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Prospective Cohort Validation Study of a Novel Foot Offloading Device

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Summary: Pressure offloading is often considered a crucial factor affecting healing after a foot injury. We have devised a novel foot offloading device (PopSole) which allows for immediate customization of the area where there is foot pain and allows for adjustable arch support and metatarsal pad height while maintaining patient stability. We hypothesize that pain and function outcomes will improve significantly after use of the device over a 1-month period. Ten participants with foot pain for longer than 6 months completed five validated outcome questionnaires during three visits (initial screening, at 2 weeks, and at 4 weeks). Devices were deflated in areas of pain specific for each patient. Validated patient reported outcomes measures showed significant improvement in pain and function from baseline to week two ($r = 0.644$, $P < 0.05$), ($r = 0.43$, $P < 0.05$), and ($r = 0.552$, $P < 0.05$), respectively, and the Foot & Ankle Ability Measure (FAAM) showed improved ability in activities of daily living ($r = 0.58$, $P < 0.05$) and sports ($r = 0.69$, $P < 0.05$). All 10 patients reported pain relief during at least one visit and/or an ability to return to standing-based activities that they previously were unable to do. PopSole rapidly improved pain and function, with sustained relief through 4 weeks. Current studies are in progress to assess long-term durability of the device and potential modifications to be made before future randomized studies to assess pressure and gait assessment, shear forces, and diabetic foot ulcer mitigation. *(Plast Reconstr Surg Glob Open 2021;9:e3950; doi: 10.1097/GOX.0000000000003950; Published online 24 November 2021.)*

INTRODUCTION

Pressure offloading has become a critical intervention in the management of diabetic ulcers and in healing foot-related injuries by reducing pressure on areas of foot pain. However, keeping people off their feet for an extended period is challenging, and is a major cause of postprocedure complications with delayed healing. Barriers to patient compliance with current postoperative shoes include bulkiness, aesthetics, and their propensity to cause asymmetry and compensatory gait problems. Additionally, many patients walk barefoot at home, especially when showering, or during nighttime bathroom use, as current devices are not waterproof and take time to put on.

We devised a novel insole that is easy to use and intended to improve compliance with offloading, reduce postoperative pain, maximize healing, and encourage early ambulation and return to function. The PopSole allows for immediate customization of the area where there is foot pain and personalization of arch support and metatarsal pad height. It fits in sensible shoes and can also augment surgical shoes and/or walking casts. The provider can mark the area of pain and select the areas of the device insole to "pocket-out" while still supporting the rest of the foot through its anatomic design. Additionally, the device is waterproof and can be placed in a slide for use in the shower.

Although there are several off-the-shelf insoles, studies on these insoles lack objective clinical data. Comparable devices such as at the Darco PegAssist are meant to offload, but there is no current data outside of metatarsophalangeal instability,[1] or studies evaluating pain using

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the device itself without any additional treatment provided to all groups.[2] There has been a paucity of studies to date using validated patient-reported outcome measures (PROMs) in foot offloading literature. Using five PROMs, our study aimed to validate PopSole in terms of improving pain, safety, quality of life (QOL), and ability with activities of daily living (ADL) and sports over 4 weeks.

METHODS

Ten participants (six women, four men; 62.5 ± 14.8 years; BMI 31.8 ± 6.8 kg/m^2) with a history of foot pain longer than 6 months consented to this University of Pittsburgh IRB-approved study (STUDY20010059). Patients with a superstructure injury that affected gait, or who had open foot ulcerations, fractures, osteomyelitis, or neuropathy, were excluded from the study. Also excluded were patients who had a surgical foot intervention in the last 6 months and those who were or intended to be pregnant. Patients were recruited through direct referral from the practice and study flyers. Phone screening and clinical evaluation confirmed eligibility.

Takeaways

Question: We have devised a novel foot offloading device (PopSole) that allows for immediate customization of the area where there is foot pain. Our study hypothesized that pain and function outcomes will improve significantly after use of the device over a 1-month period.

Findings: Using five patient-reported, validated outcome measures during screening and at 2 and 4 weeks, the device had rapidly improved pain and function.

Meaning: In patients with a history of foot pain, the PopSole improved pain, function, and quality of life, with sustained relief through 4 weeks.

