Received: 3 July 2022 | Revised: 31 July 2022 | Accepted: 8 August 2022

DOI: 10.1111/iwj.13932

ORIGINAL ARTICLE

IWJ WILEY

A single arm prospective feasibility study evaluating wound closure with a unique wearable device that provides intermittent plantar compression and offloading in the treatment of non-healing diabetic foot ulcers

David G. Armstrong[1] | Dennis P. Orgill[2] | Paul M. Glat[3] | Robert D. Galiano[4] | Zachary L Rasor[5] | Adam Isaac[5] | Marissa Carter[6] | Charles M. Zelen[2]

[1]Division of Surgery, Keck School of Medicine, University of Southern California, California, Los Angeles, USA

[2]Division of Research, Professional Education and Research Institute, Roanoke, Virginia, USA

[3]Departtment of Surgery, Drexel University School of Medicine, Philadelphia, Pennsylvania, USA

[4]Division of Plastic Surgery, Feinberg School of Medicine, Northwestern University, Chicago, Illinois, USA

[5]Foot and Ankle Specialists of the Mid-Atlantic (FASMA), Frederick, Maryland, USA

[6]Strategic Solutions, Bozeman, Montana, USA

Correspondence
Charles M. Zelen, DPM, FACFAS, FACFAOM, Professional Education and Research Institute, LLC, 222 Walnut Ave, Roanoke, VA 24016, USA.
Email: cmzelen@periedu.com

Funding information
Compedica, Grant/Award Number: 001

Abstract

The incidence and economic burden of diabetic foot ulcers continues to rise throughout the world. In this prospective study, a unique device designed to offload the wound, enhance circulation and monitor patient compliance was evaluated for safety and efficacy. The device provides offloading and intermittent plantar compression to improve the pedal flow of oxygenated blood and support wound healing while recording patient use. Ten patients with non-healing diabetic foot ulcers UTgrade 1A/Wagner grade 1 were treated weekly for up to 12 weeks. The primary endpoint was complete wound closure at 12 weeks, and secondary endpoints included healing time, percent area reduction and changes in pain using the visual analogue pain scale. Eight out of ten wounds healed within 12 weeks(80%), and the mean healing time was 41 days (95% CI:24.3–58.3). The percent area reduction was 75(SD:53.9). The baseline visual analogue pain scale was 4.5(2.9) as compared with 3.3(3.4) at end of study. No device-related or serious adverse events were reported. This unique intermediate plantar compression and offloading device may be considered as an alternative for safe and effective for treatment of non-healing diabetic foot ulcers. During treatment, wound healing was significantly accelerated, and pain was improved. Larger randomised controlled trials are underway to validate these early findings.

KEYWORDS

diabetic foot ulcer, intermittent plantar compression, offloading, wound healing

Key Messages

- plantar intermittent compression may be advantageous to healing recalcitrant diabetic foot wounds

- diabetic foot ulcers undergoing treatment with a unique wearable device with a compliance monitor was designed to offload and enhance circulation demonstrated accelerated healing and decreased pain
- eight out of ten UT grade 1A/Wagner grade 1 diabetic foot ulcers healed within 12 weeks of treatment and the mean healing time was 41 days

1 | INTRODUCTION

The incidence and economic burden of diabetes and lower extremity ulcers continue to rise throughout the world, and non-healing ulcers are at increased risk for complications such as infection and amputation. The likelihood of a patient developing a diabetic foot ulcer (DFU) at some point during their lifetime is 34%, with an estimated 9.1–26.1 million people worldwide developing a DFU every year.[1] In fact, more than half of all DFUs become infected,[2] with foot infections representing the most common diabetes-related complication leading to hospitalisation and amputation.[3-5] Furthermore, in the United States, DFUs are the leading cause of non-traumatic lower extremity amputations, accounting for greater than 80% of all major (above ankle) amputations,[6] and one-third of the annual direct cost for diabetes is associated with care of the lower extremity.[7,8] Remarkably, when compared with different types of cancer, the 5-year mortality rate following a major lower extremity amputation (56.6%) is second only to lung cancer (80%).[9,10]

