

Efficacy of a reusable total-contact cast

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Article points

1. Total-contact casting (TCC) is the most effective method of offloading plantar neuropathic diabetic foot ulcers.
2. A reusable TCC technique was used that reduced labour time and costs associated with offloading.
3. The efficacy of the casting technique was not lower than that published for other casting techniques, but a randomised controlled trial is needed.
4. TCC, with appropriate modifications, may be useful in treatment of some neuroischaemic ulcers and those not on the plantar aspect of the foot.

Key words

- Diabetic foot ulcers
- Offloading
- Total contact casting

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The efficacy of a total-contact casting (TCC) technique in everyday practice was assessed in this observational study. Seventy-nine per cent of participants achieved healing. Participants whose clinical cases and course of treatment were similar to those reported in randomised controlled trials of classic TCC achieved 100% healing in <12 weeks. The results suggest that this reusable TCC technique is no less effective than classic TCC. Furthermore, the current indications for TCC may be expanded to achieve healing for a larger patient group.

It is widely accepted that total contact casting (TCC) is the most effective method of plantar offloading for a neuropathic diabetic ulcer, with offloading be central to progression to healing (International Working Group on the Diabetic Foot, 2007). However, there are a range of TCC techniques and cast application differs between centres.

Background

The authors' diabetic foot clinics introduced a TCC method to their treatment tool kit in 2003. The casting technique used was described by Boogers and Droogmans (2000), and has been dubbed "BoDro". This technique uses a combination of rigid and semi-rigid materials to create a cast that offloads the foot and is reusable. In contrast, the "classic" casting technique (described by Kominsky, 1991) uses rigid materials and is non-reusable. The two techniques are described in *Table 1*.

The authors undertook an observational study to determine the efficacy of the BoDro technique in a consecutive series of people with diabetic foot ulceration.

Literature review

The efficacy of TCC, and its superiority over removable offloading devices, has been demonstrated in a number of randomised controlled trials (RCTs). A brief overview of these RCTs is presented in *Appendix 1*.

Most RCTs assessing TCC use the classic casting technique. This technique uses plaster of Paris or rigid casting materials to create the cast (Kominsky, 1991), but rigid and semi-rigid materials were used for the same, non-reusable method by Caravaggi et al (2000).

The efficacy, proven by RCTs, of techniques other than the classic one have not yet been reported in the literature. However, some pre-fabricated, non-removable walkers have shown efficacy similar to TCC in RCTs (Katz et al, 2005; Piaggese et al, 2007). These results suggest that various non-removable cast-like devices that redistribute plantar pressures may have comparable efficacy.

It is widely agreed that the efficacy of many treatment modalities achieved during RCTs is not reproducible in clinical practice, primarily because RCT populations are highly selected. Thus, observational studies assessing the efficacy

Table 1. A comparison of the classic[†] and BoDro[‡] total contact casting techniques.

FEATURE	TECHNIQUE	
	CLASSIC	BoDro
Casting materials	Rigid synthetic casting materials or plaster of Paris.	Rigid and semi-rigid synthetic casting materials in combination.
Padding	One layer of felt padding applied prior to the immobilising material.	Minimal, 1–3 layers of Microfoam tape protecting bony prominences.
Contact of the plantar surface of the cast with the floor during walking	An aluminum stirrup or rubber heel are fixed into the cast base – the cast is not in contact with floor.§	Immediate contact with indoor floors, a cast shoe for outdoor planar contact.
Following application, time after which the patient can ambulate (i.e. drying time)	Three hours, if an aluminum stirrup is used; 24 hours if plaster of Paris is used.	Thirty minutes.
Frequency of cast change during ulcer treatment	At every dressing change.	Between one and three casts to heal a typical ulcer.