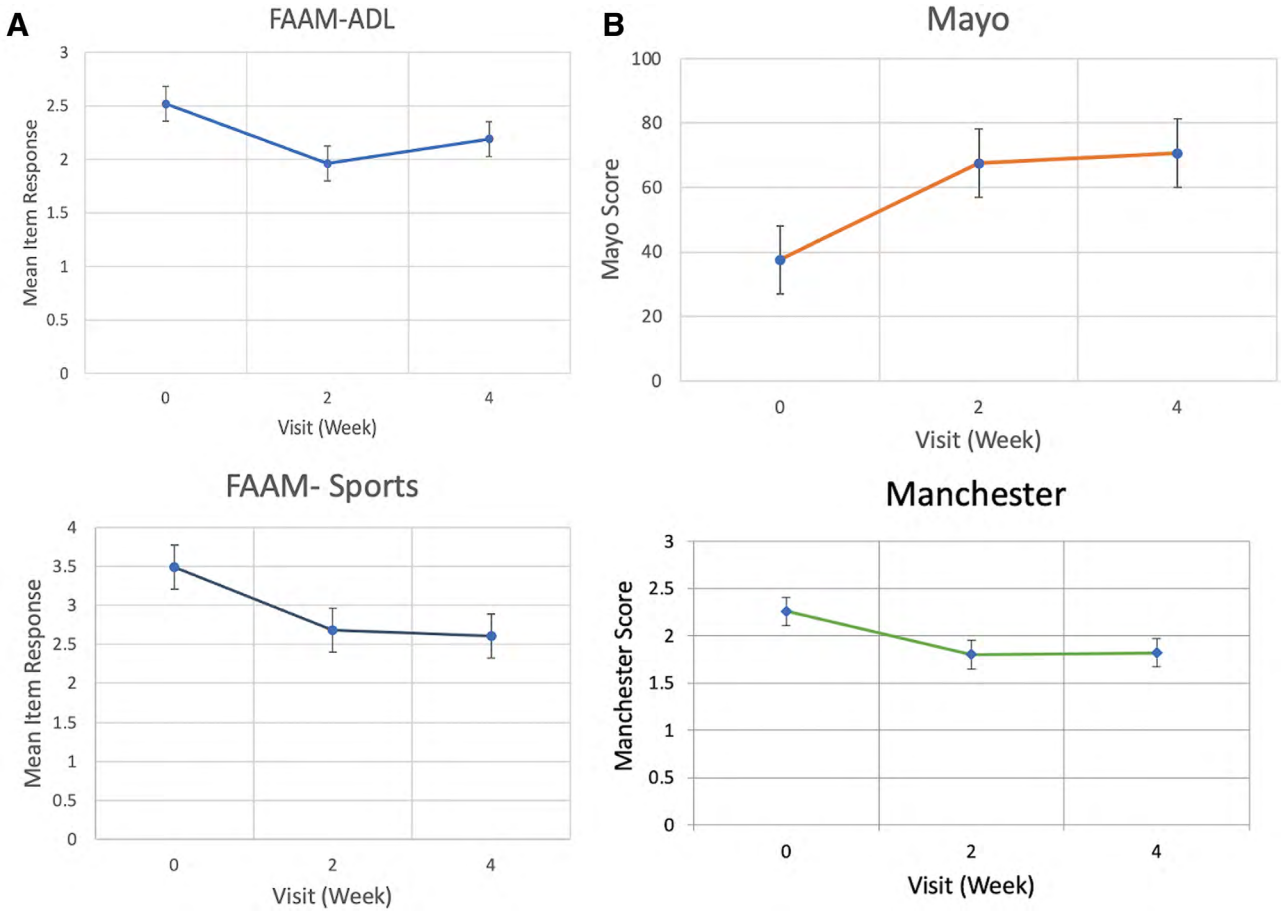

Fig. 1. Validated patient reported outcome measure results. A, Foot and Ankle Ability Measure. FAAM responses to a variety of specified activities ranging from "no difficulty" to "unable to do." A lower score indicated improved ability to perform ADLs and sports ($r = 0.58$, $P < 0.0001$ and $r = 0.69$, $P < 0.0001$), respectively. B, Mayo Pain Score and Manchester Foot Pain and Disability Index. Mayo Questionnaire Pain Score ranged from 0 (minimum) to 100 (maximum). Duration and intensity of pain, activity limitations, orthotic requirements, antalgic gait, neuropathy, and plantar heel tenderness are all graded and summated. Higher scores indicated improved pain and fewer limitations ($r = 0.64$, $P = 0.002$ from baseline to week 2). MFPDI responses to a variety of pain and specified activities ranging from "on most/every day(s)" to "none of the time." Scores were surveyed at each time point where a lower score indicated improved functionality, pain, appearance, and work/leisure activities ($r = 0.55$, $P = 0.0003$).

