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Article: Complications

Optimizing the offloading properties of the total contact cast for plantar foot ulceration

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Abstract

Aims Total contact casting is the gold standard offloading treatment for plantar foot ulceration, but the optimal technique and preferred materials are poorly defined and not readily prescribed in daily practice. We investigated in-cast pressure offloading in two types of total contact casts vs. a control condition, in patients with plantar foot ulceration.

Methods In-cast walking pressures were collected using the Novel Pedar-X system in 20 participants with a plantar foot ulcer in two types of total contact casts: a conventional total contact cast and a cushion-modified total contact cast incorporating an inlay of 6 mm slow-rebound cellular urethane and 6 mm soft cellular urethane. Casts were compared with a canvas cast shoe to establish baseline pressure values.

Results Compared with the cast shoe, the conventional total contact cast significantly reduced peak pressure at the ulcer site by 44%, mean pressure by 47% and pressure–time integral by 37% ($P < 0.001$), while the cushion-modified total contact cast significantly reduced peak pressure at the ulcer site by 70%, mean pressure by 60% and pressure–time integral by 69% ($P < 0.001$). Plantar pressure across the entire foot and each region of the foot was also reduced with the conventional total contact cast compared with the cast shoe, and further reduced by the cushion-modified total contact cast ($P < 0.05$).

Conclusions The offloading properties of the total contact cast can be enhanced with a 12 mm cellular urethane cushion modification. Further well-designed trials are required to understand and validate this cast technique and to demonstrate healing rates and safety in different patient populations.

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Keywords diabetes, foot ulcer, plantar pressure, total contact cast, unloading, wound

Abbreviations ANOVA, analysis of variance; PPG, photoplesmography

Introduction

Repetitive overload causing soft tissue damage is associated with the development of plantar foot ulceration [1–3]. If adequate pressure offloading is not achieved, delayed wound healing will ensue irrespective of the dressing, arterial flow or management of infection [4,5]. The longer an ulcer remains unhealed the greater the chance of colonization, infection and amputation [5]. Indeed, 10–30% of patients with a diabetic foot ulcer will eventually require an amputation, approximately 60% of which is preceded by an infection [6]. In addition to the financial burden of healing plantar foot ulcers, a deleterious effect on quality of life, particularly in relation to the ability to perform activities of daily living, is well documented [7].

The modalities used for pressure offloading vary widely. Surprisingly, there is very limited evidence on the effectiveness of different types of total contact casts for offloading and treating plantar foot ulcers [8,9], yet total contact casting is regarded as the 'gold standard' treatment for plantar foot ulcers [10–12]. The success of the total contact cast is attributed to its ability to reduce pressure at the ulcer site coupled with forced compliance [4,13]. Indeed, patient adherence is critical for preventing ulcer progression to the point at which amputation is necessary [14]. However, it appears that total contact casting is underutilized due to the scarcity of training programmes and clinicians' reluctance to learn the technique for fear of causing iatrogenic lesions [15]. Incredibly, less than 2% of clinicians use the total

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contact cast for treating the majority of diabetic foot ulcers [16]. While the International Consensus of the Diabetic Foot (2007) recommends a total contact cast for the effective reduction of pressure at the site of ulceration in the neuropathic foot, the optimal technique and preferred materials are unclear [6].

In a single-case study evaluating various modifications of the total contact cast for optimal pressure offloading, adding a 6 mm slow-rebound cellular urethane and 6 mm soft cellular urethane inlay to the conventional total contact cast reduced plantar pressure by a further 20% in a patient with a chronic non-healing plantar foot ulcer [17]. It is hypothesized that the benefits of adding the cellular urethane inlay to the total contact cast would greatly improve its pressure reduction capacity in a variety of patients with plantar foot ulceration. Therefore, the aim of this study was to compare the pressure offloading characteristics of the conventional total contact cast vs. a cushion-modified total contact cast in a larger sample of participants with plantar foot ulceration. The research design was an experimental, cross-over controlled trial.

