

A Randomized Trial of Two Irremovable Off-Loading Devices in the Management of Plantar Neuropathic Diabetic Foot Ulcers

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OBJECTIVE — The purpose of this study was to compare the effectiveness of a removable cast walker (RCW) rendered irremovable (iTCC) with the total contact cast (TCC) in the treatment of diabetic neuropathic plantar foot ulcers.

RESEARCH DESIGN AND METHODS — In a prospective, randomized, controlled trial, 41 consecutive diabetic patients with chronic, nonischemic, neuropathic plantar foot ulcers were randomly assigned to one of two groups: a RCW rendered irremovable by wrapping it with a single layer of fiberglass casting material (i.e., an iTCC) or a standard TCC. Primary outcome measures were the proportion of patients with ulcers that healed at ≤ 12 weeks, healing rates, complication rates, cast placement/removal times, and costs.

RESULTS — The proportions of patients with ulcers that healed within 12 weeks in the iTCC and TCC groups were 80 and 74%, respectively (94 and 93%, respectively, when patients who were lost to follow-up were excluded). Survival analysis (healing rates) was statistically equivalent in the two groups, as were complication rates, but with a trend toward benefit in the iTCC group. The iTCC took significantly less time to place and remove than the TCC with 39% and 36% reductions, respectively. There was also an overall lower cost associated with the use of the iTCC compared with the TCC.

CONCLUSIONS — The iTCC may be equally efficacious, faster to place, easier to use, and less expensive than the TCC in the treatment of diabetic plantar neuropathic foot ulcers.

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D iabetes-related peripheral neuropathy is a major etiologic factor in the development of neuropathic foot ulcers and their complications (1). Approximately 82,000 lower-extremity amputations directly related to diabetes were

performed in the U.S. from 2000 to 2001 (2). Of these amputations, the vast majority ($>80\%$) have historically been preceded by foot ulcers (3–5).

Repetitive trauma and pressure on the ulcer bed are two of the primary reasons

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Abbreviations: iTCC, irremovable total contact cast; RCW, removable cast walker; TCC, total contact cast; VPT, vibration perception threshold.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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for the persistence of ulcers once they have developed (6). Total contact casts (TCCs) are considered the gold standard in the off-loading and treatment of diabetic patients' neuropathic ulcers (4,7–9). Unfortunately, for many reasons, including cost, fear of complications, and lack of expertise, the TCC is surprisingly underutilized in clinical practice (9,10).

Removable cast walkers (RCWs) have been shown to provide off-loading equal to that of standard TCCs, but fail to provide equivalent healing in clinical studies (8,11,12). We therefore undertook a randomized controlled trial, the purpose of which was to compare the gold standard TCC with a RCW rendered irremovable (iTCC) (13,14), to test the hypothesis that if worn continuously, the iTCC should not differ in healing times or complications from the TCC.

RESEARCH DESIGN AND METHODS

In a prospective controlled trial, 41 patients were randomly assigned to one of two off-loading devices, a standard TCC placed by a trained cast technician or podorthotist or a device that has been termed an iTCC. The iTCC is a RCW (Royce Medical, Camarillo, CA) rendered irremovable by circumferentially wrapping it with a single strip of fiberglass casting material. All patients considered for the study were evaluated in a referral clinic dedicated to the treatment of diabetic foot disorders, with the diagnosis of diabetes having been made by the patients' primary care physician before study enrollment. Patients were considered eligible for study participation if they had chronic, nonischemic, noninfected University of Texas stage IA or IIA ulcers. All patients had moderate to severe neuropathy, with a loss of protective sensation, defined as a neuropathy disability score ≥ 6 (1) and a biothesiometer (Biomedical Instrument, Newbury, OH) vibration perception threshold score ≥ 25 volts at the apex of the hallux on the



Figure 1—Various cast types. Top: Standard walking cast, in a cast boot. Bottom left: Royce DH walker, as usually applied. Bottom right: iTCC.

affected side (15). Ulcers were considered chronic in nature if they were present for ≥ 7 days with a surrounding area of callus. Patients were excluded if they had clinical evidence of active infection at the ulcer site; active Charcot neuroarthropathy; significant peripheral arterial disease, defined as an absent dorsalis pedis or posterior tibial pulse; an inability to walk; or if they did not meet the entry criteria. If the patient had more than one ulcer, the largest ulcer was considered the index ulcer for study purposes.

