It's About Time (and Pressure)!

New technologies reduce mechanical forces in patients with diabetic foot ulcerations.

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Disclaimer: *Dr. Landsman is a consultant for Defender.*

Introduction

One out of every 10 Americans has diabetes,[1] and this translates to over 2 million diabetic foot ulcers and 100,000 amputations every year.[2] In fact, more diabetics are admitted to the hospital for foot ulcer complications than any other diabetes-related complication.[3] Numerous studies have been performed to determine the causes and treatments for ulcerations, and most reach the conclusion that neuropathy combined with abnormal, repetitive mechanical forces play a significant role in this process.[3]

Unfortunately, neuropathy is progressive and irreversible, but one can take action to control the mechanical aspects of wound formation and promote healing. Over 50 years ago, Dr. Paul Brand, working with patients suffering from neuropathy due to leprosy, demonstrated that repetitive mechanical stress led to soft tissue breakdown, and ultimately ulceration.[4] He proposed a system of casting to protect the insensate limbs that we know today as the Total Contact Cast (TCC). This is a highly effective technique that is designed to transfer mechanical forces from a few small areas across the bottom of the foot to a larger surface area, to help dissipate forces across the entire foot and lower leg. This process of "off-loading" has proven to be one of the most powerful tools available to help to heal diabetic foot ulcers and prevent new ulcer formation.

Using a mix of materials, sustained focal pressure is reduced and shock absorption is improved by different components of the boot.

In Dr. Brand's day, he was able to develop and implement the total contact cast system in the remote setting of a US Public Health Service Hospital in Carville, Louisiana, with sequestered patients in a tightly regulated living environment. This is quite different from most clinical practices today. Patients are only managed by their doctors for an hour or less per week, and are working, traveling, spending time with their families, while they are actively walking and standing for extended periods every day. Although TCC remains the gold standard for controlling lower extremity mechanical forces, they are technically difficult and time-consuming to apply, can result in iatrogenic complications, and patients find them impractical. Consequently, the utilization of TCC remains extremely low, multiple papers report total utilization at less than 2% of the available wounds.[5]

To provide patients with a more user-friendly option, orthopedic removable fixed ankle boots, often called CAM (Controlled Ankle Motion) walkers were adopted for the treatment of diabetic foot ulcers. These CAM walkers have been shown to be somewhat effective at reducing the mechanical forces to the plantar surface of the foot and provided some off loading.[5,6] Early CAM walker designs were simply devices used to treat traumatic injuries and were designed to decrease motion at fracture sites, rather than redistribute pressure points to the skin. As such, most fell short in controlling the ground reactive forces that cause ulcers.

There have been better modifications that take existing CAM walker designs and modify them by placing a more compliant insole on top of the existing footbeds, but these devices still fall short. More recently, a removable device has been designed "from the ground up", specifically to dissipate mechanical forces on the foot. In this paper, the authors will be examining this device, **The Foot Defender**®.

Description

In designing The Foot Defender®, the engineers began with a clean slate to create a protective walking device that mimicked a total contact cast and was designed to dissipate the complex mechanical ground reactive forces that are known to cause foot ulcerations in diabetic and other neuropathic patients. These modifications were integrated into a device that uses modern materials and textiles while more closely conforming to the shape of the

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New Concepts and Studies

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foot and lower leg. By increasing contact and conformity between the boot and the lower leg, the surface area is greatly increased to more effectively dissipate mechanical forces.

Using a mix of materials, sustained focal pressure is reduced and shock absorption is improved by different components of the boot. For example, while walking or standing, some materials compress and deform quickly to attenuate shock, while others slowly compress in response to sustained loads. Semi-rigid struts placed throughout the boot further help to transfer forces beyond the foot to the lower leg. Integrated air bladders further customize the fit to the shape of each patient's foot and lower leg.

Historically, the greatest difficulty with off-loading devices has been patient compliance. In the case of The Foot Defender®, the real breakthrough occurred when this engineering and materials science was given to a world-renowned footwear designer. The designer was tasked with incorporating this advanced science into a device that was easy to use and patients would want to keep on their feet. After years of effort and over 30 iterations, the Foot Defender® was born. (Figure 1)

Figure 1: The Foot Defender®—The Foot Defender® is a new concept in protecting and reducing pressure to the foot for patients with diabetic foot ulcers. This device includes many different and unique advances and comes in an attractive and easy-to-use package that encourages patient compliance.

