Chapter 4

Pressure-reduction and preservation in custom-made footwear of patients with diabetes and a history of plantar ulceration

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ABSTRACT

Aims
Custom-made footwear for patients with diabetes aims to prevent foot ulceration by reducing plantar pressures. The objective was to assess the value of using in-shoe plantar pressure analysis to improve and preserve the offloading properties of custom-made footwear in these patients.

Methods
Dynamic in-shoe plantar pressures were measured in new custom-made footwear of 117 patients with diabetes, neuropathy and a healed plantar foot ulcer. In 85 of these patients, high peak pressure locations (peak pressure >200kPa) were targeted for pressure reduction (goal: >25% relief or below an absolute level of 200 kPa) by modifying the footwear. After each of a maximum three rounds of modifications pressures were measured. In a subgroup of 32 patients, pressures were measured and, if needed, footwear was modified at 3-monthly visits for one year. Pressures were compared to those measured in 32 control patients who had no footwear modifications based on pressure analysis.

Results
At the previous ulcer location and the highest and second highest pressure locations, peak pressures were significantly reduced with 23%, 21%, and 15%, respectively, after footwear modification. These lowered pressures were maintained or further reduced over time and were significantly lower by 24-28% compared to pressures in the control group.

Conclusion
The offloading capacity of custom-made footwear for high-risk patients can be effectively improved and preserved using in-shoe plantar pressure analysis as guidance tool for footwear modification. This provides a useful approach to obtain better offloading footwear that may reduce the risk for pressure-related diabetic foot ulcers.
INTRODUCTION

Foot ulceration is a serious long term complication in patients with diabetes mellitus and polyneuropathy, which significantly increases the risk of infection and lower limb amputation. The lifetime risk of developing an ulcer is 15-25%. About half of all ulcers occur on the plantar foot surface. Loss of protective sensation and high levels of plantar foot pressure during ambulation are the main causative factors. To prevent ulceration, custom-made footwear is often prescribed to patients at high-risk for ulceration, and acts primarily by redistributing and relieving high plantar pressure levels.

Despite this goal, objective evaluation of the pressure-relieving properties of custom-made footwear is still not common in diabetic foot practice. Footwear is mostly evaluated based on clinical experience and a trial-and-error approach. Feedback from the patient is limited due to the presence of neuropathy. Therefore, variability may exist in the offloading properties of this footwear, which several biomechanical studies show to be the case. Consequently, the offloading capacity of this footwear may often be insufficient, which could be one of the factors that may explain the high recurrence rates of ulceration.

Offloading may be improved by modifying the patients’ footwear after delivery using objective measurement tools. A recent proof-of-principle study showed that in-shoe plantar pressure analysis is a valuable and efficient tool to guide footwear modification and achieve better offloading footwear. This study was, however, conducted in a relatively small and heterogeneous sample of patients, different footwear conditions, and in a setting where time was not constrained. Confirmation of these results in a large homogenous group of high-risk patients and footwear conditions, and in a time-constrained clinical setting is required.

Another important aspect in footwear evaluation is the preservation of offloading properties over time since only then a sustained reduction in the risk for ulceration may be assured. Wear and tear of the footwear or changes in foot shape could influence the pressure-relieving effects of custom-made footwear over time. Therefore, to maintain proper offloading, repeated in-shoe pressure assessments and (if needed) additional footwear modifications may be required.

For these reasons, we aimed to assess (1) the value of using in-shoe plantar pressure analysis for evaluating and improving the offloading properties of newly prescribed custom-made footwear in patients with diabetes, neuropathy and a recently healed plantar ulcer, and (2) to determine in these patients whether improved offloading results can be maintained over a one year period when compared to a control group of patients wearing custom-made footwear that is not modified based on in-shoe pressure analysis.
PATIENTS AND METHODS

Subjects
Thirty-four patients with type 1 diabetes and 83 patients with type 2 diabetes (mean ± SD age of 63.3 ± 10.1 years) with duration of 17.7 ± 14.1 years were included. All patients were consecutively recruited from the outpatient foot clinics of 10 hospitals in the Netherlands, which all participated in a trial on the effectiveness of custom-made footwear in preventing diabetic foot ulcer recurrence (DIAFOS trial, trial register: NTR1091). All patients had loss of protective sensation as confirmed by the inability to sense the pressure of a 10-g Semmes Weinstein monofilament at one or more of three plantar foot sites, or a vibration perception threshold at the hallux >25V. Most patients had one or more foot deformities, including claw/hammer toes, hallux valgus, Charcot midfoot deformity, prominent metatarsal heads,

Table 4.1. Anatomical locations of the previous ulcer and the two highest peak pressures per foot in the 85 patients assessed for offloading improvement.

