Novel Pressure-Sensing Smart Insole System Used for the Prevention of Pressure Ulceration in the Insensate Foot

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Summary: Wounds of the foot challenge reconstructive surgeons to manage multiple factors: sensibility, stability, and durability. In this article, we focus on the insensate foot, which poses challenges to wound prevention with its propensity to develop pressure ulceration. The authors present the innovative use of a pressure-sensing smart insole system (SurroSense Rx, Orpyx Medical Technologies Inc., Calgary, Canada) in the management of the insensate foot in a patient following foot reconstruction. The pressure-sensing smart insole system provided unique feedback to both patient and provider in ways that contributed to the prevention of pressure ulcer recurrence, as well as highlight the importance of prescribed footwear in both the affected and unaffected foot. Wearable real-time monitoring and feedback faces the challenge of patient adherence. Future studies are indicated to examine the specific behaviors that are associated with favorable outcomes and long-term behavior changes. (Plast Reconstr Surg Glob Open 2017;5:e1568; doi: 10.1097/GOX.0000000000001568; Published online 5 December 2017.)

CASE REPORT

The patient is a 22-year-old female with spina bifida, history of clubfoot, and 20 operations to her right leg who presented to the wound center for a chronic neuropathic lateral right plantar foot ulcer measuring 3 cm in diameter with surrounding callus. After 3 years of unsuccessful wound management, including offloading and local wound care, the patient underwent surgery for definitive closure using a vertical profunda artery perforator flap. The postoperative course was uneventful. After 6 weeks, the patient returned for flap debulking and revision without further complications. The patient was then fitted with the pressure-sensing smart insole system to enable ongoing plantar pressure feedback.

MATERIALS AND METHODS

The patient was fitted with the pressure-sensing smart insole system (SurroSense Rx, Orpyx Medical Technologies Inc., Calgary, Canada). The device compensates for loss of plantar protective sensation by providing on-demand smartwatch-based cues for offloading. This feedback

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is based on the identification of critical time/pressure signatures in insole sensor data from 8 pressure sensors distributed across the heel, lateral plantar surface, and medial and lateral metatarsal heads and toes. Device alerts are generated using algorithms that integrate pressure data over time; core algorithms are built on the current understanding of thresholds for pressure ulcer formation (conservatively, over > 35 mm Hg for a minimum of 15 minutes).\textsuperscript{7} When safe pressure and time thresholds are exceeded, the patient is instructed to go through offloading steps.

For comparison, the patient was evaluated with a current in-office pressure-sensing technique containing 99 sensors with spatial resolution of 1 sensor per square centimeter and temporal resolution of 90-Hz (Pedar-X, Novel Inc, St Paul, Minn.). The TruBlu calibration device set reading pressures between 20 and 600 kPa. Data from the heel, forefoot, and medial and lateral midfoot were collected as the patient walked at a self-selected speed (0.98–1 m/s), which was censored by an infrared timing system (Brower Timing Systems, Draper, Utah).

![Fig. 1. Patient ulcer free 89 days after use of the device.](image1)

![Fig. 2. Example of device dashboard showing average daily use, alerts effectively offloaded, and alerts by region.](image2)

![Fig. 3. Alert distribution by footmap region for right and left foot over the monitoring period.](image3)
RESULTS

The patient was monitored with the device for 89 days, throughout which no recurrent ulcerative events were seen (Fig. 1). Both the patient and practitioner had access to the data collected by the device (Fig. 2), which provided information on average daily use, alert offloading effectiveness, and percentage of alerts by foot region.

Patient adherence was an average of 4.02 h/d (SD = 6.63) over the monitoring period. Daily device use was an average of 8.52 h/d (SD = 7.42). Over periods of device use, the patient triggered more alerts on the contralateral (noninjured) foot than the surgical site (right midfoot; Fig. 3).

Current in-office pressure-sensing techniques showed that there was variability of peak pressure as the patient walked (Fig. 4). When looking at the distribution of pressure across the foot, the site of surgery unloaded and exhibited no evidence of focal loading, whereas the contralateral side showed focal loads under the first metatarsal head. The mean pressure was low (179 kPa).

DISCUSSION

Recent technological advances have made wearable pressure-sensing solutions available. In preliminary studies, these devices show promise in preventing foot ulcers and improving ulcer healing. This case report supports prevention of wound recurrence with the use of a pressure-sensing smart insole system in a patient with an insensate foot, though patient adherence to device use is an obstacle to care. A study of this device showed that at least 1 alert every 2 hours could optimize response to offloading, suggesting there may be a protocol to improve adherence that should be further studied.

The pressure-sensing smart insole system provided provider- and patient-level utility with respect to the management of loss of plantar protective sensation. From a provider’s perspective, the device was able to monitor and quantify device compliance. Data patterns emerged enabling one to deduce behavior with respect to plantar pressure distribution over time and call attention to the importance of proper footwear in offloading pressures. Initially, the data indicated that the patient applied more pressure to the contralateral foot, with reference to the site of surgery. The in-office pressure-sensing system supported these findings. This overloading suggests the importance of prescribed footwear for both feet.

For the patient, the device provided feedback to guide offloading. The limitation is patient adherence in wearing the device and responding to feedback. In this study, adherence was a clear obstacle, yet on days the device was worn the patient showed fairly high average daily use (8.52 h/d) without ulcer recurrence. Considering long-term effects, real-time biofeedback has been shown to be effective in correcting trunk sway deviations during stance and gait, including carry-over effects extending beyond device use.

Further evaluation of technology-enhanced interventions is necessary because behavior changes like weight loss have had equivocal, if not diminished, success compared with standard interventions. Larger and long-term studies are necessary to evaluate the reproducibility and sustainability of the results observed in this case report.

The absence of ulcerative events over the monitoring period and agreement with in-office techniques was highly encouraging. Patient adherence is a key factor to improve moving forward, but positive findings suggest that further study is merited.

CONCLUSION

The insensate foot poses challenges to wound prevention with its propensity to develop pressure ulceration. The pressure-sensing smart insole system provided unique feedback to both patient and provider in ways that contributed to the prevention of pressure ulcer recurrence, as well as highlight the importance of prescribed footwear in both the affected and unaffected foot. Wearable real-time monitoring and feedback faces the challenge of patient adherence. Future studies are indicated to examine the specific behaviors that are associated with favorable outcomes and long-term behavior changes.

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