Patients and methods

Participants

Patients attending the Westmead Foot Wound Clinic (Westmead Hospital, Sydney, NSW, Australia) were approached to participate in the study. Potential participants were eligible to be included if they were aged 18 years or older and had a plantar foot ulcer in any region. The inclusion criteria were broad to reflect the types of ulcers commonly referred to our tertiary hospital, and included patients with or without diabetes mellitus, peripheral arterial disease, peripheral neuropathy or osteomyelitis. Participants were excluded from the study if they exhibited obvious postural gait instability or associated co-existing disorders, such as Parkinson's disease or fragile skin integument; or refusal to co-operate with the requirements of the study. The study was undertaken with approval from the Human Research Ethics Committee of Westmead Hospital, and informed written consent was obtained from all participants.

Interventions

Two types of total contact casts worn with a canvas cast shoe and a cast shoe-only control condition were evaluated for each participant. The conventional total contact cast was based on previously described techniques [18,19], and materials were donated by 3M™ Health Care (Sydney, NSW, Australia). In brief, the limb was prepared with two layers of stockinette, with microfoam applied to protect bony prominences. The conventional total contact cast was fabricated using Softcast semi-rigid casting bandage and reinforced with a rigid synthetic Primacast U-splint and footplate followed by an additional two rolls of Softcast. Softcast is commonly used in the fabrication of the total contact cast [12,19,20]. Softcast is composed of fibreglass imbued with a polyurethane resin with characteristics of flexibility and resistance. Our technique uses three layers of Softcast reinforced with a Primacast splint, giving rigidity to the cast. The total contact cast has evolved over the past decades from the original use of plaster of Paris to the current variety of semi-rigid and rigid cast materials. Importantly, the principles and mechanism have remained the same; intimate moulding of the weightbearing plantar surface to reduce plantar pressure by load distribution and utilization of the conical shape of the calf to reduce plantar pressure by load sharing to the proximal shank portion of the cast [21,22].

The cushion-modified total contact cast was applied exactly the same as the conventional total contact cast, but the limb preparation was modified by adhering 6 mm slow-rebound cellular urethane and 6 mm soft cellular urethane (6 mm Poron Performance and 6 mm Poron Medical; Rogers Corp., Woodstock, CT, USA) to the stockinette on the plantar surface of the foot, thereby lining the plantar surface of the cast to create a cushioned buffer between the plantar surface of the entire foot and the cast material. Cellular urethane has been shown to be the most effective material for reducing plantar pressure [23,24]. Both casts were univalved anteriorly and worn with a canvas cast shoe during test walking. A cast shoe was selected as opposed to a rubber heel in order to reduce both the limb length difference and the likelihood of instability. For the control condition, the canvas cast shoe was worn alone to establish baseline pressure values because it was considered to have minimal influence on pressure offloading. A full demonstration of the cushion-modified total contact cast technique is available in Appendix S1.

Outcome measures

The primary outcome was change of plantar pressure at the ulcer site between cast conditions. Plantar pressure was measured in-cast with the Pedar-X® system (Novel GmbH, Munich, Germany) 20–45 min after applying each of the three different conditions to allow drying time and uniform cast compression. Due to the lack of consensus about the most meaningful pressure parameter [25], three plantar pressure variables were investigated: peak pressure (maximal pressure, in kilopascals), mean pressure (average pressure, in kilopascals) and pressure–time integral (the sum of peak pressure in each frame of foot contact multiplied by the duration of foot contact, in kilopascals seconds). The 2-mm-thick, flexible pressure-measuring insole was placed between the plantar surface of the foot, lined with stockinette, and the cast (conventional cast) or the 12 mm urethane (cushion-modified cast). Each Pedar-X® insole contains 99 sensors, samples at a frequency of 100 Hz and does not interfere with normal gait characteristics [26]. The Pedar-X® cable exited the cast through a small window cut above the lateral malleolus to avoid weakening the integrity of the cast. Following a practice trial of walking with the cast and Pedar-X® insole, data were collected as participants walked up and back along a 10 m walkway (one trial) at a self-selected natural gait speed. Pedar-X® is widely regarded as an accurate, reliable and valid measure of in-shoe pressure [27,28].

All pressure data were analysed with the Novel-win scientific analysis software (Novel GmbH). Nine straight-line walking steps from the ulcerated foot of all participants were selected from each trial using the Pedar-m expert 8.3 software (Novel GmbH). The steps selected were a representation of midgait; hence, acceleration, deceleration and turning steps were excluded. Pressure data were processed using the Novel multimask 10.37 software (Novel GmbH). Each foot was divided into three anatomically relevant regions (or 'masks'), as previously reported [23]. These regions represented the rearfoot (31% of foot length), midfoot (19% of foot length) and forefoot (50% of foot length). Ulcer site was superimposed to one of three regions of the foot for the primary analysis.