The study protocol and informed consent were approved by the University of Miami School of Medicine institutional review board. Once informed consent was obtained, randomization was performed on 41 consecutive patients, in whom the treating physician felt casting was appropriate, using a preprepared random number table.

The wounds were evaluated, debrided, and dressed by a clinician, after which the TCCs were applied in a stan-

dard fashion by either a cast technician or certified pedorthist (Fig. 1). The iTCCs were applied by placing the patient in the DH Walker RCW in the manner recommended by the manufacturer, after the wound was treated in the manner described, with additional padding placed on the leg, to match treatment to patients in the TCC group. The iTCCs were then wrapped circumferentially with a single roll of fiberglass casting material, thus rendering them “irremovable” (Fig. 1).

All study patients were followed in the diabetic foot clinic on a weekly basis. At each visit the device was inspected and removed. The wounds were then inspected, sharply debrided as necessary, measured, traced onto an acetate sheet, and photographed.

Outcomes were assessed at the earlier of either complete wound healing (complete epithelialization) or 12 weeks. The primary end point was defined before the study as the proportion of patients healed in ≤ 12 weeks in each group. Other end

points defined before the start of the study included complication rates, median healing times, time to place and remove the devices, and cost.

A two-sample *t* test was used to analyze normally distributed dichotomous variables (i.e., baseline characteristics), a Wilcoxon rank-sum test was used for non-normally distributed variables, and a log-rank test was used for survival data. The study had a power of 95% to detect a 5% difference in the proportion of patients with healed ulcers at or before 12 weeks and a 35% power to detect a 25% difference in complication rates between the two groups. All parameters were analyzed as intention to treat, were two tailed, and used an α value of 0.05.

RESULTS— There were no statistically significant demographic differences between the two groups at study entry with respect to age, sex, race, type of diabetes, duration of diabetes, comorbid conditions, severity of neuropathy, or ulcer characteristics (Table 1). Twenty patients were randomly assigned to the TCC group. Four were lost to follow-up. Twenty-one patients were randomly assigned to the iTCC group, with 2 being lost to follow-up, and 1 patient was found to have had osteomyelitis before study entry.

The proportions of patients with ulcers that healed in ≤ 12 weeks in the TCC and iTCC groups were 74 ± 45 and $80 \pm 41\%$, respectively ($P = 0.65$). If patients lost to follow-up are not included in this analysis, these proportions are 93 ± 26 and $94 \pm 24\%$ ($P = 0.97$). Of patients with ulcers that healed in the 12-week period, the median (mean) healing times were 5 weeks (1st quartile 3 weeks to 3rd quartile 7 weeks) for the TCC- and 4 weeks (1st quartile 3 weeks to 3rd quartile 7 weeks) for the iTCC-treated patients (Fig. 2). Complications (defined as any potential side effect from the treatment, no matter how minor) (Table 2) showed a relative risk reduction of 41% and absolute risk reduction of 27% (95% CI -4.3 to 58, $P = 0.09$) between the TCC and iTCC groups. Sixty-five percent of the patients in the TCC group had some form of complication, 54% of which were simple local skin maceration. Only 38% of the patients in the iTCC group had complications, 75% of which were simple local skin maceration ($P = 0.09$). When patients with maceration are removed from

