

A Newly Available Customizable Multi-Density Insole for Offloading of Plantar Diabetic Foot Ulcerations: A Case Series

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Abstract

PURPOSE:

This case series is presented to demonstrate the safety and efficacy of a newly available customizable multi-layered multi-density urethane foam insole with removable plugs to aid in pressure reduction for the treatment of plantar diabetic foot ulcers.

BACKGROUND:

Offloading is a key element for the management of diabetic foot ulcers. Total contact casting is the gold standard for focal pressure reduction of plantar diabetic foot ulcers. There are times, however, where its use is not desirable and even possibly contraindicated. In situations where total contact casting is not the most feasible off-loading modality, this product offers an offloading option for use in a post-operative shoe.

METHODS:

10 patients with varied plantar foot ulcerations were dispensed a customized offloading insole fitted into a rocker-bottom shoe. Utilizing this offloading modality, combined with local wound care the patients were followed weekly for the duration of treatment. Wound size and choice of local wound care were recorded at weekly visits. At the end of the study, patient compliance, patient-reported satisfaction, and any complications were recorded.

RESULT:

All of the patients showed excellent compliance with no major complications at the end of the study.

CONCLUSIONS:

Preliminary observation has shown that the use of the customizable multi-density offloading insole, when used in conjunction with a rocker-bottom surgical shoe, is a safe and effective modality for the treatment of plantar diabetic foot ulcers. Furthermore, when indicated, the use of this newly available multi-density insole pressure reduction device, in conjunction with modern wound care techniques, can dramatically reduce the severity of wounds, decrease healing times, and reduce amputation rates

Background

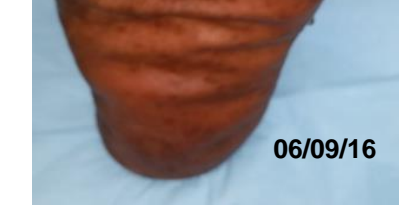
The treatment of diabetic plantar wounds is a long and trying process. Patient compliance and offloading as well as medical optimization are key components to successful healing. Total contact casts are successful offloading devices but patient dissatisfaction to the treatment option hinders its favorability. We theorized that the FORS insole is a safe and cost effective method for the reduction of plantar foot pressure and shearing forces. We propose it is an acceptable alternative for offloading of plantar foot wounds when total contact casting is not available, not favorable or is contraindicated. This offloading option allows for daily wound inspection and dressing changes. It also allows for adjunctive treatment options such as the use of Negative Pressure Wound Therapy. This offloading option also has a decreased risk for fall injuries compared to total contact casting.

Materials and Method

Ten patients with chronic diabetic foot ulcerations were fitted for multidensity offloading insoles (FORS™-15 Insole, Bonapeda, LLC) customized with removable plugs and used in conjunction with rigid rocker bottom shoes. Patients were monitored weekly and received concurrent local wound care. Patients were followed until wound closure. At the end of the study, patient compliance, comfort of use and patient satisfaction were analyzed.

Case Study:

A 58 year old diabetic male with a prior history of partial left hallux amputation presented to the wound care center with a chronic ulceration of the plantar medial aspect of the left hallux.



Insert customized for pressure reduction and use in rocker bottom surgical shoe

Case Study

A 60 year old diabetic male was admitted to the hospital through the emergency room due to an infected plantar wound resulting from stepping on a nail.

Surgical debridement was performed. The patient was discharged home from the hospital with antibiotics as per ID physicians recommendations.



Insert customized for pressure reduction

Case Study

A 40 year old diabetic male with a prior history of bilateral trans-metatarsal amputations present to the wound care center referred by his orthopedic surgeon for management of chronic ulceration of the plantar aspect of the right foot of greater than six months duration.



Insert customized for pressure reduction

Case Study

A 67 year old diabetic male presents to wound care center following recent left foot partial fourth and fifth ray amputations with a tunneling wound exiting the plantar aspect of the left foot.



Post op 2 weeks following partial 4th and 5th ray amputation



Case Study

A 72 year old diabetic male presented to the wound care center referred by his private podiatrist for a chronic plantar foot ulcer of the right foot.



