Smart Insoles: Preventing Diabetic Foot Ulcers and Reducing Carbon Footprints

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Abstract

Introduction: 5.6 million people are estimated to have diabetes in the UK. 25% of individuals with diabetes go on to develop diabetic foot ulcers (DFUs) in their lifetimes[1]. DFUs take significant time to heal and often lead to amputations. Current DFU prevention methods are inadequate, resulting in 40% of DFUs recurring within a year[2]. DFU treatment and amputations also have significant environmental costs due to the single-use consumables used in assessment and treatment which must be incinerated following use.

Methods: To tackle this, we hypothesize that using smart temperature- and pressure-sensing insoles to predict DFUs before they form and acting early can prevent DFUs and reduce the carbon footprint of DFU care. To this end, user testing and carbon footprint analysis were carried out on smart, DFU-predicting insoles*.

Results: The smart insoles had 8-16-fold smaller carbon footprint than any scenario where a patient develops a DFU. All users stated that they would act to prevent a DFU if DFU-predicting insoles* alerted them to do so. Most were comfortable with using phone apps and having their data collected and shared with their healthcare providers.

Conclusion/Discussion: We have shown that smart insoles can reduce the carbon footprint of DFUs and potential users are ready to adopt such devices into their care. Thus, smart DFU-predicting insoles present a promising device in DFU prevention.

Materials and Methods

User testing

5 individuals over 18, with either Type 1 or Type 2 Diabetes Mellitus, no current foot ulceration , owning a mobile phone were recruited for user testing at the Royal Free Hospital, London. Users were asked to use the Path Active insoles for a week. Before and after Path Active use, users were provided a questionnaire to investigate their user experience as well as an EQ-5D questionnaire to investigate any changes in quality of life (QoL). We also present a case study of a patient using Path Active insoles to successfully prevent a DFU from a separate trial conducted at St. Helier Hospital.

Carbon footprint analysis

Carbon footprint analysis was outsourced to an independent organization, Intertek. They carried out a complete Cradle-to-grave life cycle analysis for Path Active to estimate the carbon footprint of producing, distributing, and using a pair of insoles. This was compared to their estimated carbon footprints for the following DFU scenarios:

- Scenario 1: Normal evaluation of a moderate or high-risk patient without an ulcer developing
- Scenario 2: Non-infected superficial ulcer
- Scenario 3: Infected superficial ulcer
- Scenario 4: Infected ulcer penetrating tendon or capsule
- Scenario 5: Infected ulcer penetrating bone or joint

Path Active: Smart DFU-preventing insoles

Path Active insoles are smart insoles containing discretely embedded pressure and temperature sensors. They connect via Bluetooth to a smartphone application and alert users and their healthcare professionals when DFU risk is high. This lets users offload their feet to prevent ulcers and allows clinicians to personalize their appointments according to personalized risk profiles.

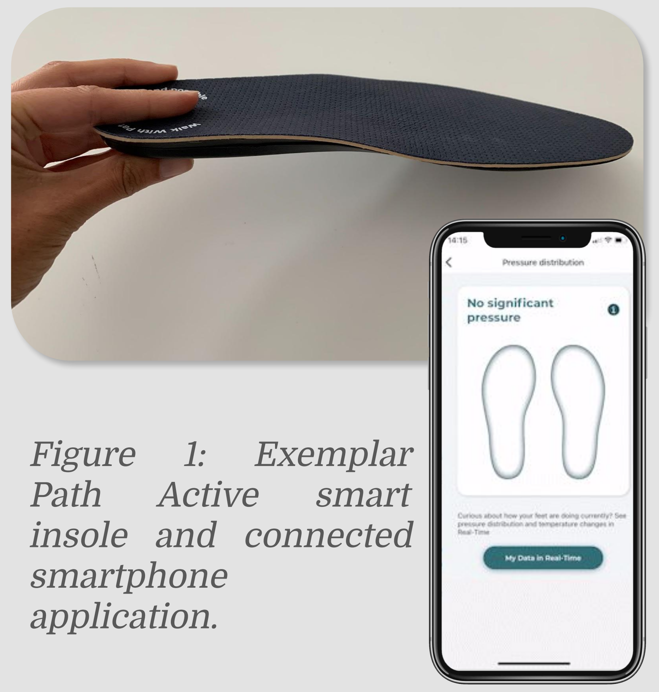


Figure 1: Exemplar Path Active smart insole and connected smartphone application.

