

## Best Method to Heal Neuropathic Diabetic Foot Ulcers

Armstrong DG, Nguyen HC, Lavery LA, et al. Off-loading the diabetic foot wound: a randomized clinical trial. *Diabetes Care* 2001;24:1019–22.

### Study Overview

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

**Design.** Randomized clinical trial with 12 weeks of follow-up and weekly visits. Analysis was not by intention-to-treat.

**Setting and participants.** The study was conducted at the Veterans Affairs Medical Center in Tucson, Arizona. 75 patients with superficial, noninfected, nonischemic, diabetic plantar foot ulcers were randomized to 1 of 3 off-loading modalities: TCC, half-shoe, or RCW. 12 patients were lost to follow-up after randomization, 6 in the TCC group, 5 in the RCW group, and 1 in the half-shoe group; they were not included in the analysis. Of the 63 patients included in the analysis, 82.5% were men with a mean duration of diabetes of 16.9 years, a mean wound size of 1.3 cm<sup>2</sup>, and a mean duration of the ulcer of 5.2 months. They all had clinically significant neuropathy, but no arterial insufficiency or evidence of infection. Exclusion criteria were patients unable to walk without wheelchair assistance and wounds located on the heel, rear foot, or any area other than the plantar aspect of the foot.

**Interventions.** TCC was applied using the technique described by Kominsky [1], which was modified using a cast boot instead of the rubber cast walker and plywood platform. It was changed on a weekly basis or as clinically necessary. RCW and half-shoes were applied using manufacturers' instructions (use at all times while ambulating).

**Main outcome measures.** Proportion of complete wound healing, measured by a computerized planimetric video wound measurement system, and activity, defined as steps per day and measured by a pedometer worn by the patients. Wound healing was defined as complete epithelialization.

**Main 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 2 other modalities (89.5% versus 61.4%,  $P = 0.026$ ; odds ratio, 5.4; 95% CI, 1.1 to 26.1). There was also a significant difference in survival distribution (time to healing) between patients treated with a TCC and either an RCW ( $P = 0.033$ ) or a half-shoe ( $P = 0.012$ ). Patients were significantly less active in the TCC ( $600.1 \pm 320.0$  daily steps) compared with the half-shoe ( $1461.8 \pm 1452.3$  daily steps,  $P = 0.04$ ). There was no significant difference in the average number of steps between the TCC and the RCW ( $767.6 \pm 563.3$  daily steps,  $P = 0.67$ ) or the RCW and the half-shoe ( $P = 0.15$ ).

**Conclusion.** The TCC seems to heal a higher proportion of wounds in a shorter period of time than the 2 other widely used off-loading modalities, the RCW and the half-shoe.

### Commentary

Armstrong et al are the first to conduct a randomized controlled trial that compares these 3 treatment modalities in this specific population. Using active treatment analysis and surrogate endpoints, the results seem to confirm the experts' opinions that TCC is a better treatment modality due to its capacity to enforce compliance and its effectiveness in avoiding pressure on the wound [2]. The desired outcome measure of this study would be the rate of amputation. Future studies should also account for other important variables, such as risk of recurrence, long-term compliance, and tolerability of the devices. It is particularly worrisome that the dropout rate in this short study was 24% in the TCC group and 20% in the RCW group, compared with 4% in the half-shoe group. Cost and support staff are other important variables that differentiate these 3 interventions and might play an important role at the time of selecting 1 of them.

### Applications for Clinical Practice

With an annual incidence close to 5% to 10%, foot ulcers in the diabetic population represent a common problem that, if not properly treated, might lead to serious complications such as amputation. Prevention through screening for diabetic neuropathy, education to prevent the development of ulcers, and specialized care should be widely applied to all

patients with diabetes mellitus and other peripheral neuropathies. Once the ulcer is present, aggressive management should be initiated immediately and should include therapeutic modalities that decrease or prevent pressure on the involved area. Several methods to decrease pressure on the sole are currently in use with the intent to prevent ulcers or accelerate their healing, including felted foam, healing sandals, half-shoes, RCWs, and TCCs. The selection of 1 of these should be individualized based on patient's characteristics, the severity of the disease, and concomitant complications (eg, infection, ischemia, anatomic abnormalities). Modalities

that enforce compliance and eliminate pressure, such as TCC, seem to be more effective.

*– Review by Pedro J. Caraballo, MD*

### References

1. Kominsky SJ. The ambulatory total contact cast. In: Frykberg RG, editor. *The high risk foot in diabetes mellitus*. New York: Churchill Livingstone; 1991:449–55.
2. Consensus Development Conference on Diabetic Foot Wound Care; 1999 Apr 7–8; Boston. American Diabetes Association. *Diabetes Care* 1999;22:1354–60.

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