†Described by Kominsky (1991). ‡Described by Boogers and Droogmans (2000), similar to that described by Caravaggi (2000). §The modified Kominsky (1991) technique described by Armstrong et al (2001) uses a cast shoe instead of a rubber heel.

of casting techniques as part of day-to-day clinical practice, like that of Nabuurs-Franssen et al (2005), contribute important insight into the healing achievable using a given method.

Methods

Participants

Three diabetic foot clinics in Moscow participated in this study. Consecutive people with diabetic foot ulcers whose treatment regimen included TCC using the BoDro technique were recruited between 1 October 2007 and 1 March 2009.

Box 1. The BoDro (Boogers and Droogmans, 2000) casting technique in brief.

Following wound care and dressing application, two layers of stockinet were applied to the extremity. Microfoam tape (3M, St Paul, MN) was then placed on all bony prominencies (i.e. malleoli and tibial tuberosity). One layer of Softcast (3M) was applied circularly. One roll of Scotchcast was used to make U-shaped and longitudinal (plantar) splints. Another roll of Softcast was used to cover all layers.

At the follow-up visit, the cast was cut along the anterior surface (Figure 1a) and removed. The leg was inspected and the ulcer treated and dressed as appropriate. The original cast was then reapplied and fixed by an additional layer of Softcast. The cast was typically worn for 1–2 months.

More frequent recasting was required for those who: were overweight; quickly broke the cast due to high activity; experienced a change in limb volume (poor cast fit compromises the cast's ability to offload and may cause skin abrasions).

The traditional indication for TCC is a non-infected neuropathic foot with a plantar diabetic ulcer (International Working Group on the Diabetic Foot, 2007). Traditional exclusion criteria for TCC in the diabetic foot are: (i) critical limb ischaemia; or (ii) moderate to severe ulcer infection. In practice, TCC is sometimes extended to the treatment of neuroischaemic ulcers or ulcers with mild infection.

The clear inclusion criterion for enrolment in the present study was a person with a non-infected neuropathic diabetic foot ulcer on the plantar surface of the foot. In addition to those who fulfilled the above criteria, people requiring offloading were included in the present study when they had:

- A neuroischaemic diabetic ulcer with non-critical ischaemia where revascularisation was not possible.
- Non-plantar diabetic foot ulceration, including the dorsal surface of the toe, the apex of a hammer toe, the plantaro-lateral surface of heel, and interdigital regions.
- Mild diabetic foot ulcer infection, where the cast was modified to expose the ulcer, or antibiotics were used to control the infection.

Treatment

The BoDro casting technique is summarised in Box 1. Examples of the cast can be seen in Figure 1.

In addition to TCC, good traditional wound care was undertaken for all participants. This included, as necessary:

- Regular debridement and saline cleansing.
- Wound dressing and dressing reapplication (every 1–7 days; more frequently in intensively exuding wounds). Dressings varied, and included a hydrofiber with silver, a polyurethane foam, atraumatic gauze with an absorbent secondary dressing, an alginate and a nanocrystalline silver dressing.
- Antibiotic therapy.
- Correction of hypoglycaemic regimen to achieve good glycaemic control.

In a minority of participants, the BoDro cast was modified and used as a removable walker for part, or all, of the treatment period.

Participants with >1 ulcer at baseline had the largest of their ulcers used as the index ulcer. Participants were followed-up until: (i) complete healing; or (ii) discontinuation of TCC treatment. Healing was defined as complete epithelialisation of the ulcer site for ≥ 4 weeks.

Statistical methods

Statistical analysis of study results was performed using Excel (Microsoft, Sacramento, CA) and Statistica (version 6.0; Microsoft). The Mann–Whitney *U*-test was used to demonstrate statistical significance.

Results

Participant characteristics

Forty-eight people presented to the participating diabetic foot clinics during the study period.

Nine people were excluded from the study. Five of those excluded were treated with a walker boot; this group had small forefoot ulcers and refused TCC. Four people were withdrawn <3 weeks after their enrolment, either at their request or due to low adherence. These four people were not included in the study population for analysis.