Furthermore, chronic ulcers in patients with diabetes tend to exhibit a prolonged inflammatory phase, which delays the formation of granulation tissue, and ultimately healing.[11] Contributing further to delayed wound healing, increased oncotic pressure in the postcapillary venules impairs the delivery of oxygenated blood and vital nutrients to the ulcer site.[12]

As part of a comprehensive strategy for treating DFUs, offloading is critical. For example, total contact casting (TCC) can reduce pressure at the site of a DFU by up to 92% and heals most wounds between 6 and 8 weeks.[13] Despite the excellent clinical results for DFUs, TCC is seldom used in clinical practice because of a variety of factors, such as patient comfort, time needed to apply and remove the cast and considerations of cost and reimbursement. Most notably, in a large multi-centre study conducted by Wu et al.,[14] the authors reported that among 895 centres involved in the treatment of DFUs, only 1.7% used TCC for most cases. In addition, by offloading pressure from the DFU site, TCC and other commonly used removable cast walkers (RCW) immobilise the ankle joint. Thus, the function of the calf muscle during treatment is limited, potentially decreasing blood flow to the foot, reducing venous return and increasing localised swelling.[15] This underscores the need to research and develop modalities that are both effective at offloading and enhancing blood flow to the affected foot to optimise healing of DFUs.

Intermittent plantar compression (IPC) is one such method for delivering mechanical compression to the lower limb. IPC can be used to treat leg swelling as a result of venous stasis disease and lymphedema,[16] and has been shown to increase localised tissue perfusion and improve healing rates among patients with chronic DFUs.[17] In a study conducted by Armstrong and Nguyen, a higher proportion of healing **was noted** in patients with infected diabetic foot ulcers who received IPC following surgical debridement (75%).[17]

The unique device used in this study (OptiPulse™ Active Therapy system [Compedica Limited; United Kingdom]) is designed to enhance blood circulation in the venules and arterioles of the lower extremities in patients with DFUs and during development was studied using doppler testing on healthy and vascular disease patients showing improvement in inline flow and venous return (Figure 1). It provides offloading and intermittent plantar compression at a cycle of 1 second inflation and 19 seconds deflation at the plantar plexus, at a pressure of 160 to 180 mmHg, which improves pedal flow of oxygenated blood to provide a healing, oxygen-rich environment for healing DFUs.[18,19] The device consists of a combined shin unit and offloading shoe that restricts leg movement and decreases pressure at the ulcer site while maintaining a normal gait pattern and velocity. In addition, the device also has a compliance monitor to ensure proper and appropriate use. The paired footwear consists of a trilaminate insole that distributes pressure evenly and supports the entire foot including the forefoot in a more anatomically correct position with appropriate offloading, along with patented D3O® technology for maximum shock absorption and impact protection. The outsole features a soft heel wedge that absorbs impact energy and slows the foot down, and a raised forefoot to reduce pressure at the ulcer site and to ensure a normal transition into propulsion. On the contralateral foot, an identical shoe (without a shin unit) is worn to maintain balance and gait, reduce the risk of falls and potentially prevent additional ulcers. Once the original index ulcer is

FIGURE 1 The OptiPulse™ active therapy system (Compedica Limited; United Kingdom) is designed to enhance blood circulation in the venules and arterioles of the lower extremities in patients with DFUs. It provides offloading and intermittent plantar compression and consists of a combined shin unit and offloading shoe (shown above). The unit restricts leg movement and decreases pressure at the ulcer site while maintaining a normal gait pattern and velocity. In addition, a wear time monitor is also part of the unit to monitor compliance

resolved, the shin unit is removed, but continued use of the offloading shoes are recommended, which can decrease the likelihood of ulcer recurrence.[20] The purpose of this study is to initially evaluate the safety and efficacy of this device in a small pilot study with patients that have non-healing DFUs.

