

Efficacy of removable casts in difficult to off-load diabetic foot ulcers: A comparative study

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ARTICLE POINTS

1 The total contact cast (TCC) is the gold standard for extremity off-loading.

2 The TCC is underused due to fear of complications. Therefore, alternative off-load methods are often recommended.

3 The TCC was found to be more effective than alternative off-loading methods in this study.

4 Although we observed some complications (pressure sores) in the TCC group, more serious complications occurred in the alternative off-load methods group.

5 Delayed healing due to inadequate off-loading causes more serious complications than total contact casting.

KEY WORDS

- Total contact cast
- Off-loading
- Diabetic foot ulcer

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Introduction

Total contact casts (TCCs) are widely used for extremity off-load, but comparative studies with some alternative off-load techniques are rare. In this article, Oleg Udovichenko and Gagik Galstyan report on a comparison between a removable semi-rigid TCC and alternative off-load methods in people with neuropathic plantar diabetic foot ulcers.

It is well known that complete and constant off-loading of diabetic foot ulcers (DFUs) is mandatory for wound healing. Total contact casts (TCCs) are now widely used for extremity off-loading in people with DFUs and diabetic neuro-arthropathy (Charcot foot). The TCC is considered to be the most effective off-load method (Caravaggi et al, 1999; Sinacore and Mueller, 2001) although comparative studies of TCCs and alternative off-loading methods are relatively rare (Mueller et al, 1989; Caravaggi et al, 1999; Ha Van, 2002).

In Russia, traditional methods of off-loading DFUs include the half-shoe (for forefoot ulcers) and bed rest, wheelchair or crutch use (for midfoot, rearfoot or bilateral ulcers). These methods were considered as an alternative in this study.

Several modifications to casting technique have been developed, so treatment results can vary widely between studies. We use semi-rigid removable non-windowed fiberglass casts invented by Boogers and Drogmans (2000) made of Softcast and Scotchcast (3M Healthcare, Bracknell) materials. With this technique, inner and outer layers are made of flexible Softcast, and between them two rigid splints made of Scotchcast (one

U-shaped and another longitudinal along the sole) are placed. Using such a semi-rigid cast has important advantages over rigid casts (such as the soft edges allowing calf muscle movements) which reduce the risk of, for example, immobilisation complications such as venous thrombosis, joint stiffness, muscle atrophy and pressure sores. Removable casts allow inspection of the wound and daily dressing changes. In the authors' experience, these casts demonstrate better safety than non-removable casts, although efficacy depends on patient concordance.

Even semi-rigid removable casts can cause complications, such as skin breakthrough (with formation of skin erosions [pressure sores] or full-thickness wounds [new ulcers]). In the authors' experience, other complications, such as mycoses and deterioration of wound infection, are much rarer. Our experience has shown that minor skin injuries are often not serious and tend to heal in a short time (usually before the main ulcer). Risk of further complications may be minimised, or even completely eliminated, by adequate training of casting personnel, proper patient education and strict follow-up until the end of the period of wearing the cast (Caravaggi et al, 1999; Clerici et al, 2000).

Methods

People were eligible for inclusion in this study if they were outpatients with type 1 or 2 diabetes with a neuropathic diabetic foot ulcer (Wagner grade 1 or 2), a non-infected or mildly infected wound and a plantar location of the ulcers requiring off-loading. Mild infection was defined using the International Working Group on the Diabetic Foot (2003) criteria. Inclusion criteria accorded to indications for TCC treatment for diabetic foot ulcer patients in our practice. People were excluded from the study if they had signs of limb ischaemia (ankle-brachial pressure index [ABI] <0.9), complicated ulcers (Wagner grade 3, 4 or 5), a moderate or severe wound infection, bilateral wounds or a serious diabetic complication or comorbidity (such as chronic renal or liver failure, haemodialysis, blindness).

Study design

Twenty-seven people entered the study, 25 successfully completed it. Randomisation was not possible, mainly due to ethical reasons, but our study was comparative: removable TCCs were offered to everyone and used in the 14 who accepted (group 1). For the 13 who refused TCCs (group 2) alternative off-load methods (half-shoe or bed rest) were used.

The study duration was 6 months. Main study endpoints were: healing rate – defined by complete ulcer site epithelialisation lasting more than 4 weeks, according to criteria of the American Diabetes Association (1999) – and complication rate. Additional endpoints were time to heal and ulcer equivalent radius reduction velocity.