Results

Carbon footprint analysis

The independent carbon footprint analysis by Intertek found that found that with the exception of Scenario 1 (no ulcer), all other scenarios had 8-16 times the global warming potential (GWP) of Path Active use (Figure 2).

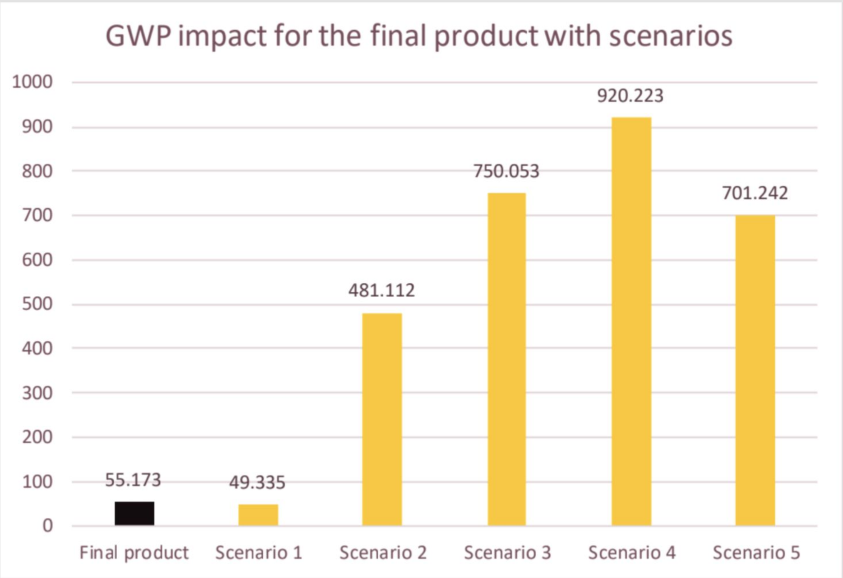


Figure 2: Scenario analysis comparing Carbon Footprint of Path Active as per Intergovernmental Panel on Climate Change (IPCC) 2021 (black) to the aforementioned 5 DFU scenarios (yellow).

User experience

User testing demonstrated that users were technologically ready and comfortable to implement Path Active in their day to day lives:

- **4 out of 5** stated that they were definitely or probably **comfortable with using phone apps**.
- **All** stated that they would definitely be comfortable with **data being collected** by Path Active and shared with their healthcare providers.
- Following Path Active use, **all 5** agreed that they would definitely examine and **offload their feet if recommended by the device**.

Users also tended to show an increase in thoughts and concerns about ulceration after using Path Active (Figure 2), although this trend was not statistically significant. This may suggest that Path Active is successful in increasing the users' awareness of their foot health.