Objectives

The objective of this investigation is to assess the forces measured on the plantar surface of the foot while standing and walking in a Foot Defender® as compared to other standard CAM walkers to illustrate how this combination of materials and unique design protects the foot. In addition, a clinical case series was conducted to demonstrate the efficacy of The Foot Defender® in the management of diabetic foot ulcers.

Methods

Using the Tekscan F-Scan (Tekscan; Boston, MA) in-shoe pressure transducer, peak pressures were measured across the plantar surface of the foot while walking (dynamic) and while standing (static). Walking tests were performed with footwear used to reduce pressure. The devices utilized were The Foot Defender®, two brands of commonly used CAM walkers, and a standard boot with insole modifications consisting of foam insole. In addition, comparisons were made to the TCC-EZ® system (Integra Lifesciences, New Jersey), and a construct which used the fiberglass portion of the TCC-EZ® cast, but with the Foot Defender® boot.

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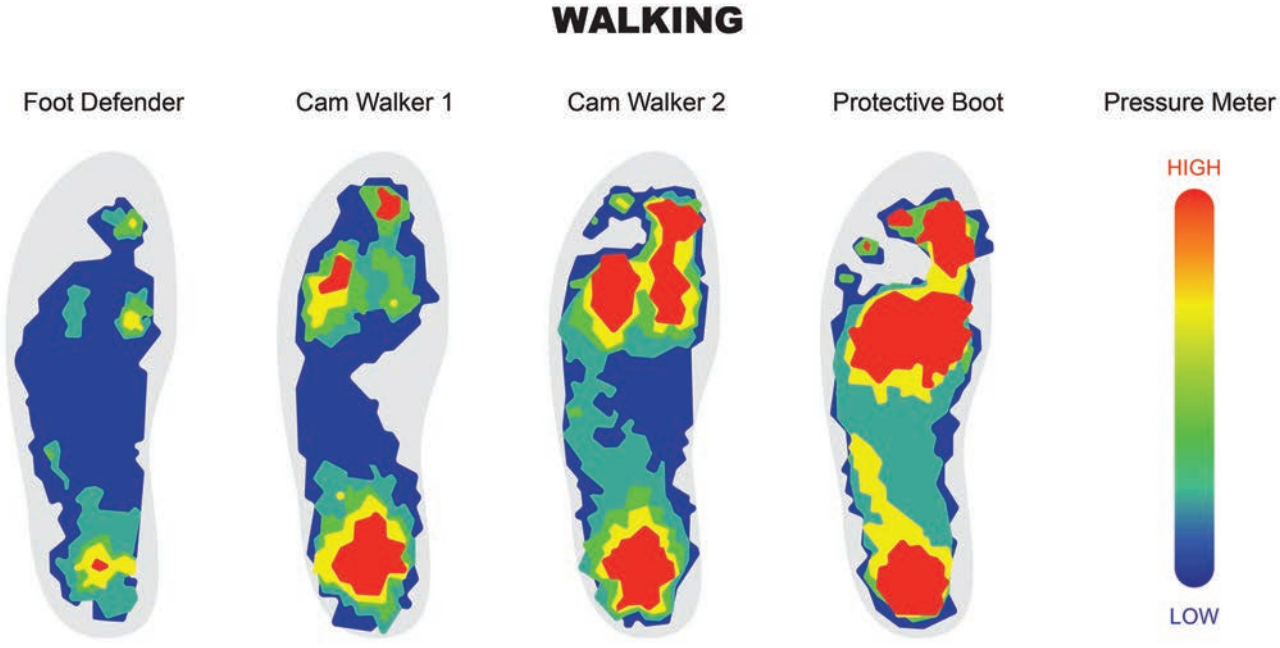

Figure 2: Average maximum pressure while walking with Foot Defender® and other devices designed to reduce pressure to the sole of the foot.

