BIOMECHANICAL OPTIMIZATION OF NEWLY PRESCRIBED THERAPEUTIC FOOTWEAR IN DIABETIC PATIENTS WITH A HISTORY OF PLANTAR ULCERATION

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SUMMARY
Prescribed therapeutic footwear for diabetic neuropathic patients aims to prevent foot ulceration by reducing plantar foot pressures. The objective was to assess the value of in-shoe plantar pressure analysis for evaluating and optimizing the offloading properties of therapeutic footwear. Dynamic in-shoe plantar pressures were measured in 58 diabetic neuropathic patients with a prior plantar foot ulcer who wore new therapeutic footwear. High pressure locations (>200kPa) were targeted for pressure optimization by modifying the footwear. After each of a maximum of three rounds of modifications, the effect on pressure was measured. In 16 identified previous ulcer locations peak pressure was significantly reduced from 290±87 to 223±53 kPa (23%). In 91 regions showing the highest peak pressure and 60 regions showing the second highest peak pressure, peak pressure was significantly reduced with 20% and 15%, respectively. These results show that therapeutic footwear for diabetic patients can be effectively optimized using in-shoe plantar pressure analysis as guidance tool for modifying the footwear. This provides an objective approach to instantly improve footwear quality which is likely to reduce the risk for pressure-related foot ulcers in these patients.

INTRODUCTION
Foot ulceration is a serious complication in patients with diabetes mellitus, with a lifetime risk of 15% [1]. Foot ulcers may lead to serious infections and, eventually, amputation [2]. Elevated plantar foot pressures have been associated with plantar ulceration in patients with a diabetic foot [3, 4]. To prevent future ulceration, the feet of diabetic patients must therefore be protected from excessive pressures. For this purpose, therapeutic footwear is often prescribed. Therapeutic footwear is currently prescribed and monitored based on clinical expertise and opinion. Objective assessment tools such as in-shoe plantar pressure analysis are generally not used to demonstrate footwear efficacy and to act as guidance tool for further optimization of the footwear. Therefore, the objective of this study was to assess the value of in-shoe plantar pressure analysis for evaluating and optimizing new therapeutic footwear in neuropathic diabetic patients with a history of plantar ulceration.

METHODS
A total of 58 diabetic patients with a mean age of 62.6 ± 10.3 years and a mean diabetes duration of 22.0 ± 15.9 years were included in this study. All patients had a healed plantar foot ulcer in the 18 months prior to inclusion and had loss of protective sensation due to peripheral neuropathy. All patients wore newly prescribed fully customized footwear or custom inserts in extra depth shoes. Dynamic in-shoe plantar pressures were measured in each patient using the Novel Pedar-X system during walking along a 10m walkway. Based on measured peak pressures, regions of interest (ROI) were selected for pressure optimization. These ROI were the previous ulcer location and a maximum of two regions per foot showing the highest peak pressures above 200 kPa, were selected. Subsequently, modifications were made to the footwear by a shoe technician with the goal to reduce peak pressure at the ROI. Choice of footwear modification was left to the discretion of the technician based on his skills and experience. After a round of footwear modification, in-shoe pressures were again measured. A maximum of three rounds of footwear modifications were applied to limit time spent on a patient. Criteria for successful optimization were a reduction of peak pressure at the ROI by 25% or to an absolute level below 200 kPa based on previous reports [5,6]. Figure 1 shows the flow diagram of the footwear optimization protocol.

Figure 1: Flow diagram of the footwear optimization protocol. The colored picture indicates a plantar pressure measurement. ROI-PU represents the region of interest at the previous ulcer location, ROI-HP1 and ROI-HP2 the regions with the highest and second highest peak pressures.
RESULTS AND DISCUSSION
In a total of 50 identified previous ulcer locations, only 16 showed peak pressure above 200 kPa at initial assessment. In these 16 regions, peak pressure was significantly reduced with 23% from an average 290 kPa before optimization to an average 223 kPa after optimization (Figure 2). In the remaining 34 previous ulcer locations, peak pressure was already below 200 kPa. Further optimization was not achieved in these regions. In 91 identified regions showing the highest in-shoe peak pressure, a significant peak pressure reduction of 20% was achieved after modifying the footwear (mean 277 to mean 221 kPa). In 60 identified regions showing the second highest peak pressure in the foot, peak pressure was significantly reduced with 15% after footwear modification (from a mean 256 to a mean 217 kPa). A mean 1.9 ± 0.9 rounds of footwear modifications was necessary to realize these results. Successful optimization at these three distinct regions was achieved in 56%, 56%, and 50% of the cases, respectively. These results show that the majority of footwear could be optimized to significant degrees using in-shoe pressure analysis. The results also show that the footwear was sub-optimal at the moment of delivery to the patient. This may be due to the fact that evidence-based or other well informed guidelines for proper footwear prescription currently do not exist. Footwear prescription and manufacturing is mainly based on clinical expertise and opinion of the physician and shoe technician.

Just over half of the regions of interest could be optimized according to the set criteria, which is lower than found in a previous study from the same research group [6]. This may be because already worn footwear was tested in the previous study, allowing for more success because of wear and tear of the shoe materials. Furthermore, more time for optimization was taken in the previous study, which may explain this difference.

In the majority of previous ulcer locations, peak pressures were already below 200 kPa. It was not possible to achieve further pressure reduction in these regions within one round of optimization. It may be that the pressure-relieving properties of the footwear were already optimal at these locations and that the shoe technician was out of options for further optimization. Shoe technicians may have also been resistant to modification of the footwear when pressures were already so low because of the potential risk of worsening the situation.

CONCLUSIONS
The majority of newly prescribed therapeutic footwear for high risk diabetic patients could be optimized to a substantial degree using in-shoe plantar pressure analysis as guidance tool for footwear modification. This provides a useful approach for clinical practice to instantaneously evaluate and optimize the offloading properties of therapeutic footwear for diabetic patients, which should contribute to reducing the risk for plantar foot (re-)ulceration in this patient group.

![Maximal Peak Pressure](maximal_peak_pressure.png)

**Figure 2:** Maximal peak pressure pre- and post-optimization for the previous ulcer location and the foot locations showing the highest and second highest peak pressures. The previous ulcer location is divided into cases showing baseline peak pressures above and below 200 kPa. Significantly different at *P<0.01

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