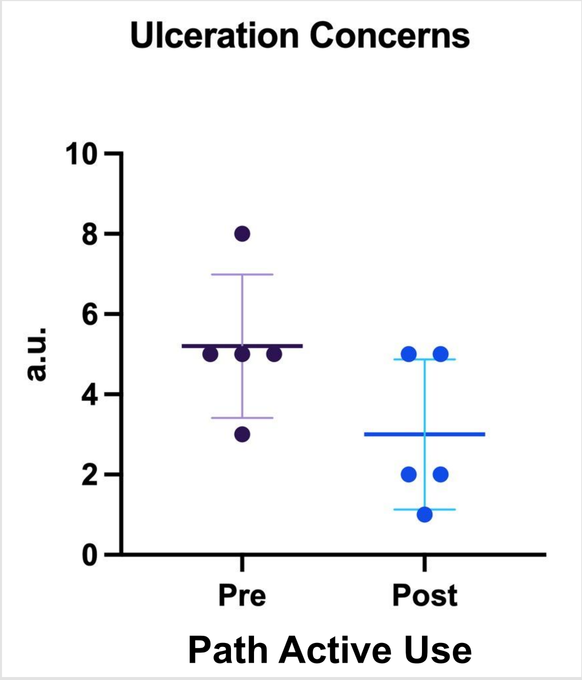
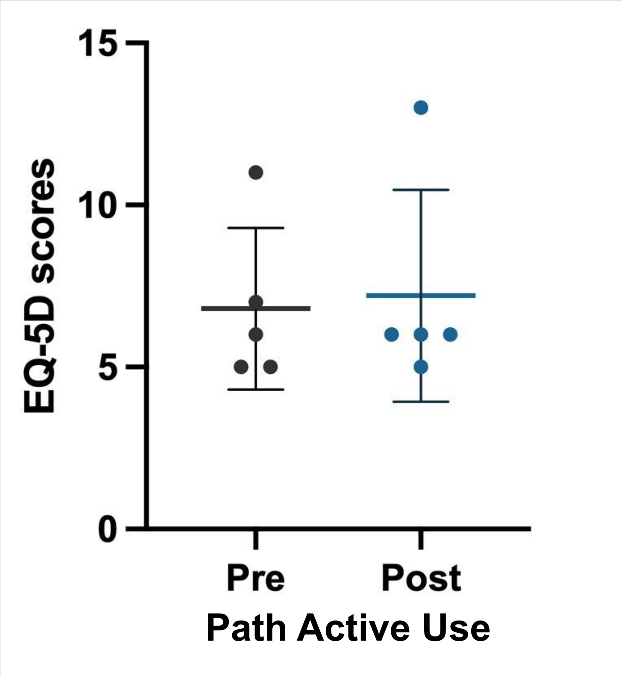


Figure 3: Concern about developing an ulcer before and after 1 week of Path Active use (1 is very concerned, 10 is not concerned at all). Mean +/- standard deviation. n=5. Abbreviations: Arbitrary units: a.u.

No reduction in EQ-5D scores was observed after one week of Path Active use, suggesting that the use of smart insoles in daily life does not have a negative impact on user quality of life.

Figure 4: EQ-5D scores before and after 1 week of Path Active use. Mean +/- standard deviation (n=5). The average VAS before use was 61, whilst the average VAS after use was 56.25, showing a small change in the right direction.



Case study

Quote from a healthcare professional working with a patient whose DFU was prevented by Path Active:

“Insoles are pretty accurate. One patient's toe was bruising and he went to clinic. It has sent alerts and we were able to see that before breaking into a wound so in its way it prevented it from ulcerating” from Maria Goldsmith, Threatened Limb Podiatry Practitioner Lead at St Helier Hospital, Epsom and St Helier University Hospitals NHS Trust.

Discussion

In addition to having a lower carbon footprint than DFUs, Path Active may increase the users' awareness of their foot health, Discussions with healthcare professionals have shown that being aware of one's own risk is a very important aspect of diabetic foot self-care, and hence this is very positive in the mission to prevent ulceration.

A previous study[3], demonstrated that insoles which monitor plantar pressure alone resulted in a 71% reduction in DFU incidence. Our work adds to the literature demonstrating the potential insoles in diabetic foot care.

However, longer term use of the product with more participants is needed for further evaluation and this is currently being undertaken in the UK. Path Active is unique as the only smart, remote-monitoring insole with a net zero analysis.

Conclusion

The clear difference in carbon footprints between Path Active use and any scenario in which a patient developed a DFU, demonstrates that Path Active has the potential to reduce the carbon footprint of DFU care.

Additionally, user testing demonstrated that users were largely comfortable with using Path Active , following Path Active 's instructions and having their data shared with their clinician, an important aspect of self-care and foot protection services. Furthermore, our EQ-5D scoring suggested that Path Active has no negative effect on users lives.

Finally, our case study demonstrates a case in which Path Active clearly prevented a DFU in a patient, highlighting the promise of this technology.

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1. North West Coast Strategic Clinical Network: Diabetes Footcare Pathway Blueprint (Mackenzie P., 2017). 2. Voelker R. What Are Diabetic Foot Ulcers? JAMA. 2023;330(23):2314. doi:10.1001/jama.2023.17291 3. Abbott CA, Chatwin KE, Foden P, et al. Innovative intelligent insole system reduces diabetic foot ulcer recurrence at plantar sites: a prospective, randomised, proof-of-concept study. Lancet Digit Health. 2019;1(6):e308-e318. doi:10.1016/S2589-7500(19)30128-1

*Path Active, Walk With Path Ltd. London.