This colorimetric diagram illustrates the average pressures experienced by the same user walking on a treadmill for 3 minutes, at 1.5mph, with 4% grade. There are significant differences in the magnitude of pressure across the entire plantar surface of the foot that the user experiences with the Foot Defender® as compared to the other devices. For reference, dark blue areas represent pressures of 4-5psi, and red areas represent pressure in excess of >20psi.

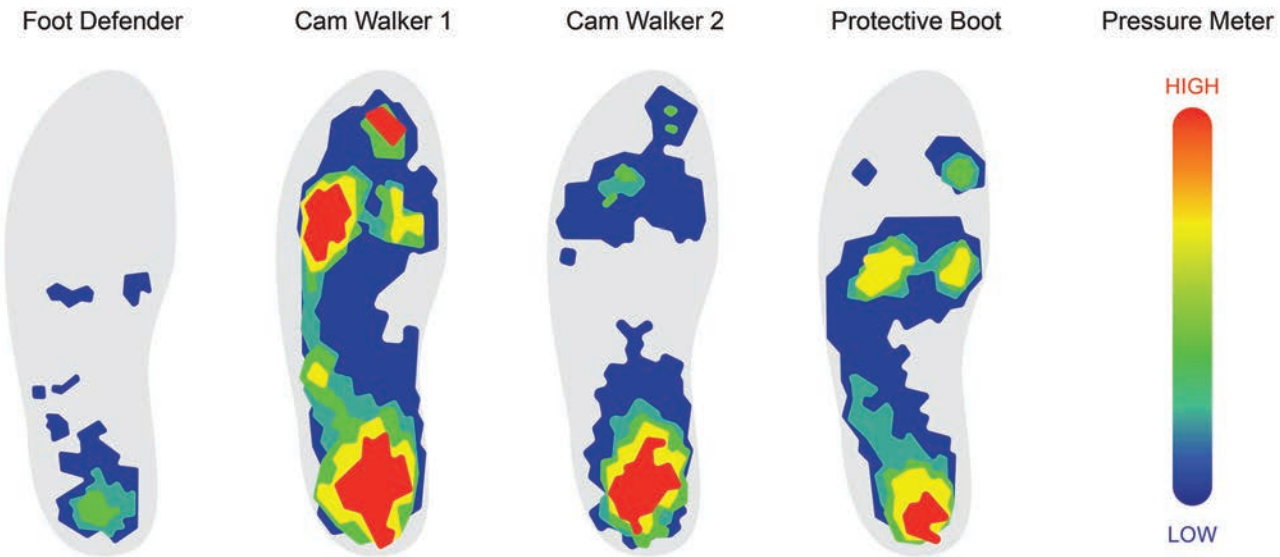

Figure 3: Average peak pressure while standing with 4 different types of footwear.

Data represents pooled data while standing in place for 30 seconds. In this sample using the same subject, it is apparent that The Foot Defender® was much more effective in reducing the peak pressures, as compared to the other devices tested. For reference, dark blue areas represent pressures of 4-5psi, and red areas represent pressure in excess of >20psi.

Tests were performed on 3 subjects with a BMI ranging from 26-33, with matched shoe sizes. Each walked on a treadmill at 1.5mph, with a 4% grade. Data was collected for 3 minutes at 750Hz, with initial and last steps discarded. Pooled averages for each type of footwear were created.

A second set of data was collected to measure peak pressures encountered in static stance (i.e., while standing). The same subjects stood for 30 seconds while data was collected at 750Hz, using the same footwear. Pooled averages for each type of footwear were created.

Results

The insole pressure mapping system allowed for collection of data between the sole of the foot and the most superficial surface of the footwear device being tested. Pressure mapping performed under both dynamic and static conditions were analyzed separately.

Sample data shown in Figure 2 demonstrates significantly less pressure to the bottom of the foot when comparing The Foot Defender® to the other devices tested while walking (i.e., Dynamic test). It is interesting to note that CAM Walker #1 and #2 were both superior to the Protective Boot, but neither CAM Walker offered much protection to the forefoot and heel, when compared to The Foot Defender®.

