Innovative Plantar Sensory Insoles to Prevent Foot Ulcer Recurrence and Guide Treatment Plans in Patients with Diabetic Peripheral Neuropathy

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Introduction

People living with diabetes have a 25% likelihood of developing a diabetic foot ulcer (DFU) during their lifetime[1]. Once an ulcer forms, the individual is susceptible to infections that can result in lower-extremity amputation (LEA) of the toes, the entire foot, and the lower leg. Even after healing is achieved, DFU recurrence is common, with 49% of DFU patients experiencing ulcer recurrence within 1 year, and 68% recurrence within 5 years[2].

High plantar pressure is a major risk factor in DFU development[3,4,5], and recent evidence shows that continuous plantar pressure monitoring and dynamic offloading guidance can lead to reduced DFU recurrence[6]. There is a significant, and yet unmet, need for an appropriate intervention that can preventatively detect the aberrant pressures and temperature increases developed during day-to-day activities, thereby reducing the frequency of foot ulcer recurrence.

This case series examines the use of sensory insoles in patients at risk of DFU formation. This sensory technology is the first to ever collect a robust data set including plantar pressure, temperature, step-count, and adherence to inform treatment decisions to reduce DFU risk.

Materials & Methods

17 patients were provided with custom-made sensory insoles (Orpyx SI® Custom Sensory Insoles, Orpyx Medical Technologies Inc., Calgary, Canada) to monitor plantar pressure, temperature, step-count, and hours of use, and were provided with real-time cues for pressure offloading as they went about their daily life. The data collected from the sensory insole system was used to track activity, ulceration, and response to feedback from real-time alerts. Patients were monitored remotely by a qualified healthcare professional (QHP) and were contacted when areas of concern were seen based on collected data. The patients were provided with coaching and education related to reducing risk factors and overall support to improve foot health. Data collected from the sensory insoles was wirelessly transmitted to a HIPPA-secure web-based dashboard that was accessible to the remote QHP, prescribing physician and other relevant clinic staff.

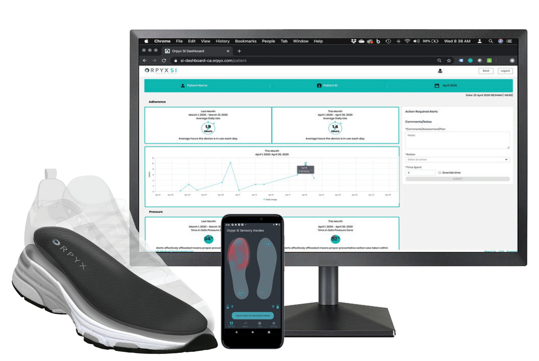

Figure 1. The Sensory Insole System

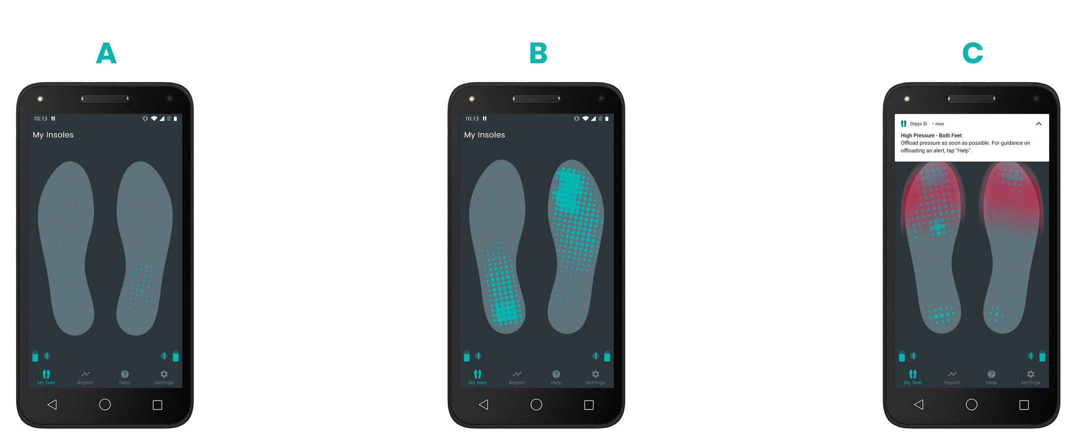

Figure 2. Proprietary Sensory Insole App – Frames A, B and C depict the main foot map screen of the app. These images illustrate an individual who has connected their insoles, who is walking or exerting pressure on their insoles, and who has received a high-pressure alert, respectively.