2 | MATERIALS AND METHODS

The authors initiated a 10-patient, prospective Institutional Review Board (IRB) approved feasibility trial to investigate the unique offloading and compression device for the treatment of non-healing DFUs. The study protocol (DBC-PUL-01) was reviewed and approved by the Western Copernicus Group (WCG) IRB (Protocol # 20010472), and informed consent was signed by all participants. Patients with non-healing, UT grade 1A/Wagner grade 1 DFUs, with a wound size between 1 and 25 cm^2, present for greater than 4 weeks, and refractory to standard of care therapies, were eligible for participation in the study. Ulcers demonstrating infection, active Charcot arthropathy and patients with a history of renal failure and/or recent HbA1c >12.0% were excluded. To ensure adequate circulation of the affected foot, a dorsal transcutaneous oxygen measurement (TCOM) or skin perfusion pressure (SPP) measurement of ≥30 mmHg, or Ankle Brachial Index (ABI) between 0.7 and 1.3, performed within 3 months of screening was required. Alternatively, arterial doppler ultrasound with biphasic signals of the dorsalis pedis and posterior tibial vessels at the level of the ankle, or a TBI (Toe Brachial Index) of >0.6 was deemed acceptable.

Baseline demographics, including age, race, gender, body mass index (BMI) and co-morbidities were obtained from the subjects. Wounds were evaluated, measured, photographed using the eKare 3D imaging system (Merrifield, Virginia) and debrided as deemed appropriate at each weekly visit for up to 12 weeks or until complete epithelialisation of the wound occurred. For all subjects, a silicone-based, non-adherent dressing (eg, Mepitel; Molnlycke Health Care AB; Gothenburg Sweden) was applied to the ulcer site, as well as a standard 3 layer secondary dressing, followed by placement of the intermittent plantar compression and offloading device. Upon wound closure, healing was confirmed by a blinded physician not involved in the treatment of the study subject's wound.

Subject safety assessments, including assessment for infection and adverse events were conducted at each visit. Ulcer-related pain was recorded at all visits based on the visual analogue pain scale. Device usage was monitored based on number of intermittent plantar compression cycles and amount of time the device was worn. The primary study endpoint was percentage of index ulcers (ulcers being treated in the study) healed at 12 weeks. Secondary endpoints included time to heal, percent area reduction (PAR) and changes in pain based on the visual analogue pain scale during treatment.

2.1 | Statistics

The intent-to-treat (ITT) and safety populations comprised randomised patients who received at least 1 treatment. All analyses used the ITT approach. The last observation carried forward (LOCF) principle was used regarding missing area data at study visits. Study variables were summarised as means and standard deviations (±SDs) for continuous variables as well as medians for

TABLE 1 Key patient-related variables. (A) Figures in parentheses are percentages for categorical variables and standard deviation (SD) of the mean for continuous variables (B) Patient and wound characteristics for each subject 1–10 are listed

(A)

Variable	Data
Age (years)	59.7 (8.6)
Race	
Caucasian	8 (80)
African American	2 (20)
Gender	
Male	6 (60)
Female	4 (40)
BMI	31.7 (6.9)
Smoking	
Former smoker	5 (50)
Never smoked	5 (50)
HbA1c (%)	
TV1	7.5 (2.08)
EOS	8.2 (1.81)
Creatinine (mg/dL)	1.5 (1.39)
Blood glucose (mg/dL)	
TV1	146 (42.57)
EOS	205 (65.01)

(B)

Subject ID	Gender	Age	Tobacco usage	BMI	Location of target ulcer	Location of DFU on the foot
001	Female	67	No	29.3	Plantar	Forefoot
002	Male	69	Former	32.1	Dorsal	Toe
003	Female	60	Former	31.3	Plantar	Forefoot
004	Male	64	Former	28.1	Dorsal	Toe
005	Male	50	Former	32.1	Plantar	Forefoot
006	Male	57	No	30.8	Plantar	Midfoot
007	Male	66	No	25.3	Plantar	Forefoot
008	Female	69	No	28.2	Plantar	Forefoot
009	Male	49	No	29.1	Plantar	Forefoot
010	Female	46	Former	50.4	Plantar	Forefoot

Abbreviations: EOS, end of study (visit); TV1, treatment visit 1.

non-normal data. Categorical variables were presented as counts and proportions or percentages.

