Comparison of two pixelated insoles using in-shoe pressure sensors to determine percent offloading: case studies

Objective: The gold standard for offloading neuropathic forefoot and midfoot wounds is the total contact cast (TCC). However, in practice TCC is rarely used and is contraindicated in patients with fluctuating oedema, poor perfusion, lack of adequate tissue oxygenation and morbid obesity. It can also be too restrictive for patients, inevitably resulting in treatment rejection and delayed healing. This paper examines the role of shoe-based offloading devices as an alternative in reducing plantar pressure and optimising the healing of neuropathic ulcers.

Method: Healthy subjects were recruited and fitted for two types of pixelated insoles: PegAssist (PA) insole system (Darco International, US) and FORS-15 (FORS) offloading insole (Saluber, Italy). An area of discreet, elevated high pressure was created by adding a 1/4-inch-thick felt pad to the plantar skin under the first metatarsal head. Subjects walked barefoot in surgical shoes with standard insoles (Condition 1), barefoot in pixelated insoles (Condition 2), barefoot with pixels removed (Condition 3). Dynamic plantar pressures were measured using F-Scan and the results were analysed to determine plantar pressure changes in each condition.

Results: Using PA, the percentage reduction of plantar pressure (kPa) under the first metatarsal between Condition 1 and Condition 2 was 10.54±15.81% (p=0.022), between Condition 2 and Condition 3 was 40.13±11.11% (p<0.001), and between Condition 1 and Condition 3 was 46.67±12.95 % (p<0.001). Using FORS, the percentage reduction between Condition 1 and Condition 2 was 24.25±23.33% (p=0.0029), between Condition 2 and Condition 3 was 23.61±19.45% (p<0.001), and between Condition 1 and Condition 3 was 43.39±18.70% (p<0.001). A notable difference in the findings between the two insoles was the presence of a significant edge effect associated with PA, indicating that the offloading was not entirely successful. No edge effect was detected with FORS.

Conclusion: Our current analysis shows that pixelated insoles exhibit potential for supplemental offloading in surgical shoes. These devices could provide an alternative way for physicians to offload plantar wounds and expedite closure for patients that cannot tolerate a TCC or other restrictive devices.

Declaration of interest: The authors have no conflicts of interest to declare.

analysis of offloading shoes • diabetic foot ulcer • diabetic neuropathic wounds • offloading

Diabetes is a worldwide epidemic that affects over 400 million people.[1] Complications of diabetes are systemic, with marked increases in the frequency of peripheral vascular disease, retinopathy, nephropathy and peripheral neuropathy.[2,3] A major challenging clinical scenario faced by healthcare providers in treating the people with diabetes is the management of neuropathic foot ulceration, which is expected in about 25% of the diseased population.[4] Diabetic foot ulcers (DFU) most often develop on the plantar surface where focal stress and hypoesthesia lead to undetected trauma on the affected anatomy, resulting in skin breakdown and ulceration.[5] The most frequent area of increased pressure plantarly is the forefoot, which correlates with the most common sites of neuropathic ulceration.[6,7]

The majority of these wounds develop an infection, and about 20% of neuropathic ulcers will necessitate amputation.[4] In 2017, medical care for diabetes was estimated at around $327 billion USD globally, with DFUs comprising about 33% of the cost.[8,9] In the US, DFUs alone cost between $9–13 billion USD annually, with money often spent on ineffective and costly products.[10] Even after ulcer resolution, Shrepnek et al. calculated that 40% of patients will have a recurrence in one year, reaching up to 65% of patients within five years.[11] As a result, effective and lasting treatments continue to be an ongoing issue.

Offloading vulnerable areas of the plantar surface is a fundamental component of the standard of care (SoC) in the treatment and prevention of neuropathic plantar ulcers. The current recognised 'gold standard' for offloading a plantar DFU is the total contact cast (TCC). However, it is reported that only 6% of patients with DFUs are offered this treatment.[12] Numerous reasons have been cited for the underuse of TCCs, which range from low financial compensation to poor patient adherence and even physician unfamiliarity with its

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Fig 1. Felt application to the first metatarsal head (**a**). Surgical shoe insole (left), PegAssist offloading insole with pixels removed (middle), FORS-15 offloading insole (FORS) with pixels removed (right) (**b**). DARCO surgical shoe with FORS replacement (**c**)

application. More commonly used offloading methods include crutches, removable cast walkers, shoe modifications, orthopaedic boots, surgical shoes, custom shoes and orthotics.[13]

