

## THE EFFECTIVENESS OF OFFLOADING-IMPROVED CUSTOM FOOTWEAR ON PLANTAR FOOT ULCER RECURRENCE IN DIABETES: A MULTICENTER RCT

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### BACKGROUND

Custom-made footwear is commonly prescribed to diabetic patients to prevent foot ulceration, but the evidence to support its use is still meager. This is probably because offloading efficacy is often not known, and footwear designs have variable effects. Therefore, an individualized approach where in-shoe pressure analysis is used as guidance tool for footwear modifications may be needed. A 17-52% reduction in peak pressures can be achieved with this approach, and may be an effective method to reduce ulcer risk (Bus et al. 2011). Therefore, the aim 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 patients.

### METHODS

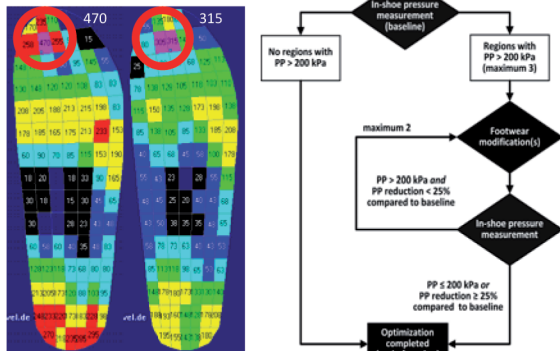


Figure 1: Protocol for offloading improvement

In a multicenter randomized controlled trial, 171 persons with diabetes, neuropathy, and a recently healed plantar foot ulcer were randomized to either footwear of which the offloading 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 using Pedar-X (intervention group, Figure 1) or footwear that was evaluated based on current practice (control group).

In an intention-to-treat analysis, the primary outcome was ulcer recurrence rate in 18 months. In

secondary analysis, we assessed ulcer classification, dynamic barefoot pressures (Emed-X), footwear adherence measured using shoe-worn sensors (@monitor), and daily step count measured using an ankle-worn activity monitor (StepWatch).

### RESULTS

In-shoe maximum peak pressures measured over time were ~20% lower in the intervention group than in control. Dropout rate was 6%. The 18-month 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 was not significantly different between groups ( $p=0.41$ ). Significantly less complicated ulcers (Texas grade 3 or C,D) were found in the intervention group compared to control (0 vs 6,  $p=0.02$ ). Mean barefoot peak pressure distal to the heel was 896 kPa for the intervention group and 954 kPa for control ( $p=.06$ ). Mean daily step count was 7113 for the intervention group and 5936 for control ( $p=.004$ ). Mean footwear adherence was 67% for the intervention group and 76% for control ( $p=.07$ ) and was lower while at home.

### DISCUSSION

Offloading-improved custom-made footwear (~20% peak pressure relief) did not reduce plantar ulcer recurrence rate compared to non-modified custom-made footwear in patients at high risk for ulceration. It did reduce ulcer severity, although numbers were small. Plantar pressure relief and improvement, whether or not based on measures of in-shoe pressure, may still be important, in prevention, but more pressure relief may be required to be effective. Alternatively, other factors, such as frequent repetitive cycles of walking unprotected on a deformed foot with high barefoot pressures may counteract any beneficial offloading effect in explaining the high recurrence rates found. Prevention may require a more comprehensive analysis of factors, including offloading footwear, education, and early recognition of pre-ulcerative lesions.

### REFERENCES

Bus et al., 2011. Diabetes Care 34: 1595-1600