The PAR for the index wound at X weeks was calculated as $([A_I - A_{XW}]/A_I) \times 100$, where A_I is the area of the index wound at randomization and A_{XW} the area at X weeks. Time to heal is the first date that the wound is considered healed and completely epithelialised, 0 cm^2 area, with no drainage.

There were no hypotheses regarding statistical testing and there was not a comparative group. The main analyses were proportion of wounds healed at 12 weeks, mean time to heal within 12 weeks, PAR at 12 weeks, difference between VAS scores at baseline and EOS visit and safety data. PASW 28 (IBM, Chicago, IL) was used to perform all analysis.

3 | RESULTS

Ten patients with non-healing UT grade 1A/Wagner grade 1 DFUs were included in this study. Each wound

was present for at least 4 weeks at the time of screening, but less than 1 year from the date at which consent was signed. Patient demographics are listed in Table 1. Patients were primarily male (60%) with a mean age of 59.7 (SD: 8.56), and average BMI of 31.7 (SD: 6.91). Wound characteristics are detailed in Table 2. At baseline, the mean wound area was 2.1 cm^2 (SD: 1.5) with an average age of 7.1 weeks (SD: 2.9). Most wounds were located plantarly (80%), on the forefoot (70%), and 90% of patients reported a prior history of ulcer recurrence. Regarding device usage, the mean number of intermittent plantar compression cycles was 401 (SD: 562.17), and the mean usage time was 100 h (SD: 140.51).

TABLE 2 Key wound-related variables

Variable	Data
Wound area (cm^2)	2.1 (1.5) Median: 1.4; IQR: 1.7
Wound age (weeks)	7.1 (2.9) Median: 5.5; IQR: 4
Plantar DFU	8 (80)
DFU location	
Toe	2 (20)
Forefoot	7 (70)
Midfoot	1 (10)
Has concurrent DFUs	0 (0)
Prior DFU count	5.9 (4.5)
Years of DFUs	5.3 (3.7)
Prior amputations	
Minor	4 (40%)
Major	1 (10%)
History of DFU recurrence	9 (90)
History of significant foot deformities	3 (30)

Note: Figures in parentheses are percentages for categorical variables and standard deviation (SD) of the mean for continuous variables.
Abbreviations: DFU, diabetic foot ulcer.

All subjects were followed for up to 12 weeks, or until wound closure was achieved. No subjects were withdrawn or lost to follow-up. Eight out of ten wounds healed within 12 weeks of treatment (80%), and the mean time to heal was 41 days (95% CI: 24.3–58.3) Representative cases are shown in Figures 2 and 3.

The Kaplan–Meier plot of wound healing is shown in Figure 4. The percent area reduction after 12 weeks of treatment was 75 (SD: 53.9) as shown in Figure 5. The baseline visual analogue pain scale was 4.5 (2.9) as compared with 3.3 (3.4) at the end-of-study visit, and the mean difference in ulcer-related pain was 1.2(SD: 2.7), illustrating the pain reduction observed in subjects during treatment. There were no device-related adverse or serious adverse events reported.

4 | DISCUSSION

Treatment of the diabetic foot is increasingly common, costly and complex. Around the world, a DFU occurs every 1.2 s, and every 20 s a limb is amputated.[21] Yet, despite recent advances in wound care and other focused treatment strategies for DFUs, the number of amputations in the United States has recently increased, particularly among young and middle-aged adults with diabetes.[22] Furthermore, following a diabetic amputation, 19% of patients will undergo another amputation within 1 year, and 37% will suffer an amputation within 5 years.[23] Therefore, the need exists to identify treatment options for DFUs that not only heal ulcers effectively and rapidly, before further complications arise, but also increase the number of ulcer-free and activity-rich days for patients as they enter into a "remission" phase.

