Patients' adherence to customised diabetic insoles as objectively assessed by a temperature sensor

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BACKGROUND & AIMS

Diabetic foot problems are still a leading cause for major amputation. Effective therapy of diabetic foot problems includes the prevention of foot ulcerations which could turn into serious problems due to diabetic neuropathy. Customised diabetic insoles are an effective means to prevent the (re)occurrence of neuropathic diabetic foot ulcerations. These insoles reduce the mechanical stress by re-distributing pressure to the plantar tissue. However, the efficacy of these insoles is highly dependent on patients' adherence. By recommendation, patients should wear their customised diabetic insoles as much as possible for the prevention of diabetic foot problems. Healthcare providers (i.e. podiatrists) have to rely on self-report in order to assess a patient's adherence since objective parameters are missing. The aim of this study was to objectively assess patients' adherence by analysing the temperature within their shoes.

MATERIALS & METHODS

Measuring temperature was performed via a sensor that was directly incorporated into the customised insoles. Performance of the insole was not influenced by the sensor. This sensor measured and stored the temperature within the footwear every 15 minutes.

Pilot study: Defining a cut-off temperature for wearing footwear:

In a pilot study the cut-off value for the optimal temperature was determined that differentiates between wearing and not wearing footwear. For this purpose, a ROC analysis was conducted that compared the temperature from the sensor with the actual wearing time accurately noted in a logbook.

- An area under the curve of .996 (p<.0001) was achieved (Figure 1). Therefore, wearing time of the customised diabetic insoles can be adequately monitored by measuring the temperature inside the footwear.
- A cut-off value of 25° Celsius was determined that achieved a sensitivity (SN) of 95.3%, a specificity (SP) of 99.8%, a positive predictive value of 98.7%, and a negative predictive value of 99.2% (Table 1).
- The distribution of temperature values achieved when the footwear was worn can be distinguished well from the distribution of temperature values achieved when the footwear was not worn by the cut-off temperature of 25° C (Figure 2).

Analysing patients' adherence:

In the main study temperature sensors were incorporated into the specialised diabetic insoles of 26 patients with type-2-diabetes and diabetic foot syndrome.

RESULTS

- Sample characteristics are shown in Table 2. Patients had a mean age of 67 years with a mean diabetes duration of 10 years.
- On average, data from 117 days per patient could be analysed (Table 3).
- Patients wore their diabetic footwear (temperature>25° C) on an average (median) of 3.4 hours per day. The inter-quartile-range (IQR) was rather wide, ranging from 0.5 - 6.9 hours per day.
- On an average (median) of 51% of days, patients did not wear their diabetic footwear at all. IQR ranged from 16.9 - 81.8%.

CONCLUSION

The pilot study showed that wearing time of diabetic insoles and other specialised diabetic footwear can be objectively and validly assessed by temperature sensors. A cut-off temperature of 25° C is best suited to determine when a patient is wearing his/her footwear.

Furthermore, this study offers objective data regarding patients' adherence to their customised diabetic insoles. With a mean wearing time of just 3.4 hours a day, it can be doubted that this is long enough to effectively prevent the (re) occurrence of diabetic foot problems (i.e. ulcerations). Nearly every second day patients did not wear their insoles at all.

Results of this study indicate that the utilization of specialised diabetic footwear is suboptimal in order to prevent re-ulcerations and other diabetes foot problems. Future studies should examine how the adherence of patients with a high risk for foot ulcerations can be enhanced. Possible ways to achieve this is via patient education or technological assistance or reminders that make the objective data on wearing time available to patients as well as to healthcare providers.

