An Off-the-Shelf Instant Contact Casting Device for the Management of Diabetic Foot Ulcers

A randomized prospective trial versus traditional fiberglass cast

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OBJECTIVE — This study was designed to test the safety, effectiveness, and costs of off-loading with a novel, off-the-shelf irremovable device in the management of diabetic foot ulceration (DFU).

RESEARCH DESIGN AND METHODS — We prospectively evaluated off-loading of neuropathic plantar ulcers in 40 diabetic outpatients attending our diabetic foot clinic and compared healing rates at the 12-week follow-up, number and severity of adverse events, healing time, costs and applicability of the device, and patients' satisfaction between those randomly assigned to total contact casting (TCC; group A) or to the Optima Diab walker (group B). Deep or infected ulcers were excluded.

RESULTS — No difference between groups A and B was observed in healing rates at 12 weeks (95 vs. 85%), healing time (6.5 ± 4.4 vs. 6.7 ± 3.4 weeks), and number of adverse events (six versus four). Treatment was significantly less expensive in group B, which showed a mean reduction of costs of 78% compared with group A ($P < 0.001$). Practicability was more favorable in group B, with a reduction of 77 and 58% of the time required for application and removal of the devices, respectively ($P < 0.001$). Patients' satisfaction with the treatment was higher in group B ($P < 0.01$).

CONCLUSIONS — The Optima Diab walker is as safe and effective as TCC in the management of DFU, but its lower costs and better applicability may be of help in spreading the practice of off-loading among the centers that manage the diabetic foot.

Diabetes Care 30:586–590, 2007

Diabetic foot ulceration (DFU) is the most frequent form of ulcer in the foot in industrialized countries and the major determinant of lower-limb amputations in diabetic patients, since up to 85% of all major amputations in diabetes are preceded by an ulcer (1,2). The presence of active DFU has been reported in 4% of the general population, but it is estimated that up to 15% of people with diabetes will experience DFUs at least once in their lifetime (3,4).

The pathogenesis of DFU is well understood and is based on the effects of peripheral neuropathy upon the target organ, the foot, over a variable amount of time. The pressure resulting from normal daily activity gradually increases until it overwhelms the resistance of the skin and creates a lesion in the plantar surface of the foot that maintains itself with the continuity of load, eventually becoming complicated by infection and ischemia (5,6). The determinant role of foot loading in the genesis and maintenance of plantar ulcers in the neuropathic foot has been demonstrated beyond any reasonable doubt, and its interruption is the key to reversing the pathogenic chain and to starting the healing process (7–9).

Unfortunately, there are no easy ways to obtain effective off-loading of the foot. Patient compliance is generally poor because of the lack of symptoms due to sensory neuropathy, and they tend to wear off-loading devices very scarcely. Total contact casting (TCC), therefore, has been indicated as the gold standard for the management of neuropathic ulceration, mainly because it is nonremovable by the patients (10,11).

Nevertheless, management of these patients with TCC presents many problems. It is costly; it relies on the availability of a cast technician; it can raise safety issues, especially in elderly patients; and it requires time for application and removal (11,12). To address these issues, Armstrong et al. (13) proposed using a removable cast walker (RCW) rendered irremovable by the application of a single-layer fiberglass band so that the patient could not remove it, and they called it "instant" TCC (i-TCC) (13,14).

Following this philosophy, a new off-loading device (Optima Diab; Molliter, Civitanova Marche, Italy) has been designed to serve as an off-the-shelf i-TCC, and it was proposed for use in the management of DFU. Its characteristics include a rigid rocker sole with an innovative design, a modular insole composed of three layers of different stiffness that can be adapted according to the actual location of the ulcer, and a posterior rigid brace to block the ankle high up to the upper leg. The device can be rendered irremovable by securing it with a plastic lace that can be removed only by cutting it

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Received for publication 18 August 2006 and accepted in revised form 9 December 2006.

Abbreviations: DFU, diabetic foot ulceration; i-TCC, instant TCC; RCW, removable cast walker; TCC, total contact casting.

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

DOI: 10.2337/dc06-1750

with a specific tool, thus rendering it nonremovable by the patients. We designed this study to compare its safety and effectiveness to TCC in the management of DFU in a group of diabetic outpatients.