The results of the Static test also demonstrated a clear advantage when using the Foot Defender® as compared to the two CAM walkers and the protective boot (Figure 3). It is interesting to note that while standing, the Foot Defender® puts almost no weight on the forefoot and redistributes the pressure to the heel as well. In essence, the foot appears to be gently suspended above the surface of The Foot Defender® platform, transferring the pressure to the upper parts of the foot and leg, not measured with this insole device.

A more detailed analysis was also performed with the data from the dynamic test. In this analysis, pressure measurements were separated into 4 regions, (a) average across the entire forefoot, (b), average beneath the entire heel area, (c) average beneath the 1st metatarsal head, (d) average beneath the central metatarsal heads (i.e. 2-4). Separate analyses were performed for each combination of footwear devices tested.

The Foot Defender® puts almost no weight on the forefoot and redistributes the pressure to the heel as well.

Data from the Foot Defender®, Foot Defender® with cast extension, 2 types of CAM walkers, a protective boot with foam liner, TCC-EZ® total contact cast/boot, and a hybrid construct using the TCC-EZ® fiberglass portions with a Foot Defender® boot, were all compared. The composite data is shown in Figure 4.

a. Foot Defender® vs. CAM Walker and Protective Boot

In all regions, the Foot Defender® is significantly better at reducing pressures as compared to the 2 CAM Walkers and the Protective Boot. The calf extension added to the Foot

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Defender® resulted in only slight improvement in pressure reduction as compared to the boot used in its regular form.

b. Foot Defender® & TCC-EZ®

TCC remains the gold standard when it comes to off-loading. But the TCC as described by Brand is technically difficult to apply, and can cause secondary ulcerations if not applied correctly. The modern version of the TCC is much more forgiving. It still utilizes a hard cast but replaces the handmade wooden platform and walking heel with a CAM Walker style boot. Pressure reduction in the standard Foot Defender® was shown to be nearly as effective at reducing pressures as the TCC-EZ® system, without the inconvenience and complications that can occur when using a hard cast on a neuropathic patient.

When The Foot Defender® boot is substituted for the CAM Walker style boot that comes standard with the TCC-EZ® system, the reduction in pressure with the fiberglass cast and The Foot Defender® surpasses the original system.

In this small sample, 100% of the wounds closed and the average time to closure was 5.28 weeks following initiation of treatment with The Foot Defender®.

Gait Study Conclusions

The Foot Defender® is the newest tool in the battle to achieve wound closure in patients with diabetic foot ulcers. The concept of off-loading a neuropathic or diabetic foot ulcer has been used successfully for nearly 3 decades. Many clinicians have moved towards a simpler device, that can be removed for local wound care, but at the same time provide greater comfort, in order to increase patient compliance. Unfortunately, most of these boots are less effective at protecting the wound site, are uncomfortable for the patient, and are esthetically not pleasing, leading to widespread non-compliance.

The Foot Defender® has broken the mold by developing a boot that is highly effective at reducing plantar pressures and yet is comfortable, easy to use, and esthetically pleasing.

Case Series

In a recent clinical case series pilot study, 10 patients with diabetic foot ulcers already treated for a minimum of 4 weeks by a wound care professional and using other offloading devices were invited to switch to The Foot Defender®.

The wounds examined averaged 3.73cm2 in size at the initial date of treatment.

In this small sample, 100% of the wounds closed and the average time to closure was 5.28 weeks following initiation of treatment with The Foot Defender®.

