Evaluation of Removable and Irremovable Cast Walkers in the Healing of Diabetic Foot Wounds

A randomized controlled trial

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OBJECTIVE — The purpose of this study was to evaluate the effectiveness of a removable cast walker (RCW) and an "instant" total contact cast (iTCC) in healing neuropathic diabetic foot ulcerations.

RESEARCH DESIGN AND METHODS — We randomly assigned 50 patients with University of Texas grade 1A diabetic foot ulcerations into one of two off-loading treatment groups: an RCW or the same RCW wrapped with a cohesive bandage (iTCC) so patients could not easily remove the device. Subjects were evaluated weekly for 12 weeks or until wound healing.

RESULTS — An intent-to-treat analysis showed that a higher proportion of patients had ulcers that were healed at 12 weeks in the iTCC group than in the RCW group (82.6 vs. 51.9%, $P = 0.02$, odds ratio 1.8 [95% CI 1.1−2.9]). Of the patients with ulcers that healed, those treated with an iTCC healed significantly sooner (41.6 ± 18.7 vs. 58.0 ± 15.2 days, $P = 0.02$).

CONCLUSIONS — Modification of a standard RCW to increase patient adherence to pressure off-loading may increase both the proportion of ulcers that heal and the rate of healing of diabetic neuropathic wounds.

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Amelioration of pressure, shear, and repetitive injury to the sole of the foot are principal tenets of neuropathic ulcer care. Total contact casts (TCCs) are considered the gold standard in redistribution of pressure over the plantar aspect of the diabetic foot (1–7). TCCs have been shown to reduce pressure at the site of ulceration by 84–92% (8), and there is a large body of work that supports the TCC's clinical efficacy. In two randomized controlled trials comparing the proportion of healed ulcers treated with a TCC compared with other readily available and popular devices (removable cast walkers [RCWs], half-shoes, and therapeutic depth inlay shoes) TCCs, healed a higher proportion of wounds compared with other modalities (7,9). This was an interesting finding because certain types of RCWs, including one used in one of the above-mentioned trials, often reduce pressure on the plantar aspect of the foot as well as TCCs (9). If patients do not heal as well in the RCW and yet it off-loads pressure about as well as the TCC, then a logical explanation for their less effective clinical performance is that these devices are being removed by the patients that use them (10).

In an effort to make the RCW more efficacious, we have modified it slightly by merely wrapping the traditional RCW in a layer of cohesive or plaster bandage. This technique has been termed the "instant" TCC (iTCC) (11). It has been our initial experience that this technique is clinically successful. If clinical results are superior to those with the RCW, we believe it could potentially auger a significant shift in the current standard of care in pressure reduction (off-loading) of diabetic wounds. We are unaware of any reports in the literature that have compared a standard RCW with the iTCC. The purpose of this project was to evaluate the effectiveness of a traditional RCW and the iTCC to heal neuropathic foot ulcerations in patients with diabetes.

RESEARCH DESIGN AND METHODS

— In this randomized controlled trial, 50 patients were randomly assigned to one of two off-loading modalities. All patients provided written informed consent, and this study was approved by the University's institutional review board. This included an RCW (Active Offloading Walker; Royce Medical, Camarillo, CA) or the same device wrapped entirely in a cohesive bandage (iTCC). The description of the application of this device has been previously described (11). The diagnosis of diabetes was made before enrollment and con-

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Abbreviations: iTCC, instant total contact cast; RCW, removable cast walker; TCC, total contact cast.

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

Table 1—*Population descriptive characteristics*

	n	Age (years)	Male	BMI (kg/m^2)	Wound size (cm^2)	VPT (V)	HbA_{1c}
Total	50	65.6 ± 9.9	88.0 (44)	33.4 ± 6.4	2.3 ± 1.2	37.1 ± 7.5	8.2 ± 1.4
iTCC	23	66.9 ± 10.1	87.0 (20)	33.3 ± 6.8	2.7 ± 1.3	37.0 ± 8.1	8.5 ± 1.5
RCW	27	64.6 ± 9.8	88.9 (24)	33.5 ± 6.2	2.0 ± 1.1	37.3 ± 7.0	8.0 ± 1.4

Data area means ± SD or % (*n*). $P > 0.05$ for all comparisons. VPT, vibration perception threshold.

firmed by either communication with primary care providers or by review of medical records. All patients had experienced the loss of protective sensation (>25 V) as measured with a vibration perception threshold meter (Xilas, San Antonio, TX) (12,13), at least one palpable foot pulse, and a neuropathic plantar diabetic foot ulcer corresponding to grade 1A (superficial, not extending to tendon, capsule, or bone, according to the University of Texas Diabetic Foot Wound Classification System) (14,15). Wound size was evaluated by measuring the maximum length by the maximum width. Patients with active infection; unable to walk without a wheelchair; with wounds in locations on the heel, rearfoot, or a location other than the plantar aspect of the foot; or with severe peripheral vascular disease (diagnosed by the criteria listed above based on the absence of both foot pulses on the affected extremity) were excluded. If patients had more than one plantar wound, the largest wound was used as the index ulcer for inclusion in this study.

