A Clinical and Quantitative Assessment of the FORS™ Insole, a Novel Shoe-based Offloading System

Harry Penny, DPM, DABPM, FAPWAc, University of Pittsburgh Medical Center Altoona, USA, James McGuire, DPM, DABPM, FAPWHc Temple University School of Podiatric Medicine, PA, USA, Payam Rafat, DPM, AACFAS, FAPWH, Montefiore Mount Vernon Hospital, NY, USA, Enrico Brocco, MD, Chief Diabetic Foot Unit, Policlinico Abano Terme, Diabetic Foot Referral Center, Regione Veneto, Italy, David Bickers, CRNP, University of Pittsburgh Medical Center Altoona, USA, Emma Kreuz, Pre-Med, Juniata College, USA, Regino Flores, MS-I, Student Member APWH, Geisinger Commonwealth School of Medicine, USA, Peter Zaki, MS-3, Student Member APWH, Penn State College of Medicine, Adam Weaver, MS-3, Student Member APWH, Philadelphia College of Osteopathic Medicine, USA, David Sylvester, Pre-Med, Lehigh University, Chad Allender, Pre-Med, Saint Francis University, USA, Mark Zaki, MS-2, Student Member APWH, Harvard Medical School

Abstract:

Purpose:
Although, the Total Contact Cast (TCC) has been recognized as the "gold standard" for the treatment of plantar diabetic foot ulcers, only a very small minority of clinicians who identify themselves as wound experts (1.7%-6%) use TCCs.[1] Our purpose is to present an alternative to TCCs and to evaluate the effectiveness of the FORS™-15 Off-Loading Insole device in a patient-based series of diabetic foot ulcers. We also discuss how use of the FORS™-15 insole may reduce ulcer recurrence while transitioning patients from the TCC to their final footwear.

Method:
Patients were selected based on previous non-compliance, contraindication to TCC, or failure of other off-loading modalities. Also, the FORS™-15 was implemented in patients transitioning out of TCC until full recovery. While not a specific requirement for selection, many patients had chronic wounds of minimum one month to one year or longer that had failed to heal using other offloading methods. FORS™-15 insoles were customized by removing plugs from the bottom of the insole that correspond to ulcer location, then inserting the insole into a surgical rocker-bottom inlay shoe provided to the patient. Wound dimensions were recorded and photographed with each visit to the wound clinic. Average pressure reduction provided by the FORS™-15 insole was also quantitatively assessed and analyzed via F-Scan™ in-shoe dynamic pressure measuring system by comparing plantar pressures with simulated ulcers in standard surgical rocker-bottom inlay shoes that included the standard inlay versus shoes where the standard inlay was removed and replaced with the FORS™-15 insole.

Results / Discussion:
In four independent trial sites (3- U.S., 1- Italy) patients using FORS™-15 insoles consistently demonstrated a high level of compliance with the device, and ulcer healing rates appeared comparable to those produced by TCC. Patients rated FORS™-15 insole as more comfortable and convenient than other offloading modalities. Features of the FORS™-15 include an Alcantara® top cover that minimizes shear forces/slippage and absorbs moisture, a polyurethane foam construction providing durable cushioning and shock absorbance, and a fabric mid-layer minimizing collapse and "edge effects". In total, >30 patients with plantar ulcers were treated using the FORS insole for offloading as part of the four independent evaluations. Wound closure was achieved in 100% of patients at Montefiore Mount Vernon Hospital in an average of 9.6 weeks. Similarly positive results were observed at UPMC Altoona, TUSPM , and PATDFRC with compliant patients; though non-compliant patients were included in the evaluation.

Non-Compliant Ambulator

10 weeks

A 38-year-old male with poorly controlled type 2 diabetes and a HgbA1C of 10 recently completed a research trial on a placental tissue graft and healed completely. He presented with a new wound after returning to his regular footwear. He was treated with debridement and offloading with the FORS Insole and healed in 5 weeks.

2/03 Start → 1.3 x 1.2 x 0.3 cm.
4/11 → Closed

Tunneling Wound /Gangrene

9 Weeks

A 67 year old diabetic male presents to wound care center following recent left foot partial fourth and fifth ray amputations. The wound was tunneling from the dorsal lateral aspect and exiting through the plantar aspect of the left foot.

6/2 Start → 2.5 x 2.3 x 5.5 cm
7/07 → 1.2 x 0.9 x 1.2 cm
8/04 → Closed

Charcot w/ Tunneling Wound

7 Weeks

A 71-year-old male with type 2 diabetes with diabetic neuropathy, active Charcot, peripheral vascular disease and bipolar disorder hospitalized with cellulitis and an infected ulcer. Patient was noted to be non-compliant and encountered a claustrophobic episode when the Total Contact Cast was removed.

8/25 Start → 0.4 x 0.5 x 3 cm
9/15 → 0.4 x 0.5 x 1.4 cm
10/13 → Closed

Recalcitrant Ulcer

5 weeks

A 68-year-old woman with type 2 diabetes with a neuropathic Charcot foot, presented with a non-healing surgical wound. Patient has history of noncompliance, contact cast complications, and osteomyelitis.