Table 1—Baseline demographics

Characteristic	Total	iTCC	TCC	P
n	41	21	20	
Lost to follow-up	7 (17)	4 (19)	3 (15)	0.63
Age (years)	50.9 (23–65)	50.7 (29–65)	51 (23–65)	0.9
Male	28 (68)	15 (71)	14 (65)	0.67
White	5 (12)	3 (14)	2 (10)	0.68
Black	14 (35)	6 (29)	8 (40)	0.45
Hispanic	25 (61)	13 (62)	12 (60)	0.9
Type 2 diabetes	38 (92.5)	20 (95.2)	18 (90)	0.53
Duration of diabetes (years)	14.1 (2–33)	14 (5–33)	14.3 (2–27)	0.9
Current smoker	5 (12)	3 (14)	2 (10)	0.68
Ever smoked	18 (44)	11 (52)	7 (35)	0.51
Insulin requiring	19 (46)	8 (38)	11 (55)	0.29
NDS*	9.2 (6–10)	9.2 (7–10)	9.2 (6–10)	0.85
Vibration perception threshold (volts)	46 (44–48)	47 (44–51)	45 (41–48)	0.27
Ulcer surface area (cm ²)†	3 (1.6, 0.9–3.7)	3.1 (1.6, 0.9–3.5)	2.9 (1.9, 0.9–3.9)	0.99
Ulcer duration (days)	216 (68, 14–255)	228 (55, 14–260)	202 (76, 19–263)	0.64
Ulcer distribution				
Forefoot	29 (71)	14 (65)	15 (76)	0.44
Midfoot	11 (27)	6 (30)	5 (24)	0.66
Heel	1 (2)	1 (5)	0 (0)	0.3

Data are n (%), means (range), means (95% CI), or mean (median, 1st and 3rd quartile). *NDS, Neuropathy Disability Score, a quantitative measure of neuropathy: patients receive 1 point each per foot for deficits in pin-prick sensation, temperature sensation, and vibratory sensation, and 1–2 points per foot for deficits in Achilles tendon reflexes, for a score from 0 to 10 with higher numbers reflecting more severe neuropathy (1). †Not normally distributed; most accurate measure of central tendency is the median.

the model, the complication rates drop to 46 and 13% in the TCC and iTCC groups, respectively, corresponding to a relative risk reduction of 71% and absolute risk reduction of 33% (95% CI –1.2 to 67, $P = 0.06$) at week 12. Of these complications there was one (5%) single toe amputation in each group, with the amputation in the TCC group resulting from a kissing ulcer and in the iTCC group from patient noncompliance (Table 2, Fig. 2).

The medium-sized iTCC, which was worn by most of the patients, weighed 1.1 kg compared with 1.5 kg for the TCC ($P = 0.0009$). The large-sized iTCC weighed 1.4 kg ($P = 0.5$ compared with the TCC).

There was also a significant difference in the time of placement and removal of the two devices. The mean times for placement of the TCC and iTCC were 12.4 ± 1.9 min (range 6.9–15.7 [95% CI 11.7–13.1]) and 7.6 ± 1.6 min (5.3–12.5 [7.1–8.1]), respectively ($P < 0.0001$), a 39% reduction (95% CI 33–47). The times for removal of the TCC and iTCC were 3.6 ± 0.8 min (range 2–5.3 [95% CI 3.4–3.8]) and 2.3 ± 0.6 min (1.4–4 [2.1–2.5]), respectively ($P < 0.0001$), a 36% reduction (95% CI 28–44).

A cost analysis was performed with

these data. The cost of a treatment course with a TCC takes into account the time to healing (i.e., number of times the cast required changing), cost of materials (including a local dressing, cast padding, fiberglass cast material, elastic wraps, and cast boots with or without the RCW), and the median cast technician salary in south Florida (\$210.67 compared with \$158.47 for the iTCC) (Table 3).

