Being preventatively Smart about diabetic foot ulcers

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I want to bring to your attention two papers that have recently been published which give us an insight to possible exciting new technologies. As you are all aware, diabetic foot ulcers (DFUs) are a tremendous burden to patients.

The first is an American, multicentre study by Frykberg et al (summarised alongside) examining the feasibility and efficacy of a wireless "smart mat" to predict the development of DFUs. This device is a low-profile mat with an array of 2000 temperature sensors that scans both feet for 20 seconds when stood upon. It uses a telemedicine system designed to enable remote temperature asymmetry monitoring and analysis.

This study enrolled a cohort of 132 people with diabetes and a previous DFU who were followed for 34 weeks. They were instructed in the use of the telemedicine system and a baseline scan was obtained. Throughout the study, participants stood barefoot on the mat at home once a day for 20 seconds while skin temperatures were recorded and relayed to a central server. Subjects were telephoned if they missed four consecutive days of data collection and were withdrawn if 28 days were missed. Subjects were instructed not to use the mat if they developed an ulcer, but to resume after healing had occurred.

The primary outcomes were development of a DFU and predictive accuracy of the device in identifying DFUs within temperature asymmetry thresholds. A total of 53 DFUs in 37 subjects were recorded. The smart mat identified 97% of DFUs at a thermal asymmetry of 2.22°C, but had a false positive rate of 57%. When the threshold was raised to 3.20°C, sensitivity dropped to 70%, but the false positive rate fell to 32%. The compliance rate was good, with 86% of subjects using the system 3 days a week.

The second study by Najafi et al (summarised on the facing page) is similar, but takes this a few steps further! This American study investigated the use of an optical-fibre-based smart textile made into socks — "SmartSox" — that enable the simultaneous measurement of plantar temperature, pressure and joint angles. Thirty-three subjects with diabetic peripheral neuropathy were recruited with a mean age of 58 ± 8 years and a BMI of 31.5 ± 8 kg/m^2. Subjects were asked to walk at a normal speed while wearing a pair of the sensor socks. An algorithm was designed to estimate temperature, plantar pressure and toe range of motion from the optical wavelengths generated by the SmartSox. Results were validated using thermography and peak pressure as measured by computerised pressure insoles (F-Scan) as gold standards.

Laboratory testing showed excellent agreement between the SmartSox and the gold standards (r>0.98; P<0.001). During clinical testing, a good correlation was also observed for pressure profile under different anatomical regions of interest between the SmartSox and F-Scan (r=0.67; P<0.05), as well as between thermography and SmartSox (r=0.55; P<0.050). The authors concluded this technology may be of significant clinical use.

If the concepts of these two studies are combined, we may in the future see smart technology aiding our ulcer prevention programmes, with the potential to improve outcomes significantly. ■

Diabetes Care

Feasibility and efficacy of a "smart mat" to predict development of diabetic plantar ulcers

Readability	✓✓✓✓
Applicability to practice	✓✓✓
WOW! Factor	✓✓✓✓

1 A multicentre evaluation was conducted to assess the impact of a novel remote foot-temperature monitoring system – a "smart mat" – on predicting impending diabetic foot ulcers (DFUs) in people with diabetes and previously healed DFUs.

2 A total of 132 people with diabetes and previous DFUs were enrolled in this cohort study over a period of 34 weeks in order to appraise the effectiveness of the monitoring system.

3 The study's primary outcome was occurrence of non-acute plantar DFUs, while the primary efficacy analysis rested on the accuracy of the system in the prediction of non-traumatic plantar DFUs prior to clinical presentation.

4 Secondary outcomes were individuals' adherence to daily use of the smart mat, any falls associated with the mat's use and device-related injury.

5 Of the 132 participants, 129 offered evaluable study data. Thirty-seven presented with 53 DFUs. An asymmetry of 2.22°C (standard threshold) correctly identified 97% of observed DFUs (false positive rate of 57%). A temperature of 3.20°C reduced sensitivity to 70% but increased the false positive rate to 32%.

6 Plantar temperature asymmetry was found to be highly predictive of imminent DFUs. This system may result in significant reductions in morbidity, mortality, and resource utilisation.

Frykberg RG, Gordon IL, Reyzelman AM et al (2017) Feasibility and efficacy of a Smart Mat technology to predict development of diabetic plantar ulcers. *Diabetes Care* **40**: 973–80

J Diabetes Sci Technol

Use of "smart socks" to assess parameters associated with DFU risk

Readability	✓✓✓✓
Applicability to practice	✓✓
WOW! Factor	✓✓✓✓

1 In this study, the authors evaluated a prototype sock which uses fibre optics to simultaneously measure foot temperature, plantar pressure and range of toe motion (SmartSox; Novinoor LLC, Wilmette, IL, USA).

