

Off-Loading the Diabetic Foot Wound

A randomized clinical trial

DAVID G. ARMSTRONG, DPN^{1,2,3,4}
HIENVU C. NGUYEN, DPN²
LAWRENCE A. LAVERY, DPN, MPH²

CARINE H.M. VAN SCHIE, PHD³
ANDREW J.M. BOULTON, MD³
LAWRENCE B. HARKLESS, DPN²

OBJECTIVE — To compare the effectiveness of total-contact casts (TCCs), removable cast walkers (RCWs), and half-shoes to heal neuropathic foot ulcerations in individuals with diabetes.

RESEARCH DESIGN AND METHODS — In this prospective clinical trial, 63 patients with superficial noninfected, nonischemic diabetic plantar foot ulcers were randomized to one of three off-loading modalities: TCC, half-shoe, or RCW. Outcomes were assessed at wound healing or at 12 weeks, whichever came first. Primary outcome measures included proportion of complete wound healing at 12 weeks and activity (defined as steps per day).

RESULTS — The proportions of healing for patients treated with TCC, RCW, and half-shoe were 89.5, 65.0, and 58.3%, respectively. A significantly higher proportion of patients were healed by 12 weeks in the TCC group when compared with the two other modalities (89.5 vs. 61.4%, $P = 0.026$, odds ratio 5.4, 95% CI 1.1–26.1). There was also a significant difference in survival distribution (time to healing) between patients treated with a TCC and both an RCW ($P = 0.033$) and half-shoe ($P = 0.012$). Patients were significantly less active in the TCC (600.1 ± 320.0 daily steps) compared with the half-shoe ($1,461.8 \pm 1,452.3$ daily steps, $P = 0.04$). There was no significant difference in the average number of steps between the TCC and the RCW (767.6 ± 563.3 daily steps, $P = 0.67$) or the RCW and the half-shoe ($P = 0.15$).

CONCLUSIONS — The TCC seems to heal a higher proportion of wounds in a shorter amount of time than two other widely used off-loading modalities, the RCW and the half-shoe.

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Neuropathic ulcers are the prime precipitant of diabetes-related amputations of the lower extremity (1). The central goal of any treatment program designed to heal these wounds is effective reduction in pressure (off-loading) (2). Total-contact casts (TCCs) are considered the gold standard of ulcer treatment by many experts in this field (3–16). This assertion, however, has been made ostensibly without any meaningful side-by-

side comparison of devices. Our and other investigators' systematic reviews have been unable to identify any studies that prospectively compare the clinical effectiveness of various prosthetic devices with off-load ulcer sites to facilitate wound healing (17). Therefore, the purpose of this study was to compare the effectiveness of TCCs, removable cast walkers (RCWs), and half-shoes to heal neuropathic foot ulcerations in individuals with diabetes.

RESEARCH DESIGN AND METHODS

— In this prospective clinical trial, 63 patients were randomized into one of three off-loading modalities, including TCC, half-shoe (Darco, Huntington, WV), or the Aircast diabetic walker (Aircast, Summit, NJ). The diagnosis of diabetes had been made before enrollment and was confirmed either by communication with primary care providers or by reviewing medical records. All patients had clinically significant loss of protective sensation (>25 V) as measured with a biothesiometer (Biomedical Instrument, Newbury, OH) (18,19), at least one palpable foot pulse or a transcutaneous oximetry (TcPO₂) measurement higher than 40 mmHg at the level of the dorsum of the forefoot, and a neuropathic plantar diabetic foot ulcer corresponding to grade 1A (superficial, not extending to tendon, capsule, or bone using the University of Texas Diabetic Foot Wound Classification System) (20). Neuropathy was defined as the inability to sense the 10-g Semmes-Weinstein monofilament and a vibration perception threshold >25 V (18,19,21). Patients who had active infection, were unable to walk without wheelchair assistance, had wounds in locations on the heel, rear foot, or area other than the plantar aspect of the foot, or had severe peripheral vascular disease (diagnosed by the criteria listed above) were excluded from the study. If patients had more than one plantar wound, the largest wound was used as the index ulcer for inclusion in this study.

