Data are *n* (%). $P = 0.001$.

treatment (cast boot or off-loading shoe) before complete healing. Data were analyzed using the intent-to-treat approach; thus, one patient who removed his cast boot was kept in the analysis and classified as a treatment failure.

In the cast boot group, eight patients failed treatment. All eight failures were related to complications: an ulcer caused by the fiberglass in five patients (secondary edema of the distal foot was a predisposing factor), secondarily diagnosed osteomyelitis in two patients, and a compound toe fracture with secondary osteomyelitis in one patient. However, because the patients were monitored daily, the cast boot–induced lesions were promptly detected and remained shallow; three patients achieved complete healing of the boot-induced ulcer after topical treatment in a mean 150 days (and the initial ulcer also healed in this period), and one patient died from a myocardial infarction. The remaining patient made no change in his daily activities, which included yard work (e.g., digging up a 1,500-m^2 plot with the cast boot on). After removal of the cast boot, the ulcer was not healed, but he did not use the off-loading shoe prescribed to him.

In the shoe group, new ulcers did not develop in any of the patients, but 15 treatment failures were recorded. Two patients did not achieve healing at the end of the study. Of the remaining 13 patients, osteomyelitis developed and was responsible for secondary worsening of the ulcer for 13 of 51 (25%) in the shoe group compared with 3 of 42 (7%) in the cast boot group ($P = 0.026$). Three patients in the shoe group experienced secondary exacerbation of ischemia (by osteomyelitis) compared with none in the cast boot group. There was no deep vein thrombosis or secondary cellulitis in both groups. Compliance with off-loading was significantly better in the cast boot group than in the shoe group ($P = 0.001$) because all patients were compliant except one who removed the cast boot himself (Table 2). Compliance with off-loading shoe use was complete in 9.8% (5 of 51) of patients and acceptable in 31.3% (16 of 51), yielding an overall compliance rate of 41.1% (21 of 51). In addition, 58.9% (30 of 51) of patients removed the shoe for walking long distances.

CONCLUSIONS — We compared two off-loading methods in the treatment of diabetic plantar ulcers. Although assignment was not randomized, we minimized potential bias by including the patient's age in the analysis, the only factor other than treatment group statistically prognostic of healing. Cast boot treatment was more likely to be offered to patients with older, wider, and deeper ulcers and Charcot foot, which carries a higher risk of failing to heal, of infection, and of amputation (19). This feature of the study design decreased the likelihood of finding greater benefits in the cast boot group.

The efficacy of off-loading by TCC has been firmly established (3–11). Whereas casts are usually changed during follow-up visits (4), we did not remove the cast boot until primary healing or treatment failure, whichever occurred first. Evaluation of safety was an important goal that was achieved by cutting a window in the cast boot at the site of the ulcer. The double heel allowed the patients to walk without putting pressure on the ulcer.

In our study, the healing rate was significantly higher with a shorter time to healing in the cast boot group than in the shoe group, which is consistent with earlier data (11–13,15,16). We offered the nonremovable, windowed, fiberglass off-loading cast boot as a last-resort treatment to patients with persistent ulcers despite local care and advice about pressure relief that was usually delivered somewhere other than at our center. These patients had longstanding ulcers; ulcer duration was within the range of the longest ulcer durations reported in the literature (20). Although noncompliance was not assessed objectively before inclusion into the cast boot group, patients whose history indicated a high degree of noncompliance were offered cast boot treatment.

Although cast boots provide high healing rates because they effectively relieve pressure on the ulcer site, they can create new ulcers (9) and can be difficult to fashion and monitor. In our study, the nurse who provided local care was able to assess the wound on a daily basis because a window was cut over the ulcer site and the toes were left free. This allowed rapid treatment of adverse events and provided acceptable safety conditions for leaving the cast boot on until complete ulcer healing. Furthermore, the window allowed the application of modern localized treatments that are intended for daily use.