During all three visits (baseline, week 2 ± 5 days, and week 4 ± 5 days), a history and foot examination were performed, foot photographs were taken, and the participant completed four validated-PROMs[3–6] and our novel, unvalidated Pittsburgh Foot Survey. Foot pain was assessed at baseline, and the correlating bubbles were deflated on an individual basis. Patients were called within 48 hours to ensure there were no problems. The patients were reassessed for any needed modifications at 2 weeks. Additionally, we administered a device-specific survey to gain individualized feedback on areas of satisfaction and recommendations for continued device improvement.

RESULTS

Linear regression analysis was performed with a level of significance set at a *P* value less than 0.05 (See Supplemental Digital Content 1–2 for regression analysis). (**See table 1, Supplemental Digital Content 1,** which shows the linear regression analysis and ANOVA tables for Mayo and MFDI. **http://links.lww.com/PRSGO/B845**.) (**See table 2**, **Supplemental Digital Content 2,** which displays the linear regression analysis and ANOVA tables for FAAM. **http://links.lww.com/PRSGO/B846**.)

Pearson's correlations indicated that improved pain and function via the MFPDI, Mayo, Pittsburgh, and FAAM surveys were directly correlated to pain relief and improvements in QOL and ability with ADL and sports from baseline to week 2, with sustained improvement at 4 weeks (Fig. 1A, B).

DISCUSSION

Despite the growing popularity of offloading devices to treat bone and soft tissue injuries, and neuropathic pain, there are no studies using PROMs to validate these devices. Moreover, apart from a few recent studies, there has been a similar dearth in literature regarding the intended plantar pressure decreases.[7] A 2019 study by Mazur et al on foot and metatarsal pressure concluded that more research is necessary to assess the benefits and side-effects of offloading devices, directing future research to focus on comparing various settings of devices using a within-subject design.[8] Our 1-month validation study used PROMs to gain insight into pain relief, function, and adverse effects.

Prior studies on other novel offloading devices have shown negative consequences regarding compromised gait symmetry and stability[9] and deterioration in stride length and gait speed.[10] In our validation study, we addressed negative consequences directly from the patient's perspective. The PopSole's strong risk–benefit profile was substantiated by both quantitative survey results and anecdotally, as patients were reluctant to return the device after the 1-month study. Some of these patients will continue wearing the device and are currently enrolled in our 3-month trial.

