

Use of bivalved ankle-foot orthosis in neuropathic foot and ankle lesions

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Abstract—The neuropathic foot is a common complication of diabetes mellitus and is associated with development of chronic ulcers and Charcot joints. Treatment of these complications presents a complex management task. This report presents long-term follow-up data on 16 patients with neuropathic changes who were treated with a total contact, laminated, bivalved, rocker-bottom-soled ankle-foot orthosis (TCAFO). Of the 16 patients, 6 were treated for Charcot changes only, 10 were treated for ulcers, and 2 of the 10 had ulcers bilaterally. Eight of the 12 ulcers (67%) healed in an average of 10 months (range 1–24 mo), 1 patient required amputation, and 2 patients with unhealed ulcers are still in TCAFOs. Of the 7 patients who had complete healing, 5 have resumed wearing TCAFOs secondary to recurrent ulcers. Three of the 5 patients with Charcot changes no longer use the orthosis and have had negative bone scans after an average of 20.7 months (range 12–28 mo). In this retrospective uncontrolled study, the TCAFO proved to be a safe, functional, and cost-effective therapy for complications of the neuropathic foot.

Key words: *Charcot joint, diabetic neuropathy, foot ulcer, healing, neurogenic arthropathy, orthosis.*

INTRODUCTION

Each year, in excess of half a billion dollars is spent in the United States on amputations secondary to

diabetes mellitus (1). Diabetes mellitus leads to peripheral neuropathy in up to 50 percent of patients. This neuropathy can lead to skin ulcerations, arthropathy, and eventually amputation (2–4). To halt the progression from arthropathy and ulceration to amputation, effective treatment is essential.

In the initial stages, neuropathic arthropathy is treated with cessation of weight bearing, immobilization, and elevation of the edematous foot (4). As improvement is seen, patients may begin to ambulate with crutches, and eventually a walking cast can be applied. Immobilization is usually needed for a minimum of 8 to 12 weeks (5,6); however, longer times are not uncommon. Return to full ambulation without a cast commonly takes 4 to 5 months (4) and special footwear is needed to prevent refracture. Walking casts must be applied with extreme care to assure that no ulcerations occur underneath the cast.

Treatment of neuropathic ulcerations requires removal of surrounding callus, eradication of infection, and reduction of forces. The most commonly used methods to reduce forces on the ulcer, and thus promote healing, are bed rest, non-weight bearing or crutch ambulation, special footwear (7–10), and total-contact casting (TCC) (9,11–15). TCC has proven to be very effective in promoting healing, with complete ulcer healing in as short as 1 to 2 months (11–13,16).

Although the above treatments are effective, problems still exist. Patient compliance with bed rest is notoriously poor (17). When patients do stay at bed rest, deconditioning and its multiple medical sequelae result

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(18). Although ambulation is possible with TCC, this treatment should not be used until after the infection has cleared (1). The casts require frequent changing, especially as swelling decreases, and there is risk of ulcer development underneath the cast in the insensate foot. Because of the perceived risk of ulceration, many physicians and patients are hesitant to use this form of treatment.

This paper describes the long-term experience with use of a rigid, removable, total contact, laminated, rocker-bottomed ankle-foot orthosis (TCAFO).

METHODS

The review board at the institution approved the study. The study design is a retrospective series without a comparison cohort. The initial TCAFO was constructed in 1984 to provide an alternative treatment for patients with neuropathic ulcerations or arthropathy. Following good experience with the initial patient, all patients who met the following clinical criteria were offered the orthosis as a treatment option: 1) ulcer present for at least 6 months; 2) other types of treatment, including footwear modification, attempted without success; and 3) amputation recommended by a surgeon if clinical improvement could not be seen. In addition, individuals with newly diagnosed neuropathic arthropathy documented by a positive bone scan were offered the TCAFO. The need for compliance with the use of the orthosis was emphasized to all patients.