Case Example 1

- 78-year-old female with previous DFU to right first metatarsal head
- Patient was outfitted with the sensory insoles and provided with remote patient monitoring from a qualified healthcare professional.
- During the 4 months that the patient wore the sensory insoles, they used the insoles on average 4.1 hours per day

Based on the physiological data collected from the sensory insoles and data from remote patient monitoring (RPM) interactions, the patient was brought into the clinic and presented with an erythematous area suggestive of a pre-ulcer lesion on the plantar surface of the first metatarsal head.

Approximately 30 days prior to the office visit, the patient began to receive elevated pressure alerts via the digital display indicating high plantar pressure to the area corresponding to the first metatarsal head. Ten days prior to the office visit, the data for this patient showed a temperature variance in the same location. This data was monitored and reviewed by the QHP via the dashboard. In each instance, a flag was generated by the dashboard associated with the corresponding pressure and temperature alerts. After review, the QHP escalated the information to the provider, per the pre-established escalation protocol. During the in-clinic visit, the provider was able to provide the appropriate offloading intervention (metatarsal bar underneath first metatarsal head) required to prevent further complications and ulcer development.

The sensory insoles and RPM resulted in timely outreach to the patient and provider so that the patient was able to be seen in office for further preventative measures before a pre-ulcer lesion (Grade 0, Stage C[7]) evolved further.

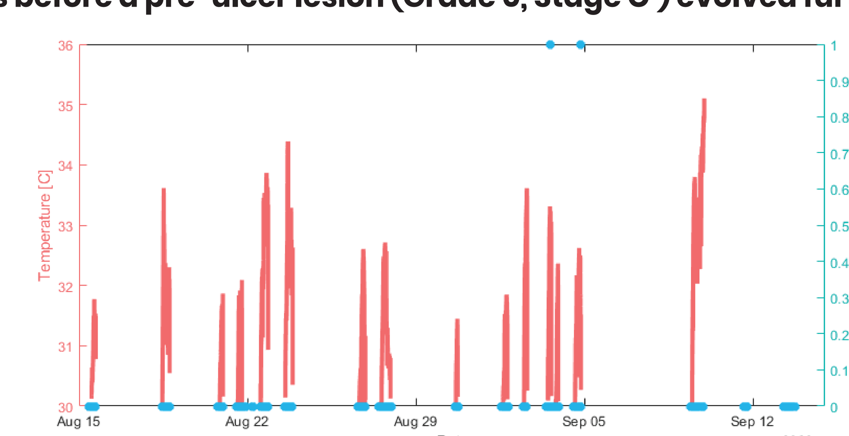

Figure 3. First metatarsal head temperature and pressure data collected from the sensory insole system. The patient was brought into the clinic presenting with an erythematous area suggestive of a pre-ulcer lesion on the plantar surface of the first metatarsal head.

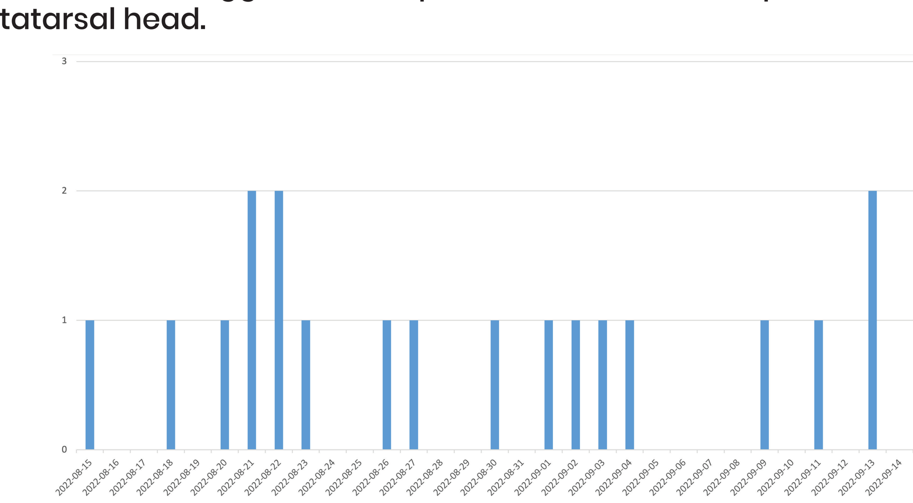

Figure 4. Number of elevated pressure alerts generated by the sensory insole system and provided to the patient in real-time via the digital display. Following an alert, the patient was provided with guidance on pressure offloading.