RESEARCH DESIGN AND METHODS

— All the patients attending the diabetic foot clinic of the University of Pisa between April and October 2005 were screened for the following inclusion criteria: They should have type 1 or type 2 diabetes for a period of at least 5 years, they should have peripheral neuropathy as highlighted by insensitivity to a 10-g monofilament and by a vibration perception threshold measured at malleolus of at least 25 volts (15), and they should have a forefoot plantar ulcer for a period of at least 3 weeks with an area wider than 1 cm^2 graded 1A or 2A according to Texas University classification (16). The exclusion criteria considered were peripheral vascular disease with an ankle-brachial pressure index <0.9; the presence of clinical signs of infection, including edema, erithema, increased local skin temperature, secretion, fever, and leukocytosis, confirmed by culture exams; previous ulcer in the same site in the last 6 months; probing to bone and/or radiographic signs of osteomyelitis; Charcot's neuroarthropathy of the foot; bilateral ulceration; serum creatinine >2 mg/dl; any systemic pathology or therapy possibly interfering with the healing process; severe visual or motor impairment that could expose the patient to risk of accidents while participating in the study; and/or a life expectancy shorter than 1 year.

Patients released a written informed consent before enrolling in the study. The information given to patients included a description of both off-loading techniques. Participants were then randomly divided into two different groups with a computer-generated randomization list. Group A was off-loaded with a nonremovable fiberglass cast as is the standard approach in our clinic, and group B subjects were placed in the Optima Diab device according to the manufacturer's instructions.

Besides the off-loading treatment, patients received specific instructions on how to manage the off-loading devices and the standard therapy of neuropathic ulceration performed in our clinic according to the international consensus on the diabetic foot (17). Ulcers were surgically debrided, eliminating all the nonviable tissue, as well as any sinus or undermined zone, and exposing the entire area of the lesion. The ulcers were then photographed and measured by means of Visitrak (Smith & Nephew, Hull, U.K.). Ulcers were dressed with paraffined gauze and covered with a single layer of sterile gauze before application of the off-loading devices.

Figure 1—*The Optima Diab device.*

Patients in group A were casted according to a technique previously described by Petre et al. (18). Positioning a layer of isolating foam (Allevyn adhesive; Smith & Nephew) in relation to the ulceration site, the lesion is better isolated from contact with the cast, paying attention to avoid friction or trauma with bony prominences by protecting them with extra layers of cotton-wool. The fiberglass material used for manufacturing each cast was produced by 3M (St. Paul, MN) and consisted of two Scotchcast longuettes (10×90 or 7.5×70 cm, depending on the size of the foot) to create the plantar support and block the ankle, and three Sofcast rolls (10.1 or 7.6 cm) to make the boot. Each cast was provided with one or two rubber heels (Lohmann, Neuwied, DE) to allow the patients to stand and walk.

Patients in group B were given the Optima Diab device, adapted according to the patient's foot condition and secured to the patient's leg with a plastic nonremovable lace, which was an integral part of the device (Fig. 1). The patients' foot and leg were protected by a layer of cotton-wool to avoid friction with the device, and the three-layer insoles were modeled to accommodate the position of the ulcer site. All the casts were made by the same podologist, certified for this particular expertise (S.M.). The manufacturing time of each cast was measured at each visit, including the first one, and cost of treatment was calculated for both groups.

Cost for TCC was calculated based on the real cost paid by the hospital to buy all the necessary materials (fiberglass bandages, rubber heel, cotton-wool, etc.) from manufacturers, while cost of the Optima Diab device was calculated based on the cost at which the device is sold on the market. Costs were calculated for each TCC based on the actually consumed materials, which could vary in amount depending on the size of the foot and location of ulcer. All the costs were inclusive of 20% tax.

Patients of both groups were followed-up weekly for 12 weeks or up to complete reepithelialization of the lesions. At each checkup, patients in group A had their cast removed with an oscillating saw. Lesions were debrided, if necessary, measured, photographed, and dressed, and a new cast was then manufactured. Patients in group B underwent the same procedure except for the removal of the off-loading device, which was performed by cutting the nonremovable lace and then opening the device. This was then controlled and repositioned by replacing the nonremovable plastic laces. The time taken to remove the device also was measured, as well as the time to reposition it on the patients.

Any eventual adverse events were recorded, with special emphasis on possible infective complications or appearance of new lesions. At the end of the study, patients were requested to express their level of satisfaction with the treatment by means of a visual analogic scale ranging from 0 (no satisfaction at all) to 10 (maximum satisfaction), answering the question "how satisfied were you with your treatment?"

The primary end point was the rate of healing at 12 weeks (i.e., rate of patients with complete reepithelialization), while secondary end points were the number and severity of adverse events, mean healing time, time of application and removal of the devices, cost of treatment, and level of satisfaction expressed by patients.

