

Problem Challenge Solution of a Home Technology System for Temperature Trending for Prediction and Prevention of Diabetic Foot Ulcers and Amputation

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Confidential

Overview

A major complication of diabetes is the development of foot wounds (diabetic foot ulcers) that ultimately lead to multiple hospitalizations; surgeries; and amputation. Amputation of a foot or leg is the greatest fear that a diabetic has. Healthcare systems in the United States and globally will react to an already existing clinical problem and have not concentrated on predictive and preventative methodologies that will significantly reduce human suffering while concurrently reduce the financial burden to health care systems of this horrific complication.

Outcomes achieved utilizing a predictive and preventive methodology by my group have shown reductions of hospitalizations; length of stay; and amputations by almost 70% in major payer populations in the United States.

A 24/7 home monitoring technology to address the major cause of tissue breakdown into diabetic foot ulceration will further reduce complications in a scalable manner to hundreds of thousands of at risk patients in the United States and world wide concurrently.

The Problem

Greater than 40% of all diabetics have neuropathy and are insensate. This clinical condition is the major cause of diabetic foot wounds leading to multiple hospitalizations, surgeries, and ultimately amputation. 84% of all amputations begin with a diabetic foot ulcer.

A 24/7 home monitoring technology will address the underlying etiology of this major complication and will allow biometric data to be analyzed to determine if tissue is in imminent danger of destruction into wounds. Distribution of the technology to insensate and highly at-risk individuals will help reduce hospitalizations, length of stay, surgeries, and amputations by 50-70% in major diabetic populations based on previous published studies and clinical outcomes.

The primary clinical goal is to address the mechanism of injury that leads to diabetic foot wounds. By understanding and addressing this mechanism of injury diabetic foot wounds can be significantly lowered in major populations and thus reduce human suffering and dramatically eliminate the financial burden of treating these complications.

The clinical formula for the mechanism of injury causing diabetic foot wounds (ulcers) is:

Neuropathy + abnormal biomechanical pressure → Inflammation → enzymatic autolysis of tissue (foot ulcer)
→ multiple hospitalizations; surgery; amputation

Key:

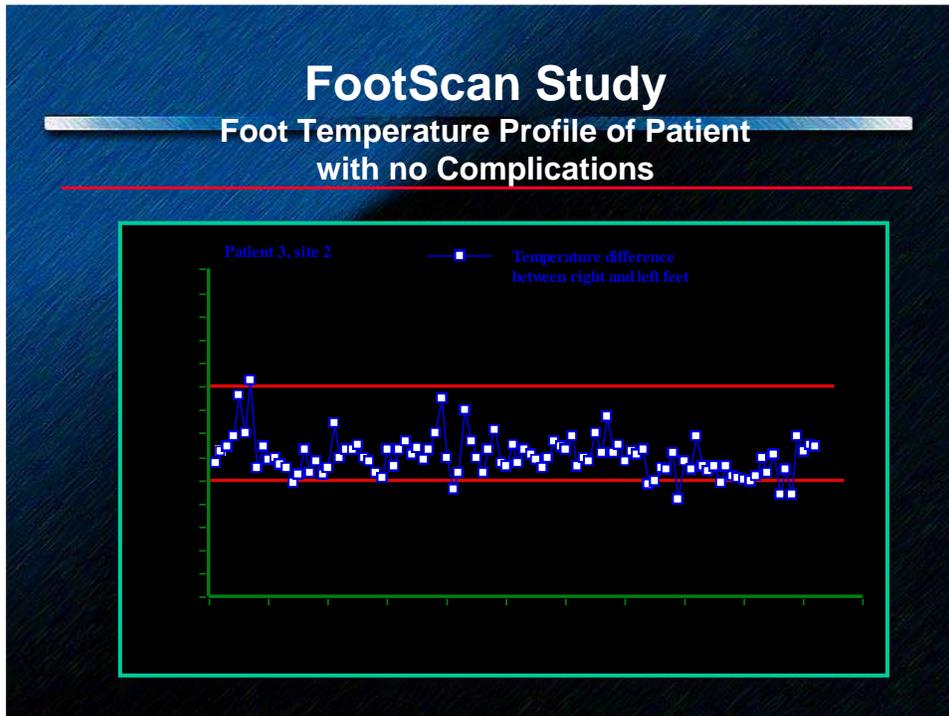
- a. Neuropathy (insensitivity) is defined as loss of the pain protection mechanism where a person is no longer able to feel pain to protect the foot from injury. This is not reversible.
- b. abnormal biomechanical pressure is measured in Newtons/cm² and can be just the pressure of walking that may lead to inflammation: pain to the normal feeling person, but not to the person who is insensate
- c. inflammation is caused by biomechanical pressure and can be measured as skin temperature in degrees
- d. Repetitive pressure on the Inflamed area over a short period of time (days) causes the skin to break open and ulcerate allowing infection to develop. This can be caused by just the pressure of walking.