In the US, the TCC is the only plantar offloading device for which reimbursement is provided when the sole diagnosis is a plantar DFU. Regardless, many physicians prefer non-reimbursed alternatives such as removable cast walkers or surgical shoes, which are more readily accepted by patients as they shorten application times and provide patients with more independence.[14] Although devices such as removable cast walkers reduce plantar pressure at rates comparable to TCCs, Armstrong et al. indicated that removable cast walkers were not as effective as TCCs in successfully closing DFUs unless they were affixed to the patient in such a way that the removable cast walker could not be removed.[14] When allowed to remove the devices, patients did not adhere with offloading times due to the inconvenience of wearing a bulky removable device.[15,16]The failure of many physicians to use the TCC, and the likelihood that they will use a shoe-based system or a removable device, illustrates the need for additional data establishing the effectiveness of shoe-based systems. A set of criteria needs to be developed to better define wounds that can be safely treated with a shoe-based device, as well as reimbursement evaluations for the devices, so patients are not without some form of offloading entirely.

Recently, our clinic began evaluating pixelated insoles for offloading plantar DFUs. The FORS-15 insole (FORS, Saluber, Italy) and the PegAssist insole offloading system (PA, DARCO International, US) are used for patients who do not qualify for or reject offloading with non-removable devices and for use during the transitional phase after patients come out of their non-removable device. These shoe-based devices can be inserted into a specially designed depth shoe, a surgical shoe or even a removable cast walker.

As research performed on in-shoe devices is limited, the purpose of this study was to determine the efficacy of pixelated insoles in offloading high-pressure areas at the forefoot.[17] We evaluated how the FORS compares with the PA in offloading an area of high-pressure created at the first metatarsal head. We additionally present four patient cases in which the FORS was used to demonstrate the potential of pixelated insoles in healing neuropathic DFUs. These cases are intended to be examples of patient scenarios that might benefit from pixelated insoles.

Methods

Plantar pressure comparison between FORS insoles and PA insoles

This comparative study of two pixelated insoles was reviewed and approved by an institutional review board. Because this was a minimal risk study, informed verbal consent was obtained from the subjects for their involvement and use of their photographs for publication. All risks and benefits of the study were explained to individuals before participating.

All chosen participants attended the Temple University School of Podiatric Medicine and were healthy adults from the Philadelphia area, who ambulated without the use of an assistive device and who had volunteered to participate in the study. Participants were excluded from the study if they had undergone surgery to the right first metatarsophalangeal joint within six months before the start of the study or had any appreciable abnormality to the first metatarsal that may alter their gait pattern. Participants were equally split into two groups: one group using PA and one group using FORS.

Participants were asked to walk under three different conditions:

- Condition 1 was barefoot in a surgical shoe (DARCO International, US)
- Condition 2 was barefoot in a surgical shoe with an unmodified pixelated insole (15 with PA/15 with FORS)
- Condition 3 was barefoot in a DARCO surgical shoe with a modified pixelated insole (15 with PA/15 with

FORS) with pegs removed under the designated area of high-pressure (Fig 1c). The pixels in Condition 3 were removed at the discretion of the clinician as they would normally remove them in a clinical situation to offload pressure from a bony prominence on the plantar aspect of the foot.

In all three conditions, a designated area of high-pressure was created by the addition of a 0.25 inch-thick, 1.5 inch circle of skived adhesive felt on the plantar aspect of the first metatarsal head (Fig 1a).

During each trial, participants were instructed to walk (Fig 2), and dynamic plantar pressures were collected at 100Hz using the F-Scan in-shoe dynamic pressure measuring system and software (TekScan, US). Pressures ranging from 30–1500kPa were collected using 1000 resistive sensors in an aligned array. For each walk, five mid-gait steps were identified and pressure distributions were calculated for a total of 15 steps for each participant. Peak contact pressure was determined using the TekScan analysis system, and the average percentage change and the average percentage deviation in the pressure of all three conditions were calculated and compared. A paired, two-tailed t-test was then performed to compare the average percentage changes among all conditions. A p-value was then calculated to evaluate for significant change, which was defined as $p<0.05$.

Case examples: using FORS to expedite wound healing

Case studies (n=4) were selected from the University of Pittsburgh Medical Center at Altoona, Pennsylvania. All individuals gave written informed consent for the publication of their case details. Any identifying information was anonymised to protect patient confidentiality.