Case Example 2

- 73-year-old female with previous history of DFU to right and left plantar first metatarsal heads
- Fusion of first metatarsophalangeal (MPJ) and first proximal interphalangeal (IPJ) joints of the left and right foot.
- Patient was outfitted with the sensory insole system and provided with remote patient monitoring from QHP.
- During the 4 months that the patient wore the sensory insoles, they used the insoles on average 6.7 hours per day

Due to the fusion of the first metatarsal head on both the left and right feet, the patient avoids placing pressure on the first metatarsal heads and tends to place more pressure across metatarsal heads 3 through 5.

The patient received elevated pressure alerts via the digital display across metatarsal heads 3 through 5 and was provided with guidance on how to offload pressure. Additionally, elevated pressure flags were generated in the dashboard and reviewed by the remote QHP. The QHP coached the patient over the phone and provided further provide further guidance on offloading pressure alerts until the patient was able to be seen in the office by the provider. While wearing the sensory insole system, the patient has seen reduced callus building on the plantar surface of the first metatarsal head, as the patient was able to successfully offload pressure and prevent further callus development.

The data collected from the sensory insole system showed the specific foot compensation made by this patient, shifting pressure away from the first metatarsal heads across metatarsal heads 3 through 5, due to the fusion of the first MPJ and IPJ. The real-time notifications provided to the patient, along with feedback from the remote QHP, allowed the patient to successfully offload pressure from these areas and prevent any redness or callus from developing.

