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Prevention of Plantar Ulcers in People With Diabetic Peripheral Neuropathy Using Pressure-Sensing Shoe Insoles

Image courtesy of Orpyx Medical Technologies

CADTH

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Summary

- The SurroSense Rx system is a set of pressure-sensing shoe insoles that connect wirelessly to a proprietary smartwatch and is intended for people with diabetes who have mild to moderate sensory loss associated with diabetic peripheral neuropathy, or nerve damage.
- By providing real-time alerts about plantar pressure distributions, or the area of pressure between the foot and the surface supporting it, users of the SurroSense Rx system can alter their activities in order to relieve unsafe pressures.
- The SurroSense Rx system is used in addition to current standard-of-care treatment for the prevention of plantar ulcers in diabetic patients.
- There is currently no available evidence that using the SurroSense Rx system prevents plantar ulcers. However, there are ongoing clinical trials that may identify patient populations that will benefit from its use.

Issue

Over time, high blood sugar in people living with diabetes causes damage to the peripheral nerves — the nerves that serve the arms, hands, legs, and feet.[1] This damage, called diabetic peripheral neuropathy, includes symptoms such as painful tingling or burning sensations in the hands and feet, and the loss of protective sensations such as feeling pain or temperature changes.[1] When pain sensation is lost, there is an increased risk of developing open sores caused by prolonged pressure or other injuries.[2]

Pressure ulcers are sores that occur from rubbing (friction) or force, such as standing or walking for long periods of time, ill-fitting shoes, or pressure from a foot deformity.[2,3] A pressure ulcer that develops on the foot of a person with diabetes is called a diabetic foot ulcer. About 40% of diabetic foot ulcers occur on the bottom, or plantar, surface of the foot.[4] In 2011, the estimated health care cost associated with diabetic foot ulcer treatment in Canada was $547 million.[5]

Preventing plantar ulcers in people with diabetic peripheral neuropathy is the most effective way to reduce the potential for infection, repeat ulcer formation, and amputation due to complications of infected plantar ulcers.[6-8]

Plantar pressure measurement devices monitor and record downward pressure exerted on the bottom of the foot for a specific period of time.[9] This is done by having a person walk barefoot on a mat that has several sensors embedded within it. Each part of the foot that contacts the mat is measured (for example, the heel, sides, and ball of the foot).[9] The device records and transfers the sensor data wirelessly to a computer that performs various analyses. These systems have been in use for several years, but because of their size and various necessary components are used only in laboratory and research settings.[10-12]

Recently, there has been an increased interest in using this technology in everyday settings in people with diabetic peripheral neuropathy. Ideally, the device would monitor plantar pressures and provide real-time feedback to alert the wearer when unsafe increases in plantar pressure are reached.[7-9,11,13] With the development of miniaturized, wireless data collection units connected to shoe insoles, appropriately placed pressure sensors with this technology may now be possible.

The Technology

The SurroSense Rx system (Orpyx Medical Technologies, Calgary, Alberta) is designed to help prevent the formation of diabetic foot ulcers in people with sensory loss associated with diabetic peripheral neuropathy.[14,15] The system consists of two, thin, pressure-sensing shoe insoles; two clip-on pod devices that connect to the insoles by a flexible wire; and a proprietary smartwatch display device. The pods collect plantar pressure data from the insoles and wirelessly transmit this information to the smartwatch, which is worn on the user's wrist. The insoles fit inside the user's diabetic or walking shoes, underneath the shoe's insole or orthotic (Chan Mean, Marketing Manager, Orpyx Medical Technologies, Calgary, AB: personal communication,

2017 Mar 20). Each insole contains eight individual pressure sensors: three positioned across the base of the toes, two along the side of the foot, one at the heel, one under the big toe, and one under the remaining toes.[7,16]

The SurroSense Rx system is connected by pressing the "Connect" icon on the menu screen of the proprietary smartwatch while the user stands on the SurroSense insoles. Once connected, the watch will beep and/or vibrate with an alert indicating that the user has been successfully connected (Chan Mean: personal communication, 2017 Mar). When the wearer receives an alert from the smartwatch, a pressure map of each foot showing the location or locations where sustained pressure is occurring over a period of time is displayed.[14] The alert thresholds are based on integrating pressure data over time and identifying tissue that is at risk. The person decreases pressure by taking appropriate measures, such as sitting down or adjusting the positioning of their feet.[7,16,17]

Users of the SurroSense Rx system can choose to download, keep, and share their data using the Orpyx Connect web portal (Orpyx Medical Technologies, Calgary, Alberta).[18] Users of the SurroSense Rx system can contact Orpyx customer services directly if they have any questions or concerns (Chan Mean: personal communication, 2017 Mar).