All patients treated with a TCAFO were located through review of the outpatient orthotics and prosthetics clinic files. The criteria for inclusion in the study was that the patient received the TCAFO 6 months prior to the beginning of the chart review. For all patients, information was obtained from a thorough review of the medical record. On completion of the review, patients were asked to attend a follow-up visit. During the follow-up visit, the patient's neuropathy and limb condition were documented with a neurologic and musculoskeletal exam. In addition, data collected during the chart review were verified and patients were surveyed by a standard questionnaire. Those patients who could not attend a clinic visit were telephoned and asked the same set of questions.

Each TCAFO was constructed by taking a cast of the affected extremity and making a positive mold from the cast. The positive mold was then modified to provide pressure relief over areas of ulceration and

callus, as well as bony prominences. During casting, the foot was placed in as anatomically neutral a position as possible. The TCAFO was then made with either a vacuum-formed thermoplastic material or a vacuum-formed thermosetting resin reinforced with carbon fiber. In both cases, the anterior and posterior shells were made in separate pullings. The shell was lined with a dense pelite inner shell which allows for adjustments and changes over time. A rocker sole and Velcro® straps were added to produce the final product (**Figure 1**). Over the past few years, acrylic resin has been used exclusively because it is lighter and stronger, and it can be colored.

RESULTS

Subjects

Of the 16 patients located through a review of the orthotics and prosthetics clinic records, one was lost to follow-up prior to healing; two patients, who had complete healing, could not be located; and one patient, who was unable to return for a clinic visit, completed a telephone interview. The remaining 12 patients completed all aspects of the study. Although little information is available on the patient who was lost to follow-up, she was included in the results to provide a complete picture of our experience with the orthosis.

The average age of the patients was 53.4 years (range 37 to 67). There were 6 females and 10 males (see **Table 1** for subject characteristics). The most common cause of neuropathy was diabetes mellitus which was present in 12 of the patients. Patient 11 had concomitant chronic renal failure and 3 patients were diagnosed as having peripheral vascular occlusive disease. Two patients had a peripheral neuropathy of unknown etiology and patient 13 had bilateral Charcot-like joints without neuropathy.

Charcot Joint Treatment

Six patients were treated for Charcot changes only (see **Table 2**). Of these 6 patients, 2 had arthropathy of both feet resulting in a total of 8 feet being treated for Charcot changes only. Three patients discontinued wearing the TCAFO after an average of 20.7 months (range 12 to 28). The decision to discontinue TCAFO use was based on a previously abnormal bone scan returning to normal. One patient (No. 13) has worn the TCAFO for 45 months for pain prevention and plans to continue to use the orthosis.

