Effectiveness and Safety of a Nonremovable Fiberglass Off-Bearing Cast Versus a Therapeutic Shoe in the Treatment of Neuropathic Foot Ulcers

A randomized study

Carlo Caravaggi, md
Ezio Faglia, md
Roberto De Giglio, md
Manuela Mantero, md
Antonella Quarantiello, md
Emanuela Sommariva, md
Michela Gino, md
Chiara Pritelli, md
Alberto Morabito, phd

OBJECTIVE — To evaluate and compare the rate of reduction of the surface area of neuropathic plantar ulcers in diabetic patients treated with nonremovable rigidity-differentiated fiberglass off-bearing casts or a cloth shoe with a rigid sole with unloading alkaform insoles. The secondary aim was to evaluate the side effects and degree of patient acceptance of treatment.

RESEARCH DESIGN AND METHODS — Fifty diabetic patients with neuropathic plantar ulcers were consecutively enrolled and randomized to one of two treatment groups. Of the 50 patients, 24 were treated with a specialized cloth shoe with a rigid sole and an unloading alkaform insole (shoe group), and 26 patients were treated with a nonremovable off-bearing fiberglass cast (cast group). All patients in both study groups returned to the clinic for weekly control visits. Their ulcers were treated with a standard dressing. Tracings of the ulcer area using a transparent dressing were performed on the day of entry to the study and after 30 days of treatment. The presence of new ulcerations caused by the use of the pressure-relief apparatus was recorded. Patient acceptance of the treatment was measured using a visual analog scale.

RESULTS — At the end of the treatment period, an 8.3% increase of the ulcer area was observed in two patients in the shoe group, whereas in the cast group, no patient presented an increase. The reduction of the ulcer area was statistically more rapid in the cast group (Mann-Whitney test, $P = 0.0004$). Furthermore, the number of ulcers completely healed at the 30-day time point was 13 (50%) in the cast group and 5 (20.8%) in the shoe group ($P = 0.03$). In both groups, no side effects were recorded. The average score ± SD of patient acceptance was 91.15 ± 9.9 in the shoe group and 88.33 ± 17.3 (NS) in the cast group.

CONCLUSIONS — Our study has shown a significant difference in the speed of the reduction of neuropathic plantar ulcers treated with a fiberglass cast compared with a specialized cloth shoe. The use of fiberglass material with variable rigidity has also shown two important results: the elimination of side effects including ulcers caused by the cast, and high patient acceptance. These data show that the use of off-bearing casts made with fiberglass bandages of variable rigidity is the elective treatment of neuropathic plantar ulcers.

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From the Center for the Study and Treatment of Diabetic Foot Pathology, Ospedale di Abbiategrasso (C.C., R.D.G., E.S., C.P.); Internal Medicine Unit (E.F., M.M., A.Q., M.G.), Policlinico Multimedica, Sesto S. Giovanni (Milan); and the Institute of Medical Statistics and Biometry (A.M.), University of Milan, Milan, Italy.

Address correspondence and reprint requests to Carlo Caravaggi, MD, Centro per la Cura e lo Studio del Piede Diabetico, Pz Mussi 1, Abbiategrasso (Milano) 20080, Italy. E-mail: cara@mail3.telnetwork.it.

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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.

Neuropathic ulcers result when several causative factors occur together. The presence of a peak in plantar pressure normally causes the onset of a neuropathic plantar ulcer (1,2).

The relief of pressure from the ulcerated area, surgical debridement, and the use of an adequate dressing are the essential treatments for complete healing of this type of ulcer (3,4). However, this approach is ineffective in treating a plantar ulcer that has not been adequately unloaded.

The treatments used most commonly to reduce the pressure peak in the ulcerated region of the foot are either a therapeutic shoe with an unloaded insole or a total contact off-bearing cast (5). Both of these devices give the patient partial walking autonomy.

Therapeutic shoes have been produced using a variety of techniques and materials, including felted foam or shoes that only provide a rear foot platform (6). In our clinical experience, we have used a shoe with a rigid rocker-bottom sole with a rolling point positioned beside the metatarsal arch. This technical solution allows unloading of the metatarsal and midfoot area, which reduces the local pressure peak (7). This shoe has always been used together with a personalized alkaform insole shaped to reduce pressure in the ulcerated area (8).