Fig 2. Plantar pressure measurement using F-Scan in-shoe measuring system placed in a standard DARCO surgical shoe

All patients were selected for shoe-based offloading because they had neuropathic forefoot DFUs and

Fig 3. Plantar pressure (kPa) under the first metatarsal of all three conditions using the PegAssist insole system (PA). The lowest plantar pressure measurement recorded on any of the 15 participants was seen with the modified PA insole. However, when examining edge effect, pressures recorded for the PA exhibited the highest pressure recordings in the entire study (participant 5) across all conditions and participants

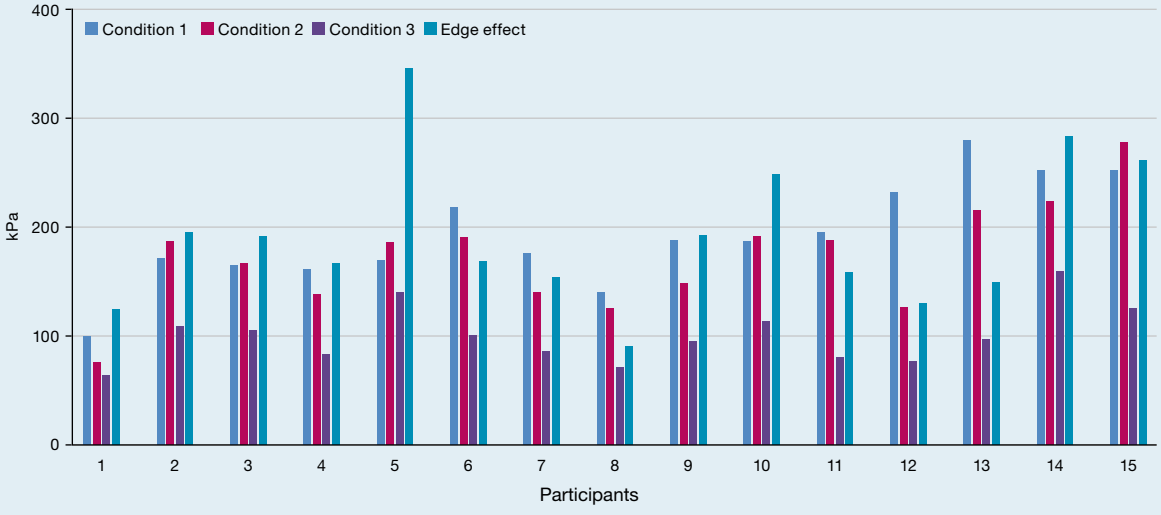
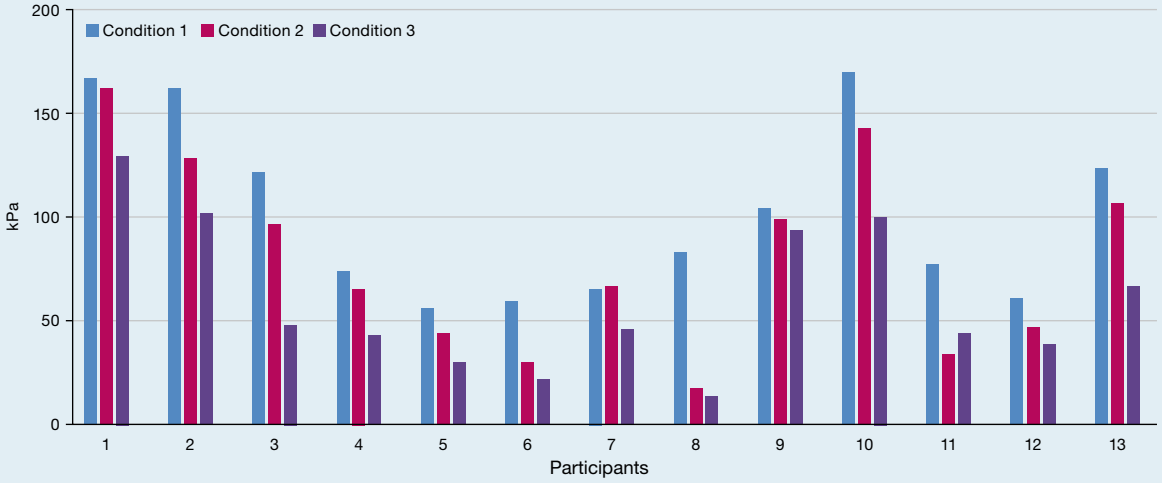


