

Total Contact Cast for Neuropathic Diabetic Foot Ulcers

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ABSTRACT

Objective: To determine the outcome of diabetic neuropathic foot ulcers treated with Total Contact Cast (TCC) in terms of percentage of ulcers healed and time to heal.

Study Design: Analytical study.

Place and Duration of Study: Department of Orthopaedic Surgery, Abbasi Shaheed Hospital, Karachi Medical and Dental College, from April 2005 to March 2007.

Methodology: The study included diabetic patients with non-ischemic neuropathic foot ulcers of upto grade 2 of Wagner's classification. Ulcers were debrided off necrotic tissues and Total Contact Cast (TCC) was applied. TCC was renewed every 2 weeks till healing. Cases were labeled as cast failure when there was no reduction in wound size in 4 consecutive weeks or worsening to a higher grade. Main outcome measures were the percentage of ulcers healed and time to heal in the cast.

Results: Thirty four (87.17%) patients were males and 5(12.82%) were females. The mean age was 62 ± 13.05 years. All patients had NIDDM. Out of the 52 ulcers, 41(78.84%) healed with TCC in an average 2 casts duration (mean 32 days). There were 11(21.15%) cast failure. Majority (63.63%) of cast failure ulcers were located on pressure bearing area of heel. Most (90%) of the ulcers on forefoot and midsole region healed with TCC ($p < 0.001$). Longer ulcer duration (mean 57.45 ± 29.64 days) significantly reduced ulcer healing ($p < 0.001$).

Conclusion: Total contact cast was an effective treatment modality for neuropathic diabetic foot ulcers of Wagner's grade 2, located on forefoot and midsole region.

Key words: Neuropathic diabetic foot ulcer. Total contact cast. Diabetes. Foot deformity.

INTRODUCTION

Diabetic foot ulceration remains a serious health problem. Foot ulcers are the prime precipitant of diabetes related amputations of the lower extremity.¹ Ulceration is caused by several factors acting together but particularly by neuropathy.² The annual incidence of foot ulceration is slightly more than 2% among all patients with diabetes and between 5 and 7.5% among diabetic patients with peripheral neuropathy.^{3,4} Peripheral neuropathy results in loss of protective sensation of pain and in autonomic dysfunction with sympathetic denervation, dry skin, edema, clawing of toes, foot deformities caused by Charcoat joints and callus formation at pressure points.^{5,6}

The central goal of any treatment program designed to heal neuropathic foot ulcers is effective reduction in pressure or off-loading.^{7,8} Several off loading devices are available such as walkers, half shoes, orthotics, felted foam and Total Contact Cast (TCC). TCC is considered as the gold standard of ulcer treatment by

many experts in this field.⁹⁻¹¹ TCC involves a moulded and minimally padded cast that maintains contact with entire plantar aspect of foot and lower leg and keeps the weight off the foot when the patient is standing. TCC have been shown to reduce the pressure at the ulcer site by 84-92%.¹² Besides off-loading pressure, there is also reduction in shearing forces and edema of the foot. It thus optimizes the healing environment and prevents further wound injury. Healing rates of upto 90% are achieved with TCC in diabetic patients with neuropathic foot ulcers.^{13,14}

It is observed that neuropathic diabetic foot ulcers are generally treated in local clinics by simple dressings that result in either non-healing of ulcers or a longer healing time. This study was conducted to find the effectiveness of Total Contact Cast (TCC) in neuropathic diabetic foot ulcers in terms of percentage of healing and healing time.

METHODOLOGY

It was an analytical study conducted at the Department of Orthopaedic Surgery, Abbasi Shaheed Hospital, Karachi Medical and Dental College, from April 2005 to March 2007. All the patients with diabetic foot ulcers of upto grade 2 of Wagner's classification system (ulcers extending into soft tissues but not abscess or osteomyelitis),¹⁵ attending the Outpatient Department of the institute were included in this study. Patients with ulcers higher than grade 2 of Wagner's classification

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Received November 21, 2007; accepted October 5, 2008.

and moderate to severe limb ischemia¹⁶ (defined as absence of both pedal pulses on the affected foot and/or ankle brachial index of < 0.9 and / or transcutaneous oxygen pressure < 60 mmHg) were excluded from the study.