CONCLUSIONS— Neuropathic diabetic plantar foot ulcers are a major public health and economic burden, for which there exists an incredibly wide range of treatments with variable efficacy. Among these, the gold standard treatment is considered the TCC (4,14). This study suggests that the “instant TCC” may be as efficacious as the standard TCC in healing and may be associated with no more or possibly fewer complications, takes less time to place/remove, and is associated with lower costs. To our knowledge, this is the first randomized clinically controlled trial in the literature comparing these two methodologies of off-loading. A parallel study (16) has suggested the superior efficacy of the iTCC compared with the RCW.

As stated, TCCs have long been con-

sidered the gold standard in the off-loading and treatment of neuropathic diabetic plantar foot ulcers (11). They are believed to work by distributing pressure equally across the entire plantar surface of the foot, by decreasing the number of steps taken, by helping to promote follow-up, and by providing a protected healing environment (7–9,11). Because most clinics, physicians' offices, and podiatrists' offices do not have cast technicians or the resources to hire cast technicians with the skills required to safely apply TCCs, it is essential that other modalities of ulcer healing be considered. Until now, no satisfactory alternative has been demonstrated; although they produce equivalent off-loading characteristics, the efficacy of RCWs in prior work has been shown to be significantly lower than that of TCCs (8). The reason for this difference has been postulated to result from patients only wearing removable off-loading devices for a minority of their steps (12). This study confirms the hypothesis that when worn continuously, a RCW (iTCC) has the same healing characteristics as a TCC. Further support for this comes from a parallel study by Armstrong et al. (16).