The unique device designed to offload the wound, enhance circulation and monitor patient compliance in

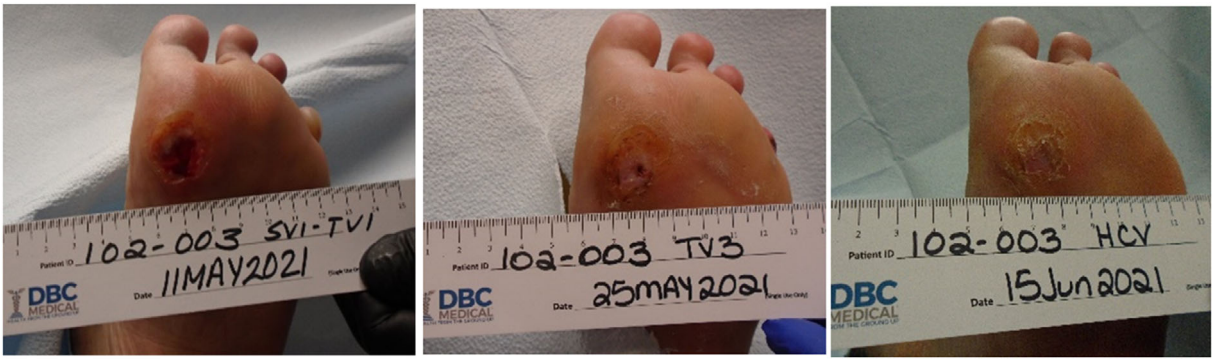

FIGURE 2 61-year-old patient with chronic DFU of five weeks duration, HbA1c: 7.8%, serum creatinine: 0.7 mg/dL; (A) ulcer size at treatment visit 1: 1.3 cm^2; (B) ulcer at treatment visit 3; (C) wound closure achieved at treatment visit 4

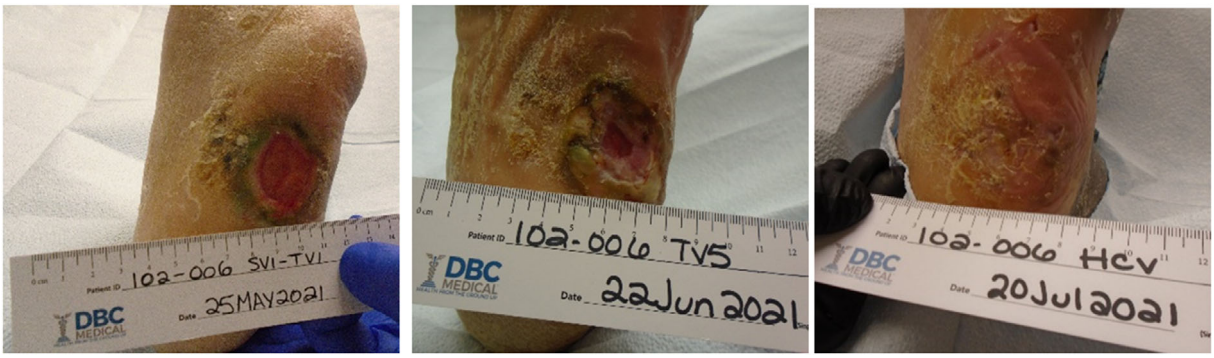

FIGURE 3 58-year-old patient with chronic DFU of five weeks duration, HbA1c: 8.1%, serum creatinine: 5.1 mg/dL; (A) ulcer size at treatment visit 1: 4.7 cm^2; (B) ulcer at treatment visit 5; (C) wound closure achieved at treatment visit 7

