Total contact casts were better than removable cast walkers or half shoes for healing diabetic neuropathic foot ulcers

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

QUESTION: In patients with diabetes, what is the effectiveness of total contact casts (TCCs), removable cast walkers (RCWs), and half shoes for healing neuropathic foot ulcerations?

Design

Randomised (allocation concealed)*, unblinded, controlled trial with up to 12 weeks of follow up.

Setting

USA.

Patients

75 patients with diabetes who had clinically significant loss of protective sensation (>25 V) as measured with a biothesiometer, ≥ 1 palpable foot pulse or a transcutaneous oximetry measurement > 40 mm Hg at the dorsum of the fore foot, and a superficial neuropathic plantar diabetic foot ulcer corresponding to grade 1A (University of Texas Diabetic Wound Classification System). Exclusion criteria were active infection; wounds in locations on the heel, rear foot, or area other than the plantar aspect of the foot; severe peripheral vascular disease; or inability to walk without wheelchair assistance. 63 patients (83% men) completed follow up.

Intervention

25 patients were allocated to each of the TCC, RCW, and half shoes groups. TCCs were applied using a modification of the technique described by Kominsky, which included use of a cast boot in lieu of a rubber cast walker and plywood platform. TCCs were changed weekly or as needed. RCWs and half shoes were applied according to the manufacturer's instructions. All patients were instructed to use the devices at all times during ambulation.

Main outcome measures

Complete wound healing (measured by computerised planimetry) and activity (steps/d, measured by pedometer).

Main results

The TCC group had a higher incidence of wound healing than the half shoes group or the RCW and half shoes groups combined (table), and were less active than those in the half shoes group (600 v 1462 steps/d, $p=0.04$). Activity did not differ for the TCC and RCW groups ($p=0.67$) nor for the RCW and half shoes groups ($p=0.15$). Among patients with wound healing within the 12 week period, mean time to healing was shorter for the TCC group than for the half shoes group (33.5 v 61.0 d, $p=0.005$); time to healing did not differ for the TCC and RCW groups ($p=0.07$).

Conclusions

In patients with diabetes, total contact casts were more effective than removable cast walkers or half shoes for healing neuropathic foot ulcerations. Patients who used total contact casts were less active than those who used half shoes.

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Total contact casts (TCCs) v removable cast walkers (RCWs), half shoes (HSs), and RCWs or HSs for healing of neuropathic foot ulcerations in patients with diabetes†

Outcome at 12 weeks	Comparison	Event rates	RBI (95% CI)	NNT (CI)
Healing of diabetic foot ulcers	TCC v HS	89% v 58%	53% (7 to 135)	4 (2 to 24)
	TCC v RCW or HS	89% v 61%	46% (6 to 96)	4 (3 to 28)

†Abbreviations defined in glossary; RBI, NNT, and CI calculated from data in article.

COMMENTARY

Although the treatment of diabetic neuropathic foot ulcers has been studied extensively, few previous randomised trials have compared the effectiveness of pressure relieving devices that reduce the mechanical stresses associated with neuropathic ulcers.¹

The strength of this study by Armstrong *et al* lies in the fact that it was a randomised trial. 3 commonly used treatments were compared, one of which, the TCC, is considered by many to be the "gold standard".² The authors indicate that TCCs are expensive (because of the need for frequent cast changes and skilled personnel), but no cost effectiveness analysis was done. TCCs were associated with a large reduction in mobility, and costs to patients resulting from employment problems, increased transport costs, and reduced social interactions may be large. Furthermore, although reduced activity is good for the healing of neuropathic ulcers, it may have a negative effect on blood glucose control and weight management. The psychosocial effects of reduced activity on a patient's physical state should be considered. Another interesting aspect that could be investigated in future studies is whether ulcers stay healed once patients resume using their usual footwear.

Before any pressure relieving device is prescribed, the needs of individual patients should be carefully considered, ideally by a multiprofessional team that includes podiatrists, diabetes specialists, and nurses. The nurse's role within the diabetes team includes ensuring that patients have sufficient information about methods of healing neuropathic foot ulcers and helping them to explore the personal implications of each of these. The evidence of clinical effectiveness from this and a previous study¹ suggest that the use of TCCs should be promoted, however an economic evaluation comparing TCCs with other off loading measures is urgently needed.

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- 1 Spencer S. Pressure relieving interventions for preventing and treating diabetic foot ulcers. *Cochrane Database Syst Rev* 2000;(3):CD002302.
- 2 Cavanagh PR, Ulbrecht JS, Caputo GM. What the practising physician should know about diabetic foot biomechanics. In Boulton AJM, Connor H, Cavanagh PR, editors. *The foot in diabetes*. Third edition. Chichester: John Wiley Ltd, 2000:33–59.