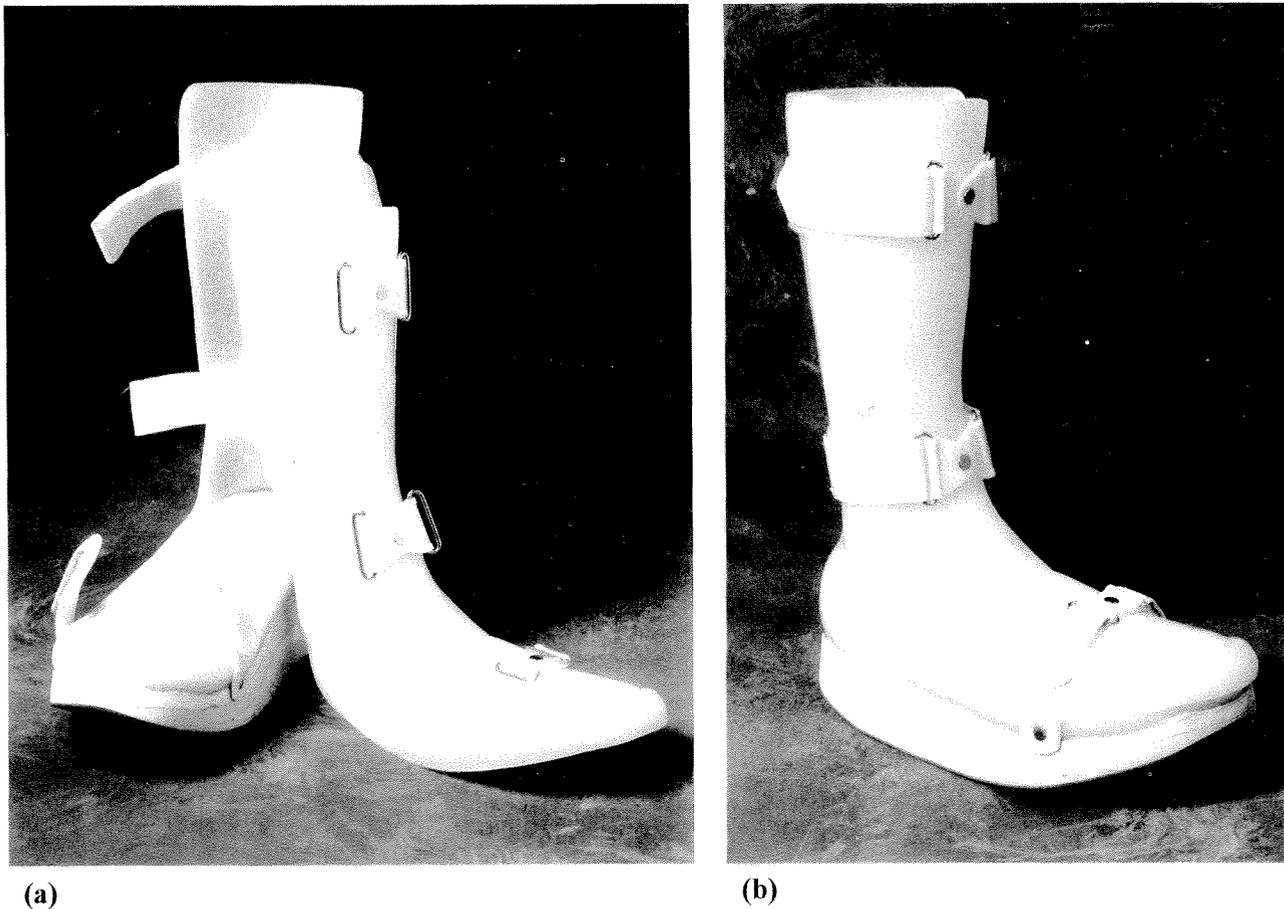


Figure 1.

The total contact, laminated, bivalved, rocker-bottom soled ankle-foot orthosis (TCAFO), (a) open and (b) closed.

Ulcer Treatment

Ten patients were treated for ulcers (see **Table 3**). Two Patients (8 and 10) had ulcers present on both feet, giving a total of 12 ulcers. Of the 12 feet with ulcers, 8 had documented Charcot changes. The time to initial healing is recorded for each patient; if the ulcer never healed, the total time in the orthosis is listed. Of the 12 ulcers, 8 healed in an average of 10 months (range 1 to 24). Patient 10 was lost for follow-up prior to healing and was reported in the chart as being noncompliant. Patient 2 reported near-complete healing of the ulcer; however, because osteomyelitis was not responsive to antibiotics, the patient underwent an amputation. Patient 6 never had complete healing despite being in the TCAFO for 66 months. Five patients have reused their TCAFO after complete healing secondary to recurrence of the ulceration.

Complications

The most serious reported complication occurred when a patient's liner slipped inside the orthosis and a

new ulceration developed over a short period of time. This ulceration later completely healed. The most common complications reported were areas of skin redness and orthotic failure. The most common orthotic failure was broken straps. In each instance, all that was required was a return visit to the orthotist. From the patient report, the TCAFO lasted between 1 and 2 years; the most common causes for replacement were generalized wear, a cracked outer shell, or changes in the patients' feet (see **Table 4**). The most common required modification was pressure relief over a reddened area.