Secondary outcomes were change in plantar pressure for the whole foot between cast conditions, as well as at each region of the foot (rearfoot, midfoot and forefoot) to assess load redistribution and potential regional overload. The temporospatial parameters of contact area (in centimetres squared) and contact time (in milliseconds) were also analysed. Long-term management of these patients involved returning the optimal offloading total contact cast to a non-removable state with the use of Softcast (3M™ Health Care).

Statistical methods

Sample size was based on our single-case study showing that the conventional total contact cast reduced peak pressure at the ulcer site by 36% and the cushion-modified total contact cast reduced peak pressure by 56% compared with baseline [17]. Assuming a power of 80% and an α level of 0.05, sample size was calculated to detect a significant difference between cast conditions of 20% in peak pressure values, with a standard deviation of 22% based on a comparative study design [29], giving a required minimal sample size of 12 participants. Descriptive statistics were used to characterize the sample in SPSS 18.0 (SPSS Inc., Chicago, IL, USA). Normality of data distribution was assessed with the Kolmogorov–Smirnov test with Lilliefors significance correction, and the appropriate parametric or non-parametric test was subsequently applied. A one-way, repeated-measures ANOVA was used to test significance of all pressure variables between test conditions. *Post hoc* paired samples *t*-tests were undertaken to compare the significance of the differences between the test conditions [30]. Difference between conditions was considered significant if $P < 0.05$.

Results

Participant characteristics

Between March and June 2008, 20 patients (18 male and two female) with a plantar foot ulcer volunteered to participant in the study, 15 of whom had diabetes mellitus, one Hansen's disease, two alcoholic neuropathy, one spina bifida and one idiopathic polyneuropathy. This composition of participants reflects the types of ulcers commonly referred to our tertiary hospital. The most common ulcer region was the forefoot (85%), with a median ulcer size of 1.1 cm^2 (25th and 75th centile 0.4 and 2.5 cm^2) and median ulcer duration of 18 weeks (25th and 75th centile 8 and 92 weeks). Complete demographics and physical characteristics of all participants are shown in Table 1.

Pressure offloading at ulcer site

There were a number of statistically significant differences in plantar pressure parameters between the three test conditions at the ulcer site (Table 2). An example is shown in Fig. 1. Peak pressure data demonstrated significant differences between test conditions ($F(2,18) = 33.6$, $P < 0.001$). Peak pressure was significantly reduced when wearing both types of total contact casts compared with the cast shoe condition (reduced by 44% with the conventional total contact cast, $t = 4.3$, $P < 0.001$; and reduced by 70% with the cushion-modified total contact cast, $t = 8.7$, $P < 0.001$). Peak pressure was more effectively reduced

Table 1 Demographic details and physical characteristics of the 20 participants

Variable	Total participants ($n = 20$)
Age (years (SD), range)	54.7 (14.4), 29–82
Sex, male (%)	18 (90)
Height (m (SD), range)	1.78 (0.11), 1.65–2.02
Weight (kg (SD), range)	100.4 (25.2), 65.0–155.0
Body mass index (kg/m^2 (SD), range)	31.4 (5.5), 21.6–42.4
Ulcer region, no. (%)	
Forefoot	17 (85)
Midfoot	1 (5)
Rearfoot	2 (10)
Ulcer size (cm^2), median (25th and 75th centile)	1.1 (0.4 and 2.5)
Ulcer duration (weeks), median (25th and 75th centile)	18 (8 and 92)
History of foot ulcer, no. (%)	14 (70)
Diabetes mellitus, no. (%)	15 (75)
Type 1	4 (27)
Type 2	11 (73)
Peripheral arterial disease status	
Toe pressure* (photoplethysmography mean (SD), range)	114.3 (32.6), 73.0–182.0
Peripheral neuropathy status	
Neurothesiometer† (V; mean (SD), range)	31.9 (15.4), 7.0–59.0
Monofilament absent‡, no. (%)	18 (90)

* Toe pressure was assessed with photoplethysmography (Hadeco Smartdop 30EX; Koven Technology, Inc., St Louis, MO, USA) at the great toe.
† Vibration perception threshold was assessed with a neurothesiometer (Bailey Instruments, Manchester, UK) at the first metatarsal head with mild neuropathy threshold of 25 V.
‡ Loss of protective sensation was assessed using the 5.07/10g Semmes-Weinstein Monofilament (Bailey Instruments, Manchester, UK) on the plantar great toe, third and fifth metatarsal heads.

