Prize Oral 3

A two-year randomised trial comparing plantar pressure from three types of insoles.

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Background: Special insoles and shoes are frequently prescribed with the aim of avoiding high and repetitive pressure on specific regions of the foot soles in patients with diabetes. There is, however, a need for increased knowledge of a) the properties of the pressure distribution for insoles used over several months and b) the differences in peak pressure and pressure time integral for different types of insoles. This paper presents the first randomised study with the aim to compare peak plantar pressure and pressure time integral between three types of commonly used insoles. **Method**: In a two year trial 114 patients with type 1 (n=31) or type 2 (n=83) diabetes, 62 men and 52 women, were randomised for intervention with one of three commonly used insoles. The 35EVA group (n=39) received custom-made insoles in soft (35 shore) ethylene vinyl acetate (EVA), the 55EVA group (n=37) received custom-made insoles in hard 55 shore EVA, the control group (n=38) received prefabricated insoles. Mean age was 57.7 ± 15.4 years and duration of diabetes 12.3 ± 11.2 years. Neuropathy was present in 38 %. Inclusion criteria was: ≥18 years old, to be diagnosed with diabetes, to be able to walk without walking aid, to understand the Swedish language and to be first time visitor to the Department of Prosthetics and Orthotics. Exclusion criteria were foot ulcers. In-shoe pressure measurement was recorded with the F-Scan® system five times during the trial and analysed in seven regions of interests (ROI) which included the hallux, metatarsal head 1 (MTH1), MTH2, MTH4, MTH5, lateral aspect of the mid-foot, and the heel. Participants used outdoor walking shoes together with the insoles. At the last follow-up patients were asked to rate how much they had used the insoles and how satisfied they were with the insoles. The self-reported answers were registered on a visual analogue scale 0-100 where higher number represented more usage and greater satisfaction. **Results:** The custom-made insoles (35 and 55EVA) showed lower peak pressure in the heel region (178 ± 64 vs. 171 ± 57 kPa) compared with the prefabricated insoles (242 ± 88) ($p<0.001$). Pressure time integral at heel region was 41 ± 19 kPa*sec for the 35EVA, 35 ± 13 for the 55EVA and 54 ± 23 for the prefabricated insoles ($p<0.001$). The six other ROI showed no significant differences in peak plantar pressure or pressure time integral and had large inter-and intra-subject variation. According to the self-reported answers the average usage of the insoles was 79 and the satisfaction was 85 (n=75). Thirty-two percent had not received foot care. **Conclusion:** Custom-made insoles in combination with stable walking shoes showed lower pressure at the heel region. The variation makes it difficult to detect a systematic difference in plantar pressure for the 6 ROI, if such a difference indeed exists. Patient reported a high level of satisfaction and usage of the insoles.