

# Wound Healing Outcomes in Diabetic Foot Ulcer Patients Treated with Total Contact Casting: Results from an Observational, Longitudinal Study from March 2011-November 2014

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### Abstract:

**Objective:** Electronic medical records of 88 diabetic foot ulcer (DFU) patients treated with total contact casting (TCC) were analyzed to evaluate incidence of wound healing, treatment related adverse events, and ulcer recurrence. **Research Design and Methods:** This is a correlational, retrospective study of repeated measures from records of (DFU) patients treated with (TCC) between March 2011 and October 2014. This study excluded DFU patients with ischemic disease or active infection. All patients had polyneuropathy, 32% had Charcot arthropathy and 28% had a prior partial amputation. Ninety percent were Wagner grade 1 ulcers, 2% were Wagner 2 and 8% received antibiotic therapy for chronic osteomyelitis during their treatment. All DFUs were on the plantar aspect of the foot, 36% percent had forefoot ulcers, 21% had mid-foot ulcers and 9% had heel ulcers. The mean wound surface area at baseline was 14cm<sup>2</sup> and the average wound age was 4.5 months. Outcomes were: Incidence of complete closure in 12, 20, and 28 weeks, incidence of recurrence (defined as wound development in the same healed anatomical location), and device related adverse events. A traditional TCC was used in all patients and consisted of a minimally padded, well molded, and rigid (plaster plus fiberglass) construct that maintains contact with the entire plantar surface of the foot and lower leg. **Results & Conclusion:** At the 12 week time point, 83% of the patients treated with TCC had healed, 88% healed within 20 weeks and 96.5% healed by week 28. A significant difference was noted in the time to healing based on the location of the wound. The mean time to healing DFUs on the forefoot was 10 weeks compared 16 and 20 weeks for mid-foot and heel ulcers respectively (p=0.41). A direct correlation was observed between wound size and time to healing but not so for wound age. Wounds recurred in nearly 7% of patients within 1 month and 25% within 3 months. The most common adverse event was hip pain occurring in 8% of the patients. Superficial injury secondary to cast removal or friction from wear occurred 7% of the patients. Three patients (3.4%) were treated for superficial wound infections and another 3 (that had not healed) had unrelated medical complications and were lost to follow up.

### Introduction

Basically DFUs can be divided into 2 types: Neuropathic (70-90%) and Neuroischemic (10-30%).

TCC has been considered the "gold standard" for the treatment of neuropathic DFUs. There are 7 randomized, controlled trials and a meta-analysis with 498 patients that have proven its efficacy. In these studies healing rates have varied from 82%-95% within a 12 week period (1-3).

In this prospective data collection study, we assessed outcome and complications of TCC treatment in neuropathic patients with-

### Study Design

- Longitudinal, Observational, Retrospective Chart Review
- Primary Endpoint : Incidence of wound healing at 12, 20 and 28 weeks
- Secondary Endpoints: Incidence of ulcer recurrence & Adverse Events

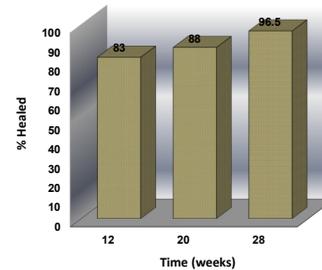
### Patient Characteristics

N	88
Sex (%male)	65
Age % (Max/Min)	58.5 (68/39)
Ulcer Location % (n)	Forefoot 36(32) Mid-foot 21 (18) Heel 9(8)
Mean Ulcer Area (cm <sup>2</sup> ± SD)	14 ±16.34
Wagner Grade (%)	1 (90), 2 (2), 3 (7)
Mean Ulcer Age months (max/min)	4.5 (18/2)
Charcot Foot % (n)	32 (28)
Osteomyelitis % (n)	8 (7)
Partial Amputation %	28 (25)

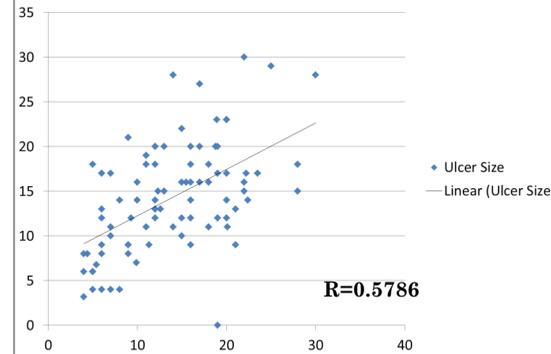
### References:

1. Consensus recommendations for advancing the standard of care for treating neuropathic foot ulcers in patients with diabetes. *Ostomy Wound Manage.* 2010; 56(4 Suppl):S1-24.
2. Armstrong DG, et al. Off-loading the diabetic foot wound. *Diabetes Care.* 2001; 24(6):1019-1022.
3. Van De Weg FB et al., Wound healing: Total contact cast vs. custom-made temporary footwear for patients with diabetic foot ulceration. *Prosthet Orthot International.* 2008; 32(1):3-11.

### Incidence of Complete Healing by 12,20 & 28 Weeks with TCC



### Correlation Between Ulcer Size and Time to Healing



### Incidence of DFU Recurrence & New Ulcer Development

	1 month follow-up	2 month follow-up	3 month follow-up
New DFU* % (n)	4.5 (4)	5.6% (5)	10.2 (9)
Recurring Ulcer** % (n)	6.8 (6)	18 (16)	25 (22)

\*A new DFU is the development of a new wound on another part of the foot  
\*\*Recurring DFU is the development of a new wound on the same anatomical location

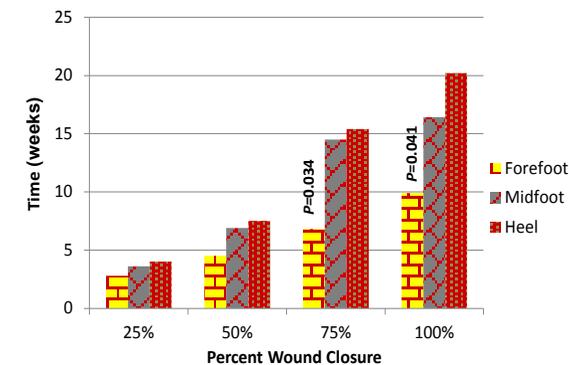


75532 at Baseline (A), Baseline after Debridement (B), Week-6 (C), Week-14 (D)



74040 at Baseline (A), Week-6, (B) and Week-12 (C)

### Time to Healing by Ulcer Location



**Conclusion:** This study supports previous findings that TCC is best-evidence based practice for the treatment of neuropathic DFUs. It seems to perform best for DFUs that are on the forefoot (over the MTJs). It is also effective for the treatment of mid-foot and heel ulceration (Charcot Foot) as well as ulcers in patients with structural deformity and partial amputations. All 7 of our patients that had osteomyelitis healed with a TCC and appropriate antibiotic therapy. In spite of appropriate orthotics and footwear, ulcer recurrence was high (25%) at the 3 month follow-up visit. Further studies are needed to evaluate the integrity of the skin/scar after long term TCC use.

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This retrospective review of patient records was exempt from IRB review in accordance with 45CFR46.101