<table>
<thead>
<tr>
<th>Region</th>
<th>Previous ulcer location</th>
<th>Highest and second highest peak pressure location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hallux</td>
<td>15 (1)</td>
<td>33</td>
</tr>
<tr>
<td>Toes 2-3</td>
<td>17 (4)</td>
<td>1</td>
</tr>
<tr>
<td>Toes 4-5</td>
<td>2 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Metatarsal 1</td>
<td>23 (2)</td>
<td>53</td>
</tr>
<tr>
<td>Metatarsals 2-3</td>
<td>15 (1)</td>
<td>90</td>
</tr>
<tr>
<td>Metatarsals 4-5</td>
<td>11 (0)</td>
<td>19</td>
</tr>
<tr>
<td>Midfoot medial</td>
<td>1 (0)</td>
<td>4</td>
</tr>
<tr>
<td>Midfoot lateral</td>
<td>1 (0)</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>85 (9)</td>
<td>202</td>
</tr>
</tbody>
</table>

Data are expressed as N with the number of amputations of that region in between brackets.

and partial foot amputation. Each patient had a healed plantar ulcer during the previous 18 months. For the first study objective (improving offloading), data were collected in 85 of the total 117 patients. For the second study objective (preserving offloading), data were collected in the first 32 of these 85 patients who had completed one year follow-up (experimental group) and in 32 patients who were measured for in-shoe plantar pressure in their custom-made footwear, but had no modifications to the footwear based on these pressures (control group). Written informed consent was obtained from each patient prior to inclusion in the study, which was approved by the Local Research Ethics Committee.
Figure 4.1. Flow diagram of the footwear modification protocol used at entry and at each follow-up assessment. The regions of interest (ROI) were the previous ulcer location (PUL) and the two highest peak pressure locations in the midfoot and forefoot with peak pressure >200 kPa (HPL1 and HPL2). Abbreviations: PP = Peak Pressure; FU = follow-up; wrt = with respect to.

Footwear

Patients wore newly prescribed fully custom-made footwear (i.e. custom-made insoles in custom-made shoes, also referred to as ‘orthopaedic footwear’ in some countries, N = 95) or semi custom-made footwear (i.e. custom-made insoles in off-the-shelf extra depth shoes, also referred to as ‘semi-orthopaedic footwear’, N = 22). The footwear was prescribed by a rehabilitation specialist and manufactured by a shoe technician working in each of the centres. Each team had a minimum of 4 years experience in diabetic foot practice. Although not enforced by any protocol, footwear design mostly followed the Delphi-based algorithm published by Dahmen and colleagues 17. The footwear was generally manufactured from a
plaster cast or foam mould of the foot. Blueprints were commonly used to identify target regions of high pressure for footwear design. The footwear generally had a stiffened rubber outsole with roller configuration. Custom-made insoles consisted of multi-density layered materials, with mouldable cork or multiform base and an open or closed-cell material top cover.

**Instrumentation**

In-shoe plantar pressures were measured using the Pedar-X system (Novel, Munich, Germany). This system consists of flexible 2-mm-thick insoles with 99 sensors which independently measure the normal pressure at a sample frequency of 50 Hz. The insoles were placed between the sock and the insole of the shoe. Multiple insole sizes were available to accommodate different foot sizes. Each pair of Pedar insoles was calibrated each 3 months using a calibration device and guidelines from the manufacturer.

