

## [O12] COST-EFFECTIVENESS ANALYSIS OF CUSTOM-MADE FOOTWEAR ON FOOT ULCER RECURRENCE IN PATIENTS WITH DIABETES IN THE DIAFOS TRIAL

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**Aim:** To determine the cost-effectiveness of offloading-improved custom-made footwear to prevent plantar foot ulcer recurrence in high-risk patients with diabetes mellitus.

**Method:** 171 neuropathic diabetic patients with a recently healed plantar foot ulcer were randomly assigned to 1) custom-made footwear which was evaluated, optimized and monitored at 3-monthly visits based on in-shoe plantar pressure management and analysis or 2) custom-made footwear, which was evaluated according to usual care. Primary outcome was plantar foot ulcer recurrence in 18 months. The economic evaluation was designed as a cost analysis with the cost-saving potential of the intervention as the primary outcome. For this analysis data from the DIAFOS trial was used. Healthcare costs included the costs of the intervention (input) and treatment costs of a recurrent plantar diabetic foot ulcer (output). Bottom-up micro costing was used to quantify intervention costs. These costs included the time investment of the footwear technician to modify the footwear, the sum of the observed volume of footwear modifications multiplied by their respective unit costs, footwear materials costs, and costs for the purchase (effectively write-off), maintenance and time use of the in-shoe plantar pressure measurement and analysis. Time investment was multiplied by gross salary. The average total for direct and indirect treatment costs of a foot ulcer were derived from existing data from the Eurodiale study.

**Results/Discussion:** On the basis of intention-to-treat, 33 of 85 patients with improved footwear and 38 of 86 patients with usual care had a recurrent ulcer (relative risk -11%, P=0.48). A total of 1183 footwear modifications in a mean 1.2 rounds of modifications per shoe pair per visit per patient were made in the improved footwear group; 33 footwear modifications were made in the usual care group patients. The total expenditures for the intervention were € 38.507 for the intervention and €206 for usual care. Average costs for treatment of a foot ulcer are €10.091. Offloading-improved custom-made footwear led to lower costs since its effectiveness offsets the added costs of the intervention and was cost-saving by €12.121.

**Conclusion:** Based on exact data for the intervention costs and reference data for ulcer treatment costs, offloading-improved custom-made footwear seems cost-effective compared with custom-made footwear that does not undergo such improvement. Although the DIAFOS trial could not demonstrate a significant risk reduction, accompanying cost-savings might still turn offloading-improved custom-made footwear into a treatment of first choice for the prevention of plantar foot ulcer recurrence in high-risk diabetic patients.