Fig 4. Plantar pressure (kPa) under the first metatarsal of all three conditions using the FORS-15 insole (FORS). For 12/13 participants, plantar pressure values in Condition 1 were consistently higher than values of both Condition 2 and Condition 3. Condition 3 demonstrated the least contact pressure under the first metatarsal. No substantial differences in edge pressure were detected



palpable pulses. Patients were additionally non-adherent or intolerant of previous offloading recommendations, including TCC application. All patients were able to weightbear as tolerated in a flat bottom surgical shoe without difficulty or fall risks. The selected individuals were managed regularly with standard wound care that included cleansing, debridement, infection control, and dry-sterile dressings. No patient underwent advanced wound care, such as cellular-based products or hyperbaric oxygen therapy. At every visit, each wound was assessed for tissue viability, area, volume and signs of complications. Treatment plans were altered when necessary to accommodate individual needs, but all individuals remained in FORS throughout the duration of the collected measurements. Images were taken before and after treatment. No follow-up assessment was performed after wound closure.

Results

Plantar pressure comparison between FORS and PA

In the group using FORS, data from 13/15 (86.7%) healthy male adults were used and two participants (13.3%) were excluded due to technical reasons. For the PA data, 11 (73.3%) healthy male adults and four (26.7%) healthy female adults were used in the analysis.

Using PA, the percentage change of plantar pressure (kPa) under the first metatarsal between Condition 1 and Condition 2 was 10.54±15.81% (p=0.022). Between Condition 2 and Condition 3 and between Condition 1 and Condition 3, the percentage changes of plantar pressure were 40.13±11.11% (p<0.001) and 46.67±12.95% (p<0.001), respectively (Fig 3).

Using FORS, the percentage change of plantar pressure (kPa) under the first metatarsal baetween Condition 1 and Condition 2 was 24.25±23.33% (p=0.0029).

Fig 5. Case 1, a 77-year-old male with a diabetic foot ulcer (DFU) under the fifth metatarsal. At initial presentation, DFU size 1.5x1.0x0.1cm (**a**); DFU closure (**b**); and percentage change in ulcer area and volume (**c**)

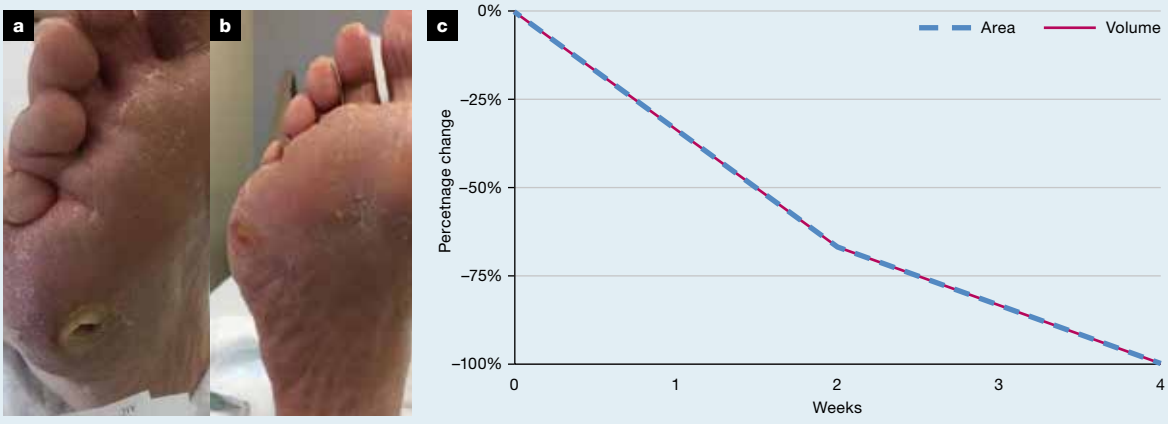
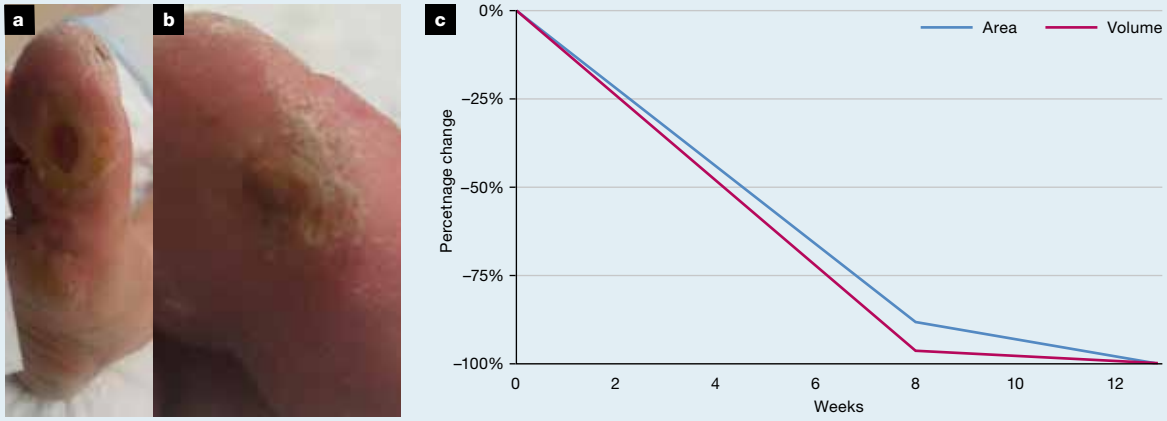