Five ulcers occurred from friction against the cast boot, even though the cast boots were fashioned with great care and liberal padding was used to protect the skin. The cast boot–induced ulcer rate would probably have been higher had these precautions not been taken. Thus, thorough training of physicians or technicians in proper cast application is essential to reduce the risk of ulceration. The cast boot was bigger than a usual TCC, but the liberal padding with Soffban allowed us to not open it until complete healing. The toes were not enclosed in the boot. A trauma-related toe fracture occurred in one of our patients. However, leaving the toes free allowed monitoring of the distal foot.

The secondary osteomyelitis rate was higher in the shoe group than in the cast boot group. Thus, our findings are in keeping with earlier data showing that

cast boot therapy reduces adverse outcomes, most notably osteomyelitis (6).

In earlier studies (4,9,10,21), compliance was often found to be poor but was rarely evaluated using objective criteria. We used a scale to improve the objectivity of compliance assessment. We sought to determine whether compliance with off-loading was associated with the healing rate. The frequent failure to comply with off-loading shoe use was disappointing because these patients received extensive education about pressure relief at study initiation and reinforcement at each follow-up visit. In this group with poor compliance, the healing rate was significantly lower than that of the cast boot group. Compliance was excellent in the cast boot group, even though a history of noncompliance was among the criteria used to select patients for cast boot treatment. These results illustrate the ability of boot casting to force compliance (11). The health care providers should give detailed explanations to the patients about the potential benefits of off-loading.

We did not measure the level of physical activity of the patients. TCC has been reported to reduce activity (11). The cast boot forces the patient to reduce daily activities. A brace or shoe can be easily removed and, consequently, does not have the same activity-reducing effect.

The direct cost of cast boot treatment in our study was lower than when the cast boot is changed every week. The cost of the daily local care, about $11.60 (€10.60) per day, delivered to our patients should be added to the cost of making the boot (fiberglass and Soffban cost about $134.20 [€122.00]) or the cost of a shoe ($50.27 [€45.70]). Mean total cost of 68.6 days of primary treatment was $934.07 (€849.16) for the cast boot and $1,467.70 (€1,614.47) (for 134.2 days) for the shoe.

Acceptability of the cast boot was excellent in our study. The patients' awareness that their desperately chronic wound was receiving the same level of care as an acute disease probably promoted compliance.

We use the following strategy for managing diabetic plantar ulcers. When the ulcer is under the hind- or midfoot, our reference standard is the cast boot. When the ulcer is under the forefoot, we evaluate the potential for compliance. When good compliance is anticipated or when the time since ulcer formation is <3 months, we start with an off-loading shoe and reevaluate treatment at 2-week intervals. Conversely, when fair or poor compliance is anticipated, we recommend first-line treatment with a cast boot without waiting 6 months.

Currently available off-loading shoes (22) are not completely satisfactory. They afford less pressure relief than a cast boot, and their acceptability is poor. The efficacy of these shoes should be evaluated on not only decreased pressure at the ulcer site but also good patient acceptability and compliance. For us, the nonremovable fiberglass cast boot remains the reference standard for the treatment of diabetic plantar ulcers because it offers satisfactory off-loading and high compliance and decreases the risk of secondary deep tissue infection.

Acknowledgments— We are indebted to Dr. Beverley Balkau, Dr. Joël Coste, and Dr. Dominique Simon for reviewing the manuscript and statistical analysis.