Thirty-nine people (21 men) were included in the study group (Table 2). Mean age was 61 years (range, 34–79). Six participants had type 1 diabetes and 33 had type 2 diabetes.

Ulcer characteristics

The majority of participants (79%, 31/39) had a neuropathic foot ulcer. Eight participants had a neuroischaemic ulcer without critical limb ischaemia. The most common ulcer site was the forefoot (69%, 27/39), followed by the rearfoot (21%, 8/39). A minority of ulcers were located on the midfoot (10%, 4/39).

Mean wound surface area was 1.60 cm² (median 0.40 cm²; range, 0.02–23.8 cm²). Using the University of Texas ulcer classification system (Lavery et al, 1996), 46% (18/39) of participants had class 1A ulcers.

Approximately half (51%, 20/39) of the participants received antibiotic therapy during the study period for the management of ulcer infection.

Healing outcomes

Ulcer healing data are summarised in Table 2. Some 79% (31/39) of ulcers healed. Of those that healed, 90% (28/31) did so in <12 weeks. Ulcer healing in <12 weeks is the traditional period in which a therapy can be considered efficacious. Median healing time was 27 days (range, 7–121).

Among the eight participants who did not achieve healing, TCC was not effective and was discontinued. The rationals for these discontinuations were:

- Lack of reduction in ulcer size ($n=4$, all neuroischaemic ulcers).
- Deterioration of the ulcer during the treatment period ($n=2$).
- Cast-induced ulcer ($n=1$).
- Participant withdrawal ($n=1$).

Side-effects of the treatment were cast-induced ulcers and abrasions. These occurred in 26% (10/39) of participants.

The relationship between participants' HbA_{1c} and ulcer healing was not analysed as part of this study. Piaggese et al (2007) demonstrated that healing time in TCC was not influenced by HbA_{1c}.

RCT-like subgroup healing outcomes

A subgroup of participants ($n=12$) who shared the clinical characteristics and treatment course of TCC RCT populations were analysed separately. This group:

- Had non-infected neuropathic plantar diabetic ulcers (University of Texas class 1A or 2A).
- Were treated with non-removable TCC from baseline until complete healing.

Healing outcomes in this RCT-like subgroup were better than for the overall study population. All subgroup ulcers (100%, 12/12) healed in <12 weeks. The median healing time was 22 days (range, 13–74).

Neuroischaemic subgroup healing outcomes

A second subgroup of participants was analysed; all those with neuroischaemic ulcers ($n=8$).

Healing outcomes were worse in this subgroup than in the overall study population. Only 38% (3/8) healed in <12 weeks. Median healing time was 37 days (range, 18–71).



Figure 1. (a) The BoDro cast (Boogers and Droogmans, 2000).

Note the line along the anterior surface down which it is cut at removal. (b) The BoDro cast in a cast shoe. Note that this is an example of a removable cast that had been fixed using adhesive tape.

Casting was discontinued in half (50%, 4/8) of this subgroup due to lack of effect on ulcer healing (i.e. no reduction in ulcer size). In one neuroischaemic subgroup participant, casting was discontinued due to lack of effect and the occurrence of a cast-induced ulcer.

Discussion

To the authors' knowledge, this is the first observational study to assess the efficacy of the BoDro casting technique.

Similar to the results of Nabuurs-Fransses et al's (2005) study, the healing rate reported here is lower than that reported by TCC RCTs (Mueller et al, 1989; Armstrong et al, 2001; 2005; Katz et al, 2005; Caravaggi et al, 2007; Piaggese et al, 2007). However, the inclusion criteria of the present study are broader than those of TCC RCTs (see *Appendix 1*). Here, the inclusion criteria extended to ulcers that were deeper, some with mild infection and some with non-critical limb ischaemia. These inclusion criteria better represent the true spectrum and complexity of the people treated day-to-day at a diabetic foot clinic.