The data, expressed as means ± SD, were analyzed according to the intention-to-treat model, with Student's t test for normally distributed variables, the Kaplan-Meier analysis for survival data, and the χ^2 tests for dichotomous vari-

Table 1—*Characteristics of patients in the two groups*

	Group A	Group B	*P*
n	20	20	NS
Age (years)	59.8 ± 8.2	61.1 ± 6.4	NS
Duration of diabetes (years)	14.7 ± 11.1	13.4 ± 7.5	NS
A1C (%)	7.9 ± 1.1	7.6 ± 0.9	NS
VPT (volts)	36.8 ± 7.4	39.1 ± 8.6	NS
Area of lesions (cm^2)	3.7 ± 1.6	3.9 ± 1.8	NS

Data are means ± SD. NS, not significant; VPT, vibration perception threshold.

ables, using commercially available software (StatView; SAS Institute, Cary, NC) running on a personal computer.

RESULTS — A total of 43 patients were screened, but only 40 were actually randomized in the two study groups. Their characteristics are reported in Table 1. Of three patients who did not enter the study, one refused to release the informed consent and two were unable to attend the scheduled follow-up visits because of the distance of traveling to the clinic. There were no significant differences between the two groups as far as demographics and clinical data are concerned. The characteristics of patients are reported in Table 1. All patients of both groups completed the study and attended all control visits. In two cases in group A and three cases in group B, one control visit was delayed for 1 day because of patient-related causes.

No significant differences emerged between the groups with regard to treatment complications. In group A, five patients reported minor adverse events during the course of the study (one TCC partial rupture due to accidental trauma and four episodes of skin maceration in the perilesional area). In group B, one patient reported one single episode of transient paresthesia in the foot with no objective signs, two patients showed skin maceration, and one patient presented a superficial emathoma of the calf due to accidental trauma, without any skin injury. No new lesions were observed in any of the patients in either group during the study. None of the adverse events led to discontinuation of the study. One patient in group A and one in group B developed local signs of infection (perilesional erithema and edema), which led to the administration of oral antibiotics (1 g b.i.d. amoxicyllin-clavulanate) for 10 days. In both cases, the signs of infection were resolved in 1 week and did not recur, and patients continued the study. No significant differences in the healing rates were observed between the groups, since 95% of group A patients and 85% of group B patients healed within 12 weeks (χ^2 1.569, $P = 0.2104$). In Fig. 2, the Kaplan-Meier plots show the survival curves of group A and group B patients with no differences between the two groups in terms of healing. The mean duration of healing time was 6.5 ± 4.4 weeks (range 2–14) in group A and 6.7 ± 3.4 weeks (2–17) in group B ($P = 0.8745$). Healing time correlated with the area of the lesion at baseline in both groups ($P < 0.01$), while it was not influenced by age, duration of diabetes, or A1C.

The time for placement of the off-loading devices significantly differed between group A and group B patients (15.1 ± 2.3 min [range 10.9–18.6] vs. 2.1 ± 0.7 min [1.9–2.6], respectively, $P < 0.001$) as did the time for their removal (2.1 ± 0.9 min [1.1–3.0] vs. 0.9 ± 0.4 min [0.5–1.0], respectively, $P < 0.01$). The cost of casting was 110.15 ± 4.38 euros (range 107.05–117.41) per cast, and the cost per patient was 727.29 ± 491.25 euros (214.11–1,827.84), while the cost of Optima Diab was 130 euros each, and the cost per patient was 162.5 ± 57.75 euros (130–260 euros, $P < 0.001$) since in five patients the device was replaced because of usage. Patients' levels of satisfaction with the treatment, evaluated with the visual analogic scale, were significantly higher in the i-TCC group compared with the TCC group (8.45 ± 1.79 vs. 6.85 ± 2.39, respectively, $P < 0.05$).

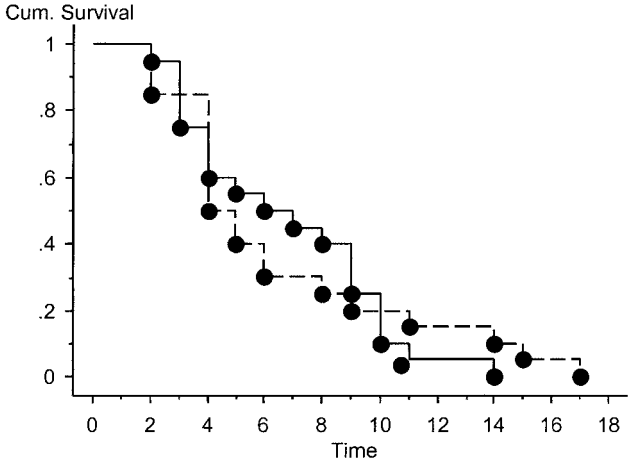

Figure 2—*Kaplan-Meier survival analysis of ulcers in group A (dotted line) and group B (solid line). No significant differences were observed between the groups.*

CONCLUSIONS — Our study confirms the effectiveness and the safety of nonremovable off-loading devices in the management of DFU, at the same level as TCC, and establishes their superiority over TCC in terms of practicability, cost, and patient acceptance.

