Evaluating the Effectiveness of Plantar Sensory Insoles and Remote Patient Monitoring for Early Intervention in Diabetic Foot Ulcer Prevention in Patients with Peripheral Neuropathy

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[1] Cutting Edge Research

Introduction

Diabetic peripheral neuropathy (DPN) affects 70% of individuals with diabetes, which often causes a loss of protective sensation, leading to tissue damage and diabetic foot ulcer (DFU) formation.[1,2] These ulcers can result in infections and lower-extremity amputations of toes, the entire foot, and the lower leg. Even after a DFU is healed, recurrence is common, with 49% of DFU patients developing another ulcer within a year, and 68% within 5 years.[3]

When caught early, DFUs are treatable; however, more than one third of ulcers are not treated until they advance to a point beyond healing and result in foot or lower extremity amputation.[4] Treatment of DFUs is challenging due to their multifactorial etiology that requires interdisciplinary care team management.[5] However, DFUs are highly preventable when caught and treated early.[6] Remote physiologic monitoring has been suggested as a solution to create a more integrated healthcare offering for patients at-risk of DFU, as well as creating the opportunity for early clinician intervention to prevent DFUs from recurring.[5,7]

This case series examines the use of sensory insoles and newly available plantar data (pressure, temperature, step-count, adherence) and remote patient monitoring (RPM) as a proactive approach for patients at risk of DFU formation.

Materials & Methods

40 participants were provided with custom-made sensory insoles and remote physiologic monitoring services (Orpyx SI® Custom Sensory Insole System, Orpyx Medical Technologies Inc., Calgary, Canada) to analyze and trend plantar pressure, temperature, step-count, and daily-use data. Participants were provided with real-time alerts for pressure offloading as they went about their daily activities. The sensory insoles were used to track subject adherence, plantar data including pressure and temperature, and response to feedback from real-time alerts. Patient's data was remotely monitored by a U.S. based qualified healthcare professional and contacted when concerning data trends were seen and provided education and coaching on reducing risk factors and overall support to improve foot health.

Figure 1. The Sensory Insole System.

Case Example 1

Patient is a 93-year-old male with type 2 diabetes, peripheral neuropathy, and previous DFUs to right and left first and third metatarsal heads. The patient was outfitted with the sensory insole system and provided with RPM services. During the 3-month period that the patient used the sensory insole system, their average use was 9.1 hours per day.

Based on the physiologic data collected and interactions with the RPM nurse, the patient was escalated to the clinician and presented in clinic with an erythematous area suggestive of a pre-ulcer lesion on the plantar surface of the left foot across the first, third, and fifth metatarsal heads. Approximately 1 month prior to the clinic visit, the patient began to receive elevated pressure flags indicating high plantar pressure across the left foot third and fifth metatarsal heads, as seen in Figure 2. Increased temperature was seen in the heel region due to compensation by the patient shifting their weight towards the heel away from the metatarsal heads and forefoot. The patient was brought into the clinic ahead of their regularly scheduled visit and was provided with mechanical offloading interventions to relieve pressure across the metatarsal heads and prevent a pre-ulcerative indication from worsening.

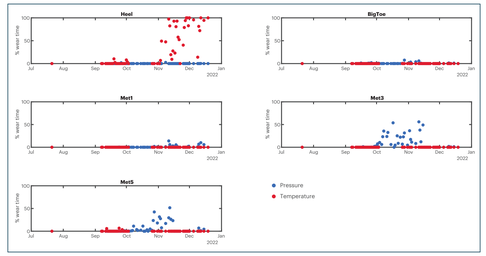
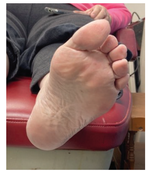


Figure 2. Pressure and temperature flags across the left plantar foot surface. Elevated pressure across metatarsal heads 3 and 5 triggered pressure flags received by RPM nurse and pressure alerts received by the patient. Increased temperature was seen in the heel region due to compensation by the patient, shifting weight back towards the heel away from the metatarsal heads and front of foot.

Case Example 2

Patient is a 76-year-old female with previous DFU to the plantar surface of the left second toe. The patient was outfitted with the sensory insole system and RPM services and wore the sensory insole system an average of 6.2 hours per day over the 5-months of use to date.

The patient has significant hammertoes on both the left and right feet resulting in a shuffling gait that causes persistent pressure loading in the left and right toes and metatarsal heads. Based on the physiologic data and interactions with the RPM nurse, the patient was escalated for an in-clinic assessment mid-October, ahead of their regularly scheduled clinic visit. The patient presented with significant callus and redness on the left first metatarsal head. The patient began to receive pressure flags across the left first and third metatarsal heads approximately 1 month prior to the clinic visit, as seen in Figure 3. During the clinic visit, the patient was provided with mechanical offloading and debridement of the callus, preventing further development of the pre-ulcer indication. Due to the patient's apropulsive gait, the pressure loading across the metatarsal heads and toes continued to generate elevated pressure, which was continuously monitored by the RPM nurse and treating clinician.



Photograph of the plantar surface of the patient's left foot: the patient has contracted digits 2, 3, 4 and 5 that are dislocated and non-reduceable generating increased pressure on the metatarsal heads. Increased pressure on the third metatarsal head was flagged by the RPM nurse and escalated to the clinician for review.