Patients were randomly assigned through a computerized randomization schedule. Randomization was performed after the initial screening, with allocation provided to the treating clinician by a single study coordinator via telephone. All patients were instructed to use their devices at all times during ambulation. All patients were followed on a weekly basis for device inspection, wound care, and wound debridement. All wounds were surgically debrided as required on each visit. Patients were followed in this manner for 12 weeks or until wound healing (defined as complete epithelialization), whichever came first.

We evaluated the influence of the effect of continuous variables on healing in general with a Mann-Whitney *U* test. Dichotomous variables were evaluated with a χ^2 test with odds ratio (OR) and 95% CI. To evaluate the healing characteristics of each device as a function of weeks of therapy and mean time to closure among patients healing within the 12-week study period, we used a Kaplan-Meier life table analysis (log-rank test). With the above analyses, a difference of 40% between groups could be detected with a sample size of 18 per group, yielding a power exceeding 80%. For all analyses, we used an α value of 0.05. Of an initial enrollment pool of 50 patients, 4 failed to complete the course of study. Reasons for this included discomfort/weight of the device (one RCW, one iTCC) or failure to return for follow-up appointments or data collection visits (two RCW). These patients were considered treatment failures (nonhealers) for the purpose of the intent-to-treat analysis.

RESULTS — Descriptive characteristics of the populations are listed in Table 1. There were no significant differences in any of the descriptive characteristics evaluated. However, wound size was nearly greater in the iTCC group (2.7 ± 1.3 vs. 2.0 ± 1.1 cm^2, $P = 0.07$).

Within the intent-to-treat population, a significantly higher proportion of patients healed at 12 weeks in the iTCC group than in the RCW group (82.6%/19 patients vs. 51.9%/14 patients, $P = 0.02$, OR 1.8 [95% CI 1.1−2.9]). This was also true for the 46 patients who completed the entire course of evaluation (86.4%/19 patients vs. 58.3%/14 patients, $P = 0.04$, 1.5 [1.0−2.2]). There was also a significant difference in cumulative wound survival at 12 weeks between patients treated with an iTCC versus an RCW ($P = 0.003$). These data are illustrated in Fig. 1. Of the patients that healed during the period of evaluation, those treated with an iTCC healed significantly sooner (41.6 ± 18.7 vs. 58.0 ± 15.2 days, $P = 0.02$).

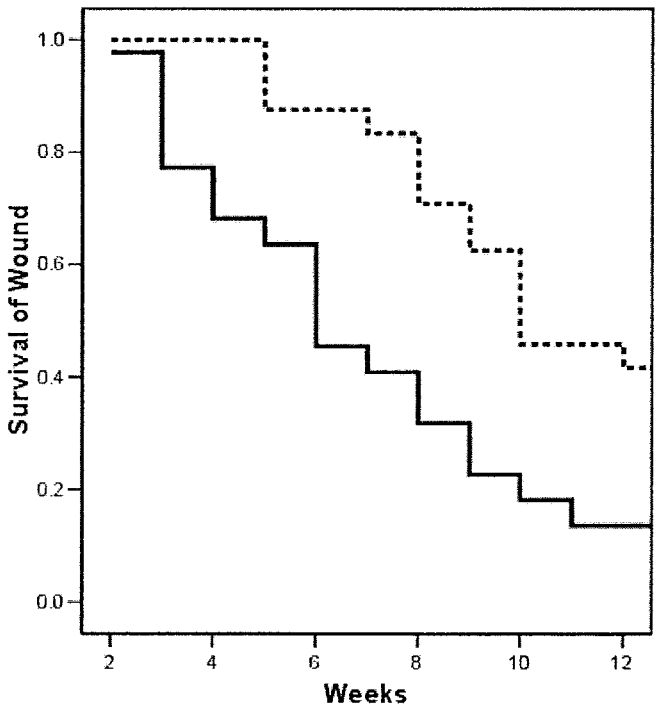

Figure 1—*Wound survival by off-loading device. There was a significant difference in cumulative wound survival at 12 weeks between patients treated with an iTCC and patients treated with an RCW (P = 0.003). - - - -, RCW; ——, iTCC.*

