



From Reactive to Proactive: Using Sensory Insole Technology to Create a Paradigm Shift in Diabetic Footcare

Orpyx's remote patient monitoring technology has shown great promise in reducing diabetic ulceration.

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Diabetic foot disease has detrimental impacts globally that are compounded every minute. Every 30 seconds, a lower limb is lost due to diabetes.¹ Diabetic foot disease complications are rooted in progressive peripheral neuropathy (PN), which leads to a loss of protective sensation (LOPs) and impacts approximately 70% of people with diabetes.² According to Cavanaugh et al., 1.7M diabet-

to diabetes, their mortality exceeds 70% after five years.⁷ This reinforces the need for a preventative approach to diabetic footcare to avoid amputations and improve mortality rates and overall quality of life.

Importance of Preventative Care

The cyclical nature of DFU development further underlines the importance of preventative care. Historically, when a DFU develops, a patient visits their clinician, receives treatment for a period of time until the wound heals, and is discharged. In this care model, it is a matter of time before most patients re-ulcerate and must begin the reactive treatment process once again. The observation of this cyclical disease state and the fact that the current treatment paradigm results in a 49% recurrence rate in the first year and a 68% recurrence rate within five years, has introduced the concept that once a DFU is closed, patients should be seen as in remission as opposed to healed.^{7,9} Creating expectations for patients and their loved ones that once their wound is healed, they will be able to move forward without regularly monitoring their feet is dangerous as it suggests that

Continued on page 130

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ic foot ulcers (DFUs) develop each year in the United States.³ With under-managed diabetic peripheral neuropathy (DPN) being the primary cause of non-traumatic lower limb amputation⁴ and 85% of lower extremity amputations (LEAs) linked to diabetes being preceded by a foot ulcer, it is estimated that up to 85% of diabetes-related amputations can be prevented.⁵ Despite these staggering statistics, there has been a longstanding approach of reactive care for diabetic foot complications.

Current combinations of the disease state and standard of care (SOC) treatments reflect a 5-year mortality rate of 30.5% for diabetic foot ulcers, more than three times that of breast cancer, which has a 5-year mortality rate of 9%.⁶ On top of the mortality resulting from DFUs, other diabetic foot complications such as Charcot arthropathy, minor, and major amputations have 5-year mortality rates of 29.0, 46.2 and 56.6%, respectively. This is appalling, especially given the preventative potential that treating diabetic foot disease has. The severity of diabetes-related mortality is further highlighted by the fact that after an individual has undergone an amputation due

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the risk of DFU recurrence is non-existent. It is imperative not only that realistic expectations be set, but that patients be provided with the appropriate tools to monitor their feet such that they are able to maintain the health of their feet while enjoying daily activities (Figure 1).

An important aspect of diabetic footcare is patient education; however, this alone is not enough. According to research, patients immediately forget up to 80% of what their healthcare provider (HCP) said, and of the 20% they do remember, 50% of it is incorrect.¹⁰ With this knowledge, it is clear that a more consistent means of supporting diabetic footcare is required. Furthermore, current care regimens focus largely on reactive treatment. As a result, even preventative education provided to a patient is diluted given that the DFU is being treated in a reactive manner. It is common that patients only see their healthcare provider once they detect a problem. This may be severe callus development, a small DFU, or a severely infected DFU. As a consequence of DPN, perceived foot problems are often more severe than expected by a patient who detects them, if the problem is detected at all. The lack of protective sensation resulting from the neuropathy often results in tissue damage going undetected for long periods of time. Once a patient sees their HCP, it is often too late for a preventative approach. Providing preventative education in these instances often seems less relevant than the issue at hand, and the importance of it from a patient perspective can easily be overlooked. According to a review of studies with a focus on patient education in DFU prevention, “there is insufficient evidence that education alone, without any additional preventive measures, will effectively reduce the occurrence of ulcers and amputations”; only short-term educational impacts were observed in this review.¹¹