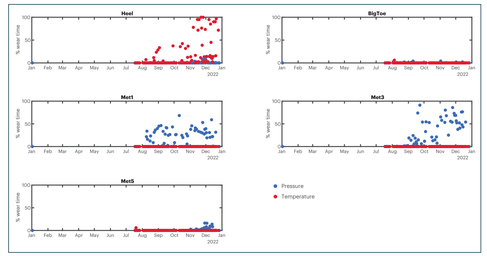


Figure 3. Pressure and temperature flags across the left plantar foot surface. Elevated pressure across the first and third metatarsal heads triggered pressure alerts received by the patient and the RPM nurse. Elevated pressure continued due to the patient's significant hammertoes and apropulsive gait, causing pressure loading of the metatarsal heads and toes, which was continually monitored by the RPM nurse and treating clinician.

Case Example 3

Patient is a 60-year-old male with type 2 diabetes, peripheral neuropathy, and previous DFU to the right fifth metatarsal head and lateral foot, and the left and right first toe. The patient has a history of chronic DFUs, and significant callus on the lateral sides of both feet due to compensation for a right first toe amputation. The patient is very aware and involved with their foot health.

The patient is a severely compromised diabetic and prior to use of the sensory insole system, the patient underwent a kidney transplant and subsequent resulting stroke, placing them at higher risk for limb loss. The patient was outfitted with the sensory insole system and RPM services and wore the device an average of 11.6 hours per day during the 5 months that the sensory insole system was used.

As seen in Figure 4, the patient and RPM team received significant elevated pressure flags across the first and third metatarsal heads of the right foot during the time the insoles were worn. Based on the physiologic data collected by the sensory insole system and interactions with the RPM nurse, the patient was brought into the clinician's office for assessment, presenting with significant callus and redness on the plantar surface of the fifth metatarsal head, indicative of a pre-ulcerative lesion. The clinician provided debridement of the callused areas and the patient continued use of the sensory insoles and remote monitoring of the high-pressure areas.

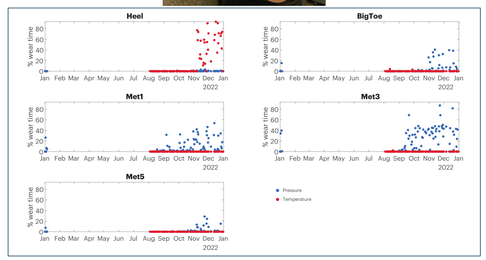


Figure 4. Pressure and temperature flags across the plantar surface of the right foot. Elevated pressure is seen across the first and third metatarsal heads, as well as the base of the first toe.

Results

Of the 40 participants provided with the sensory insole system, average daily use was 8.9 hours per day, and remained steady over time as seen in Figure 5.

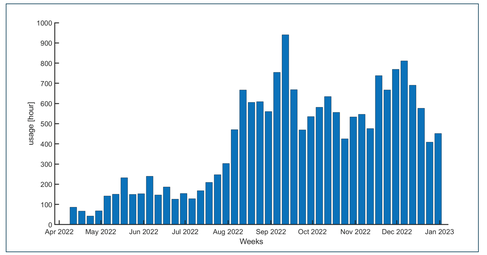


Figure 5. Average weekly usage hours across the 40 patients outfitted with the sensory insole system. Patient usage increased over time as patients became more comfortable with the technology and engaged more with their RPM nurse. Due to the high comorbidities that exist within this patient population, patients that experienced any health issues that were unrelated to their foot health but prevented wear of the insoles were placed on pause until their health improved.

Based on flags generated from the available plantar data, patients were contacted by the RPM nurse to address potentially concerning trends in the data from the insoles. A standard RPM escalation protocol detailed when and how concerns should be escalated to the clinician by the RPM nurse. Upon escalation to the clinician, patients were brought into the clinic as needed, allowing for any issues to be addressed before more serious complications might arise. Patients indicated that wearing the sensory insole system with the real-time alerts made them more aware of their feet and activities that might put them at risk for wound development.

The case examples presented highlight how a sensory insole system with RPM services can provide early intervention for patients at risk for DFU development. The information collected by the sensory insoles, in addition to remote monitoring insights, provides clinicians with data that they have never had before and provides them with the opportunity to intervene early helping to prevent a pre-ulcerative condition from developing into a wound.

Conclusions

This case series explores the use of an innovative sensory technology including remote patient monitoring to collect plantar data (pressure, temperature, step-count, and adherence) for detection of pre-ulcerative indications allowing for early intervention. Patients outfitted with the sensory insole system increased usage over time as they became more familiar with the technology and RPM nurse monitoring the data. The results from this case series suggest the importance of sensory technology and remote patient monitoring in providing proactive, preventative care for patients at risk of DFU and foot complications. Clinicians can use sensory technology that provides early warning signals to reduce the risk of tissue breakdown and DFU development. This robust plantar data, with the addition of remote monitoring, allow for patients to be seen in clinic when concerning data trends arise, giving clinicians the opportunity to intervene early and prevent more serious complications, such as wounds, from occurring.

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