Total Contact Casting in Treatment of Diabetic Plantar Ulcers

Controlled Clinical Trial

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This study compared the treatment of total contact casting (TCC) with traditional dressing treatment (TDT) in the management of diabetic plantar ulcers. Forty patients with diabetes mellitus and a plantar ulcer but with no gross infection, osteomyelitis, or gangrene were randomly assigned to the TCC group (n = 21) or TDT group (n = 19). Age, sex, ratio of insulin-dependent diabetes mellitus to non-insulin-dependent diabetes mellitus, duration of diabetes mellitus, vascular status, size and duration of ulcer, and sensation were not significantly different between groups ($P > .05$). In the experimental group, TCC was applied on the initial visit, and subjects were instructed to limit ambulation to ~33% of their usual activity. Subjects in the control group were prescribed dressing changes and accommodative footwear and were instructed to avoid bearing weight on the involved extremity. Ulcers were considered healed if they showed complete skin closure with no drainage. Ulcers were considered not healed if they showed no decrease in size by 6 wk or if infection developed that required hospitalization. In the TCC group, 19 of 21 ulcers healed in 42 ± 29 days; in the TDT group, 6 of 19 ulcers healed in 65 ± 29 days. Significantly more ulcers healed ($\chi^2 = 12.4$, $P < .05$) and fewer infections developed ($\chi^2 = 4.1$, $P < .05$) in the TCC group. We conclude TCC is a successful method of treating diabetic plantar ulcers but requires careful application, close follow-up, and patient compliance with scheduled appointments to minimize complications. *Diabetes Care* 12:384–88, 1989

Brand (1) and others (2–5) theorize chronic plantar ulcers are primarily the result of excessive pressure on the insensitive feet of diabetic patients. Based on this theory, Brand emphasizes protection of insensitive feet from further trauma and reduction of plantar pressure in the area of ulceration to promote healing (1). One method to reduce pressure at the ulcer site while allowing the patient to remain ambulatory is total contact casting (TCC) (6). The theory and application of the casts have been described in detail by Sinacore (7) and Coleman et al. (8).

Several clinical studies on TCC for the treatment of diabetic plantar ulcers provide descriptions of the treatment method and report favorable results (9–12). Successful healing of ulcers occurred in 73–100% of treated patients in reported mean times between 36 and 43 days (9–12). These studies, however, lack control groups, which renders the validity of inferences questionable.

Despite the clinical descriptions, there has been no controlled clinical study to document the effectiveness of any one treatment approach for diabetic plantar ulcers. In this investigation, we conducted a prospective controlled clinical trial to compare the effectiveness of TCC and traditional dressing treatment (TDT) for the management of neuropathic plantar ulcers in patients with diabetes mellitus. The null hypothesis was that there would be no difference between the two groups in the number of ulcers healed or the time required for healing.

MATERIALS AND METHODS

Criteria for inclusion in the study were that the patient had been diagnosed with diabetes mellitus and currently

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had a plantar ulcer but no evidence of gross infection (no significant edema or drainage), osteomyelitis (determined by radiograph or radionuclide scans), or gangrene (visibly discolored or necrotic tissue). Subjects were recruited from the diabetic foot center and physical therapy department at Washington University School of Medicine. The study was approved by the human studies committee at Washington University School of Medicine, and all patients participating in the study were randomly assigned to either the TCC or TDT group.

A total of 40 patients (27 men, 13 women) met the inclusion criteria and agreed to participate in the study. (See Table 1 for patient characteristics.) Thirteen subjects were diagnosed with insulin-dependent diabetes mellitus (onset of diabetes before 35 yr of age and prone to develop ketoacidosis) by their referring physician. The remaining 27 subjects had been diagnosed with non-insulin-dependent diabetes mellitus and were taking oral hypoglycemic agents or insulin (at the discretion of their referring physician) to improve glycemic control.

Standard protocol for patients referred to the diabetic foot center was followed for all subjects (13). Vascular studies, including ankle/arm index, were routinely done on patients, and radiographs were taken of those suspected of having osteomyelitis or neuropathic joints. Patients were seen by a diabetes nurse specialist who took random blood glucose checks. Those patients with questionable control were provided appropriate education and advised to see their primary physician. Due to independent random sampling, we assumed there was no difference in diabetic control between groups. A review of random blood glucose checks supported this assumption, although glycosylated hemoglobin and fasting plasma glucose values were not taken.

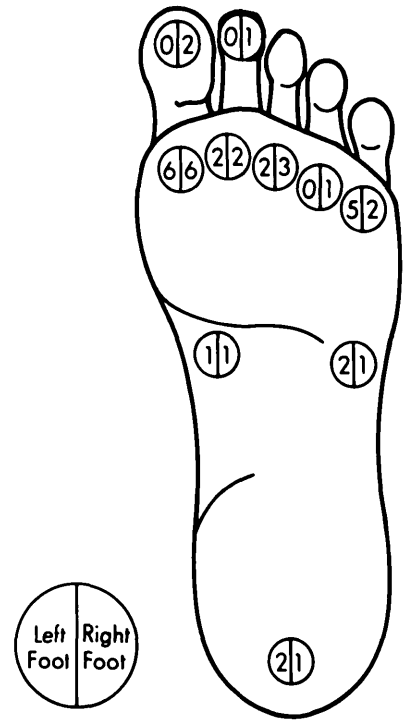

FIG. 1. Location of primary ulcers on feet of 40 patients.