The SurroSense Rx system (shoes not included).
Image courtesy of Orpyx Medical Technologies.[15]

Availability

The SurroSense Rx system (Orpyx Medical Technologies Inc., Calgary) was granted a Class II medical device licence by Health Canada in May of 2014.[20]

The system also has FDA clearance and is available in the US,[21,22] and is CE-marked for distribution in Europe.[23]

Those interested in purchasing the system can do so by using the online form located on the website of Orpyx Medical Technologies[15] (Chan Mean: personal communication, 2017 Mar).

Cost

The cost of the SurroSense Rx system is $3,399 US (Chan Mean: personal communication, 2017 Feb 6).

Who Might Benefit

Up to 50% of people with diabetes will develop diabetic peripheral neuropathy within 10 years of first being diagnosed.[24] People with diabetic peripheral neuropathy are more likely to develop foot ulcers and infection.[7,8,25,26] The risk of foot ulcer recurrence has been reported to be greater than 80% after three years.[4] As well, the repeated occurrence of foot ulcers has the potential to lead to lower limb amputation.[4,24,27,28] People with diabetes are 20 times more likely than the general population to be hospitalized for lower limb amputation due to complications of the disease.[8,28]

Other factors that increase the risk of developing foot ulcers are:

- increases in plantar pressures and temperature
- previous ulceration (strongest predictor) or amputation
- structural deformity
- limited joint mobility
- peripheral artery disease
- microvascular complications
- high glycated hemoglobin levels
- obesity
- fungal infection of the toenails.[10,25,28,29]

Current Practice

Prevention of Diabetic Foot Ulcers

The care pathway as described by Diabetes Canada (formerly the Canadian Diabetes Association) in the *2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada* and in regard to the formation of foot ulcers involves regular foot examination (which should include the assessment of skin temperature), prompt callus removal, and patient education.[28] In order to reduce pressure on the bottoms of the feet and accommodate foot deformities, people with diabetes should be advised to wear well-fitting or professionally fitted footwear.[25,28-31]

Treatment of Diabetic Foot Ulcers

Early detection and treatment of diabetic foot ulcers will prevent infection.[28-30] If a foot ulcer does occur, care must be taken to follow the fundamental basics of treatment: cleaning; cutting away dead, damaged, or callused tissue; infection control; and relieving pressure on the wound.[2,3,28,32] Temporary footwear, such as removable and non-removable cast walkers and total contact casts, are effective at relieving pressures during the healing of non-infected, non-ischemic (good blood supply to the area) plantar surface ulcers.[2]

Reduced pressure on the plantar surface should continue until the ulcer fully heals.[3,28] Total contact casts — which cover the lower leg and foot in a well-moulded, lightly padded plaster cast — are considered the gold standard for offloading pressure on the wound.[3] However, there is a reluctance to use this treatment because of the increased time in applying the cast, its cost, and the expertise needed for its proper application.[3,28,30]

If the ulcer becomes infected, an immediate change in treatment, such as adding antimicrobial therapy, is required, as infection may progress and increase the risk of amputation.[2,28]

The Evidence

There are two trials that investigate the SurroSense Rx system technology: a validation study[7] and a prospective cohort study.[16]

Comparison to the Pedar X Device

Ferber et al. compared the SurroSense Rx system plantar measurements to the pedar X (Novel, St. Paul, Minnesota), considered a reliable device for measuring plantar pressures.[3,7,12] The outcome measure was the ability of the SurroSense Rx insole to detect plantar pressures greater than 32 mm Hg in each of its eight sensors, which is the minimum pressure needed to form a diabetic foot ulcer.[7]

Ten healthy volunteers (three women and seven men) participated in the study. The results reported that six of the eight sensors on the SurroSense Rx system insole correlated to "very good" (2/8, correlation coefficient for bivariate analysis [r] = 0.86 and r = 0.84) or "good" (4/8, r = 0.67 to 0.73) alongside the pedar X system; two sensors did not correlate well (r = 0.41 and r = 0.38). The variation in correlation may be the result of the SurroSense Rx sensor not being located in the exact centre of pressure.[7]