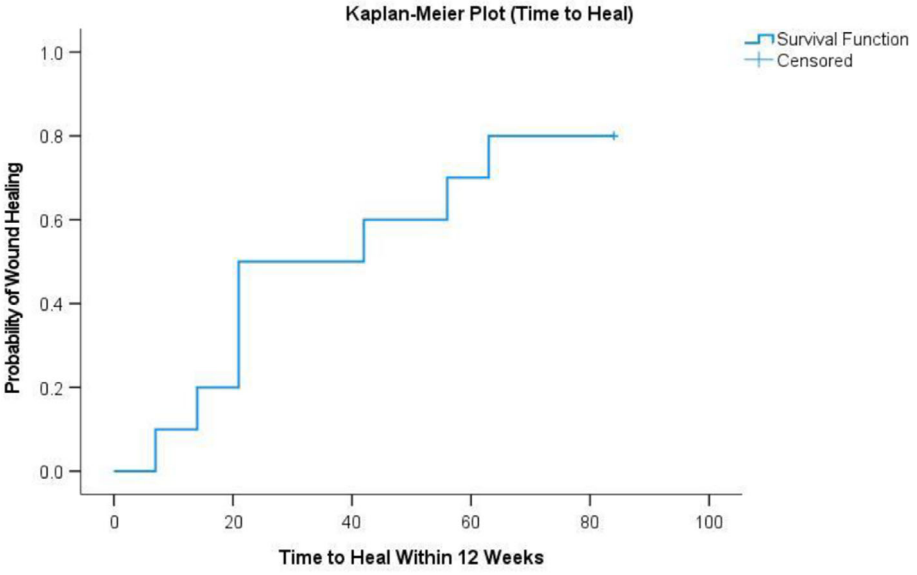

FIGURE 4 Kaplan–Meier plot of probability of wound healing within 12 weeks

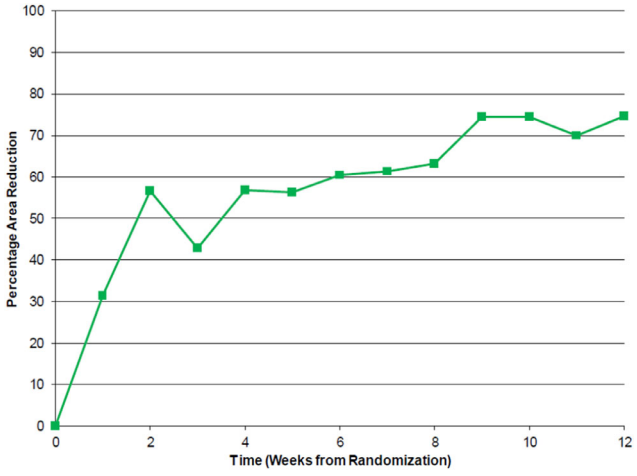

FIGURE 5 Weekly PAR values

patients with diabetic foot ulcers used in this study is one such modality. The purpose of this study was to evaluate the safety and efficacy of the use of this unique device in patients with non-healing DFUs. By combining offloading and intermittent plantar compression, the device can improve pedal flow of oxygenated blood and support wound healing. In addition, upon wound healing, the compression component of the device is removed, but use of the offloading shoe continues to reduce the chances of ulcer recurrence and additional tissue loss ideally keeping the subject in ulcer "remission."

Although offloading devices such as TCC have proven extremely effective at healing DFUs, there are significant limitations to its use in clinical practice, such as patient discomfort, limited resources, and cost.[14] Furthermore, TCC by its very design immobilises the ankle joint, potentially leading to decreased blood flow to the foot, reduced venous return and increased localised swelling.[15]

In the study conducted by Armstrong and Nguyen,[17] among 115 patients presenting with diabetic foot infections that required surgical debridement, a higher proportion of healing occurred in patients who received intermediate plantar compression (IPC) postoperatively

(75% versus 51%). Patients in that study received IPC in the form of a pump and wrap foot compression system. In addition, Kavros and colleagues[18] noted a significant improvement in wound healing (58%) among patients with chronic critical limb ischemia and non-healing foot wounds who received IPC over an 18-month period.