Table 2—*Healing times in common offloading modalities*

Offloading modality	Mean healing time (days)	Type of study	% healed	Type of wound	Ref.
TCC	Forefoot ulcers: 30; rearfoot-midfoot ulcers: 63	Retrospective cohort*	90	Wagner 1, 2	18
TCC	Forefoot ulcers: 31; rearfoot-midfoot ulcers: 42	Retrospective cohort*	—	Wagner 1, 2, 3	4
TCC	40	Retrospective cohort*	94	Wagner 1, 2	24
TCC	38	Retrospective cohort*	73	Wagner 1, 2, 3	3
TCC	44	Retrospective cohort*	82	Wagner 1, 2	6
TCC	Midfoot ulcers: 28	Retrospective cohort*	100	Wagner 1, 2	23
TCC	34	RCT†	90	UT 1A	9
RCW	50		65		
Half-shoe	61		58		
TCC	42	RCT†	90	Wagner 1, 2	7
Shoe-insole	65		32		
Removable cast boot	48	RCT†	35	UT 1A	16
Fiberglass cast shoe	34	Retrospective cohort	91	Wagner 1	19
Fiberglass cast	—	RCT‡	50	Wagner 1	20
Shoe			21		
Scotch cast boot	112, 181	Retrospective cohort*	80	Wagner 1, 2, 3	25
Windowed fiberglass cast	69	Prospective cohort*	81	UT 2A	21
Half-shoe	134		70	UT 1A	21
Half-shoe	70	Prospective cohort*	96	Wagner 1, 2, 3, 4	27
Custom splint	300	Retrospective cohort*	—	—	22
Felted foam dressing	75	RCT§	—	Wagner 1, 2	26
Half-shoe	85				
TCC	48	Prospective cohort†	92	Wagner 1, 2, 3	28
Padded dressing	36		93		
Healing shoe	42		81		
Walking splint	51		83		

*Percentage healed in no specified time; †percentage healed in 12 weeks; ‡percentage healed in 30 days; §percentage healed in 10 weeks. RCT, randomized clinical trial. UT, University of Texas.

There were no falls, device-related ulcerations, or hospitalizations reported during the course of study. However, significantly more patients using the iTCC presented with at least one episode of periwound maceration than did those using the RCW (68.2%/15 patients vs. 37.5%/9 patients, $P = 0.04$, OR 1.8 [95% CI 1.0−3.3]). With the numbers available for study, there was no significant difference between the proportion of patients requiring antibiotics to treat a soft tissue infection during the course of treatment (27.3%/6 patients iTCC vs. 41.7%/10 patients RCW, $P = 0.4$).

CONCLUSIONS — TCCs have been espoused to be one of the most effective treatments in healing neuropathic ulcers in people with diabetes. Despite evidence that several brands of RCWs, such as the Active Offloading Walker, Aircast (Aircast, Summit, NJ), and Conformer Boot (Bledsoe, Dallas, TX), may reduce peak foot pressure as effectively as a TCC (8,14,15), they have not been as effective as TCCs in clinical practice (9,16).

In a randomized trial comparing RCWs and TCCs, 65% of ulcers healed in the RCW group (using an Aircast RCW) and 90% of ulcers healed in the TCC group. Our results with the Active Offloading Walker were similar to results with the Aircast RCW. When the Active Offloading Walker was modified, the iTCC study group demonstrated a healing rate similar (86% in 12 weeks) to that in previous studies that used a traditional TCC as the off-loading treatment. There is a large body of literature that reports consistently high rates of healing (73–100%) with TCCs (Table 2) (3,4,6,7,9,17–26). However, because TCCs are technically difficult to use and time consuming to place, they are not widely used in most clinics worldwide. In essence, in most communities they remain an ideal gold standard of treatment and not the true community standard. Instead many clinicians choose to compromise and use less demanding and often less effective pressure off-loading therapies.

One of the most attractive features of the genre of RCW products is that they are easy to apply and safe to use; thus, clinicians with a wide range of experience use an effective pressure-reducing product. Many clinicians and therapists who would not be comfortable applying a TCC can readily use most RCWs. The unfortunate downside is that patients can also remove the product. Patient adherence to use of removable devices seems to be poor. By implanting a computerized activity monitor in patients' RCWs, we previously demonstrated that these offloading devices are used for less than one-third of the total activity taken per day (10). By applying a simple wrap around a traditional RCW, both the proportion and rate of wound healing was substantially improved by preventing patients from re-

moving the device. Like most therapies, the iTCC requires thoughtful patient selection and diligent monitoring, but our initial clinical results are thought provoking and may be a catalyst for modifying our current clinical approach.

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