



CLINICAL STUDY

Intelligent Prophylaxis of Diabetic Foot Ulcer

Arthur Grünerbel¹  and Lorenz Grünerbel² 

¹Diabeteszentrum München Süd, Fußnetz Bayern, Germany

²Fraunhofer EMFT, Germany

*Corresponding author: Dr. Arthur Grünerbel, Diabeteszentrum München Süd, Fußnetz Bayern, Stockmannstr. 47, 81477 Munich, Germany



Abstract

A high skin surface pressure at the feet over a longer period of time can cause foot ulcers. It can occur due to insufficient relief of tissue and a lack of alarm signals from the nervous system, especially for patients with Diabetic Polyneuropathia. A healthy person would move and relieve the foot after a while. A medical wearable can warn a patient without natural alarm signals. However, the required wound indicators are not known, yet. This work presents a medical wearable that is able to measure pressure load at wound risk areas as well as the skin temperature and the blood oxygen saturation nearby. Combined with the data analysis by artificial intelligence we want to identify the relevant wound predictors. Therefore, we conduct a clinical study with patients at risk for diabetic foot ulcers.

Keywords

Diabetes foot ulcers prophylaxis, Medical wearable, Ulcer prediction, Machine learning, Diabetic polyneuropathia, KIPRODE

Introduction

The occurrence of diabetic foot ulcers increases because of the growing number of diabetic patients all over the world. As known, about 8-15% of the diabetes population will get ulcers once upon their lifetime. In Germany, every 13.4 minutes a diabetes related amputation is required [1]. Hence, it is a major task for all of us to reduce these numbers and avoid diabetic ulcers, the main reason for amputation. Loss of peripheral sensitivity is the main reason for wounds, as it makes it impossible to sense an increased pressure load. Thus, we search for a tool to prevent patients from too much plantar pressure.

Materials and Methods

Within the founded project “KIPRODE”, the consortium of Fraunhofer EMFT, Munich; Technical University Munich, MRI, and Foot Net Bavaria developed a wound prophylaxis tool, with a sole foil as shown in Figure 1, connected to a wearable electronic kit [2]. Figure 2 shows the electronic wearable device, that is connected with the sensor foil and fixed above the ankle. Additionally, we gain data about skin temperature, oxygen saturation and movement to differentiate between sitting, standing and walking. The data is analyzed by means of machine learning to find patterns that allow to predict wound occurrence. The research hypothesis is, that in early stages of wound occurrence, and even before that, pressure load changes the skin and leads to development of hyperkeratosis. That can result in skin breakdown and further injury, possibly followed by infections and deeper wounds, which are the forebodes of amputation [3,4]. To prevent that, we introduce a small and portable tool as displayed in Figure 2, that detects and signals the risk of a pressure injury based on machine learning methods.

Results

Our patients had to use the tool at least for 4 hours during daytime when sitting, walking and offloading. The different pressure patterns could be monitored and either correlated to other sensor data such as skin temperature, patient movement, SpO₂ values and a patient's diary. Also, there was a constant link to the nurses and doctors to visit the foot twice weekly. The



Figure 1: In-shoe sensor: A sensor system continuously monitors pressure load at wound risk areas.

time of moving, the amount of pressure, the skin temperature and SpO₂ can be clearly extracted.

Machine learning will be used for further investigations and help extracting the required early wound indicators. A signal will be sent to the patient to offload at immediately and the physician or podiatrist can be notified.

References

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Figure 2: Installed wearable for foot ulcer prophylaxis at a patient's foot.