In this pilot study, 80% of DFUs treated with the combined IPC and offloading device healed within 12 weeks of treatment which is incidentally similar to the above percentage noted in the Armstrong and Nguyen trial.[17] In addition, in the current pilot the mean healing time was 41 days, and the PAR was 75. Lastly, patients reported a significant decrease in pain during treatment. These early results suggest that use of this unique intermediate plantar compression and offloading device is safe and effective and may be useful for treatment of non-healing DFUs. Further, based on all the findings seen in this preliminary study there is additional supportive data that elucidates that offloading externally (normal stress and shear stress) combined with offloading excessive osmotic pressure and volume may be beneficial and synergistic in these diabetic extremities. Finally, the addition of a compliance monitor in this notoriously non-compliant patient population may have added to the positive effect that we have observed.

The strengths of our study includes a robust trial design with appropriate procedures for screening, ethical IRB review, a standardised approach to standard of care (SOC) wound treatment, ITT analysis and appropriate adjustment for multiple statistical testing. Weaknesses in the study, include only one arm for treatment and no comparator, a lack of multiple sites with different geographic distributions, the need for a longer follow up period for patients after wound healing to determine the rate of recurrence, and a larger sample size. The importance of level one evidence to confirm or refute these initial positive finding is essential and the authors look forward to providing subsequent data from the ongoing randomised controlled trial to confirm or refute these initially promising results.

5 | CONCLUSION

This pilot study suggests that intermittent plantar pressure combined with offloading and patient monitoring can have significant benefit to healing difficult DFU's. Larger scale level one studies are underway to provide more clarity on the success of this combined treatment for non-healing DFU's.

FUNDING INFORMATION

This study was funded through a research grant from Compedica provided to the Professional Education and Research Institute (PERI).

CONFLICT OF INTEREST

David Armstrong, DPM, MD, PhD received research funds from PERI to design and administrate the study and also assist with the writing and review of the manuscript. Dennis Orgill, MD, PhD received research funds to serve as a validating/adjudicating plastic surgeon to review study photos and assist with the writing and review of the manuscript. Paul Glat, MD received research funds to serve as a validating/adjudicating plastic surgeon to review study photos and assist with the writing and review of the manuscript. Robert Galiano, MD received research funds to serve as a validating/adjudicating plastic surgeon to review study photos and assist with the writing and review of the manuscript. Zachary Rasor, DPM has no conflict of interest to disclose. Adam Isaac, DPM has no conflict of interest to disclose. Marissa Carter, PhD received research funds to provide the statistical analysis plan and provide the statistical analysis for this trial and assist with the writing of the result section of the manuscript. Charles M Zelen, DPM is the medical director of the PERI and his company received research funds to administrate the clinical trial and write the paper for publication. There are no other conflict of interests with any of the authors in relationship to this study, or with regard to Compedica. IRB conflict of interest statements are on file with PERI.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ORCID

David G. Armstrong https://orcid.org/0000-0003-1887-9175
Dennis P. Orgill https://orcid.org/0000-0002-8279-7310
Robert D. Galiano https://orcid.org/0000-0001-9552-6483
Adam Isaac https://orcid.org/0000-0001-5338-3445
Marissa Carter https://orcid.org/0000-0002-2265-6639
Charles M. Zelen https://orcid.org/0000-0001-5682-7056

REFERENCES

1. Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. *N Engl J Med*. 2017;37624:2367-2375.
2. Prompers L, Huijberts M, Apelqvist J, et al. High prevalence of ischaemia, infection and serious comorbidity in patients with diabetic foot disease in Europe. Baseline results from the Eurodiale study. *Diabetologia*. 2007;501:18-25.
3. Lavery LA, Armstrong DG, Murdoch DP, Peters EJG, Lipsky BA. Validation of the Infectious Diseases Society of America's diabetic foot infection classification system. *Clin Infect Dis*. 2007;444:562-565.

