A Novel Offloading Insole System Designed for Healthcare

Yajie Zhang[1], David John Barton[2], Heather Smart[2], Sean Jenkins[1]

[1]Assistive Technologies Innovation Centre (ATiC),

University of Wales Trinity Saint David, United Kingdom

y.zhang@uwtsd.ac.uk, sean.jenkins@uwtsd.ac.uk

[2]Kaydiar Ltd, United Kingdom

david@kaydiar.co.uk, heather@kaydiar.co.uk

Abstract:

Foot pressure is the focus to manage the lesions and/or pain for a broad range of people, such as the elderly (Menz et al., 2007), people with diabetes (Chatwin et al., 2020), or cyclists (Bousie et al., 2018). Common foot lesions like corns and calluses can cause pain and impact quality of life (Farndon et al., 2015). The authors have investigated an offloading technology in a prototype insole, which is potentially used by people with low-risk pressure-induced foot lesions, such as corns and calluses, to reduce plantar pressure.

It is designed with a modular cell structure allowing cells to be removed to create a customised cavity to relive pressure on the target zone. To evaluate the effects of the insole prototype on the user, foot pressure distribution was measured during normal walking cycles. Fifteen healthy participants walked under four conditions: wearing their normal footwear without the prototype; with the prototype but without cavities; with the prototype and cavity on one insole; with the prototype and cavity on both insoles. Ultra-thin, in-shoe pressure mapping technology was used to measure the pressure under both feet, synchronised with a motion capture system. User experience (UX) data were collected in terms of insole fitting, comfort rating and balance feeling.

The results confirmed the modular design has an offloading effect without affecting gait. On average, wearing the prototype insoles with cavity reduced around 28% of mean pressure in the target zone than wearing normal shoes. In addition, the prototype has cushioning effects, evidenced by reduced plantar forces. UX data also showed their satisfaction in comfort and provided insights for future design development.

The research demonstrates that for a novel insole system to benefit people it is essential for the design development process to measure both subjective and objective responses to the product. Using triangulation between methods, the researchers have been able to validate the design with human factors considered and tested, as well as gain insights from a sample of end users that can be fed into an iterative cycle of designing, prototyping and evaluation to ensure inclusivity.

Keywords:

Insole, mobility, footwear, human factors

References:

Bousie, J. A., Blanch, P., McPoil, T. G., & Vicenzino, B. (2018). Hardness and posting of foot orthoses modify plantar contact area, plantar pressure, and perceived comfort when cycling. *Journal of Science and Medicine in Sport*, *21*(7), 691–696. https://doi.org/10.1016/j.jsams.2017.11.013

Chatwin, K. E., Abbott, C. A., Boulton, A. J. M., Bowling, F. L., & Reeves, N. D. (2020). The role of foot pressure measurement in the prediction and prevention of diabetic foot ulceration—A comprehensive review. *Diabetes/Metabolism Research and Reviews*, *36*(4), 1–14. https://doi.org/10.1002/dmrr.3258

Farndon, L., Concannon, M., & Stephenson, J. (2015). A survey to investigate the association of pain, foot disability and quality of life with corns. *Journal of Foot and Ankle Research*, *8*(1), 1–7. https://doi.org/10.1186/s13047-015-0131-4

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Handle with care/ Inclusivity

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- It is designed with a modular cell structure allowing cells to be removed to create a customised cavity to relive pressure on the target zone. To evaluate the effects of the insole prototype on the user, foot pressure distribution was measured during normal walking cycles. Fifteen healthy participants walked under four conditions. Ultra-thin, in-shoe pressure mapping technology was used to measure the pressure under both feet. User experience (UX) data were collected in terms of insole fitting, comfort rating and balance feeling.
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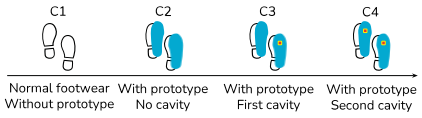
Research methods

Participants: 15 healthy users (7 males, 8 females, age: 43.0 ± 10.3 years, height: 172.5 ± 10.1 cm, weight: 79.4 ± 18.3 kg).

Walking conditions



User experience

- How does the prototype insole fit inside your shoe?
- How do you rate its comfort form 1-5 (1 being very uncomfortable, 5 being very comfortable)?
- Does wearing the insoles cause you to feel any imbalance when you are walking?

Results

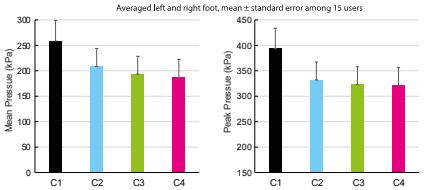
Gait analysis

The basic gait parameters were not affected by putting the prototype insoles. Those parameters included stance time, swing time, gait cycle and symmetry index.

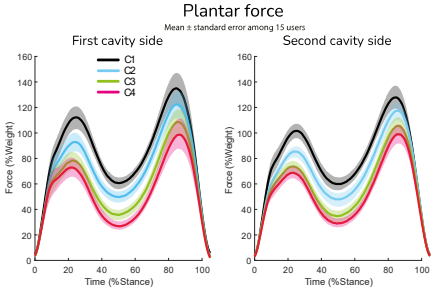
User experience

- Fitting: slight tightness in the footwear (2/15), friction at the front (2/15), lift-up feeling (2/15), and more arch support (1/15).
- Comfort rating: 4.5 ± 0.5 (mean ± standard deviation).
- No imbalance feeling.

Pressure of target zone



Plantar force

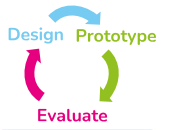


With the innovative insoles customised and put into the participants' footwear, their foot pressure was reduced in the target zone during walking, as well as the total plantar forces.

Acknowledgement
The study was facilitated through the Accelerate Wales programme, led by Life Sciences Hub Wales, co-funded by the European Regional Development Fund (ERDF) through Welsh Government.

Inclusive design

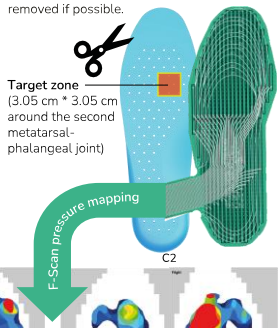
- Removable modular cells to customise cavity
- Trimmable in size to adjust fitting in the shoes

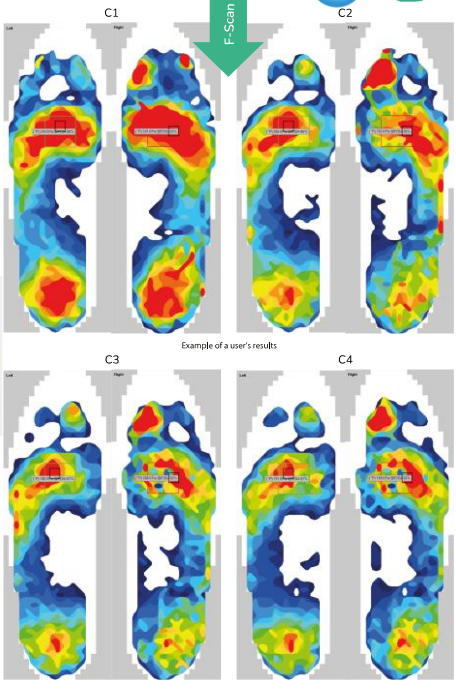


Validate the design with human factors considered and tested, both subjective and objective responses.

In-shoe pressure mapping

The original insoles of the footwear were removed if possible.





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