The clinical problem results when the patient does not recognize the pain of inflammation and thus most times presents to the clinician with an already existing wound. The technology will act to take the place of

the warning signals that pain elicits. Through the science of temperature trending, an algorithm has built to determine when tissue will breakdown in the presence of neuropathy.

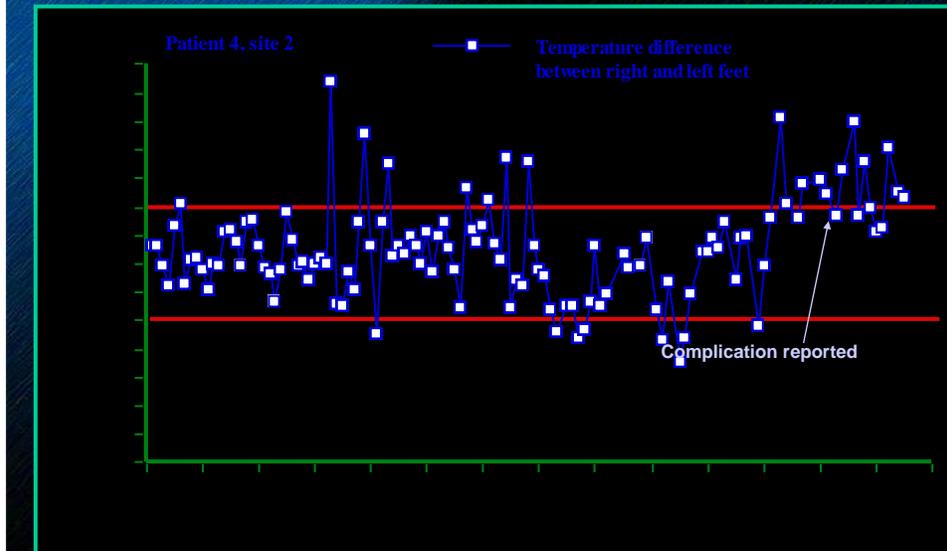
Example of What the Technology/Clinical Analyst Sees Daily

The Red Zone boundary is the “safe zone.” It takes two to three weeks to establish the baseline of what is the safe zone, which is the normal baseline in temperature measurement for an individual patient. Every patient is different. If the temperature spikes over a short period of time outside the safe zone, then the patient is at risk for imminent breakdown and is notified by the care manager to utilize an “off weight bearing” device that has been distributed to the patient at the time of evaluation. If we utilize this strategy, the biomechanical pressure causing the spike will be reversed, thus the inflammation (temperature) reverses itself back into the safe zone, and the patient is out of danger.



Patient 1

Temperature profile of patient that developed ulceration



Patient 2

Each point is a comparison of temperatures between contra-lateral points. Infra red technology was used in these cases.

Over a three month period of time, patient (1) remained out of danger of breakdown.

In patient (2): this patient, who was a construction worker, continually was in danger, spiking above his safe zone multiple times. Ultimately at month three, because he was not allowed to take off from work any longer, developed a severe complication, and was admitted to the ICU with resultant amputation.