Patients were randomized through a computerized randomization schedule. Randomization was performed after the initial screening. The clinical study protocols and the informed consent that each patient was required to sign were approved by the appropriate Institutional Review Board. TCCs were applied using a modification of the technique described by Kominsky (22). The modification to this technique included the use of a cast boot in lieu of the rubber cast walker and plywood platform. TCCs were changed on a weekly basis or as clinically necessary. RCWs and half-shoes were applied

From the ¹Audie L. Murphy Veterans Affairs Medical Center, Tucson, Arizona; the ²Department of Orthopaedics, University of Texas Health Science Center, San Antonio, Texas; the ³Department of Medicine, Manchester Royal Infirmary, University of Manchester, Manchester, U.K.; and the ⁴Department of Surgery, Southern Arizona Veterans Affairs Medical Center, Tucson, Arizona.

Address correspondence and reprint requests to David G. Armstrong, Department of Surgery, Southern Arizona Veterans Affairs Medical Center, 3601 South Sixth Ave., Tucson, AZ 85723. E-mail: armstrong@usa.net.

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Abbreviations: RCW, removable cast walker; TCC, total-contact cast; TcPO₂, transcutaneous oximetry.

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

Table 1—Descriptive characteristics

Group	Total	TCC	RCW	Half-shoe
<i>n</i>	63	19	20	24
% Male	82.5	73.7	90.0	83.3
Duration of diabetes	16.9 ± 8.8	17.8 ± 8.7	18.2 ± 10.1	15.3 ± 7.9
TcPO ₂ (mmHg)	60.4 ± 12.3	60.7 ± 9.0	62.0 ± 16.3	58.6 ± 10.4
Wound size (cm ²)	1.3 ± 1.1	1.3 ± 0.8	1.4 ± 1.4	1.3 ± 1.2
Wound duration (months)	5.2 ± 6.3	4.3 ± 5.7	5.6 ± 6.2	5.5 ± 7.1
Vibration perception threshold (V)	44.6 ± 8.0	41.5 ± 10.5	46.7 ± 4.8	45.4 ± 7.7

Data are means ± SEM unless otherwise indicated.

using the directions dispensed with the original packaging. All patients were instructed to use the devices at all times during ambulation.

All patients were followed on a weekly basis for device inspection, wound care, and wound debridement. All wounds were surgically debrided as required on each visit. Wounds were measured using a computerized planimetric video wound measurement system (23). Patients were instructed to wear a pedometer (Sportline, Campbell, CA), which was calibrated upon initiation of the study, as a general measure of activity. The total number of steps was recorded on each visit by study personnel.

Outcomes were assessed at wound healing (defined as complete epithelialization) or at 12 weeks, whichever came first. Primary outcome measures included proportion of complete wound healing at 12 weeks and activity (defined as steps per day). Of an initial enrollment pool of 75 patients, 12 failed to complete the course of study. Reasons for this included discomfort (four TCC, three RCW), instability (one half-shoe), or failure to return for follow-up appointments and data-collection visits (two TCC, two RCW).

We used an analysis of variance with Tamhane's post-hoc test for multiple comparisons to evaluate all continuous variables between off-loading groups. We evaluated the effect of continuous variables on healing in general using a Mann-Whitney *U* test. Dichotomous variables were evaluated with a χ^2 test with odds ratio and 95% CI. To evaluate the healing characteristics of each device as a function of weeks of therapy and mean time to closure among patients healing within the 12-week study period, we used a Kaplan-Meier life-table analysis (log-rank test). Using the above analyses, a difference of 40% between any two arms could be de-

tected with a sample size of 60 yielding a power exceeding 80%. For all analyses, we used an α of 0.05.

RESULTS— Descriptive characteristics for the subgroups are listed in Table 1. No significant differences were observed in any of the characteristics evaluated, including age, sex, duration of diabetes, size or location of wounds, or duration of plantar wounds. With the numbers available, we could not detect a difference in

wound healing based on sex ($P = 0.15$) or degree of glucose control ($P = 0.78$). However, healed wounds were smaller at baseline than unhealed wounds (1.1 ± 1.0 vs. 1.9 ± 1.3 cm², $P = 0.02$).

