Multimodal in-shoe sensing and soft robotic insoles, to advance understanding and management of diabetic foot ulceration

A. Weightman[1], A. Haron[1], L. Li[1], J. Shuang[1], M. Mansoubi[2], C. Lin[1], D. Crosby[1], G. Massey, H. Dawes[2], G. Cooper[1]
[1]Medical Engineering Research Group, School of Engineering, University of Manchester, United Kingdom
[2]NIHR Biomedical Research Centre, University of Exeter, Exeter, United Kingdom
Email: andrew.weightman@manchester.ac.uk

Summary

The two-year happier feet project sought for the first time to: (1) collect and analyze normal stress, shear pressure and temperate data from people with and without diabetes; and to (2) develop an actuating insole to modulate plantar pressure without negatively effecting gait kinematics. The project resulted in (1) novel data sets demonstrating differences in thermal regulation of the foot in people with and without diabetes; (2) new calibration procedures demonstrated to be essential for accurate shear pressure measurement; (3) a proof-of-concept soft actuating insole for pressure modulation. The project advanced our understanding and developed potential technologies to reduce the risk of diabetic foot ulceration formation.

Introduction

Diabetic Foot Ulcers (DFUs) cost the UK NHS £1 billion annually, affecting up to 25% of people with living with diabetes [1]. Smart insoles offer a potential low-cost, self-management prevention method. While current technology uses static offloading based on normal plantar stress, DFU risk is associated with both normal and shear stress, and plantar pressure varies dynamically with activities. The Happier Feet project aimed to develop "sensing insoles" and "active insoles" to collect novel data and intelligently modulate peak plantar pressure (PPP) and pressure-time integral (PTI), potentially reducing ulcer formation risk and providing new understanding of DFU biomechanics.

Methods

The project developed: (i) Temperature, Normal and Shear (TNS) sensing insoles, and (ii) active offloading insoles (Figure 1). The TNS sensing insole produced novel shear sensors coupled with commercial normal sensors for personalized in-shoe plantar stress measurement at the calcaneus, first metatarsal head, and the hallux. TNS sensor calibration and its relationship to measurement accuracy was also investigated [2]. TNS data were collected in 10 people living with diabetes and 10 healthy people during a laboratory-based gait and rest protocol [3]. A novel active insole was designed facilitating local actuation to create global foot pressure change informed by normal plantar pressure data [4].

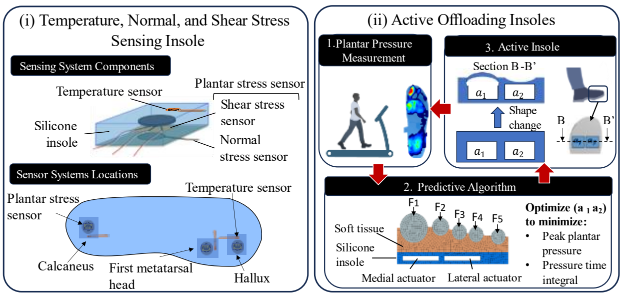

Figure 1: Novel healthcare technologies developed in the project.

Results and Discussion

Figure 2 highlights the results of the project. The validation of the TNS sensor highlighted that patient-specific calibration enhances shear stress measurement accuracy. Individual variations in temperature profiles and plantar stress (normal and shear) were observed among participants, likely attributable to differences in physiology and gait patterns. Notably, people living with diabetes may exhibit impaired temperature regulation compared to healthy controls. The active offloading insole achieved a global redistribution of pressure, effectively reducing both PPP and PTI without adversely affecting gait or balance.

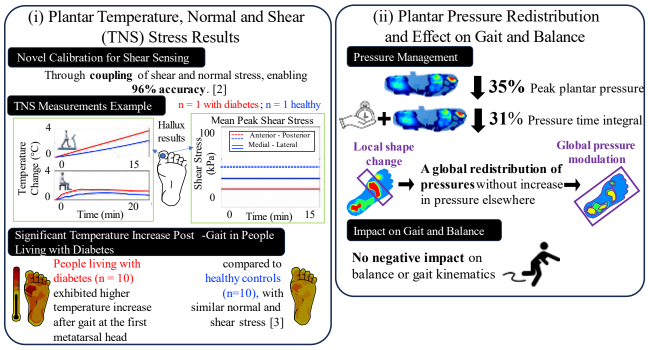

Figure 2: Sensing and active insole results from gait and rest periods.

Conclusions

Novel sensing insoles and active insole technology were developed. Data analysis showed that calibration methodology is essential for in-shoe shear sensing [2], people living with diabetes may have impaired temperature regulation [3], and active insoles can change shape locally but modulate plantar pressure globally [4]. Future investigations will use the novel technology developed to study plantar tissue biomechanics [3] and gait kinematics.

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References

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