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Using Temperature Sensors to assess the Course of Adherence to Customised Diabetic Insoles

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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 via customised diabetic footwear that reduces the mechanical stress by re-distributing pressure to the plantar tissue. Adherence to the customised diabetic footwear is crucial for a preventive effect regarding serious diabetic foot problems. However, adherence data often rely on self-report or cover rather short time spans. The aim of this study was to objectively assess the course of patients' adherence with a temperature sensor. In addition, possible gender effects on adherence were analysed.

METHODS

Temperature sensors were incorporated into the specialized insoles of 26 patients with type-2-diabetes and diabetic foot syndrome without impairing the performance of the insole. Every 15 minutes, the sensor stored the current temperature.

In a preceding 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 with the wearing time accurately noted in a logbook.

- An area under the curve of .996 (p<.0001) was achieved (Figure 1): Wearing time of the customised diabetic insoles can be adequately monitored via temperature measurement.
- A cut-off value of 25° Celsius was determined (Figure 2) 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%.

Per patient, wearing time and the percentage of days the shoe was never worn (temperature never exceeded 24.9 °C) were calculated. Observation time for each patient was divided into quartiles to analyse the course of adherence via repeated measures ANOVA with gender as between factor.

RESULTS

- Sample characteristics are shown in Table 1. Patients had a mean age of 67 years with a mean diabetes duration of 10 years.
- On average, data from 133.5 days per patient could be analysed.
- Over the course of the study, patients wore their diabetic footwear (temperature > 25°C) on 4.2 ± 3.6 h/day. On 51% of days, patients did not wear their diabetic footwear at all (Table 2).
- Analysing the wearing time per day for the quartiles (Figure 3) indicated a different course of adherence for men and women
  - Mens' wearing time per day constantly increased over time
  - Women showed a decrease in wearing time with a slight increase in the fourth quartile
  - However, the time*gender interaction failed to reach significance
- There was a significant time*gender interaction (F(3,63) = 3.810, p = .014) for the number of days the footwear was never worn (Figure 4).
  - Early adherence was similar between men and women
  - Men showed a significant increase of adherence as the percentage of days they have never worn their shoes substantially dropped
  - Women showed a continuous decrease of adherence as the percentage of days they have never worn their shoes constantly increased

CONCLUSION

There was a substantial gender effect on adherence in high-risk patients with diabetic foot syndrome. Men and women showed a comparable early adherence but women had more problems with late adherence as they were more and more unwilling to wear their footwear. Especially for women, the preventive effect of the insoles can be doubted and specific interventional measures should be employed.

In general, feedback of the temperature sensors could be used to timely detect problems with adherence in order to enhance it.

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Table 1: 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 2: Analysis of wearing time

N = 26	M ± SD Median (25 – 75% quartile)
Number of days	133.5 ± 80.7 days 117 (73 – 183 days)
Wearing time per day	4.2 ± 3.6 hours 3.4 hours (0.5 – 6.9 hours)
Percentage of days without ever wearing the shoes	50.6 ± 31.4 % 51 % (16.9 – 81.8%)

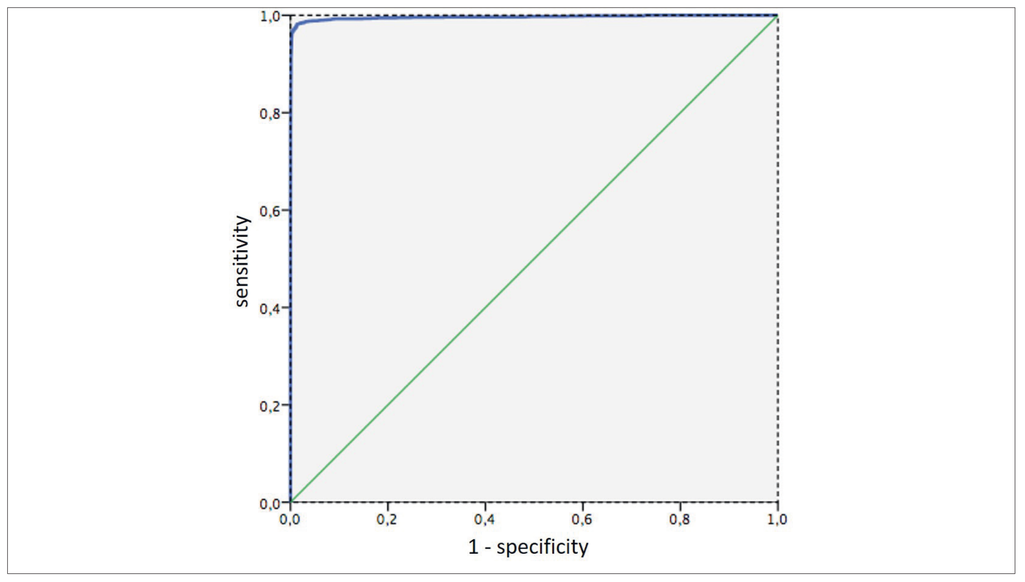

Figure 1: ROC curve for the diagnostic performance of the temperature measurement

