

Diabetic Foot Ulcer Early Detection

BMEN 3151 Medical Device Practicum

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Clinical Problem

In 2015, the CDC reported that there were over 30 million Americans living with diabetes and the diagnosis rates are increasing every year. Diabetes mellitus is an insulin dysregulation disorder with systemic manifestation, including peripheral neuropathy. 45 –59% of diabetic patients will experience some degree of neuropathy. Peripheral neuropathy with loss of sensation increases the risk of foot ulcerations. The lifetime incidence rate of foot ulcers in diabetic patients is 19 –34%. Ulcers are treatable, but if not caught early there is high risk of infection. The 5-year mortality rate for diabetic foot ulcer patients is 43-55%, for diabetic lower extremity amputation patients, it is 74%.



Medical Device Solution

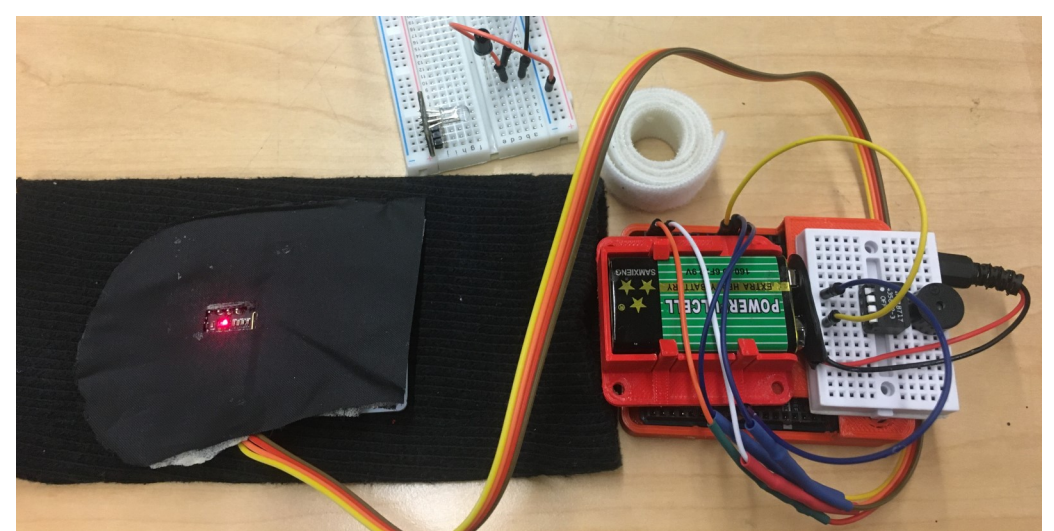
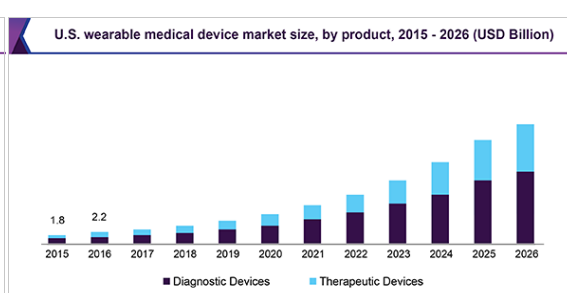
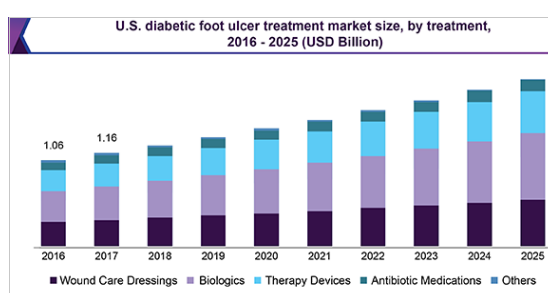
The ulcer prevention device was built using an Arduino Uno microcontroller and an integrated LED-photodiode sensor chip. The LED emits 660nm wavelength red light into the foot of the patient and the photodiode sensor detects nonabsorbed/reflected light. Oxygenated hemoglobin absorbs light 660nm, so the percent of light detected by the photodiode was taken to be inversely proportional to blood/oxygen load passing to the foot. The immune response to repeated mild-trauma that would precede an ulcer or infection increases oxygen consumption at the site (foot). The increase in oxygen required at the injury site would increase the blood flow to the foot and the increase in blood/oxygen load is what the device detects. The system provides audio output via a speaker when the patient's oxygen readings are abnormal. The system's software records a patient's oxygen levels for a 60-second calibration period and then calculates an acceptable range about the baseline. If a reading is above or below what has been calculated as the acceptable range, the speaker emits a sound to warn the patient. The sensor was placed in a sock and the remaining circuitry is attached to the patient's leg in a small light-weight control box, which will have minimal interference with their daily life and allow for continuous monitoring of oxygen levels and potential ulceration.

Needs Statement

Diabetic neuropathy patients need a way to be alerted to potential development of a diabetic foot ulcer before more serious and expensive complications occur

Market Analysis

In 2017, the diabetic foot ulcer treatment market was valued at 3.6 billion US dollars. This market size is expected to expand 8.2% annually through 2025. This expansion can be attributed to a growing geriatric population and the increasing prevalence of diabetes. The wearable device market which was valued at 10.3 billion US dollars and is expected to increase 26.1% through 2025. The ulcer detection device will tap into both of these markets as it will allow more patients to be diagnosed earlier and receive the appropriate treatment, and will also mitigate the large financial burden seen by the insurance companies associated with covering infection/amputation healthcare costs.



Team Photo

