Removable Cast Walkers: More Successful When Rendered Irremovable

A modified removable walker was cheaper, easier to use and had equal efficacy to total contact casts.

By David G. Armstrong, PhD, DPM

Total contact casts (TCC, Figure 1) are considered the gold standard of care for healing diabetic neuropathic ulcers. Various clinical trials have confirmed that this modality heals wounds in 73% to 100% of cases.¹

Because of the difficulty, time and cost associated with TCCs, however, most clinicians compromise this standard for more cost-efficient and timely methods of offloading pressure. My colleagues and I, reporting in Diabetes Care, have found that rendering a removable cast walker (RCW) irremovable may be an alternative to its more expensive counterpart. We have termed this new device an instant total contact cast (iTCC, Figure 2).

Pressure offloaded from the plantar foot by some RCWs is actually similar to that offloaded by TCCs. These include the Active Offloading Walker (Royce Medical, Camarillo, Calif); Aircast (Aircast, Summit, NJ); and the Conformer Boot (Bedsoe, Dallas). Even so, RCWs are less effective than TCCs in healing diabetic ulcers. This has been proven in many clinical trials; one of which was done with the Aircast and resulted in a healing rate of 65% versus 90% in the TCC.

Lack of Compliance

One reason for the lack of efficiency is patient compliance. We have shown in a previous study of diabetic patients that fewer than one-third of the daily total steps were taken while the RCW was worn. By modifying the RCW with one layer of plaster bandage wrapped around the cast, we have been able to ensure that patients keep the cast on at all times.

We randomized 50 patients to wear either a RCW (Active Offloading Walker, Royce Medical) or the same device wrapped in a cohesive bandage for 12 weeks. They were told to wear the device at all times and underwent weekly check-ups where debridement was performed. Our objective was to test the standard RCW against the iTCC and to test the effectiveness of each method in healing diabetic neuropathic foot ulcers. A total of 46 patients completed the study. All patients had diabetes, were experiencing protective sensation loss (>25 V) and had at least one grade 1A diabetic foot ulcer on the University of Texas Diabetic Foot Wound Classification System. We excluded patients who had vascular disease or an active infection.

Foot ulcerations healed in more patients within the iTCC group (86.4%) versus the RCW group (58.3%), and the healing time was also quicker (41.6 ±18.7 vs 58 ±15.2 days, P =.02). Both findings were statistically significant.
The only adverse event that was different between the two groups was periwound maceration. Patients in the iTCC group experienced more episodes than those in the RCW group (68.2% vs 37.5%, P = .04, OR 1.8 [95% CI 1.0-3.3]). There were no falls reported, no reports of ulceration related to the use of the two devices, and no patients were hospitalized during the study due to ulceration.

SECOND STUDY

We compared the rate of healing in the iTCC group to previous studies that used the TCC, noting that healing rates between the two devices were similar. This similarity prompted the initiation of a second clinical study to test the efficacy of iTCCs versus the standard TCC. In this prospective trial, my colleagues and I randomized patients to either a standard TCC or the same iTCC used in the above mentioned study. TCCs were placed by a trained cast technician or a pedorthodist on 20 patients. All patients, enrolled from foot clinics treating diabetic foot disorders, were neuropathic and had ulcers categorized by the University of Texas scale as IA or IIA. All wounds were chronic, nonischemic and noninfected. As in the previous study, patients returned to their clinics once a week for 12 weeks to have the ulcers checked and debrided. The endpoint was either 12 weeks or the presence of complete epithelialization.

Findings confirmed our hypothesis that iTCCs produce the same healing rates and times as TCCs. Furthermore, we found that the device did so with fewer complications and at a lower cost. After excluding patients lost to follow-up, wounds in 94 ±24% of the iTCC patients versus 93 ±26% of the TCC patients were healed within 12 weeks (P = .97). The mean TCC healing time was 5 weeks, and the mean iTCC healing time was 4 weeks (first quartile 3 weeks to third quartile 7 weeks for both). Sixty-five percent of patients in the iTCC group experienced a complication, and the majority of complications noted were simple local skin maceration. Patients in the iTCC group also experienced maceration, however, only 38% of patients suffered from a complication. Seventy-five percent of these were macerations (P = .09).