TABLE 1
Subject characteristics

	Group	
	TCC	TDT
Age (yr)*	54 ± 10	55 ± 12
n (M/F)†	13/8	14/5
IDDM/NIDDM†	5/16	6/13
Duration of diabetes (yr)*	17 ± 6	17 ± 9
Ulcer duration (days)*	155 ± 195	175 ± 200
Ulcer size		
Area (cm^2)*	1.8 ± 2.5	2.8 ± 3.4
Depth (mm)*	3.6 ± 3.2	2.4 ± 0.9
Ulcer grade†		
1	15	13
2	6	6
Sensation (Semmes-Weinstein monofilament)†		
4.17 (Intact)	0	0
5.07 (Decreased)	0	1
6.10 (Severely decreased)	6	6
>6.10 (Absent)	15	12
Vascular disease†		
Ankle/brachial ratios 0.5–0.99	2	3
Ankle/brachial ratios <0.5	1	1

TCC, total contact casting; TDT, traditional dressing treatment; IDDM, insulin-dependent diabetes mellitus; NIDDM, non-insulin-dependent diabetes mellitus.

*No significant difference between groups of patients ($P > .05$ by *t* test between 2 independent means).

†No significant difference between groups of patients ($P > .05$ by χ^2 and 2 independent variables).

Other data collected at the initial visit included *1*) location of ulcer (Fig. 1), *2*) size and classification of ulcer, and *3*) sensation on the plantar surface of the foot. Most (75%) ulcers were located under the metatarsal heads as has been previously described (12,14,15). The ulcer was outlined on sterilized clear plastic film, and area was obtained by tracing the outline of the ulcer with a sonic digitizer (16). Depth of the ulcer was measured at its deepest point with a modified slide ruler. Mean area was 2.3 ± 3.0 cm^2, and mean depth was 3 ± 2.1 mm. Ulcers were classified as described by Wagner (17; Table 1). Sensation on the plantar surface of the foot was measured with Semmes-Weinstein (SW) monofilaments (15,18,19). The lowest perception of monofilament (4.17, 5.07, or 6.10) was recorded for each patient similar to the method described by Birke and Sims (15) and Diamond et al. (18). Sites for testing were the first, third, and fifth toes and metatarsal heads; medial and lateral midfoot; and heel. Multiple trials were taken at each site, and the subject needed to per-

ceive 80–100% of the trials to be graded a given level at that site. If subjects were unable to sense 80% of the trials, they would be graded the lower score for that site. If patients were unable to sense 80% of the trials with the 6.10 monofilament, they were graded >6.10. The lowest site grade was taken as the grade of the foot (Table 1). We and other investigators have demonstrated the reliability of measuring sensation with SW monofilaments in a diabetic population (15,18,19).

Casts were applied by a physical therapist on the initial visit as described elsewhere (7,8). Briefly, the ulcer was covered with one thin layer of gauze. Cotton was placed between the toes to prevent maceration, and a stockinette was applied to the lower leg with ⅛-inch felt pads applied to the malleoli and anterior tibia and a foam pad placed around the toes. A total contact plaster shell was then molded around the lower leg. The shell was reinforced with plaster splints, and a walking heel was attached to the plantar surface. A fiberglass roll was applied around the plaster for extra durability and to allow bearing weight sooner than would be allowed with plaster alone. Patients were given a written list of precautions and instructed to limit ambulation to 33% of their usual activity (7). Assistive devices (walkers or crutches) were provided to patients requiring them. Casts were removed after 5–7 days, and the ulcer and skin inspected. If there were no complications (i.e., additional skin breakdown, deterioration of the ulcer, or patient refusing additional casting), the cast was reapplied and changed every 2–3 wk until the ulcer was completely healed.

Procedures, except for casting, were identical for the TDT group. The wound was covered with a wet-to-dry dressing (sterile saline), and patients were instructed to change the dressing two to three times daily. If indicated, patients having difficulty performing dressing changes were provided with visits from a home-health nurse to assist them and monitor their treatment. All patients were prescribed appropriate accommodative footwear (i.e., healing sandal and extradepth shoe with plastazote insert) as described by Coleman (20). Patients were instructed to avoid bearing weight on the involved lower extremity (with walkers or crutches) and were followed at least every 2–4 wk for routine wound care and debridement.

All subjects had the option to discontinue treatment at any time. Subjects refusing to receive treatment from their assigned treatment group before complete wound closure were considered not healed. Ulcers that became grossly infected, increased in size, or showed no improvement after 6 wk were considered not healed. Ulcers were considered healed if they showed complete skin coverage and no drainage.