Among the off-bearing devices, the total contact cast (TCC) has been effective in healing more ulcers in a shorter time than the accommodative shoe (9). The TCC is considered by many authors to be the "gold standard" for the treatment of neuropathic plantar ulcers (10). However, the use of the TCC made of plaster of Paris bandages and fiberglass bandages has been associated with numerous side effects (11). The most frequent side effects are abrasions or cutaneous ulcers caused by friction of the cast on bony protrusions. Joint rigidity and muscular atrophy caused by prolonged immobilization in rigid casts have also been documented.

Table 1—*Clinical characteristics of study population*

Clinical characteristics	Shoe group	Cast group	*P*
Age (years)	59.2 ± 9.9	60.5 ± 10.7	0.70
F/M	8/16	8/18	0.94
Tablet treatment	12	13	—
Insulin treatment	12	13	—
Diabetes duration (years)	16.2 ± 9.1	17.3 ± 10.7	0.93
Prior lesion	9	10	0.24
BMI (kg/m^2)	27.3 ± 2.5	27.0 ± 1.6	0.54
Smoking	10	5	0.08
Hypertension*	11	13	0.78
Retinopathy†	13	14	0.98
Microalbuminuria‡	4	4	
Proteinuria§	3	5	0.56
Renal impairment‖	2	5	
ABI¶	1.03 ± 0.8	1.00 ± 0.7	0.18
Transcutaneous oxygen tension on dorsum of the foot	52.6 ± 11.6	53.5 ± 12.6	0.80

Data are *n* or means ± SD. *According to World Health Organization criteria for antihypertensive treatment; †fundus oculi by ophthalmologist; ‡albumin excretion rate >18 < 200 mg/24 h; §albumin excretion rate >200 mg/24 h; ‖creatinine >133 mol/l; ¶ankle-brachial blood pressure ratio measured with Doppler continuous wave technique.

Figure 1—*Application of a stirrup for ulcer of the midfoot or rear foot* (A) *and application of a rubber heel for ulcer of the forefoot* (B).

Cloth shoes present some advantages to the TCC because they are light, removable, and accepted by patients (12). Nevertheless, this type of shoe cannot completely reduce pressure in the ulcerated zone when the patient is walking or standing upright (13,14). It must be emphasized that the effectiveness of the shoe also depends on how long the patient wears it (15). Therefore, the effectiveness of this device is strictly related to patient compliance and the training and information given by the health care provider (16).

Irremovable off-loading devices allow for total unloading of the plantar pressure in the ulcerated area even during walking (17). Unfortunately, these devices have an increased risk of side effects (11). For many years, in accordance with the international literature and our clinical experience, we used the TCC made with plaster of paris bandages, and our patients also experienced the same side effects reported by other authors. More recently, we have started to use fiberglass materials with variable rigidity to construct nonremovable off-bearing devices and have noticed a dramatic reduction in side effects with this new technique.

In this study, we compare the effectiveness in the treatment of neuropathic plantar ulcers using either the nonremovable total off-loading cast made with fiberglass bandages with variable rigidity (cast group) or therapeutic shoes with a rigid rocker-bottom sole with unloading insole (shoe group).

RESEARCH DESIGN AND METHODS

— From April 1998 to March 1999, we consecutively enrolled 50 diabetic patients with neuropathic plantar ulcers and assigned them by phone to one of two prerandomized treatment groups. The randomization required that a patient was assigned to the shoe or cast group by calling the Biometrics Institute, University of Milan, Milan, Italy, where a table of random numbers was consulted.

All the subjects were insensitive to Semmes-Weinstein 5.07 monofilament and had a vibration perception threshold of 25 V, measured on the malleolus with a biothesiometer (Neurothesiometer; S.L.S., Nottingham, U.K.). The exclusion criteria were the clinical presence of deep or superficial tissue infection or underlying osteomyelitis (bone exposure or X-ray of the foot), transcutaneous PO_2 (30 mmHg and/or ankle-brachial index [ABI] of 0.6), severe problems in maintaining equilibrium, severe visual deficit, skin lesions of the foot (other than

the ulcer under study) or leg, amputation of a limb, or plantar bilateral ulcerations. No patients were treated with antibiotic therapy or local antiseptic. Twenty-four patients were randomized to receive the therapeutic shoe and 26 patients were randomized to receive the fiberglass off-bearing cast treatment. The ulcer area in each patient was traced using a transparent dressing. The area was then calculated from the tracing with an image analysis software service (Mouseeyes R&D). Tracings of the ulcer area were performed on the day of entry to the study and after 30 days of treatment. All ulcers were subjected to surgical debridement when necessary and were medicated with a paraffin gauze dressing throughout the study period. Patients changed the dressing every 2 days.