Fig 6. Case 2, a 72-year-ol male with an ulcer diabetic foot ulcer (DFU) under the right hallux. At initial presentation, ulcer size 1.2x0.4x0.6cm (**a**); DFU closure (**b**); and percentage change in DFU area and volume (**c**)



Between Condition 2 and Condition 3 and between Condition 1 and Condition 3, the percentage changes of plantar pressure were 23.61±19.45% ($p<0.001$) and 43.39±18.70% ($p<0.001$), respectively (Fig 4).

Case examples

Patient 1

A 77-year-old male with a long-standing history of non-adherence and morbid obesity, who presented with a DFU under the fifth metatarsal (Fig 5). Medical history included type 2 diabetes, insulin dependent with peripheral diabetic neuropathy, atherosclerosis of the lower extremities, and cardiovascular disease. He had a normal ankle-brachial index (ABI), and his HbA1c levels were around 8.1%. The DFU was present for approximately six months before being transferred into FORS after previous failure with both a TCC and a short controlled ankle motion walking boot fitted with PA. FORS was introduced when the DFU measured 1.5 x1.0x0.1cm (length x width x depth). At two weeks after introduction of FORS, the DFU measured 0.5x1.0x0.1cm. The wound eventually closed about four weeks after starting use of FORS.

Patient 2

A 72-year-old male with type 2 diabetes presented for a routine podiatry care appointment, but was found to have a DFU underneath the right hallux (Fig 6). The patient's medical history included type 2 diabetes with atherosclerosis of the lower extremities, dementia, venous insufficiency and coronary artery disease. His HbA1c level was around 6.6% and his ABI was within normal limits. After inspection and measurement of the DFU, the patient was placed in FORS at his follow-up visit at the wound clinic. The initial measurement of the DFU was 1.2x0.4x0.6cm (length x width x depth). At approximately six weeks' the ulcer measured 0.6x0.1x0.2cm. The DFU eventually healed at approximately 12 weeks after starting use of FORS.

Patient 3

This patient was a 60-year-old male who presented with

Fig 7. Case 3, a 60-year-old male with an ulcer under the right first metatarsal. At initial presentation, ulcer size 0.5x0.3x0.1cm (**a**); ulcer closure (**b**); and percentage change in ulcer area and volume (**c**)