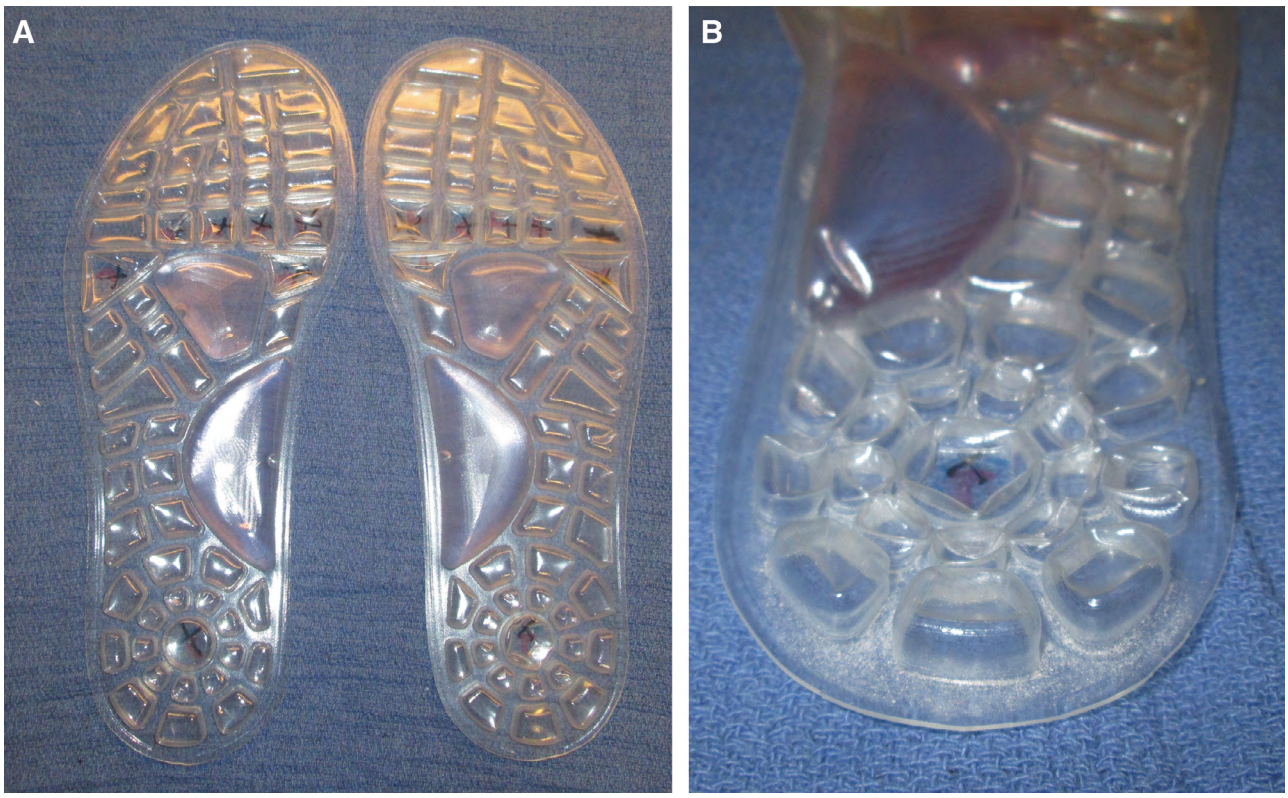

Fig. 2. The PopSole Device. A, Photograph of a PopSole device (at screening) for a 37-year-old female patient with central forefoot and heel pain for several years. She has been treated for neuromas with steroid injections and has failed conservative management with orthotic devices. The PopSole was fitted to her foot and bubbles were popped under the metatarsal's heads and heel. B, Photograph of the same patient's PopSole device at the 1-month check-in, demonstrating some unintended bubble deflation surrounding the bubbles that were initially popped, most notably in the heel area.

Although patients saw significant improvement in pain, QOL, and ADL over 1 month, much of the improvement was noted in the first two weeks. A small number of patients reported that some bubbles had deflated during their final check-in. With increased duration and velocity of walking, the device must support more of the human body's force. The accumulation of force with each "heel strike" may eventually stretch the plastic, cause air to dissipate, and decrease bubble volume, resulting in a loss of contour and/or a decreased ability of the bubbles to mold to the foot (Fig. 2A, B). (**See figure 1, Supplemental Digital Content 3,** which displays the view of the PopSole device (for one foot) with bubbles intact at screening. **http://links.lww.com/PRSGO/B847**.) (**See figure 2, Supplemental Digital Content 4,** which displays the view of PopSole device bubble deflation (for both feet) after 1 month. **http://links.lww.com/PRSGO/B848**.)

Addressing this deflation may be critical in sustaining positive outcomes in our ongoing 3-month study. We are also assessing foot pressures and forces comparing the PopSole to the Darco shoe with PegAssist insert as a gold standard for selective offloading in future studies.

CONCLUSIONS

The PopSole is a novel offloading device that rapidly improved pain, function, and QOL with duration up to a month. Current trials, including a 3-month follow-up and a trial to establish a standard of care using pressure mapping insoles, are in progress to assess durability of the device. Our results will help tailor a new iteration for future randomized studies to assess pressure, gait assessment, shear forces, and foot ulcer prevention/treatment in patients with diabetes.

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This study (STUDY20010059) was approved by the IRB of the University of Pittsburgh. Clinical trial registration information: Clinicaltrials.gov, NCT04378270 "Validation of a Novel Foot Offloading Device (PopSole2)," registered 05/04/2020.

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