The biometric shoe: could 3D printed footwear and machine learning theoretically reduce complications from diabetes?

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Citation: Jones P, Harrison M, Davies M et al (2019) The biometric shoe: could 3D printed footwear and machine learning theoretically reduce complications from diabetes? *The Diabetic Foot Journal* 22(2): 28–31

Article points

1. Shoe fitting is a major issue in diabetic foot care. Scanning technology and 3D printing have advanced sufficiently to provide the potential for customised footwear designed for individual foot morphology
2. Microclimate data (temperature, pressure, shear, and humidity) is now available via in-shoe sensors.
3. A biometric shoe that combines 3D printed customisation and real-time data is an invaluable source of data and should be the subject of further research.
4. Microclimate could be combined with accelerometer data on physical activity, and machine learning techniques to develop better predictive early warning systems of diabetic foot ulceration.

Key words
- Diabetic foot
- 3D printing
- Footwear
- Machine learning
- Microclimate
- Ulceration

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Recent advances in technology have given us 3D printed footwear for marathon runners, along with insoles capable of measuring in-shoe temperature and pressure. Custom 3D printed biometric footwear for those with diabetes and neuropathy therefore seems a natural development but has yet to emerge. The authors discuss both the feasibility of developing a 3D printed shoe incorporating sensors to provide real-time microclimate data and some of the practical problems that remain, including a brief outline of recent advances in this field.

Foot ulcers account for 163,471 bed days in England and Wales, 9% of people with diabetes have active foot disease on admission to hospital and rates of ulcer healing vary markedly across the country (National Diabetes Inpatient Audit 2017; National Diabetes Foot Care Audit, 2018a, 2018b). Yet we seem to be missing a trick in not making greater use of the humble shoe in our war against neuropathic foot disease (Singh, 2014).

Using embedded sensors, a biometric shoe is potentially a gold mine of data, measuring everything from temperature, pressure and shear to humidity. When combined with 3D printers and machine learning, we could potentially both end the misery of a long wait for prescription shoes and develop an in-shoe early warning system for infection and injury prevention, wirelessly forwarded by patients' mobile phones as alerts to individuals and healthcare professionals.

Ensuring the perfect fit

The first challenge to making a biometric shoe is the fitting and design. Incorrectly fitted footwear is already a problem. A review by Buldt and Menz (2018) revealed almost two-thirds of older people in the general population were wearing ill-fitting shoes. Another study found only 24% of patients with diabetes were wearing shoes of the correct length and width for both feet when standing (Harrison et al, 2014).

There is also a need for standardisation around fit (Jones et al, 2019). One alternative is to trial the use of 3D scanners to capture foot dimensions. While currently used predominantly to produce custom inserts, toe filler prosthetics or orthoses, the techniques are also being used for 3D quantitative analysis of foot shape, which could be applied to shoe fitting for people with neuropathic conditions (Stankovic et al, 2018).

Shoe fit remains crucial, particularly for patients such as those with plantar hallux ulcers, who are more likely to develop additional ulcers (Peters et al, 2007). This is an extremely important area which could revolutionise current practice and improve the design of bespoke footwear to prevent ulceration, aid healing of active lesions and provide additional protection for rarer deformities associated with diabetic foot disease such as Charcot's arthropathy. A review by Smith et al (2007) found a lack of clinical trials evaluating the effectiveness of non-surgical interventions in the management of Charcot foot, such as footwear and orthotics. The protecion of at-risk neuropathic feet and prevention of ulcer recurrence remain under-researched key areas.

Artificial neural networks may play a role in both shoe fitting and analysis. They are modelling tools capable of finding patterns in statistical data, for classification or prognostic purposes. These brain-inspired systems can make use of 3D image or sensor data to classify overlapping patches as belonging to a region of interest. They have been used in the diagnosis of plantar fascia injuries using ultrasound and prediction of dorsal pressures on feet (Rupérez et al, 2012; Boussouar et al, 2017). Artificial neural networks are now being used to automatically segment an ulcer from its surrounding skin in some instances. One study has shown ulcers are identified around 79% of the time, based on a dataset of 705 digital images (Goyal et al, 2017).

Four different models were assessed on their segmentation ability aiming to colour code the foot ulcer from surrounding and bordering areas of skin (Goyal et al, 2017). Both the shoe fitting and subsequent monitoring could be opportunities to check for problems, with artificial neural networks providing an additional surveillance tool.