Coupling the cyclical nature of DFU development and the need for consistent reinforcement of preventative behaviors, the importance of a comprehensive diabetes management solution is quite clear. Given the abundance of comorbidities associated with diabetes, it is essential to optimize the amount of support that can be offered to patients yet allow them to continue living their everyday lives. When solutions specific to diabetic foot treatment are developed, it is important that they can be integrated not only into a patient’s life, but also into a healthcare setting. Healthcare settings for those with diabetes typically offer services for several related comorbidities (i.e., dietary guidance, wound care etc.). For a preventative solution to be as beneficial as possible, it is important that it can be used by both the patient and HCP and compliment the diabetes management services offered to patients.

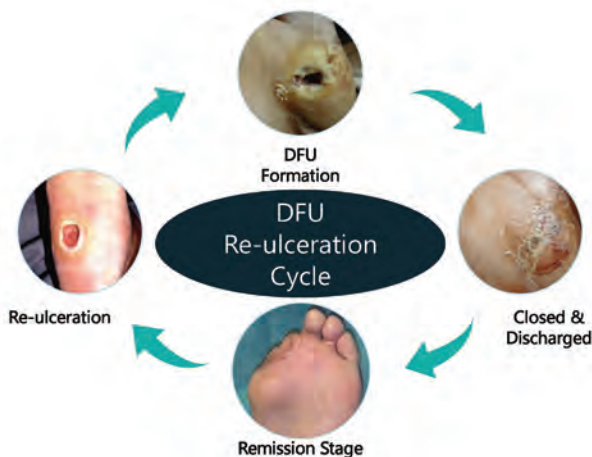


Figure 1: The recurrence cycle of a diabetic foot ulcer.

From a patient standpoint, it is important for solutions to afford a certain degree of autonomy over their foot health such that complications can be prevented and visits to the clinic can take place at a frequency that doesn’t deter the patient from attending their visits altogether. Especially during the remission stage of the DFU development cycle, some patients feel that regular footcare is not necessary; this perception is dangerous as it has the potential to shorten the duration of the remission stage. From a clinician standpoint, it is important to be provided with remote feedback from the patient such that pre-ulcerative indications can be detected, and preventative measures can be taken as needed. Remote patient feedback allows

for care to be tailored to each patient on a continuous basis. Altogether, a solution customized to both patients and clinicians encourages a unified approach to care where the patient and HCP can work as a team to maintain the patient’s long-term foot health, improve their quality of life, and decrease office visits.

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Value of Remote Patient Monitoring Services

Remote patient monitoring (RPM) has become increasingly common over the past two years given the current global health climate. It has become clear that there is great potential to expand existing RPM services to both chronic and acute conditions.¹² This allows for increased convenience, personalization of care, data-based decisions and reduced downstream costs to the healthcare system.¹² Beyond this, entities such as Centers for Medicare and Medicaid recognize the value of RPM services. This is evidenced by the remote physiological monitoring CPT codes that were introduced in 2019.¹³ These codes include coverage for the initial set-up and patient education of the equipment being used (99453), data alert transmissions (99454), and treatment management time based on interactive patient communications (99457, 99458).¹³ The introduction and use of these codes has enabled HCPs to provide increasingly comprehensive care to their patients.

Continued on page 132



The Orpyx Sensory Insole System

The Orpyx SI[®] Sensory Insole System (Orpyx Medical Technologies Inc, Calgary, Canada) is a comprehensive solution which supports a paradigm shift from reactive to preventative care. It addresses the need for recognition of the remission stage in the DFU development cycle, increased patient engagement in day-to-day footcare and the availability of reliable data to help HCPs make informed decisions in between office visits. This innovative



Figure 2: Orpyx SI Sensory Insole System with sensory insoles and a digital display which collect data for RPM purposes.

system is comprised of two sensory insoles and an app-based digital display which collect data for RPM purposes. It targets preventative care, specifically the prevention of DFU development and LEAs. This solution monitors pressure, temperature, adherence, and step count. It provides patients with audiovisual alerts, thus allowing them to make behavioral adjustments and proactively address high-pressures that put the plantar surface of the foot at risk of tissue breakdown. The cloud-based, HIPAA-compliant dashboard allows for the remote monitoring of real-world data and for preventative, patient-specific care to be delivered consistently by HCPs (Figure 2).

