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The effectiveness of offloading-improved custom-made footwear on plantar foot ulcer recurrence in diabetic patients: a multicenter randomized controlled trial

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Background: The aim of this study was to assess the effectiveness of custom-made footwear, of which offloading was improved based on in-shoe plantar pressure analysis, in preventing plantar foot ulcer recurrence in high-risk diabetic neuropathic patients.
Methods: In a multicenter randomized controlled trial design, 171 persons with diabetes, neuropathy, a healed plantar foot ulcer (<18 months), and mostly mild to severe foot deformity were included. Patients were randomized to either custom-made footwear of which the pressure-relieving properties were improved and preserved over time by modifying the footwear at delivery and at 3-monthly follow-up visits based on in-shoe pressure analysis (intervention group) or custom-made footwear that was clinically evaluated based on current practice (control group). Primary outcome was the ulcer recurrence rate in 18 months follow-up. In secondary analysis, dynamic barefoot pressures, objective footwear adherence, and daily step count) were assessed.
Results: In-shoe maximum peak pressures measured over time were 15-20% lower in the intervention than control group. Dropout rate was 6%. In an intention-to-treat analysis, 18-month cumulative ulcer recurrence rate was 39% in the intervention group and 44% in the control group (p=0.48, OR: 1.25, 95%CI: 0.68-2.30). Ulcer free survival curves were not significantly different between groups (p=0.40). Mean barefoot peak pressure at forefoot/midfoot was 896 kPa for the intervention group and 954 kPa for control. Mean daily step count was 7287 for the intervention group and 6170 for control (p=0.04). Mean footwear adherence was 69% for the intervention group and 76% for control.
Conclusions: The results show that offloading-improved custom-made footwear does not reduce plantar ulcer recurrence rate compared to non-modified custom-made footwear in diabetic patients at highest risk for ulceration. Pressure relief and improvement, whether or not based on measures of in-shoe pressure, may still be important, but more pressure relief than 15-20% may be required to show efficacy in ulcer prevention. Alternatively, other factors, such as frequent repetitive cycles of walking unprotected on a deformed foot with high barefoot pressures may counteract any beneficial pressure-relieving effect in explaining the high ulcer recurrence rates found in both study groups.