Production and adherence challenges

Three-dimensional printers produce a physical object, by laying down many layers of a material in succession. They are being used to produce customised insoles for patients, anatomic models for surgical training or planning and simulating surgical interventions (Auricchio and Marconi, 2016; Giannopoulos et al, 2016). The idea of footwear with variable densities capable of offering customisable levels of support to different parts of a patient's foot is not new, but the possibility of 3D printing specialist footwear within hospital-based multidisciplinary services has yet to be explored (Jenkyn et al, 2011).

Research has examined 3D printing for other areas of footcare such as orthopaedic trauma surgery (Elitorai et al, 2018; Lal and Patralekh, 2018). Research into embedding soft sensors so that they do not cause discomfort or problems is also under way (Nagano and Begg, 2018).

In one study, patients only wore prescription custom-made footwear 71% of the time, with home usage dropping to a mean 61% with great variance over a seven-day period (Waaijman et al, 2013). Armstrong et al (2003) demonstrated that people with diabetic foot ulcers wore their offloading devices for only 28% of their total daily activity. A sensor small enough to fit inside the patient's shoe was used to verify adherence.

This raises the question of why patients do not wear prescription footwear: is it because they are uncomfortable or unfit for purpose, or for other reasons, such as appearance? (Paton et al, 2014; Crews et al, 2016). Certainly, current custom-made footwear has room for improvement. In one study, 39% of patients still had a recurrent ulcer risk (Bus et al, 2013). Smart shoes offer the potential to begin to evaluate why those designs fail to work effectively.

Custom footwear must also address an individual's needs at home. Reiber et al (2002) found that people with diabetes and a history of foot ulceration spent nearly 30% of their time out of bed either in slippers (worn typically five times per week), wearing stockings or barefoot. A significant proportion of individuals typically only wear their prescribed footwear outdoors, and so both appropriate indoor and outdoor footwear is necessary to ensure adherence and to capture activity in both environments (Knowles and Boulton, 1996).

Microclimate and accelerometer data

Basic in-shoe systems for monitoring the microclimate (temperature, pressure and humidity) within footwear have already been tested. Sandoval-Palomares et al (2016) developed five temperature and humidity sensors placed in the forefoot, midfoot and heel areas of each shoe. The difference in temperatures between corresponding regions on both feet has been used as a threshold for ambulatory activity reduction, as part of an ulcer prevention strategy and for monitoring adherence to offloading treatment (Bus, 2015). The remaining practical obstacles appear to be miniaturising some devices and replacing cables with wireless versions to relay sensor signals via the wearer's mobile phone.

Progress has also been made in the evaluation and optimisation of therapeutic footwear for neuropathy using plantar pressure analysis (Bus et al, 2011). *Figure 1* provides an illustration of how such a system might work, built around a 3D printed shoe with embedded sensors that transmit real-time data using Bluetooth to the individual's mobile phone. The phone could then securely send the data to the cloud for machine learning analysis to decide