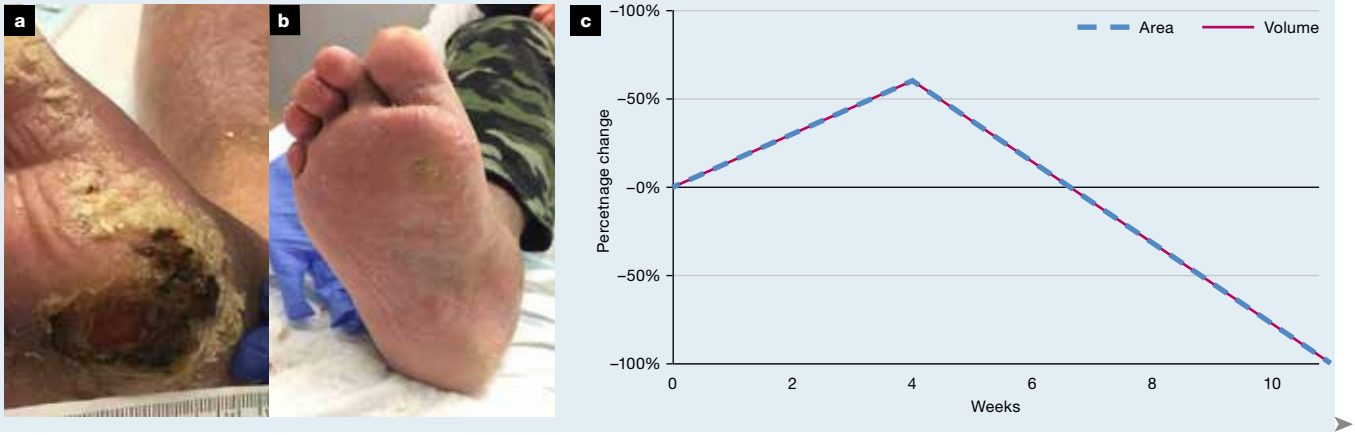
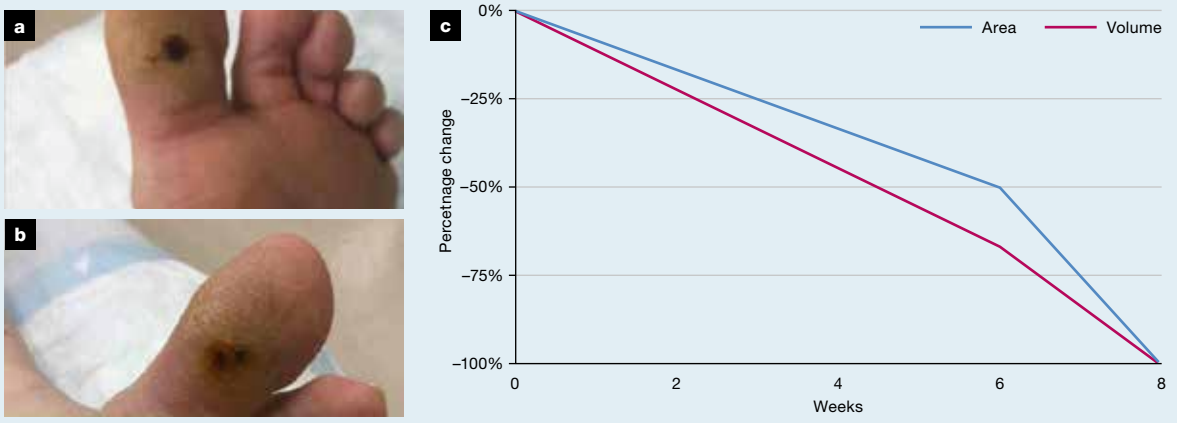


Fig 8. Case 4, a 58-year-old male with an ulcer under the left hallux. At initial presentation, ulcer size 0.2x0.4x0.3cm (**a**); ulcer closure (**b**); and percentage change in ulcer area and volume (**c**)



a wound under the right first metatarsal (Fig 7) in 2017. His medical history included alcoholism, alcoholic polyneuropathy, alcoholic cirrhosis of the liver and hypertension. The patient had an extensive history of various plantar wounds and non-adherence as well as foot/ankle pain and lymphoedema. During this course of wound management, he was hospitalised for cellulitis and possible osteomyelitis in his right foot based on initial X-ray imaging and blood work. Multi-scan testing did not show osteomyelitis, but it did indicate a neuropathic ankle joint with a possible stress fracture at the heel. Upon completion of his hospitalisation for cellulitis, the patient returned to our clinic for continued management of the ulcer under his first metatarsal. The patient had previously been provided a standard (flat bottom) postoperative shoe to offload the wound because he refused to have a TCC and lymphoedema prevented him from fitting into a controlled ankle motion walking boot. He also stated that he had balance issues, which made him at risk of falling in any wedged forefoot relief shoe. Consequently, the patient was dispensed FORS to treat his wound. The initial measurement of the wound at the start of using FORS was 0.5x0.3x0.1cm (length x width x depth). At approximately four weeks, measurement showed a reduction in wound size to 0.6x0.4x0.1cm. Approximately 11 weeks after starting use of FORS, the DFU was completely healed.

