

Foot-reading device for personalised footwear

Personalised footwear to relieve patients from diabetes-related foot complications could soon become available, thanks to joint efforts under the DIABSMART project.



© Dr Naemi Roozbeh

Foot complications are one of the main sideeffects of diabetes, especially for patients who suffer from neuropathy. Symptoms start with tingling, burning, stinging or overall weakness of the foot, but can very quickly degenerate into skin changes, calluses, foot ulcers and even amputation caused by 'Peripheral arterial disease' (PAD).

Relieving patients' feet before getting to such extremes is one of the main challenges facing

specialists. Of course patients have been offered 'Diabetic shoes' for decades, but are they really effective? While scientific studies tend to agree on their proactive benefits, varying results from one patient to another have highlighted the need to explore individual strategies, which is what the team in the EU-backed project DIABSMART (Development of a new generation of DIABetic footwear using an integrated approach and SMART materials) has been focusing on since 2011.

Completed at the end of October, DIABSMART has developed a fully-fledged method that goes from integrated sensor-based analysis of the foot to the development of personalised footwear thanks to novel materials. Dr Naemi Roozbeh, Associate Professor in biomechanics at Staffordshire University, agreed to discuss the project's findings — which promise to improve quality of life for diabetes patients while generating tremendous cost savings for health services across Europe and beyond.

What are the main benefits of the DIABSMART footwear for diabetes patients?

We have come up with a systematic approach to identify cushioning properties of the insole material that can lead to a more favourable pressure distribution underneath

the foot. This approach includes a smart selection of insole material based on a patient's weight and walking pattern as well as taking into account the mechanical properties of the fat pad underneath the foot.

What does the foot assessment process consist in?

The foot assessment includes measurements such as pressure and load underneath the foot during daily life activities like standing and walking. Furthermore other biomechanical measurements such as ankle strength, ankle and intersegmental foot range of motion as well as foot alignment are also evaluated during our assessment.

Can you tell us more about the design and development process? What were the main challenges you faced and how did you overcome them?

The main strategic challenge was to create a common ground between engineering, manufacturing and the clinical sector. This was imposed as a result of the interdisciplinary nature of the work which required translating and combining knowledge from different disciplines. This has been achieved via knowledge generation and exchange through secondments between industry and academic partners within the consortium.

Another key aspect was the development of an integrated system for foot assessment and footwear prescription, for which the measurement of biomechanical parameters in the clinic was essential. However due to the severity of the condition, and the labour-intensive nature of biomechanical assessment, it was not possible to rely on a trial-and-error approach to identify the most appropriate insole material for each patient. To overcome this issue we developed a combined use of experimental and computational tests, where numerical tests were used to identify the most relevant parameters and inform the insole design criteria for optimal cushioning.

What makes the material you developed stand out compared to current market offerings?

Currently the selection of the material is intuitive and is based on subjective assessment of the foot that is very much influenced by the experience of the practitioner. What we have developed, on the other hand, is a scientific, objective and evidence-based method for finding optimal cushioning properties adapted to each individual. This will ensure that the insole provides the optimal pressure distribution underneath the foot based on each individual's needs and movement characteristics during activities of daily living.

When do you expect your work to start benefitting patients?

We have completed a small-scale clinical trial, and are in the process of analysing

the results. We are now aiming to conduct a multi-centre clinical trial within the coming years, after which we can have more concrete evidence of the effectiveness of the system in reducing the ulceration risk in patients with diabetic neuropathy.

Do you already have plans for commercialisation?

We have worked with a number of companies throughout the project and hope to be able to use their experience in the commercialisation process.

Will you keep building on the project's results in the future?

During the project we have developed considerable know-how in the area of diabetic foot assessment and footwear prescription. This includes establishing a number of methods for the assessment of mechanical properties of the soft tissue of the foot and a systematic approach for identifying the optimal insole cushioning.

Furthermore we pioneered the use and application of clinically-viable biomechanical measures in a diabetic foot clinic, which proved to be useful in identifying the patients with a higher risk of foot ulceration incident. As I mentioned before we hope to build further on these results through clinical trials that show the effectiveness of such systems in reducing ulceration incident in high-risk diabetic neuropathic patients.

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