A two-way χ^2-test for two independent variables with two levels was used to determine whether there was a significant difference in the distribution of healed compared with not healed ulcers in the two groups (21). The α-level was .05.

RESULTS

As shown in Table 1, there was no significant difference in distribution of subject characteristics between the two groups ($P > .05$). In the TCC group, 19 of 21 (90%) ulcers healed in a mean time of 42 ± 29 days (range 8–91 days). In the TDT group, 6 of 19 (32%) ulcers healed in a mean time of 65 ± 29 days (range 12–92 days). Five of 19 (26%) patients in the TDT group showed serious foot infection that required admission to a hospital. Two of these patients required a forefoot amputation. None of the TCC group required hospitalization during this study. The χ^2-value was statistically significant ($P < .05$), both for the number of ulcers healed ($\chi^2 = 12.36$) and incidence of infection ($\chi^2 = 4.1$).

DISCUSSION

Results of this controlled study are in agreement with previous descriptive studies that show the positive effects of TCC (9–12). Covering the ulcer (an area of potential infection) with a cast may seem counterintuitive to some clinicians. However, these results indicate that treatment with TCC is associated with less chance of infection and subsequent hospitalizations than TDT. These results also support the theory that increased local pressure coupled with insensitivity is a major contributing factor in the development of plantar ulcers. Although having the foot remain non–weight bearing (without a cast) should allow a plantar ulcer to heal, our observations indicate patients are often noncompliant with their prescribed non–weight-bearing status and accommodative footwear. We often observe patients (including patients in the TDT group) walking without gait deviations on ulcerated feet without an assistive device (sometimes carrying their crutches) with little or no reports of pain. Brand has described similar observations in patients with insensitivity (1). Ambulation on the ulcerated foot appears to make the wound more susceptible to infection and subsequent problems as seen in the TDT group. TCC immobilizes the foot and seems to protect the wound from outside contaminants. The prevention of serious infection is a functional and financial benefit of casting.

All but two ulcers healed in the TCC group. One of the ulcers showed considerable improvement while in the cast but was not completely healed after 3 mo. Treatment with casting was discontinued; 3 wk later the patient was hospitalized with an acute infection in the involved foot. Further vascular studies revealed an ankle/arm index of 0.42 on the affected side, and the patient was referred to a vascular surgeon. The other subject showed considerable improvement in 3 wk of casting but refused additional casting, stating that the

cast was too burdensome and interfered with his daily activities. Complaints of difficulty with ambulation or sleeping were common in the TCC group. Other patients wanted to terminate casting before complete closure, but our experience indicates the cast should remain on until complete wound closure (22).

The TCC treatment has potential risks. Three of 21 patients in the TCC group showed signs of a fungal infection, which was resolved with topical cream and did not prevent continued casting. None of the subjects in the TCC group showed new blisters or frank skin breakdown while in the cast, although such complications of TCC have been documented (11). These abrasions usually heal quickly because they are not on a weight-bearing surface. Severe edema in the lower leg and foot should be reduced before application of the cast. Treatment with TCC is contraindicated in the presence of active gross infection (≥grade 3 ulcer) or severe vascular disease (Doppler pressure <0.4) (7). Patients at greater risk (i.e., borderline Doppler pressure, fragile skin, or edematous lower leg) should have their cast changed more frequently (every 5–10 days) than would otherwise be necessary. With these potential risks in mind, casts should be applied and removed carefully by those trained in the procedure.

Based on these and other results, clinicians should consider protecting the insensitive foot as the primary consideration in the treatment of diabetic plantar ulcers. Other modalities may accelerate wound closure, but unless excessive pressure is reduced at the ulcer site, healing cannot occur (1). Future studies that assess the effects of modalities to improve wound healing must strictly control such factors as pressure reduction and weight-bearing status. Leslie et al. (23) assessed the benefit of topical hyperbaric oxygen for the treatment of diabetic foot ulcers. They controlled patient's weight-bearing status by imposing inpatient bed rest in both groups. Although both groups improved, hyperbaric oxygen was no more successful in wound healing than dressing changes alone. Perhaps this is another example in which pressure relief (due to bed rest) was the primary factor in wound healing. Other modalities such as electrical stimulation may prove beneficial to diabetic plantar ulcer management, but controlled studies with homogeneous patient populations and controlled weight-bearing status are needed (24,25).

In conclusion, use of TCC in the treatment of diabetic plantar ulcers was significantly more effective in the number of ulcers healed than conventional treatment with dressing changes and accommodative footwear. TCC can be a highly successful treatment of diabetic plantar ulcers but requires careful application, close follow-up, and patient compliance with scheduled appointments to minimize complications. The initial cost of TCC may be slightly greater than treatment with dressing changes alone, but long-term cost appears to be significantly less, due to fewer complications such as infections, hospitalizations, and amputations.

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