Table 2 Plantar pressure at the ulcer site in each test condition

Pressure variable	Control (cast shoe)	Conventional total contact cast	Cushion-modified total contact cast
Peak pressure (kPa)	267.3 (114.4)	149.0 (122.9)*	80.4 (52.2)*†
Maximal mean pressure (kPa)	104.4 (32.8)	55.3 (26.9)*	41.3 (19.8)*†
Pressure–time integral (kPa s)	61.0 (29.3)	38.9 (27.3)*	19.2 (12.5)*†

Values are expressed as means (SD).
* Significant difference compared with the canvas cast shoe control condition ($P < 0.01$).
† Significant difference between conventional cast and cushion-modified cast ($P < 0.01$).

in the cushion-modified total contact cast than in the conventional total contact cast ($t = 3.4$, $P = 0.004$; Table 2).

Mean pressure also differed between all test conditions at the ulcer site ($F(2,18) = 41.7$, $P < 0.001$). Mean pressure was significantly reduced when wearing both types of total contact casts compared with the cast shoe condition (reduced by 47% with the conventional total contact cast, $t = 6.2$, $P < 0.001$; and reduced by 60% with the cushion-modified total contact cast, $t = 9.3$, $P < 0.001$). Mean pressure was more effectively reduced in the cushion-modified total contact cast than in the conventional total contact cast ($t = 3.5$, $P = 0.003$; Table 2). Pressure–time integral also differed between all test conditions at the ulcer site ($F(2,18) = 28.5$, $P < 0.001$). Pressure–time integral was significantly reduced when wearing both types of total contact casts compared with the cast shoe condition (reduced by 37% with the conventional total contact cast, $t = 3.6$, $P = 0.002$; and reduced by 69% with the cushion-modified total contact cast, $t = 7.9$, $P < 0.001$). Pressure–time integral was more effectively reduced in the cushion-modified total contact cast than in the conventional total contact cast ($t = 4.3$, $P < 0.001$; Table 2).

Pressure offloading by foot region

Pressure offloading across the entire plantar surface of the foot and each region of the foot was reduced with the conventional total contact cast compared with the cast shoe condition ($P < 0.05$; Table 3). The cushion-modified total contact cast further reduced all plantar pressure variables compared with the conventional total contact cast ($P < 0.05$; Table 3).

Temporospatial gait parameters

Contact area did not differ significantly between the cast shoe (144 cm^2, SD 21 cm^2), conventional total contact cast (150 cm^2, SD 30 cm^2) or cushion-modified total contact cast (133 cm^2, SD 37 cm^2; $F(2,18) = 1.1$, $P = 0.37$). Analysis of contact time (as a surrogate for walking speed) showed no significant differences between the three conditions (cast shoe, 486 ms, SD 127 ms; conventional total contact cast, 613 ms, SD 295 ms; and cushion-modified total contact cast, 514 ms, SD 147 ms; $F(2,18) = 1.9$, $P = 0.18$). Furthermore, differences of contact time between conditions did not correlate with change of peak