References

1. Cavanagh PR, Ulbrecht JS: Biomechanics of the foot in diabetes mellitus. In *The Diabetic Foot*. 5th ed. Levin ME, O'Neal LW, Bowker JH, Eds. St. Louis, MO, Mosby, 1993, p. 199–232
2. Cavanagh PR, Ulbrecht JS, Caputo GM: The biomechanics of the foot in diabetes mellitus. In *The Diabetic Foot*. 6th ed. Bowker JH, Pfeifer MA, Eds. St. Louis, MO, Mosby, 2001, p. 125–196
3. Helm PA, Walker SC, Pulliam G: Total contact casting in diabetic patients with neuropathic foot ulcerations. *Arch Phys Med Rehabil* 65:691–693, 1984
4. Sinacore Dr, Mueller MJ: Total-contact casting in the treatment of neuropathic ulcers. In *The Diabetic Foot*. 6th ed. Bowker JH, Pfeifer MA, Eds. St. Louis, MO, Mosby, 2001, p. 301–320
5. Boulton AJM, Bowker JH, Gadia M, Lemerman R, Caswell K, Skyler JS, Sosenko JM: Use of plaster casts in the management of diabetic neuropathic ulcers. *Diabetes Care* 9:149–152, 1986
6. Walker SC, Helm PA: Total contact casting and chronic diabetic neuropathic foot ulcerations: healing rates by wound location. *Arch Phys Med Rehabil* 68:217–221, 1987
7. Laing PW, Cogley DI, Klenerman L: Neuropathic foot ulceration treated by total contact casts. *J Bone Joint Surg Br* 74:133–136, 1992
8. Lavery LA, Vela SA, Lavery DC, Quedebeaux TL: Reducing dynamic foot pressures in high-risk diabetic subjects with foot ulcerations: a comparison of treatments. *Diabetes Care* 19:818–821, 1996
9. Myerson M, Papa J, Eaton K, Wilson K: The total-contact cast for management of neuropathic plantar ulceration of the foot. *J Bone Joint Surg Am* 74:261–269, 1992
10. Holstein P, Larsen K, Sager P: Decompression with aid of insoles in treatment of diabetic foot ulcers. *Act Orthop Scand* 47: 463–468, 1987
11. Burden AC, Jones R, Blandford RL: Use of the Scotchcast boot in treating diabetic foot ulcers. *Br Med J* 286:1555–1557, 1983
12. Needleman RL: Success and pitfalls in the healing of neuropathic forefoot ulcerations with the IPOS postoperative shoe. *Foot Ankle Int* 18:412–417, 1997
13. Chantelau E, Breuer U, Leisch AC, Reuter M: Outpatient treatment of unilateral foot ulcers with half shoes. *Diabet Med* 10:267–270, 1993
14. Boninger ML, Leonard JA: Use of bivalved ankle-foot orthosis in neuropathic foot and ankle lesions. *J Rehabil Res Dev* 33: 16–22, 1987
15. Mueller MJ, Diamond JE, Sinacore DR, Delitto A, Blair VP, Drury DA, Rose SJ: Total contact casting in treatment of diabetic plantar ulcers: controlled clinical trial. *Diabetes Care* 12:384–388, 1989
16. Armstrong DG, Nguyen HC, Lavery LA, Van Schie CHM, Boulton AJM, Harkless LB: Off-loading the diabetic foot wound: a randomized clinical trial. *Diabetes Care* 24:1019–1022, 2001
17. Armstrong DG, Lavery LA, Harkless LB: Validation of a diabetic wound classification system: the contribution of depth, infection, and ischemia to risk of amputation. *Diabetes Care* 21:855–859, 1998
18. Sosenko J, Kato M, Soto R, Bild DE: Comparison of quantitative sensory threshold measures for their association with foot ulcer in diabetic patients. *Diabetes Care* 13:1057–1061, 1990
19. Margolis DJ, Allen-Taylor L, Hoffstad O, Berlin JA: Diabetic neuropathic ulcers: the association of wound size, wound duration, and wound grade on healing. *Diabetes Care* 25:1835–1839, 2002
20. Sinacore DR: Total contact casting for diabetic neuropathic ulcers. *Physical Therapy* 76:296–301, 1996
21. Cavanagh PR, Ulbrecht JS, Caputo GM: What the practicing physician should know about diabetic foot biomechanics. In *The Foot in Diabetes*. 3rd ed. Boulton AJM, Connor H, Cavanagh PR, Eds. Chichester, U.K., Wiley, 2000, p. 33–59
22. Elfman N: Alternative weight redistribution methods in the treatment of neuropathic ulcers. In *The Diabetic Foot*. 6th ed. Bowker JH, Pfeifer MA, Eds. St. Louis, MO, Mosby, 2001, p. 321–332