Table 1 shows the clinical characteristics of the study population.

Technique for constructing the fiberglass off-bearing cast

Two types of fiberglass bandages were used for the construction of the pressure-relief apparatus. The first type of bandage (Softcast 3M; 3M Health Care, St. Paul, MN) was composed of fiberglass imbued with a polyurethane resin with characteristics of flexibility and resistance. The other bandage (Scotchcast 3M; 3M Health Care) was composed of fiberglass imbued with a polyurethane resin of two different concentrations that confers high resistance to loading. Before using both types of bandages, a tubular stockinet was placed onto the lower limb, which was first covered with German cotton to protect the skin adequately, especially on bony protrusions. To further protect bony protrusions, such as the malleolus and tibial crista, some pieces of protective rubber foam (Microfoam 3M; 3M Health Care) were also applied. The plaster bandages were applied so that the boot conformed to the shape of the leg as much as possible.

The first two layers were applied using the Softcast bandage. The structure was then reinforced with a stick made with a Scotchcast bandage placed in the middle of the two malleoli, extending beyond them for at least 20 cm, giving rigidity to the cast. The same material was used to build a rigid plantar sole. The number of layers applied to construct the sole depended on the weight of the patient (range 3–8 layers). The final structure was reinforced with more Softcast bandages.

An aluminum stirrup or rubber heel was anchored to the structure as a support to allow walking (Fig. 1). The side supports were secured with an outer layer of Softcast. The choice of using the stirrup or the rubber heel as a support for walking depends on the position of the ulcer. The stirrup is used if the ulcer is localized in the midfoot region. This support leaves the entire plantar surface of the boot free from pressure and permits the construction of an opening precisely in the ulcerated region. Therefore, examination and changes of dressing to the ulcer can be performed as frequently as needed. A rubber heel is used when lesions are located on the forefoot, the plantar surface of the toes, or the heel because it allows an open window directly above the ulcer (Fig. 2). The rubber heel is positioned in the center of the plantar surface to allow comfortable walking. In all subjects, the sole of the unaffected foot's shoe was elevated to ease walking. After very brief training, all patients were able to walk properly without crutches.