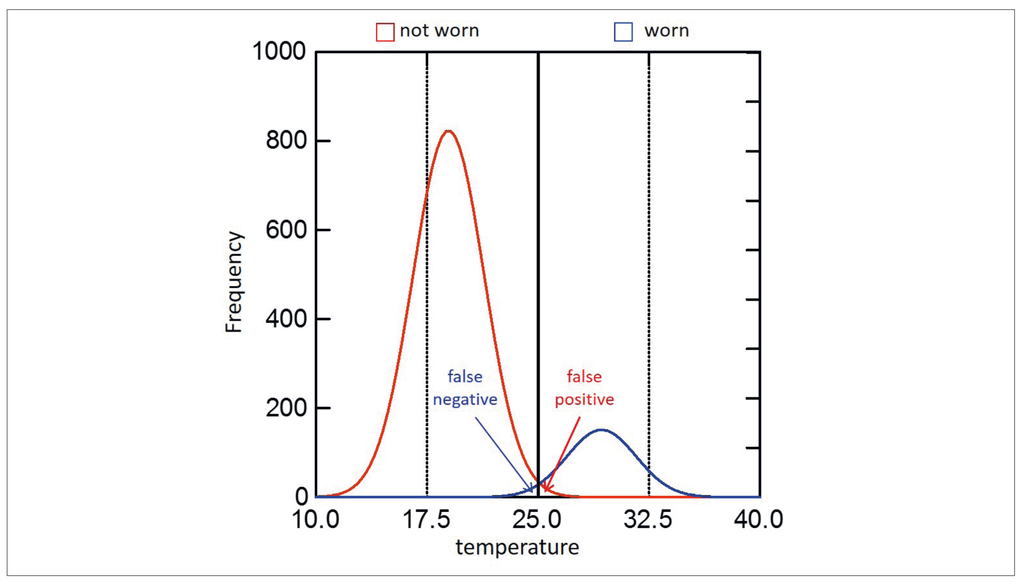

Figure 2: Distribution of the frequency of temperatures when footwear was worn vs. not worn

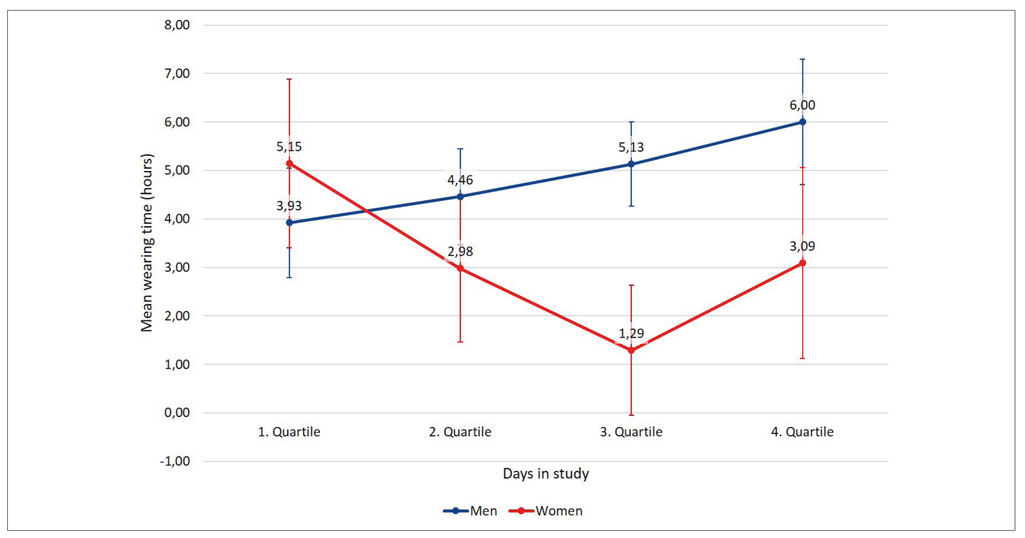

Figure 3: Course of wearing time for men and women (mean ± standard error). Adjusted for age and observed number of days.

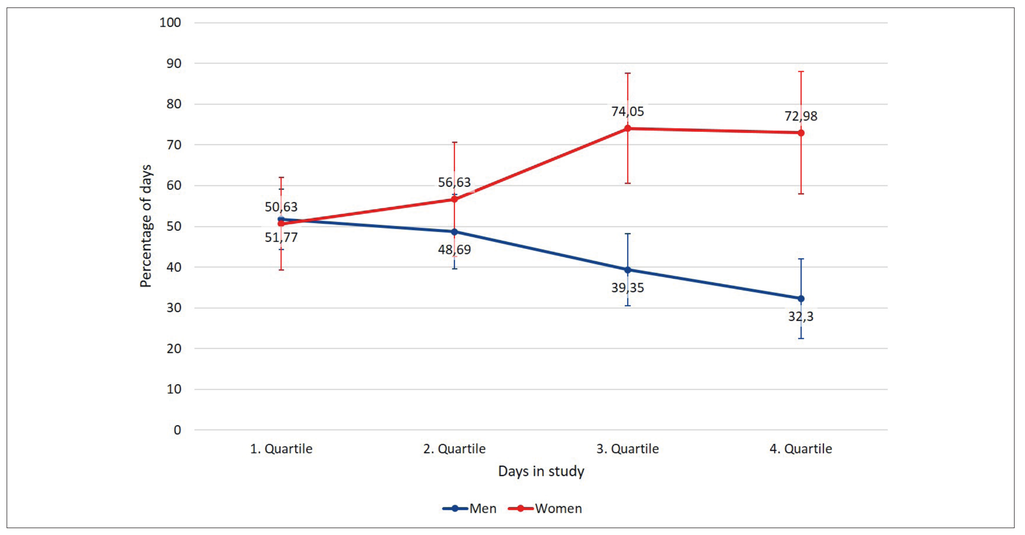

Figure 4: Percentage of days on which the shoes were never worn over the course of the study (mean ± standard error). Adjusted for age and observed number of days.