The proportion of healing in the patients treated with TCC, RCW, and half-shoe was 89.5, 65.0, and 58.3%, respectively. At 12 weeks, the proportion of healing was significantly higher in the TCC group than in the patients treated with the two other modalities (89.5 vs.

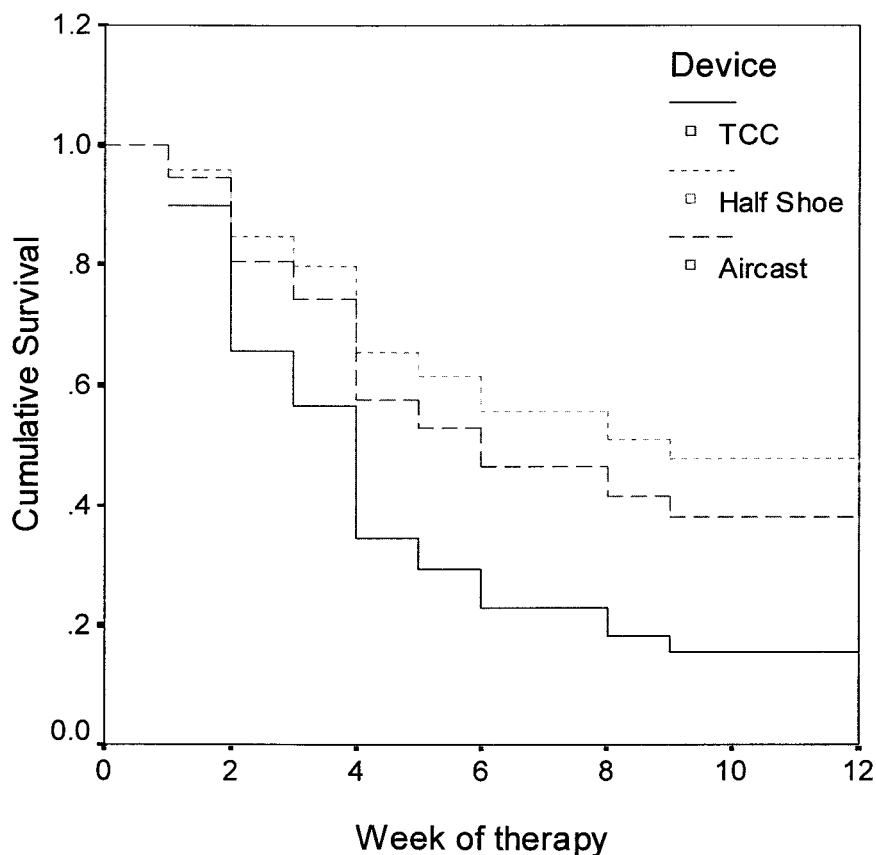


Figure 1—A significant difference in cumulative wound survival was noted at 12 weeks between patients treated with a TCC half-shoe and a RCW (Aircast). $P = 0.012$ and 0.033 , respectively.

61.4%, $P = 0.026$, odds ratio 5.4, 95% CI 1.1–26.1). There was also a significant difference in cumulative wound survival at 12 weeks between patients treated with a TCC and both the RCW ($P = 0.033$) and the half-shoe ($P = 0.012$). This is illustrated in Fig. 1. Among patients healing within the 12-week period, the mean time to healing was significantly shorter in patients treated with the TCC compared with those treated with the half-shoe (33.5 ± 5.9 vs. 61.0 ± 6.5 days, respectively; $P = 0.005$) but not the RCW (50.4 ± 7.2 days, $P = 0.07$), with the numbers available for study. No falls or device-related ulcerations were reported during the course of study.

Activity of the patients was also measured. Patients treated with the TCC were significantly less active (600.1 ± 320.0 daily steps) than those treated with the half-shoe ($1,461.8 \pm 1,452.3$ daily steps, $P = 0.04$). There was not a significant difference in activity between patients treated with the TCC and with the RCW (767.6 ± 563.3 daily steps, $P = 0.67$) or between those treated with the RCW and with the half-shoe ($P = 0.15$).