Insert customized for pressure reduction and use in rocker bottom surgical shoe



Application of Amniotic Membrane Allograft

Case Study

A 50 year old diabetic male presented to the wound care clinic with a chronic plantar midfoot diabetic ulcer of right foot.



Insert customized for pressure reduction

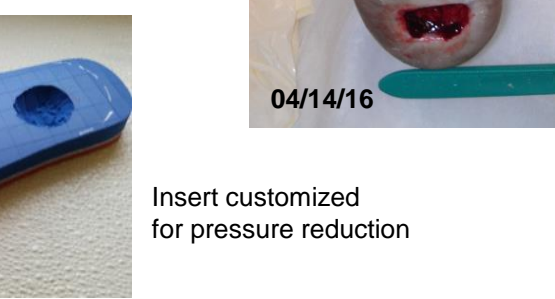


Case Study

A 59 year old diabetic female with ESRD on hemodialysis presents to wound care center referred by her primary care physician for a chronic heel ulceration. Patient has developed an abscess of the right heel after stepping on a nail.



Insert customized for pressure reduction



Case Study

A 45 year old diabetic male presented to the wound care center referred by a local hospital podiatry clinic for a chronic diabetic foot ulcer with a prior history of underlying osteomyelitis.

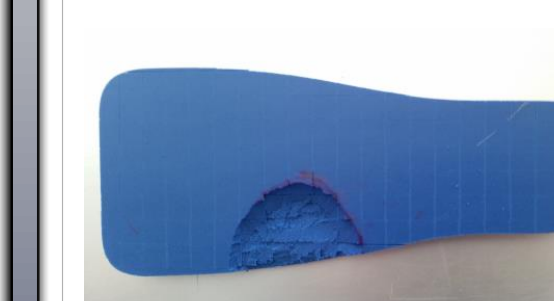


Insert customized for pressure reduction.

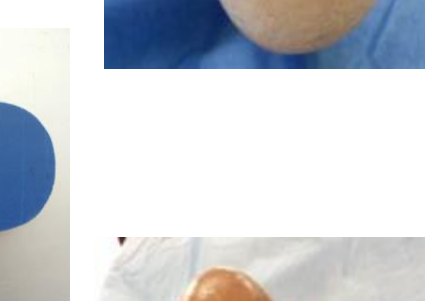


Case Study

A 39 year old diabetic male presents to wound care center following partial right foot fifth ray amputation and chronic ulcerations to right plantar lateral foot. Patient has had a history of prior partial second toe and hallux amputation.



Insert customized for pressure reduction.



Analysis & Discussion

Total contact casting is considered the gold standard of offloading for diabetic patients with diabetic foot ulcers.¹ However, total contact casting is not without its drawbacks. An inability to perform frequent wound inspection for treatment, gait disturbance,² increased fall risk, reduced quality of life and patient acceptance are potential limitations of its use.³

The purpose of this study was to determine whether the FORS-15 multidensity insole was a viable alternative for offloading in patients with plantar diabetic foot ulcer ations when total contact casting is either contraindicated or not desirable.

Due to the limited number of cases, the authors cannot formulate any definitive conclusions; however, the authors do note favorable patient satisfaction and final outcomes with use of the customizable multi-density insoles for offloading of plantar diabetic foot ulcerations. Benefits of this removable device over the TCC include: versatility in wound care modality options, allowing frequent wound inspections, decreasing fall risk, improving cost effectiveness and increasing patient comfort.

In the presented cases complete wound closure was achieved and in an average of 9.6 weeks from the start of implementation of this offloading modality.

The authors have found that the use of this newly available customizable multi-density insole may provide an affordable offloading alternative that can be utilized to minimize plantar pressures. Further long term studies are needed to evaluate its use as an alternative to total contact casting.

References

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3. Crews RT, Shen BJ, Campbell L, et al. Role and Determinants of Adherence to Off-loading in Diabetic Foot Ulcer Healing: A Prospective Investigation. Diabetes Care. 2016;39(8):1371-7.