Treatment Adherence

Custom insoles that relieve pressure from vulnerable plantar areas are frequently prescribed to diabetic peripheral neuropathy patients, but in many cases they are not worn.[4,29,31] Najafi et al. used the SurroSense Rx system in a study to examine whether alert-based cues would increase adherence to treatment in people with diabetic peripheral neuropathy. Twelve patients with a history of plantar ulcers in the last 12 months, between the ages of 53 and 71 and with an average body mass index of 33 kg/m^2, completed the six-month study — three months wearing an active device followed by three months of follow-up to check for ulcer formation. Patients were surveyed on the number of hours they wore their diabetic footwear, how quickly they responded to alerts, and user experience (i.e., device usefulness, ease of use, satisfaction, and usability). Patients reported that they wore their diabetic shoes with inserted SurroSense Rx insoles for longer periods of time (2.22 hours [29.2%] more) than what was recorded on the SurroSense Rx system. The authors reported a trend that patients who received a higher number of alerts were more likely to wear their shoes fitted with the SurroSense Rx insoles (eight hours compared with 3.6 hours per day). Over the duration of the study, these people were also significantly more likely to respond more quickly to alerts. For example, at the third month of the study, those who had received a low number of alerts responded to them in about 57.3 minutes compared to those receiving a high number of alerts, who responded in about nine minutes. [16]

Experience Using the SurroSense Rx System

Patients in the Najafi et al. study were asked about their experience using the SurroSense Rx insoles. Responses showed that, overall, users found the device pleasant and easy to use, and that the performance of the system was high.[16]

Limitations and Ongoing Research

Because of the low number of patients in the Najafi et al. study, it is difficult to make conclusions about whether or not the SurroSense Rx system increases treatment adherence in people with diabetic peripheral neuropathy.

To date, there is no evidence identified to support the use of the SurroSense Rx system as a means to prevent plantar ulcers in people with diabetic peripheral neuropathy. One limitation of the device is that the sensors located in the insoles measure only downward pressure at eight areas of the plantar surface. But there are other stresses that contribute to the formation of plantar ulcers, such as increases in plantar temperature and side-to-side movement, or shear.[10,17,33] It has been reported that patients who did not use temperature monitoring were four times more likely to develop foot ulcer recurrence than those who did.[30,33]

However, there are two clinical trials underway in Canada that may provide evidence of the efficacy of the SurroSense Rx system as an addition to standard treatment in specific patient groups:[34,35]

- Investigators from the University of Alberta are currently recruiting participants for a randomized controlled trial (RCT) that will evaluate the efficacy of the SurroSense Rx system to improve diabetic foot outcomes by preventing future wounds in high-risk patients who have recently been treated for active foot ulcers.[34]
- In an upcoming RCT, investigators from the University of Calgary will examine the capability of the SurroSense Rx system in managing and monitoring adherence to plantar pressure offloading through alert-based feedback.[35]

Safety

There were no adverse effects from using the SurroSense Rx system reported in the published studies.[7,16]

Concurrent Developments

Pressure-Sensing Insoles

There are other new technologies similar to the SurroSense Rx system being applied in different patient populations.[36,37] For example, Lin et al. have developed the Smart Insole to dynamically measure and assess changes in plantar pressures over time. The Smart Insole version 2.0 has 48 pressure sensors embedded in the insole and is unobtrusive, without any extra cable, antenna, or need for adhesives. The intended users of the Smart Insole are those at risk of overexertion injury, such as nurses and other health care workers.[38]

"The device does not provide real-time measurement, an issue to be addressed in future research."

Smart Diabetic Socks

In 2014, Perrier et al. developed a prototype device called Smart Diabetic Socks for people with diabetic peripheral neuropathy as a possible preventive measure against the development of foot ulcers. The prototype device has three main components:

- a 100% textile sock with eight pressure sensors knitted within
- a central unit (a battery-operated data collection device) connected to the upper part of the sock
- a wireless external device that receives data collected by the central unit.