Patient 4

A 58-year-old male with uncontrolled type 2 diabetes presented with a neuropathic plantar ulcer of the left hallux (Fig 8) in 2017. His ABI was normal, although further arterial studies showed mild small vessel disease noted in the left hallux. The patient's medical history also included stage 1 kidney disease, non-adherence, hypertension, coronary artery disease with coronary bypass grafting (CABG), smoking and a body mass index (BMI) of 40.44kg/m^2. The patient was not a candidate for TCC due to obesity and history of non-adherence. He was instead provided with a FORS insole and inlay surgical shoe at the initial appointment. However, in subsequent appointments, he presented wearing sneakers. The DFU remained unhealed for 22 weeks before he eventually agreed to wear the FORS at all times and the DFU at this point measured 0.2x0.4x0.3cm. After approximately six weeks of strict adherence to wearing FORS, the DFU measured 0.2x0.2x0.2cm, and had fully resolved two weeks later.

Discussion

The under-use of TCCs is well-established in existing literature. Across the US, in 2010, TCC was used regularly in only 6% of wound care clinics.[13] Despite higher healing rates achieved using TCC, skin substitutes bring a much greater return on financial investment prompting more frequent usage.[13] However, reimbursement concerns are not the principal reason for under-use of the TCC. In a study involving 901 foot clinics, physicians most frequently cited patient intolerance as their justification for not using the TCC.[18] If physicians and patients are resistant to the use of the TCC, despite its 'gold standard' standing, then other offloading modalities must be seriously considered to improve the use of offloading therapy in the US.

In each of the cases described in this paper, FORS was chosen to replace the TCC. There were a number of reasons why FORS was chosen over the PA, the most important of which was the materials used in its construction and the thickness of the insole. The offloading capacity of FORS results from construction that includes multiple layers of Poron (Rogers Corporation, US) of variable densities. Soft and medium-density Poron layers (2mm and 3mm thickness) are permanently bonded to the top of a thin fabric support material. A 9.5mm layer of Poron is also bonded to the bottom of the fabric. The thick bottom layer of Poron is pre-cut into 10mm^2 pixels that can be

removed easily using just fingers up to and including the edges to facilitate segmental offloading. The top layer is covered with a soft suede-like foot-insole interface.

Poron is a material that completely rebounds following compression and maintains its offloading capacity over significant periods of time due to its resistance to dynamic molding or deformation (compaction). In contrast, Plastazote (Zotefoams plc, UK) and similar polyethylene foams blown with nitrogen, and ethylene-vinyl acetate (EVA) compact relatively quickly with pressure and warmth, decreasing their ability to offload effectively over time.[19]

The PA insole is constructed from a 3mm Poron top layer which is adhered via tacky adhesive to a 14mm thick composite mid-layer. The mid-layer consists of an upper layer of 4mm Plastazote bonded to 10mm EVA. The interior of the Plastazote/EVA midlayer is pre-cut into 10mm removable hexagonal 'pixels' (pegs) to enable targeted offloading. The circumference of the Plastazote/EVA midlayer is not cut into pixels to create an intact perimeter frame with a width of 1.3–1.5cm to stabilise the interior pixels that are removed from the bottom of the insole. The interior pixels are primarily supported by neighboring segments and when removed lead to instability of the remaining pixels. A 1mm thick 'stabiliser board' constructed from paperboard with a tacky adhesive on the dorsal surface is applied to the bottom of the PA after pegs have been removed to reduce peg mobility.

Because the FORS insole primarily consisted of Poron, they were believed to better endure compaction and provide lasting pressure reduction during wound healing as compared with the PA insole. As a result, FORS was selected for use in the four case studies.

Each of the patient's DFUs were of a reasonable size and depth to be considered for a shoe-based system. By using FORS in a shoe-based system, we were able to enhance patient adherence and obtain closure of the DFUs. In the four case studies presented, all patients were successfully treated with standard wound care and offloading using FORS. When previous attempts at DFU closure failed, we were able to achieve healing by optimising adherence in a device with empirical offloading potential.

Our comparison study evaluated the efficacy of the two commercially available pixelated insole devices in offloading the right first metatarsal head. Our findings indicate that with pixels removed to relieve pressure (Condition 3), PA ($p<0.01$) and FORS ($p<0.01$) each demonstrated a significant pressure reduction when compared with the data of Conditions 1 and 2.