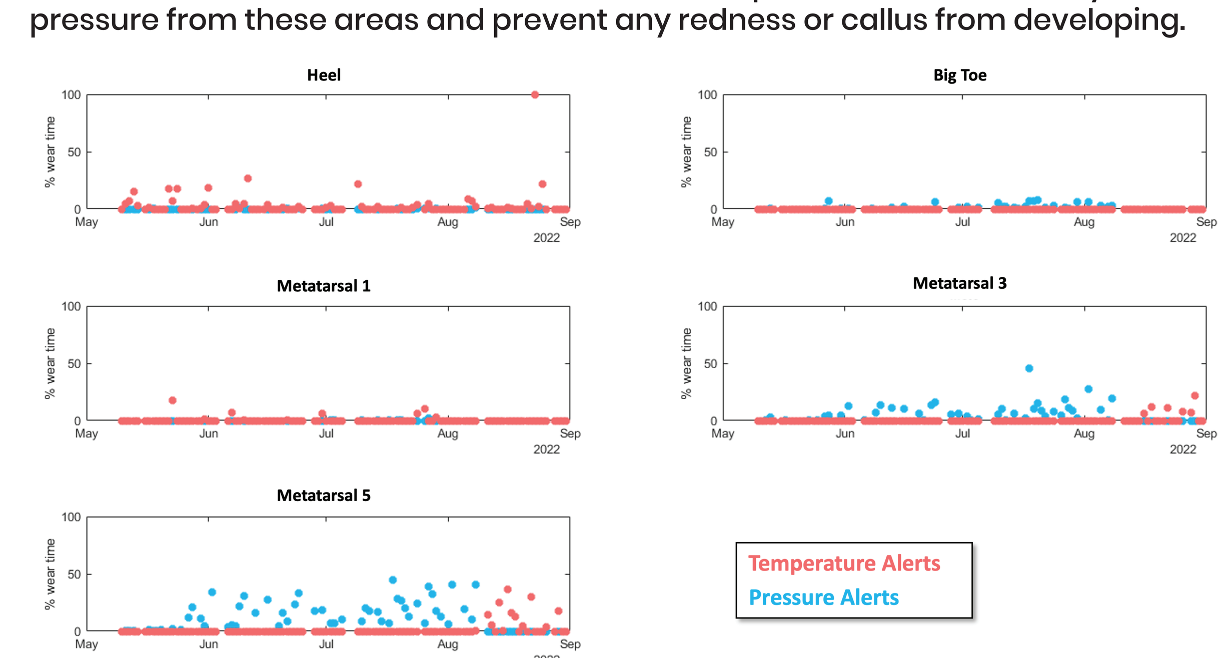

Figure 5. Pressure and temperature alerts across the plantar foot surface. Elevated pressure across metatarsal heads 3 through 5 triggered pressure alerts, received by both patient and remote QHP, due to the patient over-compensating pressure distribution away from the first metatarsal head.

Results

Of the 17 patients provided with the sensory insole system, 1 withdrew (no data collected) and 1 presented with a DFU. On average, patients used the sensory insole system for 4.7 hours per day, and increased usage over time. The patient who presented with a DFU had below average adherence (2.2 hours per day) prior to DFU development, so minimal data was collected.

Patients indicated that wearing the insoles with the real-time alerts increased their awareness to activities that due to their peripheral neuropathy, they were previously unaware put them at risk for development of a wound. During clinic appointments, patients asked more questions about their foot health and the notifications that they received from the insoles. This generated more open communication between the patient and provider, as the patient was provided with contextualized information to guide foot health conversations with their provider.

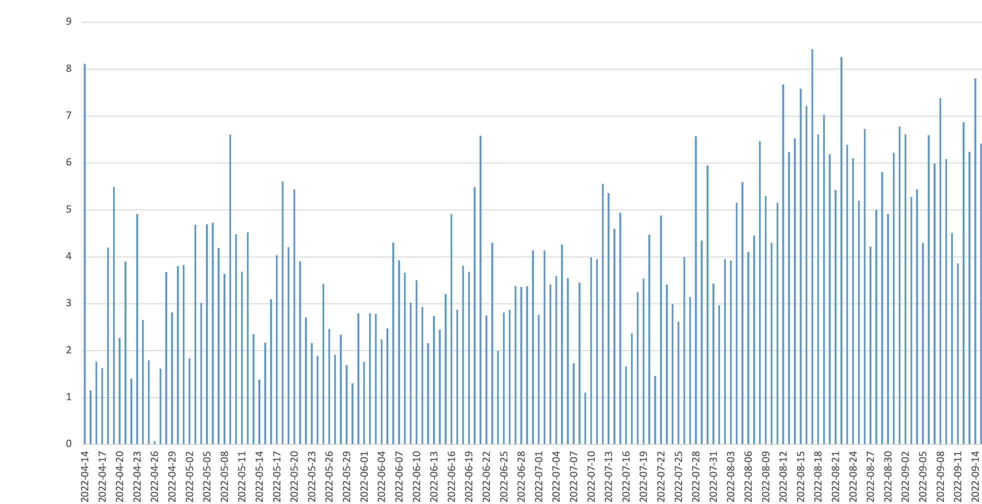

Figure 6. Average hours of use per day across patients outfitted with the sensory insole system (n=16). Participant usage increases over time. Based on previous findings6, patients who wore the device for 4.5 hours or more each day saw an 86% reduction in ulcer recurrence.

The two cases presented above highlight how a sensory insole system incorporating RPM services can provide early intervention for at-risk patients, preventing more serious complications from occurring. For both patients presented, prior to use of the sensory insoles, the patient would not come in to see their provider until after development of a wound, preventing the provider from intervening early and avoiding ulceration. This sensory insole system that incorporates RPM services, gives providers information they have never had before so that they can proactively bring patients into the clinic or office as soon as a potential risk is identified. This creates an opportunity for the provider to proactively intervene before a wound develops.

Conclusions

This case series explores the use of a novel sensory insole technology to collect newly available plantar data (pressure, temperature, step-count, and adherence) for DFU detection and prevention. The results from this case series suggest that feedback generated by sensory technology is effective in helping to reduce the incidence of DFUs in patients with diabetic peripheral neuropathy. The data collected from this sensory technology can be used to inform and guide treatment decisions in clinic. The results also suggest the importance of remote patient monitoring in helping to reduce DFU recurrence and provide early intervention for lesions that may develop.

References
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