All patients provided written informed consent for inclusion in this study. A detailed history was taken from each patient intended to obtain information regarding the general biodata of the patient, duration and type of diabetes, duration of ulcer, any treatment taken for ulcer and any other co-morbid condition like ischemic heart diseases, renal or vision problem. General and systemic examination was performed. Detailed examination of involved foot were done to determine the ulcer location, size, shape, any discharge, tenderness or warmth. Ulcer depth was assessed with a sterile probe. Ulcers were graded according to Wagner's system. Sensation of the involved foot was tested using a 10-g monofilament and 128 Hz tuning fork. Neuropathy was defined as the patient's inability to sense the 10-g monofilament and vibration perception threshold > 25 V.¹⁷ Any foot deformity caused by neuropathy or Charcot joint such as clawing, cavus or valgus foot was noted. Vascular evaluation was done by checking pedal pulses (dorsalis pedis and posterior tibial), capillaries filling time to the digits, ankle brachial index, transcutaneous oxygen measurements and Doppler ultrasound studies. Aerobic and anaerobic cultures were taken from infected ulcers. A two projection X-ray film of the foot was obtained to exclude the presence of osteomyelitis and Charcot disease.

Ulcers were surgically debrided off all the necrotic tissues, periwound callus, foreign and infected material down to viable tissues, wound was then irrigated with saline and properly dressed with a povidone soaked gauze pad. For infected ulcers, appropriate antibiotics were given according to culture and sensitivity. Repeated debridements of infected wounds were done till the elimination of clinical signs of infection. Once the ulcer became clean, total contact cast was applied. It was a 5 - 6 layers Gypsona cast applied over cast padding, starting from one inch distal to fibular head and extending upto the tip of the toes, which were left open dorsally moulded to the exact contour of the leg and foot to provide maximum contact (Figure 1). The patients were then provided with a thin soft rubber cast shoe to walk on and advised to decrease their activity levels to possible extent.



Figure 1: Total contact cast with shoe brace.

Patients were followed fortnightly till the ulcer healed (defined as complete epithelialization). TCC was renewed every two weeks. On each visit, ulcer size was measured and any complication like chafed skin, any new ulcer

or pre-ulcer (defined as non-ulcerative lesion related to local pressure in the cast), or any joint problem was noted. Cast treatment was terminated when there was no reduction in wound size or depth during 4 consecutive weeks, when an infection greater than grade 2 developed, or when the patient had some discomfort with the cast. These cases were defined as cast failure. Main outcome measures included the percentage of the ulcers healed and time to heal (defined as number of days from baseline until healing in the cast).

Data was collected and analyzed on SPSS. Chi-square test of significance was applied to compare the qualitative data like location of ulcer and presence of foot deformity and student's t-test to compare quantitative data such as mean duration of diabetes, presence of other complications of diabetes, mean size and duration of ulcer at $p < 0.05$.

RESULTS

Forty one patients were enrolled in the study. Two patients were lost to follow-up, so finally there were 39 patients with 52 ulcers treated with total contact cast. Five patients had multiple ulcers. Two patients had recurrent ulcers; one in midsole plantar surface and other on plantar surface of 1st meta-tarsal head. Thirty four (87.17%) patients were males and 5 (12.82%) were females. The mean age was 62 ± 13.05 years. All patients had non-insulin dependent diabetes mellitus. Out of 52 ulcers, 41 (78.84%) ulcers in 28 (71.79%) patients healed with TCC in mean duration of 32 days (average two cast's duration). The remaining 11 (21.15%) ulcers in 11 (28.20%) patients did not heal in total contact cast and these cases were labeled as cast failure. Out of the 11 non-healing ulcers, 2 in midsole region worsened by progressive infection and these patients underwent below knee amputation. Similarly, 2 non-healing ulcers on ray 2 and 5 resulted in respective ray amputation. The rest of the 7 non-healed ulcers on heel did not respond to total contact casting and were also labeled as cast failure. When the treatment result were compared with location of the ulcer (Table I), it was found that out of 9 ulcers on heel, only 2 healed and the rest were cast failure ($p < 0.05$). All the ulcers on plantar surface of big toe and 1st metatarsal head healed in TCC ($p < 0.001$). Overall 90% of ulcers located on mid

Table I: Distribution of ulcers at different locations and their outcome.

Anatomical site of ulcer	Total number (%)	Healed number (%)	Non-healed number (%)	p-value
First metatarsal head (plantar)	18 (34.61)	18 (100)	0	$p < 0.001$ (s)
Midsole	12 (23.07)	10 (83.33)	2 (16.66)	$p < 0.001$ (s)
Heel	9 (17.30)	2 (22.22)	7 (77.77)	$p < 0.05$ (s)
Ray 2,3,4 (plantar)	5 (9.61)	4 (80)	1 (20)	$p > 0.2$ (n.s)
Ray 5 (plantar)	4 (7.69)	3 (75)	1 (25)	$p > 0.47$ (n.s)
Big toe (plantar)	4 (7.69)	4 (100)	0	$p < 0.03$ (s)

Key: n.s = non significant, s = significant

sole and forefoot areas (Figure 2) successfully healed in total contact cast. Table II shows the effect of different variables on treatment outcomes. Type and duration of diabetes, other complications of DM and ulcer size did not affect the result. Longer ulcer duration (mean 57.45 ± 29.64 days) had a negative effect on ulcer healing ($p < 0.001$). The presence of an obvious foot deformity had also yielded better result. The different neuropathic foot deformities encountered with ulcers included valgus, cavus and clawing of toes. Both the patients with recurrent ulcers on the same site had successful healing in total contact cast again.