**Protocol**

In-shoe plantar pressures were measured while walking at a self-chosen comfortable speed along a minimum 10-m long walkway. Walking speed was measured using a stopwatch and kept constant during subsequent measurements in the same session or during follow-up measurements (maximum 5% deviation in average walking speed). A minimum of 20 mid-gait steps per foot were collected per measurement. Patients were provided with thin seamless socks during the measurement sessions.

The protocol used for evaluating and modifying the footwear is shown in Figure 4.1. In-shoe plantar pressures were measured in the footwear as delivered (baseline assessment). Based on the average peak pressure pictures obtained over multiple foot steps, regions of interest were selected (peak pressure was the parameter used throughout the study). These included the previous ulcer location and, if present, per foot the two highest peak pressure locations in the midfoot and forefoot with peak pressure >200 kPa. In the 85 patients assessed for offloading improvement, the footwear was subsequently modified by the shoe technician with the goal to reduce peak pressure at the regions of interest. Choice of modification to the shoes or insoles was left to the shoe technician and/or rehabilitation specialist. Multiple modifications were allowed at once.

Criteria for successful improvement in offloading were defined. These were a peak pressure reduction at the region of interest of 25% compared to baseline levels or a reduction to an absolute level below 200 kPa. Using in-shoe pressure within this context as a surrogate indicator for risk of foot ulceration, both criteria were considered to be indicative of a relevant reduction in risk of ulceration. If the criteria were not met, a maximum of two subse-
sequent rounds of footwear modifications and in-shoe pressure measurements were applied. If the criteria were eventually not met, offloading improvement was considered as a failure.

Follow-up in-shoe pressures were measured at three-monthly intervals (Figure 4.1). The regions of interest that were defined at baseline were also the regions of interest during follow-up. In the 32 experimental group patients in-shoe pressure was measured and the footwear was modified if the criteria for successful offloading were not yet achieved at entry visit (0 months) or when, compared to the final pressure measured at entry, peak pressure at the region of interest had increased with 5% or more. After each round of footwear modifications, in-shoe pressures were measured, similar to how this occurred at entry.

Footwear modifications that occurred in the control group in-between study visits were identified by asking the patient about visits to the shoe technician. If confirmed, the shoe technician was asked about modifications made and details were recorded.

Data analysis and statistics
During the testing sessions, data analysis was done on-screen from the peak pressure distribution pictures of the foot. After the testing session, formal data analysis was conducted by masking the regions of interest in the pressure pictures and calculating mean peak pressures for each mask using Novel multimask software.

High-pressure locations may shift from the region of interest to neighbouring (anatomical) regions as a result of modifying the footwear. To assess this possible effect, change in peak pressure between the first and final assessment within one session was calculated in each of 10 masked foot regions: lateral and medial heel, medial and lateral midfoot, metatarsal 1, metatarsals 2/3, metatarsals 4/5, hallux, toes 2/3, and toes 4/5. These transfer pressure effects were considered excessive when peak pressure increase was more than 25 kPa and more than 25%, and when peak pressures reached a level >200 kPa.

Descriptive analyses were done using SPSS version 16.0 (SPSS Inc., Chicago, United States). Outcomes for offloading at entry and follow-up pressure measurement were modelled by multilevel linear regression analysis using MLwiN software, version 2.23 (Institute of Education, University of London, UK). The foot pressure data were nested at four levels, participating centre (fourth level), patient (third), foot (second), and time (first), to determine and (if needed) account for dependency of the data on these factors 21. To analyse footwear modification effects, in-shoe peak pressure was regressed on the variable ‘time’ (pre-modification, post-modification), and on the covariate ‘type of footwear’ (fully custom-made or semi custom-made). To analyse follow-up effects, in-shoe peak pressure was regressed on the variables ‘study group’ (experimental, control), ‘time’ (each 3-month visit), and their interaction.
Table 4.2. Results for in-shoe pressure offloading at entry in 85 patients.