The device does not provide real-time measurement, an issue to be addressed in future research.[39]

A 2014 poster presentation of a validation study by Najafi et al. described the accuracy of a prototype device called SmartSox. It measures plantar pressure, temperature, and joint motion in real time. The wearable garment, with integrated optical fibre containing multiple sensors, was tested in 21 people at high risk for developing diabetic foot ulcers. The SmartSox prototype was found to be feasible for the safe in-shoe measurement of temperature and pressure during walking. It is estimated that the socks will cost upwards of US$70,000.[40-42]

An abstract from the 2014 meeting of the International Conference on Advanced Technologies & Treatments for Diabetes describes the development of a smart sock.[43] Researchers from the Fraunhofer Institute for Silicate Research, together with colleagues from the Fraunhofer Institute for Integrated Circuits, developed a prototype of a special stocking with 40 very fine, dielectric elastomer sensors that measure compression load and distribution for people with diabetic peripheral neuropathy.[43] The sensors are attached to the stocking's sole, at the heel, the top of the foot, and the ankle, so that they can take readings in three dimensions. A pair of stockings is expected to cost no more than €250 and can be manufactured in a series to keep costs down. Measurement data are transmitted wirelessly to a smartphone or tablet, which then informs the diabetes patient that it is time to change foot position or weight distribution.[44]

Siren Smart Socks (Siren Care, San Francisco, California) track temperature increases on the plantar surface and alert the wearer by way of a smartphone if there is a significant difference between the same two spots on both feet. The US$120 purchase includes seven pairs of machine-washable socks that last for six months and with batteries that provide continuous monitoring, a smartphone application for receiving the data from the socks, and written instructions. The socks, expected to be available in the spring of 2017, are marketed as a health and wellness device, not a medical device, as they do not claim to prevent or diagnose any medical condition.[45]

Other Research

Orpyx Medical Technologies Inc. is applying the functionality of the SurroSense Rx system to develop the SurroGait Rx system. It comprises sensor-embedded inserts that are worn inside running or walking shoes, and an ergonomic back display worn on the user's back. Pressure information collected from the insert is wirelessly sent to the back display, which transposes sensation that would otherwise be felt on the foot onto the back, so that the user can "feel" their feet through the back.[46]

Rate of Technology Diffusion

As part of Alberta Health Services' implementation and evaluation of the Diabetes Foot Care Clinical Pathway Development Project,[34,47] the SurroSense Rx system is being tested at sites across the province with the intention of assessing clinical outcomes and clinician and patient satisfaction with the system, and to increase exposure of the product within the Alberta health care system.[48]

No other information about the diffusion of the SurroSense Rx system in the Canadian health care system was identified.

Implementation Issues

The SurroSense Rx system is intended for use as an addition to the current treatment of diabetic peripheral neuropathy patients (Chan Mean: personal communication, 2017 Mar).

Additional information about the SurroSense Rx system is needed to inform decisions about adopting the technology. For example:

- How is the device fitted for individuals who use the technology to ensure that they are using it properly — i.e., that they have correctly placed the insoles such that the sensors are recording the areas at highest risk of injury?

Pressure sensor readings can drift over time.[49] As well, a person's centre of pressure on the plantar surface can change.[11,12] There has been mention in the scientific community about the lack of standardization related to the appropriate use, measurement protocols, data extraction, and interpretation of plantar pressure measurement devices.[13] Some factors that are considered important to address in the clinical setting are the repeatability of results, calibration, and accurate centre of (plantar) pressure measurements in any plantar pressure measurement device.[11-13,49] To ensure accurate readings, it is recommended that SurroSense Rx system inserts be replaced after 12 months or 500,000 steps (Chan Mean: personal communication, 2017 Mar).

Final Remarks

The SurroSense Rx system is intended for people with diabetic peripheral neuropathy who are at risk of developing, or have recovered from, a plantar ulcer. While there is currently no available evidence to support its use in this group of people, the results of upcoming clinical trials may help in identifying a patient population that will benefit from its use.

Methods — Literature Search Strategy

A limited literature search was conducted using the following bibliographic databases: MEDLINE, PubMed, Embase, and the Cochrane Library. Grey literature searching included relevant sections of the *Grey Matters* checklist (https://www.cadth.ca/grey-matters). No methodological filters were applied. The search was limited to English-language documents published between January 1, 2015, and January 20, 2017. Conference abstracts were included in the search results. Regular alerts updated the search until project completion; only citations retrieved before March 6, 2017 were incorporated into the analysis.

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