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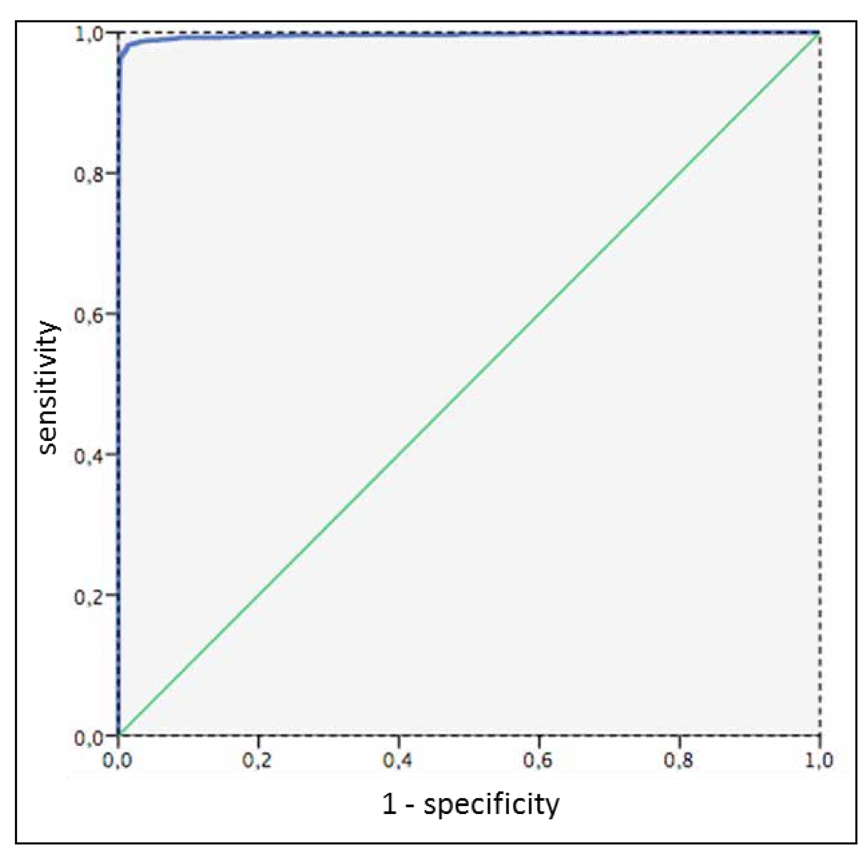

Figure 1: ROC curve for defining the cut-off temperature

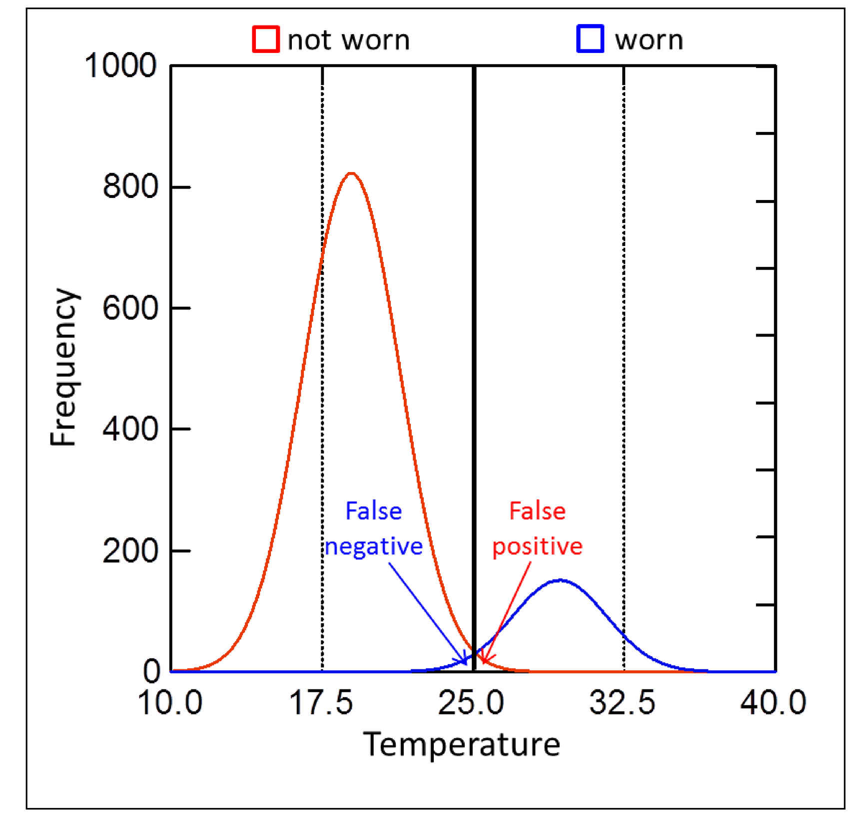

Figure 2: Distribution of the frequency of temperatures when shoes were worn vs. not worn

Table 1: Diagnostic characteristics of the cut-off temperature of 25° C. Shown are the measured data points of the sensor.

	Temperature (sensor) ≥ 25° C	Temperature (sensor) < 25° C	Sum
Shoes worn	1604	79	**1683 (SN = 95.3%)**
Shoes not worn	21	9393	**9414 (SP = 99.8%)**
Sum	**1625**	**9472**	**11097**

Table 2: Sample characteristics

N = 26	M ± SD / %
Age	67.5 ± 10.8 years
Gender	35% female
Diabetes type	100% Type-2-Diabetes
Diabetes duration	10.4 ± 6.8 years
BMI	30.3 ± 4.7 kg/m²
HbA1c	7.7 ± 0.6 %

Table 3: Analysis of wearing time

N = 26	Median (25 – 75% quartile)
Number of days	117 (73 – 183 Tage)
Wearing time per day	3.4 hours (0.5 – 6.9 hours)
Percentage of days without ever wearing the shoes	51 % (16.9 – 81.8%)