Questionnaire Results

Thirteen of the 16 patients completed the survey portion (see **Table 4**). All 12 patients with ulcers felt the orthosis helped to heal their feet. All of the patients wore their orthoses for more than 8 hours a day and were functional community ambulators. Only two required a cane for safe ambulation. Eight of the 13 patients felt the TCAFO improved their ability to walk, usually because of decreased deep pain and increased

Table 1.
Patient characteristics.

Patient Number	Age*	Reason for wearing TCAFO	Presumed Etiology of Pathology
1	59	Ulcer, Charcot changes present	DM
2	48	Ulcer, Charcot changes present	DM
3	69	Charcot joint	DM, PVOD
4	58	Charcot joint	DM
5	61	Charcot joint	Unknown
6	67	Ulcer, Charcot changes present	Unknown
7	50	Charcot joint	DM, PVOD
8	57	Ulcer, Charcot changes present	DM
9	56	Ulcer, Charcot changes present	DM
10	37	Ulcer	DM
11	39	Charcot joint	DM, CRF
12	59	Ulcer	DM
13	35	Charcot joint	Unknown†
14	56	Ulcer, Charcot changes present	Spina bifida
15	39	Ulcer, Charcot changes present	DM, PVOD
16	64	Ulcer, Charcot changes present	DM

*Patient age is recorded at the time the patient started wearing the AFO.
†This patient had pseudo-Charcot joints based on repeated trauma and malignment when healing.
TCAFO—total contact ankle-foot orthosis
DM—diabetes mellitus
PVOD—peripheral vascular occlusive disease
CRF—chronic renal failure.

stability. All 13 patients recommend the TCAFO as a form of treatment.

DISCUSSION

This paper presents data on the use of total contact, bivalved, laminated, ankle-foot orthoses for Charcot joints and neuropathic foot ulcers. This method of treating diabetic foot complications has only recently been reported in the literature (19,20). As in all retrospective studies, the conclusions which can be drawn are limited by a number of factors. The data were collected through a chart review and the records were occasionally incomplete. In order to verify the data, subjects were interviewed; however, this process is limited by patient recall. Having made these qualifications, some general observations can be made.

The TCAFO was effective in stabilizing 62.5 percent of the Charcot joints as defined by return to a negative bone scan. Patients who had no pain complaints were effectively weaned when their ankles were no longer inflamed. For the patient with continued pain, despite a negative bone scan, the TCAFO was effective in reducing pain and became permanent footwear. All of the patients with Charcot joints were functional ambulators in their orthoses and those who were working continued to work while being treated with the TCAFO. In 1993, Morgan et al. reported use of a similar device in patients with neuropathic arthropathy. In their series, the device showed similar effectiveness (20).

The TCAFO was effective in healing 67 percent of the ulcerations; however, the times to healing were longer than those reported with TCC (11–13,16). The average healing time in this study was 10 months,

Table 2.
Outcome of patients with charcot changes.

Patient Number	Side	Study Follow-up	Total Time in TCAFO or Time to Healing (mos.)	Condition at Follow-up
3	Right	Complete	7	Still in TCAFO with positive bone scan
4	Left	Complete	12	Now in custom shoe
5	Left	Complete	28	Now in custom shoe
7	Bilateral	Complete	7	Still in TCAFO
11	Right	Complete	22	Now in custom shoe
13	Bilateral	Complete	45	Still in TCAFO for pain control

TCAFO—total contact ankle-foot orthosis.

Table 3.
Outcome of patients with ulcers.