2 SmartSox measurements were compared with infrared thermography, goniometry and computerised pressure insoles (F-Scan; Tekscan Inc, Boston, MA, USA).

3 Laboratory testing revealed strong correlations between SmartSox and the references in terms of temperature and toe angles ($r>0.98$; $P<0.001$ for both comparisons).

4 Testing in human subjects (33 people with T2D and diabetic peripheral neuropathy) revealed a significant, moderate correlation between measurements of temperature change in response to walking ($r=0.55$; $P<0.05$). Walking 50–60 steps was enough for the SmartSox to identify thermal changes in foot areas at risk of ulceration.

5 A significant, moderate correlation was also observed between SmartSox and F-Scan in terms of peak pressure during walking ($r=0.67$; $P<0.05$).

6 No noticeable interference was observed between parameters, suggesting that SmartSox can be used to assess all three risk factors simultaneously.

7 These results support the potential of using SmartSox to assess foot biomechanics; however, further study of clinical outcomes will also be needed.

Najafi B, Mohseni H, Grewal GS et al (2017) An optical-fiber-based smart textile (smart socks) to manage biomechanical risk factors associated with diabetic foot amputation. *J Diabetes Sci Technol* **11**: 668–77

J Foot Ankle Surg

Increased brake response times in drivers with lower-limb neuropathy

Readability	✓✓✓✓
Applicability to practice	✓✓✓
WOW! Factor	✓✓✓✓

1 This case–control study was performed to assess braking response times in drivers with diabetes and lower-limb neuropathy.

2 Twenty-five drivers with neuropathy (mean age, 56 years; mean HbA_{1c}, 62 mmol/mol [7.8%]) and 25 controls without diabetes (mean age, 33 years) performed eight tests each using a driving simulator.

3 The mean brake response time was significantly higher in the neuropathy group (0.757 seconds vs 0.549 seconds; $P<0.001$).

4 An abnormally delayed response time, defined as ≥0.7 seconds, was observed in seven of 200 tests (3.5%) in the control group, with one participant (4%) having multiple delayed responses.

5 However, in the neuropathy group, delayed responses were seen in 115 tests (57.5%), with 20 participants (80%) having multiple delayed responses.

6 Within the diabetes group, *post hoc* analyses suggested that gender, history of lower-limb ulceration, history of minor or major foot amputation, and history of Charcot foot were associated with response times; however, the low number of response times <0.7 seconds precludes the drawing of firm conclusions.

7 The authors conclude that delayed brake response times are common in people with diabetes and lower-limb neuropathy. Driving behaviours may need to be adjusted to account for this.

Meyr AJ, Spiess KE (2017) Diabetic driving studies-part 1: brake response time in diabetic drivers with lower extremity neuropathy. *J Foot Ankle Surg* **56**: 568–72

J Am Podiatr Med Assoc

Factors associated with DFU outcomes

Readability	✓✓✓
Applicability to practice	✓✓✓✓✓
WOW! Factor	✓✓

1 The aim of this prospective, observational study was to identify factors associated with diabetic foot ulcer (DFU) outcomes in people living with diabetes in Malta.

2 A total of 99 people who presented with a new DFU were followed up every 4 weeks until ulcer resolution or up to 1 year.

3 At study close, 77% of DFUs had healed/resolved completely and 23% had required amputation.

4 No participant characteristics were significantly associated with DFU healing; however, lower HbA_{1c} was associated with reduced time to healing ($P=0.09$).

5 The six-factor logistic regression model explained 48% of the variance in outcomes and identified three significant baseline factors: ulcer stage ($P=0.03$), presence of biofilm ($P=0.02$) and ulcer depth ($P=0.03$).

6 The presence of slough, necrosis and eschar at baseline increased the odds of amputation by 704% compared with the granulating and epithelialising stage.

7 For every 1-mm increase in ulcer depth at baseline, the odds of amputation increased by 17.6%. The presence of biofilm at baseline increased the odds of amputation by 199%.

8 These results are broadly in line with previous studies.

9 The findings are important in that these are simple risk factors that can easily be measured and identified during routine clinical assessment. The authors recommend that early treatment should be initiated to address them accordingly.

Vella L, Formosa C (2017) Characteristics predicting the outcome in individuals with diabetic foot ulcerations. *J Am Podiatr Med Assoc* **107**: 180–91

"The authors conclude that delayed brake response times are common in people with diabetes and lower-limb neuropathy. Driving behaviours may need to be adjusted to account for this."

20 · YEARS ·