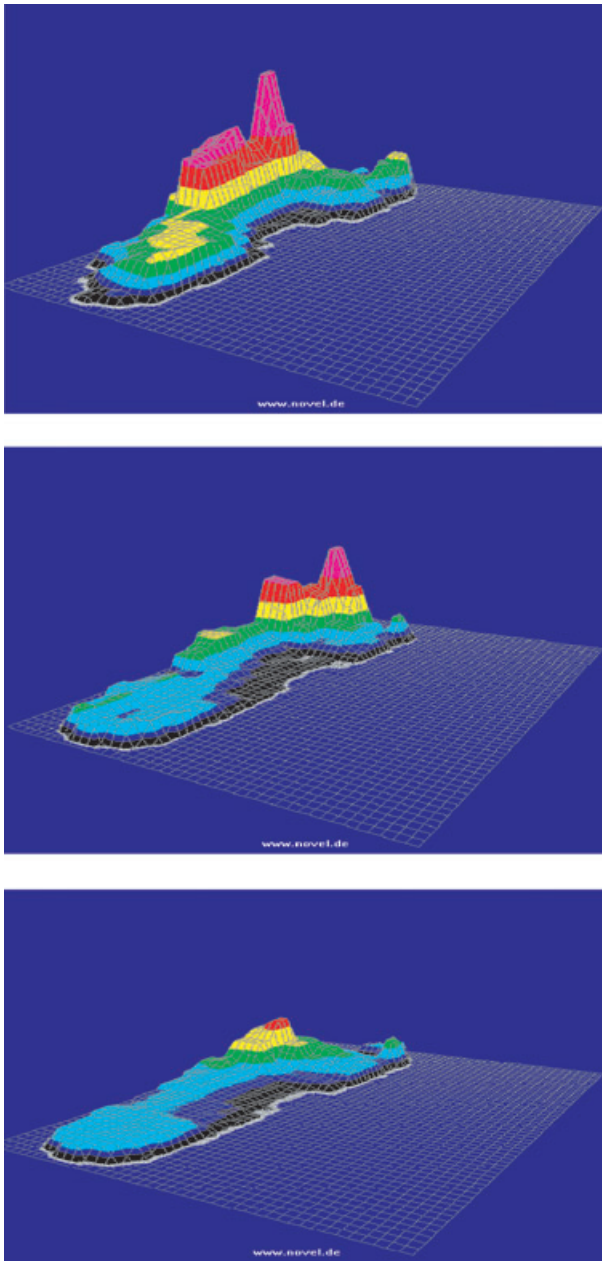

FIGURE 1 An example of the pressure offloading capability of the two total contact casts in a participant with a plantar ulcer at the base of the fifth metatarsal (measuring 3.4 cm × 2.1 cm × 0.2 cm): cast shoe (top); conventional total contact cast (middle); and cushion-modified total contact cast (bottom). The participant had a history of diabetes mellitus, peripheral neuropathy and foot deformity secondary to neuroarthropathy.

Table 3 Pressure offloading by foot region between test conditions

Pressure variable	Control (cast shoe)	Conventional total contact cast	Cushion-modified total contact cast
Whole foot			
Peak pressure (kPa)	333.0 (88.7)	222.2 (90.5)*	143.2 (38.7)*†
Maximal mean pressure (kPa)	115.0 (28.6)	71.7 (12.4)*	61.2 (12.7)*†
Pressure–time integral (kPa s)	98.8 (30.1)	79.3 (36.4)*	47.5 (16.2)*†
Rearfoot			
Peak pressure (kPa)	261.5 (107.3)	184.3 (57.8)*	130.2 (40.7)*†
Maximal mean pressure (kPa)	131.1 (45.7)	99.3 (27.1)*	77.6 (20.0)*†
Pressure–time integral (kPa s)	61.8 (32.1)	71.0 (35.8)	44.7 (18.0)*†
Midfoot			
Peak pressure (kPa)	147.3 (99.4)	106.1 (78.0)	69.6 (20.9)*†
Maximal mean pressure (kPa)	73.9 (35.7)	46.9 (16.9)*	39.7 (8.8)*†
Pressure–time integral (kPa s)	42.0 (30.7)	37.7 (29.0)	22.8 (8.2)*†
Forefoot			
Peak pressure (kPa)	262.8 (109.3)	137.5 (122.2)*	79.2 (53.8)*†
Maximal mean pressure (kPa)	99.0 (31.3)	50.3 (24.4)*	38.6 (17.7)*†
Pressure–time integral (kPa s)	60.4 (26.7)	34.9 (25.6)*	18.1 (12.2)*†

Values are expressed as means (SD).
* Significant difference compared with the canvas cast shoe control condition ($P < 0.05$).
† Significant difference between conventional cast and cushion-modified cast ($P < 0.05$).

pressure ($r < 0.09, P > 0.73$), mean pressure ($r < 0.26, P > 0.27$) or pressure–time integral ($r < 0.31$, $P > 0.20$), suggesting that pressure reduction was not related to walking speed.