Notably, an analysis of a subgroup of the present study who clinically resembled a TCC RCT population, yielded treatment efficacy outcomes comparable with TCC RCTs (100% healed in <12 weeks). However, comparison between data reported here and in TCC RCTs has limitations. First, the mean and median ulcer area at baseline in the present study was significantly smaller than that reported in many TCC RCTs ($P=0.05$; Armstrong et al, 2001; 2005; Katz et al, 2005; Caravaggi et al, 2007; Piaggese et al, 2007; Van De Weg et al, 2008). Second, the population reported here differed from TCC RCT populations in the more frequent administration of antibiotics during the study period.

However, as is highlighted in *Appendix 1*, a number of TCC RCTs fail to report on a range of population data (e.g. age, diabetes duration, ulcer duration, BMI, etc.). In the absence of data, study group comparison for a number of factors are not possible.

Conversely, many RCTs (Armstrong et al, 2001; 2005; Katz et al, 2005; Van De Weg et

Table 2. Baseline data and results summary.

	Study group (n=39)	Subgroups	
		RCT-like (n=12)	Neuroischaemic (n=8)
Baseline participant and ulcer characteristics for the study group.			
Age (years)†	61 (34–79)	53 (34–73)	69 (53–79)
Sex (male/female)	21/18	4/8	5/3
Diabetes (type 1/2)	6/33	2/10	0/8
Ulcers per participant (n)			
1	32		
>1	7		
Ulcer area (cm ²)‡			
Mean ± standard deviation	1.56±4.01	1.05±1.35	0.27±0.25
Median (range)	0.42 (0.02–23.76)	0.47 (0.04–3.27)	0.20 (0.02–0.69)
Ulcer classification (n)§			
1A	18	10	
2A	5	2	
1B	5		
2B	2		
3B	1		
1C	5		5
2C	1		1
1D	2		2
Region on foot of ulcer (n [%])			
Forefoot	27 (69)	10 (83)	5 (62)
Midfoot	4 (10)	2 (17)	
Heel	8 (21)		3 (38)
Location on foot of ulcer (n)			
Plantar	21	12	3
Plantarolateral	7	-	2
Interdigital	3	-	1
Dorsum of forefoot	2	-	
Anterior (apex of a toe, post-amputation)	6	-	1
Medial (i.e. Hallux valgus)	2	-	1
Antibiotic therapy (n [%])	20 (51)	5 (42)	6 (75)
Average antibiotic duration (days [range])	14 (10–42)	12 (10–15)	15 (10–23)
Cast type (n)			
Non-removable	26	12	5
Removable	13	0	3
Healing outcomes for the study group.			
Healed in <12 weeks (n [%])	28 (72)	12 (100)	3 (38)
Healed by study end (n [%])	31 (79)	12 (100)	3 (38)
Unhealed by study end (n [%])	8 (21)	0 (0)	5 (62)
Healing time (days)			
Mean ± standard deviation	40.5±32.9	28.3±18.5	42.0±26.9
Median (range)	27 (7–121)	22 (13–74)	37 (18–71)
Discontinuation of TCC use (n [%])	8 (21)	0 (0)	5 (62)
Cause of TCC discontinuation (n)			
Patient refusal	1	0	0
Ulcer deterioration	1	0	0
Osteomyelitis	1	0	0
No healing effect	4	0	4
Cast-induced ulcer	1	0	1
Adverse events (n [%])¶	10 (26)	3 (25)	4 (50)

†Data are mean (range). ‡Ulcer size calculated using the formula: $S = \pi ab$ (where a=half the largest ulcer diameter, b=half the second largest diameter). Ulcer size estimation using the PEDIS guidelines (Schaper, 2004) would give a larger study group mean of 2.0±5.2 cm². §University of Texas classification (Lavery et al. 1996). ¶Adverse events comprised cast-induced ulcers and skin abrasions. RCT, randomised controlled trial; TCC, total contact casting.