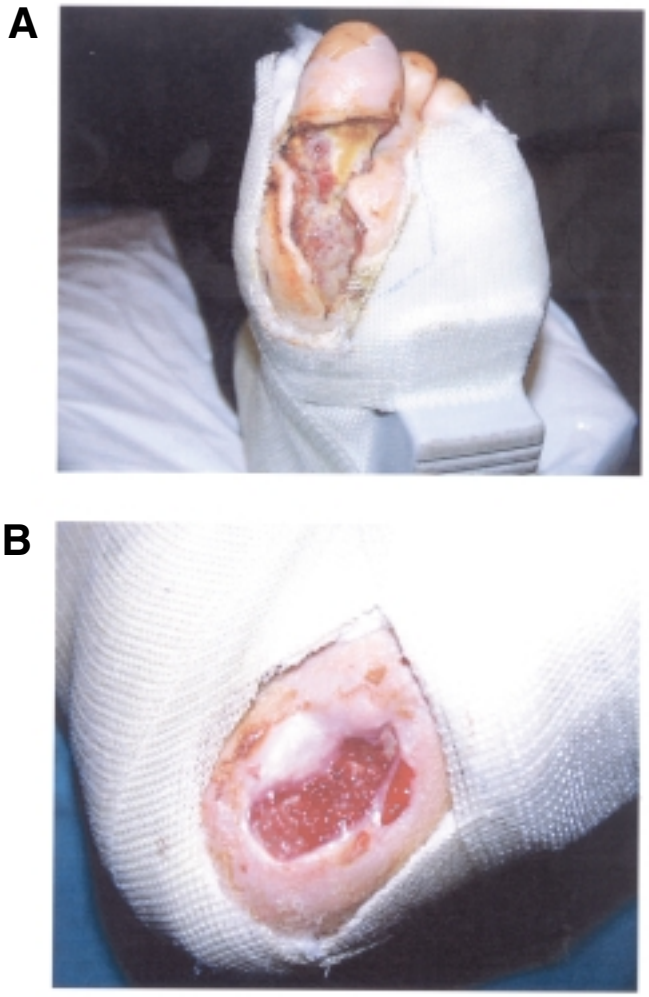

Figure 2—*Open window corresponding to an ulcer of the forefoot (A) and the heel (B).*

Therapeutic shoe

In this study, we used a cloth therapeutic shoe with a rocker-bottom sole and a rolling point that is situated beside the metatarsal arch during walking. The shoe is predisposed (extra depth) for lodging an 8-mm–thick cushioned elastic insole made of plastazote (alkaform) on which an area of unloading is prepared in the area of the plantar ulcer. The unloading area must be 5–8 mm larger than the perimeter of the ulcer. The shoe is opened dorsally with velcro straps that permit the dressing to stay in place (Fig. 3). All patients used the same type of shoe, with a plantar insole but no area of unloading, for the unaffected foot.

Visual analog scale for the evaluation of patient acceptance of treatment

At the end of the study, each patient was asked to evaluate the acceptance of the

Figure 3—*Extra deep therapeutic shoe with rocker bottom sole* (A) *and insole made by plastarote and covered with PPT layer with unloading area* (B).

treatment using a visual analog scale ranging from 1 to 100.

Statistical analysis

The sample size ($n = 50$) was determined by considering the ulcer reduction rate at 30 days equal to 33% in the group treated with a cloth shoe and 75% in the group treated with a fiberglass off-bearing cast and requiring a significance of $\alpha = 0.05$ for a two-sided Student's t test with $1 - \beta = 0.80$. Eligible participants were randomized to treatments by telephone calls to the clinical trial office. Mean values and SDs were calculated for all the variables measured in continuous scale and percentages for discrete variables.

The Pearson χ^2 test was used to compare the rates of events in the two treatment arms, and the Student's t test was used to compare the averages of continuous variables to follow the Gaussian distribution (Shapiro-Wilk test). The response rate was subdivided in quintiles of the percentage of healing of the ulcer surface, starting from complete healing (100%) and ranging to <20% of healed surface. The test for trend in the quintiles of response in the two treatment arms was done by the Mann-Whitney two-sample test for independent samples.

RESULTS — No noteworthy differences were found between the two groups with respect to clinical characteristics (Table 1). There was no statistical difference in ulcer area at enrollment between the two study groups (431.7 [391.7 mm^2] in the shoe group and 587.3 [587.7 mm^2] in the cast group, $P = 0.415$).

After a 30-day observation period, two patients who were enrolled in the shoe group presented an increase in ulcer size, whereas no subject enrolled in the fiberglass off-bearing cast group showed an increase in ulcer size. After 30 days, 5 subjects treated with the shoe reached complete recovery, and ulcers healed in 13 patients treated with the fiberglass off-bearing cast. The difference is statistatically significant ($\chi^2 = 4.6079$, $P = 0.032$).

The trend of reduction in ulcer size, measured with the Mann-Whitney U test, shows a significantly faster reduction in the fiberglass off-bearing cast group ($z = 3.529$, $P = 0.0004$) (Fig. 4).

No side effects were observed in both groups: in particular, no skin abrasions or new ulcerations and edema of the limb were observed in either of the groups.

There was no difference in patient acceptance of the two treatments: the average score ± SD obtained from the visual analog scale submitted to all patients was 91.15 ± 9.9 in the shoe group and 88.33 ± 17.3 in the cast group (NS).