Cost analyses showed a $52.20 difference in cost between the modalities, the iTCC being the cheaper of the two. Our analysis referenced time to healing, cost of materials and the price of a cast technician ($210.67 for TCC vs $158.47 iTCC).

Using iTCCs in diabetic patients with plantar neuropathic foot ulcers has further advantages: It is easier and faster to place and remove. This can be paired with the fact that many clinicians do not know how to properly apply a TCC, nor do they have immediate access to cast technicians.

In conclusion, iTCCs may be a beneficial alternative to TCCs. We recommend the use of the iTCC in patients with diabetic foot ulcers in which using a cast has been deemed an appropriate offloading method. In patients without gait or severe foot deformities, who have significant stability, iTCCs are as safe and effective as TCCs and can be used as an alternative to the gold standard of care. Further studies are needed to confirm this data, however, we do believe that iTCCs have the ability to change the way we treat plantar diabetic foot ulcers.

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Removing calloused tissue, debriding the wound and using total contact casts or removable cast walkers are acceptable methods of offloading pressure. 

By Laura Suarez, Associate Editor

Diabetic foot ulceration on the insensate foot, caused by external pressure, will heal if the pressure is correctly offloaded. "We are not bad at controlling infection," said Andrew J.M. Boulton, MD, FRCP during a presentation at the American Professional Wound Care Association National Clinical Conference 2005, in Philadelphia. “But, we are terrible at offloading pressure.”

Ulceration and calluses are strong predictors of high pressures in a diabetic foot that has lost sensation. By removing callused tissue around the ulcer with aggressive debridement, diabetic patients have faster healing times. However, in the majority of instances, wounds are not completely debrided, Dr. Boulton said.

**TCC IS GOLD STANDARD**

The gold standard for healing plantar neuropathic ulcers, he said, is total contact casting. This device reduces foot pressure and forces patients to comply with its use. In a 12-week, randomized trial published in Diabetes Care, Armstrong et al. showed that the total contact cast (TCC) was better at healing ulcers than a half-shoe or a removable cast walker. Wounds from the TCC healed better and faster at each throughout the trial, Dr. Boulton said.

Patients who have University of Texas wounds IA or IIA are traditionally treated with TCC, he said. However, this method of offloading pressure may also be used in those patients with neuroischemic wounds without infection and in patients with neuropathic ulcers with superficial infection. It may also be used in patients with recurring wounds, although this study has yet to be published.

Removable cast walkers are also effective offloading methods if patients consistently wear the device. "The key word in the removable cast walker is that it is removable." When rendered irremovable, known as the instant total contact cast (iTCC), the device is comparable to the standard TCC.

Dr. Boulton suggested that upcoming studies on diabetic wound healing should include casting techniques. "The widespread use of the iTCC has the potential to change the management of neuropathic foot ulcers," he said.

**DRESSINGS AS AN OFFLOADING METHOD**

Pressure-relieving dressing may also provide pressure offloading. In 18 diabetic patients with diabetic peripheral neuropathy in which vibration detection was performed, Dr. Boulton and his colleagues reported a 25% reduction in foot pressure. Over the course of 3 days, pressure was reduced by 30%, 26% and 26%, respectively. “So, what we suggest is that the pressure of relief of the dressing does compare to conventional offloading methods," he said. "We believe that such an offloading pressure device may come in to use in the future, although this remains to be seen.”

Other methods of offloading are bed rest, wheel chair and crutch-assisted gait, but their usefulness is minimal in the insensate patient. This is because they can walk on the foot without feeling pain or pressure. "We know that bed rest doesn’t work," Dr. Boulton said. "We put the patient to bed, and after the first day … off they go, walking on the ulcer.”

The most important practice that a physician can perform is to always check the feet of their diabetic patients. Over 50% of patients with significant neuropathy do not have symptoms, and experience loss of sensation. "Neuropathy cannot be diagnosed on history, and that is the key here. … Any patient walking in to the foot clinic with a foot ulcer who is not limping must have neuropathy," Dr. Boulton said, noting that The International Diabetes Federation has designated 2005 as the “Year of the Diabetic Foot.”

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