Page points

1. The inclusion of fore-, mid- and hind-foot ulcers in the present study could be expected to have increased the mean time to ulcer healing.
2. Whether the higher rate of cast-induced skin injuries reported here is a feature of the BoDro casting technique, or the result of poor cast application by insufficiently experienced clinicians, requires investigation.
3. In the authors' clinical experience, careful application of modified forms of the BoDro cast have been effective in the treatment of a number of foot ulcer types not usually indicated for total-contact casting.
4. BoDro casting's reusability and speedy application make it an attractive offloading option in terms of materials cost and clinician time.

al, 2008) excluded hindfoot ulcers, which are known to heal more slowly than those located on the forefoot. While Piaggese et al (2007) only included participants with forefoot ulceration. Thus, the inclusion of fore-, mid- and hind-foot ulcers in the present study could be expected to have increased the mean time to ulcer healing.

The healing outcomes achieved in the present study are positive, but an RCT is needed to compare the efficacy of the classic and BoDro casting techniques.

Adverse events and casting competency

The rate of adverse events (i.e. cast-induced skin injuries) in the present study was higher than that reported in most TCC RCTs (Caravaggi et al, 2000; Armstrong et al, 2001; 2005; Piaggese et al, 2007). The results reported here are similar to those seen by Katz et al (2005; 25% of participants) and Nabuurs-Franssen et al (2005; new ulcers in 9% and pre-ulcerative lesions in 28% of participants), both of whom used modified Kominsky casting techniques. In the present study, all cast-induced skin injuries healed and did not cause any serious complications.

Whether the higher rate of cast-induced skin injuries reported here is a feature of the BoDro casting technique, or the result of poor cast application by insufficiently experienced clinicians, requires investigation. The authors speculate that the incidence of cast-induced skin injuries could be reduced with increased clinician training and experience.

TCC indications

Offloading of the ulcerated diabetic foot is necessary not only in plantar ulcers, but also in all ulcers that experience increased pressure during walking. This includes, for example, ulcers on the interdigital or plantarolateral surfaces, or the inferoposterior aspect of the heel.

Some ulcer types can be offloaded using half-shoes or therapeutic shoes with multilayered insoles. However, compliance with these therapeutic modalities is known to be problematic (Wu and Armstrong, 2006). Thus, a role for modified TCC might be found for a range of foot ulcer types.

In the authors' clinical experience, careful application of modified forms of the BoDro cast have been effective in the treatment of a number of foot ulcer types not usually indicated for TCC. For example, in selected cases of infected ulcers, where the cast does not impede wound drainage. Furthermore, people with neuroischaemic ulcers with non-critical limb ischaemia without the possibility of revascularisation may also benefit – although successes in this group have been fewer.

Nabuurs-Franssen et al (2005) reported a population treated with TCC, where 44% of participants had neuroischaemic foot ulceration. The healing rates in that subgroup were 69% without infection and 36% in superficially infected ulcers. In the present study, 38% of participants with neuroischaemic ulcers healed in <12 weeks. However, given the impossibility of revascularisation in this group, the choice to use TCC led to the healing of three ulcers that otherwise had little chance of resolution.

Cost considerations

The BoDro casting technique produces a cast that may be reused for 1–2 months (see *Box 1*) and does not include the time-consuming step of adding an aluminium stirrup. Thus, BoDro casting's reusability and speedy application make it an attractive offloading option in terms of materials cost and clinician time.

Conclusion

The results reported here suggest that the efficacy of the BoDro casting technique is no worse than that reported for classic TCC techniques. However, direct comparison between this technique and the classic technique in an RCT is needed.

The authors suggest that the current indications for TCC may be broadened from non-infected neuropathic plantar ulcers. Future indications may include the use of modified TCC to treat some cases of neuroischaemic ulceration without critical limb ischaemia, ulcers with mild infection and ulcers not on the plantar aspect of the foot. ■