4. Ndosi M, Wright-Hughes A, Brown S, et al. Prognosis of the infected diabetic foot ulcer: a 12-month prospective observational study. *Diabet Med*. 2018;351:78-88.
5. Lavery LA. Discussion: off-loading the diabetic foot for ulcer prevention and healing. *Plast Reconstr Surg*. 2011;127(Suppl 1): 257S-258S.
6. Hicks CW, Selvarajah S, Mathioudakis N, et al. Burden of infected diabetic foot ulcers on hospital admissions and costs. *Ann Vasc Surg*. 2016;33:149-158.
7. Driver VR, Fabbi M, Lavery LA, Gibbons G. The costs of diabetic foot: the economic case for the limb salvage team. *J Vasc Surg*. 2010;523(Suppl):17S-22S.
8. American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. *Diabetes Care*. 2013;364:1033-1046.
9. Armstrong DG, Swerdlow MA, Armstrong AA, Conte MS, Padula WV, Bus SA. Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer. *J Foot Ankle Res*. 2020;131:16-12.
10. Barshes NR, Sigireddi M, Wrobel JS, et al. The system of care for the diabetic foot: objectives, outcomes, and opportunities. Diabet. *Foot Ankle*. 2013;4:1-8. doi:10.3402/dfa.v4i0.21847
11. McLennan S, Yue DK, Twigg SM. Molecular aspects of wound healing in diabetes. *Primary Intention*. 2006;141:8-13.
12. Tooke JE. Microcirculation and diabetes. *Br Med Bull*. 1989; 451:206-223.
13. Cavanagh PR, Bus SA. Off-loading the diabetic foot for ulcer prevention and healing. *J Vasc Surg*. 2010;523(Suppl):37S-43S.
14. Wu SC, Jensen JL, Weber AK, Robinson DE, Armstrong DG. Use of pressure offloading devices in diabetic foot ulcers: do we practice what we preach? *Diabetes Care*. 2008;3111:2118-2119.
15. Ho TK, Leigh RD, Tsui J. Diabetic foot disease and oedema. *Br J Diabetes Vasc Dis*. 2013;131:45-50.
16. Nelson EA, Mani R, Vowden K. Intermittent pneumatic compression for treating venous leg ulcers. *Cochrane Database Syst Rev*. 2008;2:CD001899.
17. Armstrong DG, Nguyen HC. Improvement in healing with aggressive edema reduction after debridement of foot infection in persons with diabetes. *Arch Surg*. 2000;13512:1405-1409.
18. Kavros SJ, Delis KT, Turner NS, et al. Improving limb salvage in critical ischemia with intermittent pneumatic compression: a controlled study with 18-month follow-up. *J Vasc Surg*. 2008; 473:543-549.
19. Solanki P, Vig S. Case report: a novel, dual-action treatment for diabetic foot ulcers. *Diabetic Foot J*. 2016;194:210.
20. Lyons C. Breaking the cycle of recurrent diabetic foot ulceration: a novel and sustainable offloading modality to treat diabetic foot ulceration and prevent recurrence. *Wounds*. 2021;331:E1-E5.
21. Armstrong DG, Kanda VA, Lavery LA, Marston W, Mills JL Sr, Boulton AJM. Mind the gap: disparity between research funding and costs of Care for Diabetic Foot Ulcers. *Diabetes Care*. 2013;367:1815-1817.
22. Geiss LS, Li Y, Hora I, Albright A, Rolka D, Gregg EW. Resurgence of diabetes-related nontraumatic lower-extremity amputation in the young and middle-aged adult U.S. *Popul Diabetes Care*. 2018;421:50-54.
23. Liu R, Petersen BJ, Rothenberg GM, Armstrong DG. Lower extremity reamputation in people with diabetes: a systematic review and meta-analysis. *BMJ Open Diabetes Res Care*. 2021; 91:e002325.

How to cite this article: Armstrong DG, Orgill DP, Glat PM, et al. A single arm prospective feasibility study evaluating wound closure with a unique wearable device that provides intermittent plantar compression and offloading in the treatment of non-healing diabetic foot ulcers. *Int Wound J*. 2023;20(3):853-860. doi:10.1111/iwj.13932