

[O13] PATIENTS' ADHERENCE TO CUSTOMIZED DIABETIC INSOLES AS OBJECTIVELY ASSESSED BY A TEMPERATURE SENSOR

Dominic Ehrmann¹, Monika Spengler², Michael Jahn², Hendrik Siebert³, Dea Niebuhr³, Thomas Haak¹, Bernhard Kulzer¹, Norbert Hermanns¹

¹Research Institute Diabetes Academy Mergentheim, Bad Mergentheim, Germany

²Ietec Orthopaedic Insoles, Kuenzell, Germany

³University of Applied Sciences, Fulda, Germany

Aim: Customized diabetic insoles reduce the mechanical stress by re-distributing pressure to the plantar tissue. Thus, customized diabetic insoles are an effective means to prevent the reoccurrence of neuropathic diabetic foot ulcerations. However, the efficacy of these insoles is highly dependent on patients' adherence. By recommendation, patients should wear their customized diabetic insoles as much as possible for the prevention of diabetic foot problems. However, adherence data often rely on self-report since objective parameters are not available. The aim of this study was to objectively assess patients' adherence with a temperature sensor directly incorporated into their insoles.

Method: In a pilot study, the cut-off value for optimal temperature was determined that differentiates between wearing and not wearing footwear. For this purpose, a ROC analysis was conducted that yielded an area under the curve of 0.996 ($p < 0.0001$). A cut-off value of 25° Celsius was determined that achieved a sensitivity of 95.3%, a specificity of 99.8%, a positive predictive value of 98.7%, and a negative predictive value of 99.2%. In the main study, temperature sensors were incorporated into the specialized diabetic insoles of 26 patients with type-2-diabetes and diabetic foot syndrome (age: 67.5±10.8 yrs.; 35% female; BMI: 30.3±4.7 kg/m²; diabetes duration: 10.4±6.8 yrs.; HbA1c: 7.7±0.6%).

Results/Discussion: On average, data from 133.5 days per patient could be analysed. Patients wore their diabetic footwear (temperature > 25°C) on an average (median) of 3.4 hours per day (inter-quartile-range (IQR): 0.5 - 6.9 hours/per day). On an average (median) of 51% of days, patients did not wear their diabetic footwear (IQR: 16.9 - 81.8%).

Conclusion: Wearing time of diabetic insoles and other specialized diabetic footwear can be objectively and validly assessed by temperature sensors. This study offers objective data regarding patients' adherence to their customized diabetic insoles. Nearly every second day, patients did not wear their insoles at all. Results of this study indicate that the utilization of specialized 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, e.g. by patient education or technological assistance or reminders.

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