Figure 2: Forefoot ulcer treatment with total contact cast.

Table II: Effect of different variables on treatment outcome.

Variable	Healed ulcers nou=41 nop=28	Non-healed ulcers nou=11 nop=11	p-value
Mean duration of DM (years)	12.64 ± 3.38	13.82 ± 4.87	$p > 0.395$ (n.s)
Other complications of DM (patient percent)	23 (82.14%)	10 (90.9%)	$p > 0.84$ (n.s)
Mean ulcer duration (days)	31.59 ± 16.57	57.45 ± 29.64	$p < 0.001$ (s)
Mean ulcer size (cm ²)	4.37 ± 2.95	3.27 ± 2.05	$p > 0.20$ (n.s)
Presence of foot deformity (patient percent)	16 (57.14%)	2 (18.18%)	$p < 0.02$ (s)

Key: DM= diabetes mellitus, nou= number of ulcers, nop= number of patients, n.s= non significant, s= significant, cm²= centimeter square

DISCUSSION

Addressing pressure reduction is a critical component of therapy in the management of diabetic foot wounds. The total contact cast has proved to be the standard treatment because of its ability to reduce pressure on the ulcer area and facilitate patient's adherence to the off-loading regimen.^{9,18} Though off loading can be achieved by several orthotics, but most of these are removable and strict compliance is not achieved thus reducing their effectiveness. TCC has the advantage that it cannot be easily removed by the patient and limits the activity of patients, which helps in rapid healing of ulcers.^{14,19} When correctly applied, it has proved not only to interrupt the chain of pathogenesis that produces the ulceration but also to induce modifications in the histology of the ulcer, shifting it from a chronic inflammatory state to a much more evolutive condition.¹⁹ Using TCC, majority of the ulcers in this study healed in a relative short time (mean 32 days). These results are

in accordance with international studies which report healing rates between 72-100% in times ranging from 1 month to several weeks.^{13,14,20}

The anatomical location of the ulcer affected healing rates in this study. All the ulcers on forefoot and most of midsole ulcers healed with TCC. Poor results were obtained in patients with heel ulcers. As suggested by previous biomechanical studies, the peak plantar pressures were markedly reduced in the forefoot with TCC; however, there was no effective reduction in elevated plantar pressures at the heel region. TCC achieves forefoot unloading by transfer of load from the leg directly to the cast wall and greater proportionate load sharing by the heel.²¹ Current studies, therefore, recommend that heel ulcers should be treated with TCC with the addition of a terminal cast device such as a rubber rocker heel or a flat rubber heel as these provide best hind-foot pressure reduction.²²

The duration of the ulcer had a negative effect on the time to heal in our study as also shown in other studies on wound healing.²³ Therefore, in patients in whom casting is considered, it should be started as soon as possible. Though infection was once thought a contraindication for TCC but recent studies recommend it for even superficially infected neuropathic ulcers without peripheral arterial disease.¹¹ Pre-requisites are close monitoring of the patient, repeated debridements and dressings and proper antibiotic cover. Once infection settles, TCC can be applied. In infected cases, a removable cast is rather a better option because it allows changing of daily dressing. In two patients, recurrent ulcers developed on foot during study period, which healed again in TCC. Repeated casting is as effective in recurrent ulcers as in primary ones.²⁴ Patients with obvious foot deformity yield better results because ulcers were due to mechanical derangement caused by diabetic neuropathy, which was corrected with TCC. Poor patient's compliance has been a problem with TCC which require repeated counseling and reassurance. Four patients, who underwent amputations, were because of progressive limb ischemia. TCC should not be applied in patients with limb ischemia. There was no significant complication with TCC in this study. TCC should be applied only by the experts who understand its mechanics.

The limitations of the study were the small number of patients (n=39) and the lack of control subjects for comparison. Prospective comparative studies are needed to evaluate the treatment outcome of diabetic neuropathic foot ulcers, treated with and without total contact cast.

CONCLUSION

Total contact casting is an effective treatment modality for neuropathic non-ischemic diabetic foot ulcers of

early grades, located on fore and midfoot areas. It should be brought in practice by clinicians dealing with diabetic foot ulcers.

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