7/18 Start: → 0.7 x 0.3 x 0.7 cm
8/01 → 0.5 x 0.5 x 0. 2 cm
8/22 → Closed

Additional Cases:

5 Weeks

8 Weeks

16 Weeks

11 Weeks

2 Weeks

11 Weeks

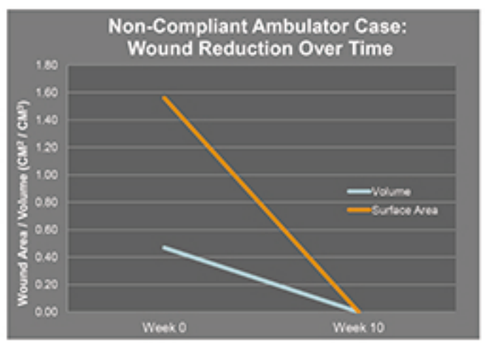
6 Weeks

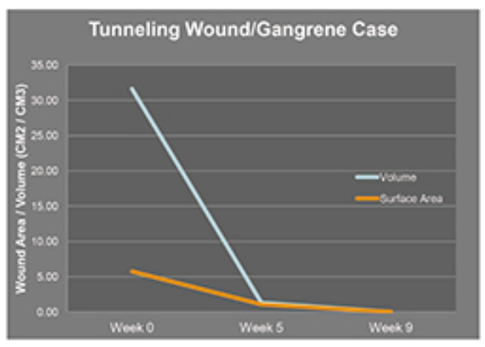
8 Weeks

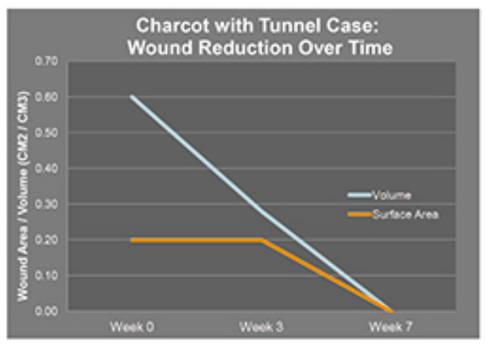
8 Weeks

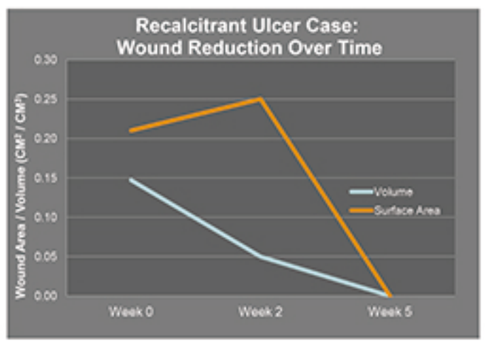
5 Weeks

Data & Conclusion:









The FORS™-15 Insole, combined with a surgical rocker-bottom inlay shoe, provides an effective shoe-based alternative to Total Contact Casting for plantar offloading, with no observable contraindications in this study. Sub-metatarsal pressure measurements during gait analysis using the F-Scan™ in-shoe dynamic pressure measuring system showed an average pressure reduction of 24.3% with use of the insole without alteration. With the pixels removed, the pressure was reduced by 43.4%, reflecting an average additional pressure reduction of 19.1% when the pixels were removed. When used in conjunction with modern wound care techniques, the FORSTM-15 insole improved patient compliance, reduced healing times, reduced DFU recurrence rates, and reduced amputation and mortality rates in comparison with other shoe-based approaches we have used.

The FORS™-15 insole is a viable, cost-effective, highly durable, and easy-to-use alternative to the total contact cast offloading system that should be seriously considered when TCC is contraindicated, impractical, or when patient compliance is a concern. Considering that 20% of ulcers reoccur within 90 days[2], consideration should also be given to using the FORS™-15 insole as a transitional method of treatment out of the total contact cast until patients are fitted for their final diabetic shoes.

References

1. Fife CE, et al; "Why is it so hard to do the right thing in wound care" Wound Rep Reg : 18 p 154-158 2010
2. Diabetic Foot Ulcers and Their Recurrence, David G. Armstrong, D.P.M., M.D., Ph.D., Andrew J.M. Boulton, M.D., and Sicco A. Bus, Ph.D., N Engl J Med 2017; 376:2367-2375, June 15, 2017, DOI: 10.1056/NEJMra1615439
3. Boulton AJ. Pressure and the diabetic foot: clinical science and offloading techniques. Am J Surg 2004;187(5A):17S-24S.
4. Brill LR, Stone JA. New therapeutic options for lower-extremity ulcers: adequate debridement, control of infection, off-loading of pressure, and appropriate topical management are the most important interventions in treating nonhealing wounds. New treatments such as recombinant human growth factors and skin substitutes can help expedite healing. Patient Care 2004; 38(10): 23-31.
5. Bus SA, van Deursen RW, Armstrong DG, Lewis JEA, Caravaggi CF, Cavanagh PR. Footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes: a systematic review. Diabetes Metab Res Rev 2015; 32(Suppl. 1): 99-118.