Off-loading is an etiologic therapy of neuropathic diabetic foot ulcers. When correctly applied, it has been proven not only to interrupt the pathogenic chain that produces the ulceration but also to induce modifications in the histology of the ulcer, shifting it from a chronic inflammatory state to a much more evolutive condition (19,20).

The rate of success of off-loading strategies is strictly related to the nonremovability of the devices applied, as opposed to their peculiar characteristics. Previous studies emphasize how the rate of healing at 12 weeks is >80% in patients treated with irremovable devices, while it drops to <60% in patients treated with removable devices (21).

The nonremovability is effective in both maximizing the off-loading application time and minimizing the role of patient compliance, which is generally very poor. Ha Van et al. (22) demonstrated how the rate of patients completely adher-

ing to an off-loading regimen may vary from 10% when it is removable to 98% when it is nonremovable. Armstrong et al. (23) demonstrated that patients wearing RCWs not only tended not to wear them but also increased their activity when they were not wearing them, thus reducing even further the benefit of off-loading.

Our study confirms the efficacy of an i-TCC off-loading regimen, since no differences in healing rates at 12-week follow-up emerged between TCC and Optima Diab. It also focuses more attention on the philosophy of complete, durable, and sustainable off-loading rather than on the strategy used to obtain it. The easier it is to pursue an off-loading strategy the more likely it is to be effective because of its actual application on patients. In this sense, TCC, although effective and safe, represents an option often difficult to pursue because it requires specific expertise, time, and many different materials to be assembled in a complex way, and, depending on how often it is changed, it is expensive (22).

A recent survey in European centers of excellence for diabetic foot, not yet published but quoted by Naaburs-Franssen et al. (24), shows how little the TCC is actually used in the management of DFU despite it being indicated as the gold standard for off-loading in the international guidelines for DFU management (17,24). The nonremovable device we used, although presenting good technical features (rigid rocker sole, posterior brace that blocks the ankle joint, composite multilayered insoles—all features that have been demonstrated to effectively reduce the plantar pressure of the forefoot [25,26]), can be considered as a valid alternative to TCC, mainly because it has been designed to be nonremovable by the patient.

The availability of an off-the-shelf nonremovable device would help in increasing the actual application of off-loading to more patients not only because it is easier but also because it takes significantly less time to apply and remove, and this can make a difference in a busy diabetic foot clinic. Patient acceptance of the treatment was clearly favorable to i-TCC, and this should not be surprising in view not only of the effectiveness but also of the relatively low impact on everyday activities of this option compared with TCC.

Cost of treatment is also an issue in the management of DFU, since it has been demonstrated that diabetic foot is likely to be the most expensive and resource consuming among the chronic complications of diabetes (27). Our study demonstrated how the cost of the treatment with an i-TCC, which can be repositioned only by changing the plastic lace, is less than one-quarter of the treatment with TCC. This is possible because, in contrast to TCC, which is replaced at every checkup, i-TCC can last for the whole treatment. Because of its effectiveness, these costs can be considered an investment, as they stop the progression of ulceration toward more severe and costly stages of the pathology of the diabetic foot. A recent study with an econometric model calculated 874 U.S. dollars as the 6-month treatment cost for a superficial ulcer and 1,872 U.S. dollars as the cost for a deep ulcer, with an increase of 114% in the management costs (28).

Our data are consistent with those reported by Katz et al. (14) in a recent well-designed study comparing TCC with a cast walker rendered irremovable. Results in terms of efficacy, placement, and removal times of the TCC and RCW were superimposable, while in our study higher costs for TCC were observed, probably due to higher costs of materials in Italy compared with the U.S.

Our study, though encouraging, is not conclusive because it has many limitations. The number of patients is small; it was conducted by highly specialized personnel in a single center, which is a site of excellence for diabetic foot management; and the results cannot be extended to other centers in which there is no such focused clinical activity and where there would be potentially the most interest in an easily applicable, effective, and safe off-loading option. For these reasons, we are designing a prospective multicenter trial involving diabetes centers throughout Italy to test i-TCC in a larger sample of patients and in different clinical settings.

The irremovable Optima Diab walker is as safe and effective as TCC in the management of neuropathic foot and is more practical, less expensive, and more accepted by the patients. Its application may help in expanding the possibilities of real application of an effective off-loading regimen to diabetic patients with a neuropathic ulceration also in the many centers that cannot afford the technology and investments for manufacturing TCCs. It therefore contributes to reducing the risk of evolution of the pathology toward more severe stages and eventually to preventing amputations.

Acknowledgments— We acknowledge the generous contribution of Salvatelli srl, Civitanova Marche, Italy, manufacturers of the Optima Diab Molliter walkers used in this study.

We also acknowledge the help of Bridget Walker for revising the English in this article.

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