CONCLUSIONS— The results of this study suggest that the TCC heals a higher proportion of wounds in a shorter amount of time than two other widely used off-loading modalities, the RCW and the half-shoe. Additionally, it seems that patients are less active when treated with the TCC than with the half-shoe. This reduction in activity and ability to aggressively off-load the plantar aspect of the foot may partially explain the success of the TCC. To our knowledge, this is the first randomized clinical trial in the medical literature examining the clinical effectiveness of these modalities.

As noted earlier, TCCs are considered by most diabetic foot specialists to be the gold standard off-loading modality for treatment of wounds on the sole of the foot (3). The technique has come to be known as total-contact casting because it involves a molded and minimally padded cast that maintains contact with the entire plantar aspect of the foot and the lower leg. Total-contact casting has been frequently reported as effective in treating noninfected, nonischemic plantar diabetic foot wounds, with proportions of healing ranging from 72 to 100% in times ranging from 1 month to several weeks (5,7–9,12,13,15,16). Generally, peak

plantar pressures are highest in the forefoot, whereas they tend to be of a lower magnitude in the rearfoot and medial arch. Shaw et al. (24), and later Armstrong and Stacpoole-Shea (25), noted that a large proportion of the pressure reduction realized in the forefoot with the TCC is transmitted along the cast wall or to the rearfoot.

TCCs are effective for a number of reasons in addition to their ability to mitigate pressure. They may help reduce or control edema and potentially protect the foot from infection (10). However, the most important attribute of the TCC may be its ability to “force compliance.” The patient has little choice other than to adhere to the regimen prescribed by the clinician, because the device is not easily removable. Furthermore, based on the results of the present study, it seems that the TCC may significantly curtail activity, thereby reducing the number of cycles of repetitive stress on an already open wound. It should be noted in this study that patients were relied upon to wear the pedometers just as they were relied upon to wear the off-loading devices. Ideally, we could use an activity monitor that was less reliant on patient compliance.

Lavery et al. (14) reported that there was not a practically appreciable difference between some RCWs (such as the Aircast) and TCC with respect to ability to off-load the plantar aspect of the foot. However, the present study suggests that a higher prevalence of healing exists in patients treated with TCCs. When discussing a removable device, it is perhaps the removability that is its biggest detriment. Perhaps two additional variables that should be added to the equation leading to device selection should be level of activity and compliance of the patient.

The above-described advantages make the TCC an attractive choice to off-load the diabetic foot ulcer. However, there are a number of potential negative detractors that may dissuade some clinicians from using this modality. Most clinics or practices do not have a physician or cast technician with training or experience to safely apply a TCC. Because improper cast application can cause skin irritation and, in some cases, even frank ulceration, which can be a most unappealing characteristic. In addition, TCCs do not allow patients, family members, or health-care providers to assess the foot or wound on a daily basis. Therefore, ad-

vanced wound healing modalities that require daily applications may not be suitable for use with patients using a non-removable device such as the TCC. Additionally, many patients experience problems with activities of daily living, such as bathing and sleeping. Also, certain designs of TCCs may exacerbate postural instability (26). Finally, TCCs generally are contraindicated for wounds with soft-tissue infections or osteomyelitis. Any one of the above reasons may compel the clinician to elect to use devices other than the TCC for off-loading the wound for a given patient. Additionally, one may argue that upfront costs for treatment of wounds with a TCC are higher. The general cost in materials alone for a TCC is approximately \$50–75. When multiplied by the cost of each subsequent cast change (generally at least weekly for the duration of the wound), this can certainly exceed the \$150–200 for the RCW and \$25–75 for accommodative sandals such as the half-shoe. However, one may argue that a significantly faster healing time would negate the added cost in supplies. Clearly, this issue requires further study.

In conclusion, this study suggests that there are significant differences in wound healing based on the off-loading device selected. The central tenets of healing the noninfected, nonischemic diabetic wound have and will continue to be appropriate debridement and pressure reduction. There is no single off-loading device that is appropriate for every patient. It is for this reason that we hope that work will continue in this area to assess various treatments to provide the clinician with the evidence necessary to make informed treatment decisions. It is in this manner that we believe we may realize more consistent wound healing and, commensurately, a meaningful and widespread reduction in the rate of amputations of the lower extremity.

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