A notable finding of the PA insoles was the presence of a marked 'edge effect' at the medial aspect of the first metatarsal head (Fig 3) in Condition 3. Armstrong et al. described 'edge effect' as an increased area of pressure at the edge of the DFU, which is prone to a combination of repetitive vertical and shear stress forces, potentiating tissue breakdown.[20] Areas exhibiting edge effect recorded pressure measurements that were comparable to the average contact pressure of Condition 2, where the insole was evaluated with none of the pixels removed, indicating that the offloading was not entirely successful. The PA is built with a non-removable 'frame' of EVA material around the circumference of the bottom of the insole (Fig 1b) that limits offloading at the edge of the insoles by simple pixel removal. In contrast, there is no frame on FORS, and pixels can be removed entirely at the edge, eliminating the problem of edge effect. While both devices significantly reduce pressure at the first metatarsal head, the edge effect exhibited by PA may act as a hindrance to wound healing if the patient is repeatedly exposed to this high-pressure area.

Between Conditions 1 and 2, neither PA ($p=0.24$) nor FORS ($p=0.23$) showed significant reductions in plantar pressure over the standard insole found in the DARCO surgical shoe. Clinicians who rely on the insoles alone should note that unless the relevant pixels are removed, such insoles are unlikely to produce any appreciable therapeutic pressure reduction.

Both the PA ad FORS insole devices used in this study demonstrated significant pressure reduction for an area of excess pressure on the plantar foot. However, 'edge effect' seen along the borders of the PA insole must be addressed and is a concern regarding the use of this offloading device. The time it takes to heal a diabetic plantar ulcer is considerable and construction materials that are known to be prone to compaction and 'bottoming out', such as Plastazote and EVA should lead clinicians to choose devices constructed from materials known to be less likely to lose their offloading capacity over time, such as Poron.

Despite the array of literary data recommending the use of the TCC, the majority of physicians use shoe-based devices, which are considered the least effective method to offload DFUs.[18] McGuire et al. coined the term 'reverse gold standard' in reference to this practice, highlighting the disparity of research in the face of clinical practice.[21] If most health professionals insist on using a shoe-based system for offloading, even with substantial evidence supporting the outcomes of TCC, it is reasonable to suspect that there must be a significant group of patients benefitting from shoe-based offloading. It is the aim of this analysis and studies to follow to demonstrate a system of evaluative tools that could be used to identify patients who would benefit from a shoe-based system. Our research and case studies demonstrate that with proper offloading, adherence and standard wound care, patients have the potential to heal without a TCC and other more expensive wound care technologies. Applying the Temple University Off-Loading Classification System[22,23] and validated risk assessment tools (Lavery Armstrong Foot Risk Classification[24]) patients can be chosen that would benefit from a pixelated insole such as the offloading devices used in this study. Clinicians can expand their offloading choices, provide a safe alternative to the TCC, and reduce unnecessary expenses for patients with low-risk forefoot ulcers.

Limitations

The clinical case examples were selected to highlight positive clinical results that were achieved using the FORS. The presented cases were not part of a randomised controlled trial and only successful cases were presented. The number of cases presented was not intended to draw statistical conclusions or to represent a clinical trial.

Limitations of our plantar pressure comparison study included the homogenous nature of the subjects in both data sets and by having mostly healthy male participants our analysis was only able to represent one gender type and was also likely to underrepresent the incidence of obesity among the population of patients with diabetes. The participants were also not randomised, and the number of participants was low, leading to an underpowered study. Additionally, given the wide average standard deviation of plantar pressure changes amongst all conditions, the participants were likely not allotted enough time to adjust to the surgical shoes and insoles. Each subject recorded large peak pressure variances as a result. The brief period of time over which plantar pressure data was collected also precluded measuring suspected changes in offloading performance between the two products due to differences in materials used in their construction. Also, the comparison study did not prospectively measure clinical results versus the two pixelated insoles or standard of care. Future studies should include a prospective clinical evaluation, and a longitudinal wear study focused on changes in pressure relief over time.

Conclusion

Our data and case studies suggest that pixelated insole devices are effective in offloading forefoot wounds. Specific patients based on measurable risks can be safely placed in a shoe-based system and be expected to heal in a reasonable period of time. Shoe-based offloading devices should, therefore, be considered in the management of these neuropathic wounds. **JWC**

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Reflective questions

- What protocols do you have in place to ensure that patients with plantar diabetic foot ulcers are offered effective off loading therapy?
- When total contact casting is contraindicated or impractical, what is your alternative plantar offloading approach?
- How do you adjust your treatment strategy to optimise patient adherence with prescribed plantar offloading devices?
- What strategies do you employ to prevent DFU recurrence in the weeks and months immediately following wound closure?