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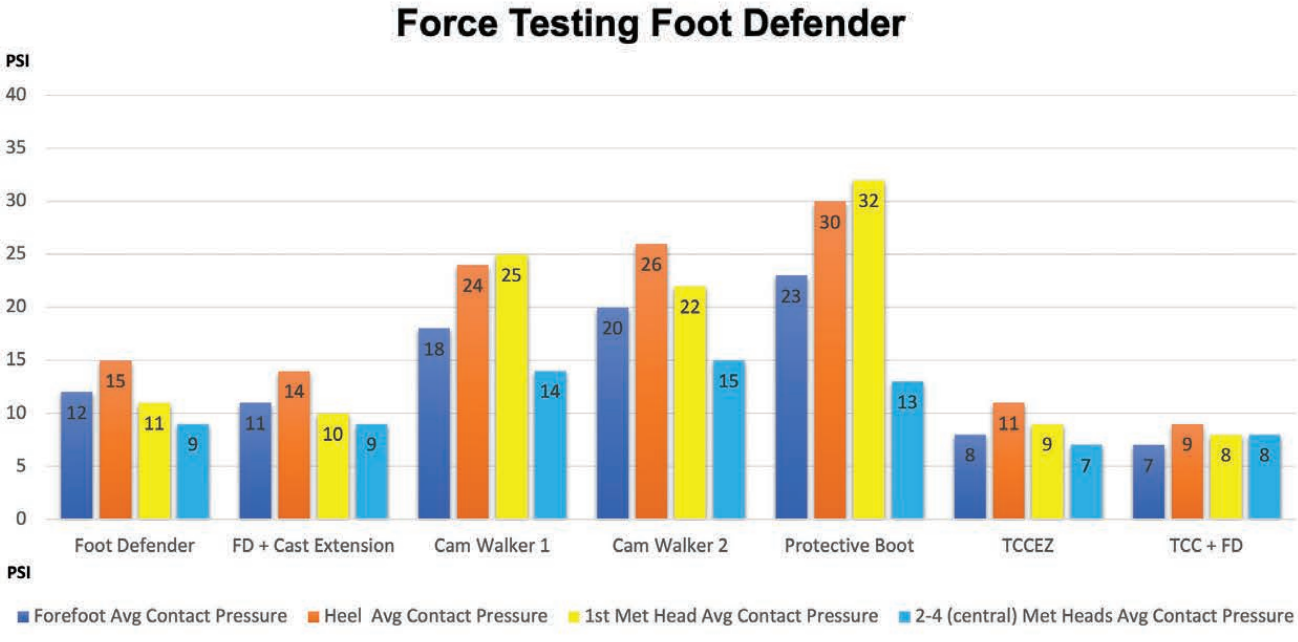

Figure 4: Average contact pressure while walking (Dynamic) separated into various regions of the foot.

Data demonstrates that in all regions of the foot, pressure reduction with the Foot Defender® is superior to both CAM Walker devices as well as the Protective Boot with foam liner. In addition, the Foot Defender® is comparable in efficacy to the TCC-EZ®, and the TCC-EZ® is slightly improved when the Foot Defender® boot is substituted for the standard CAM Walker boot used with the TCC-EZ® device.

Numbers represent pressures in PSI.

TABLE 1

Early Clinical Results

This is data from a few early adopters of the Foot Defender® which show excellent clinical outcomes and enthusiastic patient compliance.

Boot Size	Ulcer Location	Area (cm2)	Time to Closure (weeks)	Patient Comments
XL	DFU sub 5th met	4.4	4	"Best walker I have worn" (previous Aircast user)
L	DFU sub 1st met	1.8	6	"Best boot I have used in 5 years"
M	DFU sub 1st met	3.5	4	Subject will not return device, "best ever"
M	DFU sub 2nd MPJ	6.6	7	"Best boot I have had, and this is my 4th"
L	DFU under cuboid w/charcot	4.8	5.5	
L	DFU sub 5th met	4.4	6	"Milagro" (miracle)
L	DFU sub 1st MPJ	2.5	5.5	"Love it I want one for both feet" and "Better than shoes"
M	DFU hallux and second met	1.6	3.3	
M	DFU sub 5th met	3.2	5	"How do I buy a pair?"
L	DFU sub 1st MPJ	4.5	6.5	"My favorite of all the boots I have worn"
	AVERAGE	**3.73**	**5.28**	

When asked what their impression of The Foot Defender® was, all of them mentioned considerable satisfaction with the device itself. A summary of the clinical data is shown in Table 1.

Discussion

The Foot Defender® is a breakthrough device in the treatment of diabetic foot ulcerations. Initial data indicates that it provides far superior off-loading to that provided by traditional CAM Walkers or protective boots. Early clinical date points to the Foot Defender® being highly effective at healing diabetic foot ulcers while encouraging and enhancing patient compliance.

The Foot Defender's® combination of purpose-built design, engineering and attention to the patient's needs for comfort, ease of use, and style, will encourage patient utilization. A functional device that patients will actually use may be the biggest advantage of all. **PM**

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