Promising Results from Randomized Controlled Trial

Results from a randomized controlled trial showed that use of the Orpyx Sensory Technology resulted in an 86% reduction in ulceration for those that wore the insoles for at least 4.5 hours per day and a 71% reduction in ulceration regardless of how long the insoles were worn.¹⁴ This study involved both patient groups using the sensory technology, thus allowing for insight into the value of the real-time alerts and actionable behavioral change suggestions. It is widely known that the elevation of plantar pressure is a causative factor in DFU formation, and that pressure offloading is key to both DFU healing and prevention.¹⁵ Sensory technology is a means of monitoring offloading effectiveness¹⁵ which enhances SOC treatment and suggests that this solution is a beneficial adjunct to SOC. The Orpyx SI Sensory Insole System offers both adherence monitoring and a means of verifying appropriate pressure offloading; this combination is known to provide the greatest clinical benefit.¹⁵ The importance of plantar pressure relief is further highlighted by its inclusion in the

DFU prevention guidelines outlined by the International Working Group on the Diabetic Foot (IWGDF).¹⁵ There are other factors linked to DFU development that are known to be indicative of tissue damage; temperature is one of these factors. The difference between plantar pressure and temperature is that while pressure is linked to prevention, temperature is considered an indicator of inflammation and is primarily linked to prediction of DFU development.¹⁶ Un-

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fortunately, DFU prediction alone does not lend directly to an effective preventative solution. According to literature, “it is a well-established theory in medicine that prevention strategies are based on early detection and prediction of pathological change”.¹⁶ This is an important point as it highlights the need for multi-factorial monitoring in order for a DFU prevention solution to be effective (Figure 3).

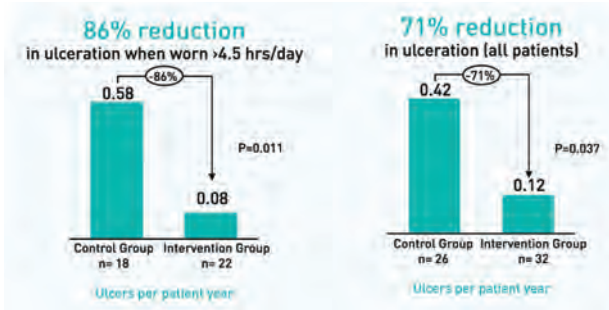


Figure 3: Randomized controlled trial results indicating statistically significant reductions in ulceration rates for patients using the Orpyx Sensory Technology

Reactive and Preventative Spectrum

Figure 4 outlines the spectrum of reactive and preventative windows in the DFU development process. It illustrates the early stages of elevated pressure followed by tissue inflammation and temperature increases. While both pressure and temperature are part of this spectrum, it is clear that elevated pressures are introduced earlier in the DFU development process, thus making pressure a more appropriate primary variable to target as part of DFU prevention strategies. Temperature, adherence, and step count are all supporting factors that are beneficial to monitor such that the preventative efficacy can be evaluated (Figure 4).

Overall, a total shift in DFU prevention approaches is needed. Although progress has been made, there is a long way to go before an effective treatment model is achieved. It is imperative to have a multi-faceted solution that will

Continued on page 133



Figure 4: A preventative approach for diabetic foot ulcers needs to address the causative factors in real-time.

allow the monitoring of preventative AND predictive factors, patient engagement and clinician insight into data. Together these components offer a comprehensive solution that can help to prevent diabetic foot complications in the short- and long-term, and in doing so, save limbs and save lives. **PM**

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Continued on page 134



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