Patient Number	Side and Location	Study Follow-up	Total Time in TCAFO or Time to Initial Healing (mos.)	Conditions at Follow-up
1	Right: 1st met head	Completed	24 healed	Now in custom shoes
2	Right: plantar aspect	Completed	6	Amputation
6	Left: 1st met head	Phone interview	66	Still in TCAFO
8	Left: plantar aspect Right: plantar aspect	Completed treatment; unable to locate	3 healed 11 healed	In TCAFO bilaterally secondary to recurrence at last follow-up
9	Right: medial plantar	Completed treatment; unable to locate	3 healed	In custom shoes at last follow-up
10	Right: 1st met head Left: great toe	Lost to follow-up prior to healing	58 28	Bilateral ulcers present at last clinic visit
12	Left: 1st met head	Completed	13 healed	In TCAFO secondary to recurrence
14	Right: 5th met head and 1st toe	Completed	1 healed	In TCAFO secondary to recurrence
15	Left: 2nd met head	Completed	11 healed	In TCAFO secondary to recurrence
16	Left: 5th met head and lateral aspect	Completed	14 healed	In TCAFO secondary to recurrence

TCAFO—total ankle-foot orthosis
met—metatarsal.

Table 4.
Questionnaire results.

Question	Choices	Results
How long has your TCAFO(s) lasted?	A) Until the foot healed or until the present	2
	B) Less than 6 mos.	0
	C) Less than 1 year	1
	D) Greater than 1 year	10
How often has your TCAFO(s) required modification?	A) Never	1
	B) Only when initially purchased	5
	C) 2—4 times	3
	D) Greater than 4 times	4
When you wear/wore your TCAFO(s), your ability to walk was:	A) Decreased and limited (could only use in home)	0
	B) Decreased functional (could walk outside home)	3
	C) Unchanged	2
	D) Increased	8
In your opinion has the TCAFO helped heal your foot?	A) Yes	12
	B) No	1
Would you recommend the TCAFO as a form of treatment?	A) Yes	13
	B) No	0

TCAFO—total contact ankle-foot orthosis

versus one-and-a-half months for TCC. The ulcer recurrence rate in this study was 87 percent. This recurrence rate is higher than the 20 percent rate reported for TCC (14). The reason for the differences in healing times and recurrence rate is probably multifactorial. This study was not randomized and the patients selected were biased toward difficult to heal cases. Because the TCAFO is bivalved, it is not as rigid as a cast, and thus, pressure relief is not as complete as with TCC. The pelite liner used in the TCAFO is compressible and this too may lessen its ability to relieve pressure. Patients in this study were very mobile, 61 percent reported improved ability to walk with the orthosis, and may have walked more than patients using TCC. Another factor is patient compliance; although only one patient was reported as being noncompliant, all of the patients stated that at night they would walk limited distances at home without their special footwear.

The cost of the TCAFO at our institution is approximately \$1,800. This is more expensive than casting; however, even with continuous use, the TCAFO usually lasted over a year. In addition, all of the patients who had a recurrence of their ulceration

were able to reuse their orthoses. Only one patient in this series required an amputation, and this patient had a diagnosis of osteomyelitis prior to receiving the TCAFO. Methods which prevent amputations have been shown to provide substantial cost savings to patients with diabetic foot ulcers (21). The TCAFO provided a long-term solution for patients who found walking painful, or who had ulcer or Charcot joint recurrence on resuming use of modified footwear.

Complications of the TCAFO were limited for the most part to skin redness and failure of the orthosis after prolonged wear. Because the TCAFO is removable, the patient and physician were able to monitor the foot continuously; thus, areas of redness were treated before skin breakdown could occur. The one patient who developed skin breakdown had a contralateral below-knee amputation and was attempting to walk with the TCAFO, but without his prosthesis. The subject slipped, resulting in a large shear, which caused a skin tear at the heel. This area of skin breakdown later healed through use of the TCAFO.

The TCAFOs offered the patient and the caregiver a number of advantages. The TCAFOs were well

tolerated, functional, and reusable. The majority of patients reported improved ability to walk while in the TCAFO. Physicians were able to monitor ulcerations and because of this, patients could become ambulatory prior to eradication of infection. The TCAFO provides the clinician with another useful weapon in the battle against neuropathic foot ulcers and Charcot joints. Further research into the effects of the orthosis on gait, and randomized studies comparing TCAFO to other forms of treatment are needed.

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