Discussion

Adequate pressure offloading is required to promote wound healing [4,5]. Our results clearly show the offloading properties of the total contact cast in patients with a plantar foot ulcer, and that the offloading capacity of the total contact cast can be enhanced with a 6 mm slow-rebound cellular urethane and 6 mm soft cellular urethane inlay cushion modification. Compared with the cast shoe control condition, the conventional total contact cast significantly reduced plantar pressures at the ulcer site by 37–47%, while the cushion-modified total contact cast significantly reduced plantar pressures at the ulcer site by 60–70%.

Several cross-sectional and uncontrolled studies show that total contact casts are very effective at reducing plantar pressure at sites of ulceration [9]. The magnitude of offloading in our study is greater than some previous total contact cast trials, which have evaluated 25 patients with an existent or recently healed diabetic neuropathic heel ulcer [31] and 10–28 asymptomatic healthy volunteers [11,32,33]. However, our offloading results are not as large as other total contact cast trials (76–86%), which have evaluated 25–26 patients with an existent or recently healed diabetic neuropathic forefoot ulcer [26,34,35] and five asymptomatic healthy volunteers [36]. Inconsistencies between studies might relate to the diversity of study design, sample size and patient characteristics, intervention and control conditions, and outcome measures. Pressure reduction can also be achieved by several other modalities, including custom-moulded foot orthoses, footwear and prefabricated walkers in healthy individuals [11] and in those with diabetes [31,37]. However, given that percentage reduction of plantar pressure is relative to the magnitude of baseline or control values, direct comparison of study results is limited.

The addition of a 12 mm cellular urethane cushioned inlay, which increased the offloading capacity of the total contact cast, is the important finding of our study. Indeed, similar pressure mitigation has been reported for total contact casts modified with 12.7 mm soft Sifoam (Omni Medical Specialties, San Diego, CA, USA) under the metatarsal heads [36] and full-length 10 mm sponge padding with an adjustable airbag [22]. This enhanced degree of offloading is likely to be an important aspect of plantar foot ulcer healing, but further research is needed to define the ideal therapeutic pressure.

The mechanism of offloading plantar pressure with a total contact cast is thought to be by redistributing weightbearing force across the entire plantar surface of the foot [26,38,39] and by increasing the plantar surface contact area [40]. However, an examination of our contact area data and regional pressure patterns between conditions suggests this is not entirely the case. Instead, our results generally support the theory that total contact casting transfers load to the cast walls. This is by utilizing the conical shape of the calf to the proximal shank portion of the cast [36,41], a type of load sharing [21] with the foot in an almost 'suspended-like' position as the cushioning provides extra space during the casting process [22], and that the 12 mm cellular urethane cushion modification removed pressure from the ulcer site by creating a buffer between the wound and the cast [36,42]. Further work is needed to fully understand the mechanism of pressure offloading by investigating the interaction between cellular urethane and the ulcer region during walking combined

with biomechanical examination of the cast walls and moulding of materials.

Despite gold-standard treatment status, only a minority (1.7%) of clinicians use total contact casting for the treatment of plantar foot ulcers [16]. Application of the total contact cast is not technically difficult to perform. With adequate clinician training (see Appendix S1), it is anticipated that application of the cushion-modified total contact cast would expedite the potential for healing and facilitate an enhanced quality of life [43].

This study is not without limitations. The thorough evaluation of an optimal total contact cast technique requires longitudinal and randomized assessment of pressure offloading coupled with healing rate, adverse events, patient satisfaction and comfort, and ulcer recurrence. It would also be important to compare the offloading properties and healing rates of the cushion-modified total contact cast with prefabricated alternatives, which may be the only available option in certain circumstances, such as removable and irremovable walkers [20,44,45], pneumatic cast walkers [12], orthoses and footwear [37]. A cost analysis would also be important to rationalize the applicability of the cushion-modified total contact cast in the public and private healthcare setting.

In conclusion, our results show that the offloading properties of the total contact cast, measured in-cast during walking, can be substantially enhanced with a 12 mm cellular urethane inlay modification in patients with plantar foot ulceration.

Competing interests

3M™ Health Care (Sydney, NSW, Australia) supplied total contact casting materials for all participants. There are no other competing interests relevant to this article.

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Supporting information

Additional supporting information may be found in the online version of the article:

Appendix S1. Demonstration of the cushion-modified total contact cast technique.

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