Two participants from group 1 did not comply with the TCC-wearing regimen and were excluded from the final analysis. After comparison of treatment results in both groups, six people from group 2 were treated using TCCs.

Patient characteristics

Mean age of those completing the study was 47 ± 16 years and mean diabetes duration was 18 ± 9 years. Fourteen were men and 11 were women. Thirteen had type 1 and 12 had type 2 diabetes. Of those with type 2 diabetes, five received insulin treatment and seven oral glucose-lowering medications at baseline.

We considered the probability of healing with the alternative off-loading methods as very low. This conclusion was based upon long-term unsuccessful treatment with these methods in the participants (on average 225 ± 137 days) or inapplicability of these methods due to a midfoot or rearfoot ulcer location (half-shoe not being applicable) or walking activity (necessity of continuing to work during treatment) when bed rest was not possible.

Diagnostic procedures

Metabolic control was assessed using glycosylated haemoglobin (HbA_{1c}). Wound size was measured (after ulcer debridement and callus removal) as longest dimension (first diameter, D1) and maximum length perpendicular to it (second diameter, D2). Based on these measurements we calculated wound equivalent radius ($R_{eqv} = [D1+D2]/4$) using the methods described by Cavanagh et al (2001).

Clinical signs of infection were assessed according to the criteria of the International Working Group on the Diabetic Foot (2003). Infected ulcer specimens for culture were taken by deep swab (from cleaned ulcer base). Standard Doppler examination with ABI measurement was made in all participants to assess limb ischaemia.

Treatment characteristics

Besides off-loading (either by TCC or alternative method) ulcer treatment included: daily dressing changes (at the participant's home) with irrigation of the wound by antiseptic solutions (miramistin, dioxidine, chlorhexidine); application of atraumatic gauze and ensuring strict metabolic control.

PAGE POINTS

1 The main study endpoints were healing rate and complication rate.

2 Group 1 participants (n=12) received a total contact cast and group 2 participants (n=13) received alternative off-load methods, such as the half-shoe.

3 The two groups did not differ significantly in terms of age, diabetes duration, ulcer duration, gender or type of diabetes.

Table 1. Wound and baseline characteristics of people in the study.

	TCC (n=12)	alternative methods (n=13)	P-value
Age (years)	48 ± 14	45 ± 18	ns
Males/females	7 / 5	7 / 6	ns
Type 1/type 2 diabetes	6 / 6	7 / 6	ns
HbA _{1c} (%)	8.7	8.3	ns
Diabetes duration (years)	19 ± 9	18 ± 8	ns
Ulcer duration (days)	221 ± 140	230 ± 135	ns
Wound Equivalent Radius (R _{eqv} in mm)	13.3 ± 3.1	6.7 ± 1.4	<0.05
Midfoot or rearfoot wound location	8 (67%)	1 (8%)	<0.05
Infected wounds*	4 (33%)	4 (31%)	ns

*Infected wounds were only mildly infected
ns, not significant; mm, millimeters

Eight participants had infected wounds and oral antibiotics (co-amoxiclav, cefalexin, clindamycin or ciprofloxacin) administered. Antibiotics were changed if necessary when laboratory culture results became available (three patients). Duration of antibiotic treatment was 21 ± 7 days.

Casting technique

A fiberglass semi-rigid removable non-windowed cast was applied according to manufacturer’s recommendations. A removable cast allows daily dressing changes, and is typically used in our practice. Additional measures have been invented to reduce pressure inside a cast (such as a window or additional inlay padding); however, these do have some disadvantages, such as causing

oedema of soft tissues in a low pressure area, so such practice is not recommended by the casting materials manufacturers (Schuren, 2002).

Statistics

For data presentation, averages and standard deviation (M ± SD) were used. Mann-Whitney and exact Fisher’s tests were used to analyse the significance of differences between groups.

Results and discussion

Metabolic control was good in only a minority of participants: average HbA_{1c} was 8.5 ± 1.1%, with only two people having adequate metabolic control (HbA_{1c} <7%). On Doppler examination signs of ischaemia were absent in everyone (ABI >0.9 and no stenotic sounds). Clinical signs of mild infection

PAGE POINTS

1 After 6 months, 73% of ulcers in group 1 had healed compared with 46% in group 2.

2 Despite the larger ulcers present in group 1 patients, healing time was virtually the same as for those in group 2.

3 Four patients in the total contact cast group experienced a pressure sore, but this did not lead to treatment discontinuation.