CONCLUSIONS — It is well known that the relief of peak pressure on plantar ulcers when a patient is in the upright state or, even more importantly, walking, represents the central point of treatment in this type of lesion (17). Reducing pressure on the ulcerated area may be achieved with several approaches (18). Bed rest is an effective method but is not practical because it drastically limits the patient's autonomy and the patient seldom remains completely at rest. Moreover, in elderly patients, this approach could involve the risk of serious bed hypocinetic syndrome, considering the length of time generally needed to heal completely. The use of a wheelchair or crutches (19) can be equally effective, but represents once again a serious limitation to the quality of life of the patient. The methods currently recommended are therapeutic shoes or the TCC (20,21). Even if the TCC is the treatment of choice, the frequency of side effects referred to in literature and minimal patient acceptance do not make this approach widely applicable (22). Thus, the lack of use of this effective therapeutic approach prolongs the healing of the ulcers (23). The principal cause of side effects attributed to the use of the TCC may be related to the rigidity of the boot constructed with plaster bandages. This characteristic is responsible for muscular hypotrophy, joint rigidity, fungal infections, and skin ulcers and abrasions (24).

In an effort to retain the total unloading ability of the TCC yet reduce its classic side effects, we used fiberglass bandages of variable flexibility and rigidity. We obtained a

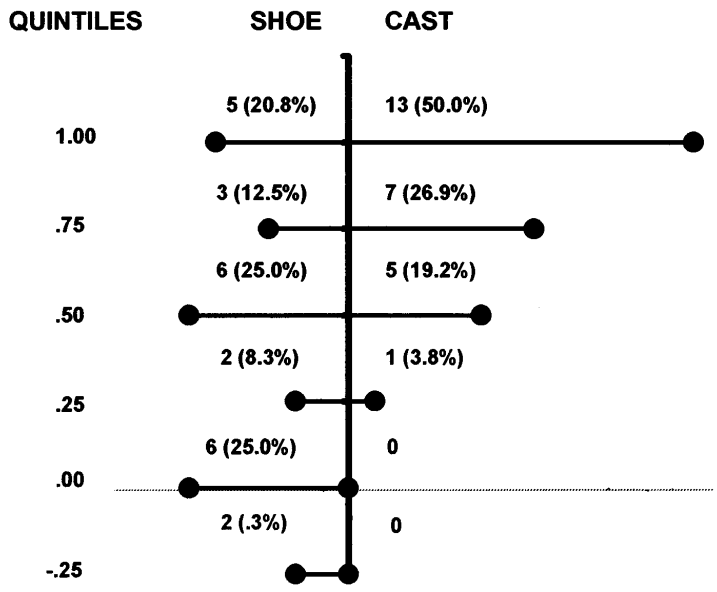

Figure 4—*Trend in ulcer area reduction. Mann-Whitney* U *test for trend: z = 3.529, P = 0.0004.*

very light off-bearing cast, which reduced friction with the skin and did not impair the positive effect of muscular contraction on venous circulation. This is important because it avoids the potentially dangerous consequences of edema caused by venous stasis. Since this device is very light, even elderly patients maintain acceptable walking autonomy. However, the most interesting advantage that comes from the flexibility of this type of off-bearing device built with the previously described technique is the absence of the typical skin lesions caused by using the classic TCC (25). We are convinced that this new technique can eliminate side effects, allowing a wider application of the off-bearing casts, which in our study have proven to be a more effective approach in the treatment of neuropathic plantar ulcers. Finally, attention should be given to the opening in the cast created over the ulcer. In the classic technique, the TCC does not allow for a window that enables monitoring of the ulcer. This leads to many disadvantages, such as the impossibility of draining secretions, thus increasing the risk of infection; the presence of unpleasant odor derived from the unremoved secretions; and the inability to detect any worsening of the ulceration. The impossibility of evaluating these clinical modifications through the window has been addressed in the past by replacing the TCC every 7 days (26). With the open area over the ulcer, it is possible to avoid the majority of the problems described and use the off-bearing device for a longer period. At the beginning of the treatment, the size of the window has to be calibrated in relation with the dimensions of the ulcer, because the window must be as small as possible. This characteristic minimizes the appearance of the skin edema from the window and may slow down the process of the healing of the ulcer. The size of the ulcer is evaluated during the treatment, and the off-bearing device can be changed when the window is much larger than the ulcer.

We found no significant difference in patient acceptance of treatment between the treatment groups. However, the therapeutic shoe used in this study did show efficacy in the treatment of neuropathic plantar ulcers. These data affirm that the off-bearing device built with nonremovable fiberglass bandages with variable flexibility and rigidity represents the elective treatment of the neuropathic plantar ulcer.

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