The iTCC performed as well as or out-

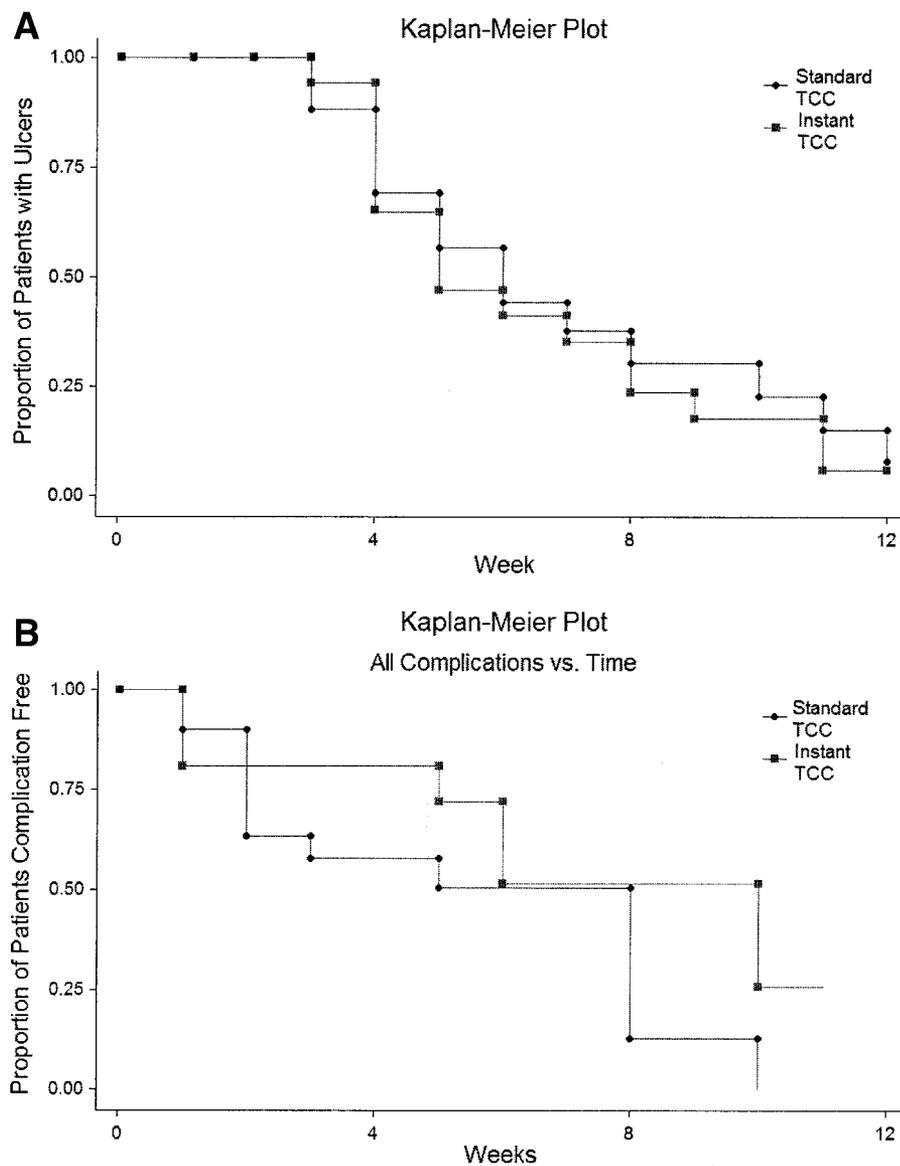


Figure 2—Kaplan-Meier analyses. A: Persistent ulcers versus time. B: Complication-free patients versus time.

performed the TCC in all aspects studied. Some of the major advantages of the iTCC include the lower costs described previously and faster placement and removal times, verified by very narrow confidence intervals for these times, which will allow quicker patient flow in clinics and offices. Perhaps most important is the ease of application of this device. The iTCC, as described here, can be placed by any clinician, because the application requires only minimal training to learn its proper technique.

As always, there are some important limitations to this study. Most importantly, the sample size is relatively small,

limiting the ability to detect differences, which may have been present. It is important to note that casts are not appropriate for every patient. Ulcers that have a significant ischemic component are not considered appropriate for this therapy (17,18). Moreover, such therapy may not be suitable in patients with active infections. They may not be appropriate for patients with significant stability or gait problems and may simply be unacceptable to some patients. The iTCC, by its definition, is prefabricated and is not appropriate for patients with severe foot deformities. Standard molded casts will be needed for these patients until alternative RCWs/iTCCs are designed. Finally, this study was powered to show superiority of one device (TCC) over another (iTCC). The results of the current study might prompt future investigators to consider studies powered to equivalence, which might confirm or refute the results of this current project.

In conclusion, the results of this study suggest that the iTCC may be as efficacious as the TCC in healing of superficial plantar diabetic foot ulcers. Additionally, the very strong trend toward lower complications in the iTCC group may show significance in larger studies. If future findings do confirm these data, it is likely that the iTCC may dramatically change the treatment of nonischemic, neuropathic diabetic plantar ulcers. Additionally, given the much shorter time for placement and removal and the ease with which the iTCC can be placed, it should make this new therapy available to almost all patients with neuropathic foot ulcers, wherever they receive treatment.

Table 2—Complications

Complication	Total	TCC	iTCC	P
n	41	20	21	
Complications	21 (51)	13 (65)	8 (38)	0.09
Maceration	13 (32)	7 (35)	6 (29)	0.49
Broken cast	4 (10)	3 (15)	1 (5)	0.29
Second ulcer	3 (7)	2 (10)	1 (5)	0.53
Abrasions	2 (5)	2 (10)	0 (0)	0.15
Toe amputation	2 (5)	1 (5)	1 (5)	0.97
Edema	1 (2)	1 (5)	0 (0)	0.33
Kissing ulcer	1 (2)	1 (5)	0 (0)	0.33
Fall	1 (2)	0 (0)	1 (5)	0.35

Data are n (%).

Table 3—Cost breakdown

	Standard TCC	iTCC	Difference
Materials/week	\$38.36	\$14.70 + one-time \$89.95 cost for reusable RCW	
Direct cost of treatment course	\$210.67	\$158.47	\$52.20 (24.8%)

Materials include supplies for a local dressing, padding, fiberglass cast material, a protective stocking, cast boot, and, in the iTCC group, a RCW. The median salary for a cast technician adjusted for the time to place/remove a cast and number of cast changes in each group is additionally used in the cost analysis.

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