Table 2. Treatment results and complication rates with different off-loading methods.

P-value	TCC (n=12)	alternative methods (n=13)	
Healed in 6 months	9 (75%)	6 (46%)	<0.05
Healing time in days (min–max)	109 (10–188)	111 (27–180)	ns
R _{eqv} reduction velocity (mm/day)	0.2 ± 0.05	0.1 ± 0.03	<0.05
Complications	pressure sores (n=4)	phlegmon (n=1) new ulcer (n=1)	NA

ns, non-significant; R_{eqv} wound equivalent radius; mm, millimeters; NA, not applicable

were apparent in eight people, the rest had non-infected ulcers.

The two groups did not differ significantly by age, diabetes duration, ulcer duration, distribution of gender and diabetes types (Table 1). The number of infected wounds and antibiotic treatment duration was similar in both groups.

As our study was not randomised, people with a TCC appeared to have larger ulcers (R_{eqv} 13.3 mm versus 6.7 mm for those in the alternative group). Two-thirds of the participants in this group had midfoot or rearfoot ulcers, which are, in the authors' experience, most difficult to off-load. Nevertheless, 75% of ulcers in group 1 healed in 6 months compared with 46% in group 2 ($P<0.05$; Table 2).

These results are worse than our usual experience, but this is explained by the fact that only those with a low probability of ulcer healing were included in this study. Despite the larger wounds, average healing time in group 1 was nearly equal to group 2 (non-significant; Table 2). Accordingly, R_{eqv} reduction velocity was significantly higher in the TCC group ($P<0.05$).

There are a number of reasons for the low efficacy of the alternative off-loading methods in this study. The half-shoe is widely used in Russia, Germany and some other countries. Its efficacy in treatment of certain types of DFUs is quite high (Chantelau et al, 1993; Needleman, 1997). But this method is less effective than total contact casting if the patient does not adhere to the treatment or has to continue to work during the ulcer treatment. Additionally, the half-shoe is indicated only for forefoot ulcers. Bed rest, wheelchair or crutch use may be effective in terms of weight redistribution but they are very difficult for individuals to fulfil, therefore adherence is, in the authors' experience, generally low.

In our study we did not specifically measure walking activity, but it is known that adherence of people with DFUs to prolonged bed rest is poor (Mueller et al, 1989). People prescribed bed rest or

half-shoe have serious problems when it comes to visiting a doctor. Climate should also be considered: in Russia the half-shoe may be used outdoors only during the summer and short parts of spring and autumn. In reality these patients walk without any off-loading if they have to visit, for example, a doctor or the social security office. On the other hand, TCC application allows participants to walk, but generally reduces daily walking activity (Cavanagh et al, 2001). In our study, all participants were outpatients so walking could not be eliminated completely and only TCCs allowed outdoor walking without ulcer overload.

Treatment complications

In the TCC group pressure sores occurred in four people, none of whom required TCC treatment discontinuation and the pressure sores healed earlier than the main ulcer.

In the alternative off-loading group, serious complications occurred in two people: a new ulcer and a foot phlegmon. These data stress that TCC complications should be analysed in comparative studies. Comparison of cast and half-shoe efficacy by Ha Van (2002) provided similar results: osteomyelitis (as a wound complication) manifested in 7% of cast boot treated people but in 25% of half-shoe treated. Thus, delayed wound healing due to poor off-loading is more likely to lead to serious complications than TCC in the hands of experienced practitioners.

Conclusion

There is no one 'ideal' off-loading method to suit all people with DFUs. Some ulcers heal with cheap and simple off-load methods such as the half-shoe. However, in many people TCC appears to be the only effective off-loading method. In this comparative study, TCC showed good efficacy overall and in difficult to treat patients. Risk of serious complications is low if application technique is good and adequate precautionary measures are taken. ■

PAGE POINTS

1 Two patients in the alternative treatment group experienced a treatment complication (new ulcer and foot phlegmone).

2 The authors state that in many patients, total contact cast appears to be the only effective off-loading technique.

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