

Title: In-home Diabetic Foot monitoring technology

Clinical Problem: Patients with severe diabetic (DM) neuropathy (e.g. severe numbness in feet) are at increased risk for developing diabetic foot ulcers (DFUs) and/or applying uneven pressure on the foot that can result in foot deformities. Undiagnosed DFUs or poorly controlled DFUs can often result in osteomyelitis (infection of the bone) and, hospitalization/ re-hospitalizations (~ 15 to 25% of patients with DFUs). Severe DM neuropathy in the feet can also result in uneven pressures placed on the foot that can result in malformations of the foot arch. Many patients are unaware of such foot pressure changes or arch malformations over time. This can result in a collapsed foot (e.g. Charcot foot) and further increase the risk of DFUs or osteomyelitis.

While many patients with diabetic neuropathy are aware of the risks of developing diabetic foot ulcers (DFUs) or altered foot arch, many patients do not check their feet regularly. The decreased sensation in the feet results in a lower recognition of events that can result in DFUs, awareness of ulcers on their foot, or arch changes in the foot. Patients also reported that inspection of foot was difficult due to decreased sight, decreased flexibility of lower limbs, and poor recollection of skin changes in the foot. In addition, patient's remarked that they do not know how to detect changes in the foot arch.

Translational importance: Patients with DM need a device for routine home inspections of their feet and to document foot changes over time. A method to detect cuts/puncture wounds in the skin, foot ulcers, and alterations in the foot arch at a patient's home may result in significant reductions in morbidity, health resource utilization, and increased ambulatory time. This can help limit DFUs and arch changes. Undetected or poorly treated DFUs and abnormal foot pressures can result in hospitalizations, morbidity from infections, increased healthcare utilization, abnormal gait/decreased ambulation, and/or limb amputations. DFUs and arch malformations can occur in ~1 - 7% annually of individuals with DM and result in a cost of \$1.6 B - \$12 B to the US health care system. Currently there is no home monitoring devices that patients can use to inspect and document their feet as part of routine home diabetes care.

Desired outcomes: I would like to work with our engineers to develop a device that patients with DM can inspect their feet and toes and document changes in their feet over time. This device a) Can image the feet with magnification and transmit images to a screen so the patient can view the feet look for cuts/puncture wounds in the skin or foot ulcers. b) record the image the of feet so these can be viewed over time (e.g. JPEG, PDF). c) Determine the area & pressures at the positions on the foot (e.g. the heel, midfoot, ball of foot/metatarsophalangeal joints, hallux (big toe), and lesser toes). d) Report changes in area and pressures (e.g. color code with ascending order of pressures) over time. e) Send the collected information wirelessly/Bluetooth to a recording device/iphone based app. The development of this device will help patients with reduced range of vision or range of motion to help monitor their feet regularly and aid physicians to understand changes to DFUs and arches of feet in real time. This proposal will lay the groundwork for future multidisciplinary collaborations between biomedical engineers, the medical School, and public health.

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