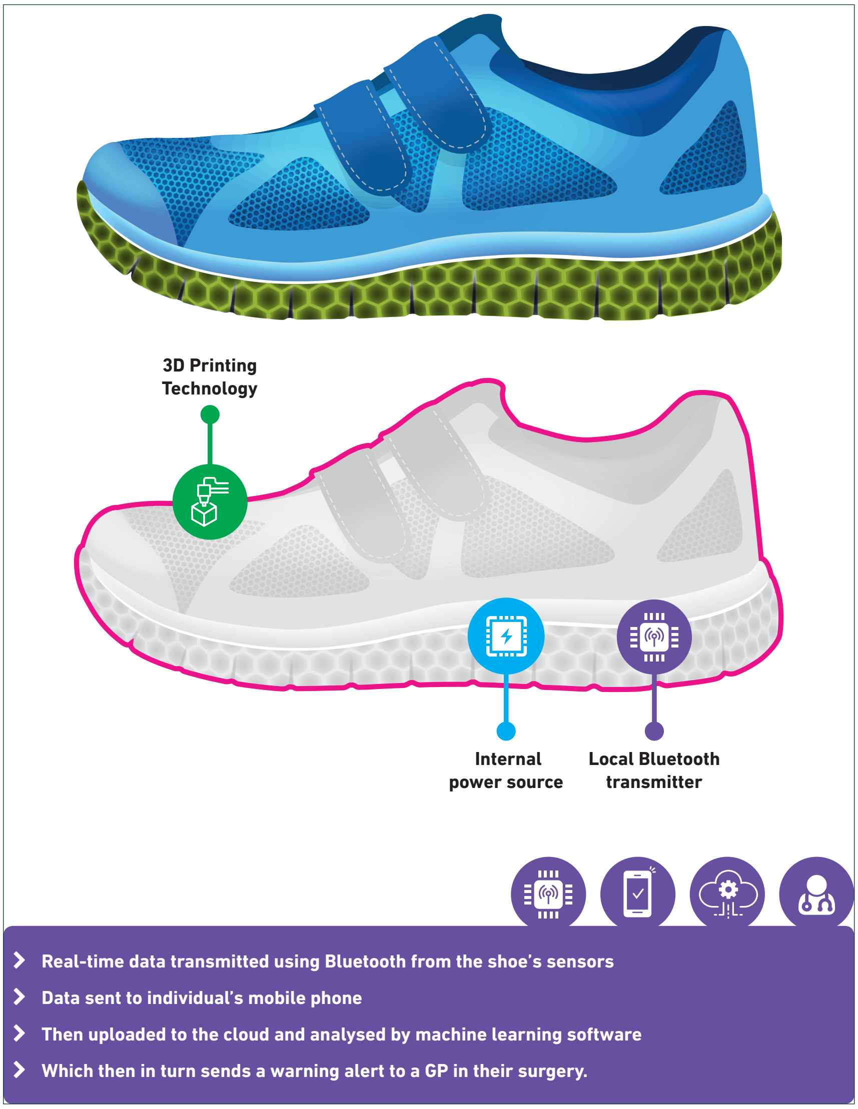

Figure 1. An illustration of how a 3D printed biometric shoe might work.

whether microclimate conditions suggest a high risk of ulceration that should trigger a warning alert to a healthcare professional

Wrist and hip-based accelerometer devices coupled with machine learning algorithms already work well to gauge the intensity and frequency of exercise, with more than 90% accuracy in classifying walking, running, and sedentary pursuits (Chowdhury et al, 2017). Accurate information could be obtained on how a biometric shoe is being used each day, augmented with foot microclimate data and even gait analysis (Grewal et al, 2016). The potential utility of a gait database for people with diabetes has already been suggested by Brown et al (2016). It would be interesting to analyse the effects of certain gaits on microclimate in different areas of the foot, and for a machine learning model to be informed by data from other people with similar gaits.

Supervised machine learning techniques usually rely on getting labelled sample data from the patient in order to train the model to be able to classify future physical activities (Chowdhury et al, 2017). However, progress is also being made in unsupervised machine learning — attempting to classify physical activity without any labelled data available for the particular patient (something that works 'out of the box'). These work by training a model on a group of other people's physical activity that we can then apply to someone else's data to provide a rough outline of physical activity (Kerr et al, 2016; Montoye et al, 2018; Ray et al, 2018). This combination of smart shoe, gait and accelerometer data with other datasets such as diet and glucose monitoring may offer even more analytic potential.

Conclusion

It seems reasonable to suggest that the biometric shoe is within reach. The technology to produce one is already here, but we need a brave step to assess whether a prototype could be built cheaply and efficiently that can offer patients improved protection and optimised mobility. The goal is to reduce the costs from foot-related complications and amputations. Additionally, 3D printed footwear could provide individuals with access to footwear at the point of need.

Once we have the shoe, we can begin to actively gather feedback on diabetes footwear design from the footwear itself that informs the development and refinement of microclimate thresholds associated with an increased risk of ulceration. Footwear performance could be assessed by a combination of patient feedback (no injury events, comfort scores); positive outcomes from biometric shoe data (real-time temperature/humidity/pressure within given target ranges, etc); and accelerometer data (using machine learning algorithms to determine step counts and shoe use and activity intensity levels from free living data).

Adherence will remain an issue (Keukenkamp et al, 2018; Yuncken et al, 2018). However, technology offers us an opportunity both to try to improve the initial fitting using 3D scanners and via sensors to build a better shoe that we can actively learn from to improve outcomes for this important disease. ■

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