<table>
<thead>
<tr>
<th>Region of interest</th>
<th>N</th>
<th>Baseline, Mean (SD)</th>
<th>After footwear modification, Mean (SD)</th>
<th>β0, Mean (SE)</th>
<th>βopt, Mean (SE)</th>
<th>Successful optimization, %</th>
<th>No. of rounds of modifications, Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PUL&lt;200</td>
<td>49</td>
<td>123 (43)</td>
<td>127 (46)</td>
<td>123 (6.3)**</td>
<td>ns</td>
<td>94</td>
<td>0.6 (0.5)</td>
</tr>
<tr>
<td>PUL&gt;200</td>
<td>27</td>
<td>287 (79)</td>
<td>221 (49)</td>
<td>287 (12.5)**</td>
<td>-66 (12.4)**</td>
<td>59</td>
<td>1.4 (0.6)</td>
</tr>
<tr>
<td>HPL1</td>
<td>123</td>
<td>277 (67)</td>
<td>220 (61)</td>
<td>276 (6.3)**</td>
<td>-57 (3.9)**</td>
<td>59</td>
<td>1.5 (0.8)</td>
</tr>
<tr>
<td>HPL2</td>
<td>79</td>
<td>247 (44)</td>
<td>210 (44)</td>
<td>246 (5.8)**</td>
<td>-38 (3.9)**</td>
<td>51</td>
<td>1.4 (0.8)</td>
</tr>
</tbody>
</table>

Measured in-shoe peak pressures are shown for baseline and for final in-shoe pressure assessment (after all rounds of modifications).

Abbreviations: PUL<200, PUL>200 = all previous ulcer locations with measured peak pressures below and above 200kPa, respectively; HPL1, HPL2 = Highest and second highest peak pressure location with peak pressure >200 kPa, respectively; SD = Standard deviation; SE = Standard Error. Regression model: Outcome variable = β0 + βopt * time, in which β0 = intercept; βopt = regression slope; time = before (0) and after (1) footwear modification. Significance: ns = not significant, ** P<0.01.
RESULTS

The previous ulcer location and the two highest peak pressure locations are shown in Table 4.1. A peak pressure >200 kPa at the previous ulcer location was found in 27 patients, a peak pressure <200 kPa in 49 patients of 85 patients assessed for offloading improvement. These groups were analysed separately. In nine patients, the previous ulcer location was amputated.

Table 4.2 shows the outcomes for offloading improvement at entry. In-shoe peak pressure was reduced significantly after modifying the footwear with 23% at the previous ulcer location with peak pressure >200 kPa, with 21% at the highest peak pressure location, and with 15% at the second highest peak pressure location (P < 0.01). To achieve these results, an average 1.4 (SD 0.7) rounds of footwear modifications were needed. In 64% of the cases, one round of footwear modifications was used. In both footwear types, modifications were made to the shoes and insoles. The most applied modifications were the removal of material in the insole at the region of interest (33% of all modifications), replacement of the

![Figure 4.2. Mean in-shoe peak pressure measured at entry and at 3-monthly intervals over the course of 1 year follow-up in the experimental group (E, solid symbols) and the control group (C, open symbols) for all regions of interest with peak pressure >200kPa (ROI_{>200}) and the previous ulcer location with peak pressure <200kPa (PUL_{<200}).](image)
Table 4.3. Results for in-shoe pressure offloading during follow-up assessments.

<table>
<thead>
<tr>
<th>Region of interest</th>
<th>Study group</th>
<th>Measured in-shoe peak pressure (kPa)</th>
<th>Successful optimization</th>
<th>Rounds of modifications (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Before footwear modification</td>
<td>After footwear modification</td>
<td>0 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N</td>
<td>Mean (SD)</td>
<td>%</td>
</tr>
<tr>
<td>PUL&lt;200</td>
<td>Control</td>
<td>17</td>
<td>127 (40)</td>
<td>100</td>
</tr>
<tr>
<td>ROI&gt;200</td>
<td></td>
<td>78</td>
<td>272 (55)</td>
<td>0</td>
</tr>
<tr>
<td>PUL&lt;200</td>
<td>Experimental</td>
<td>20</td>
<td>130 (41)</td>
<td>95</td>
</tr>
<tr>
<td>ROI&gt;200</td>
<td></td>
<td>95</td>
<td>265 (51)</td>
<td>53</td>
</tr>
</tbody>
</table>

Results of multilevel linear regression model

<table>
<thead>
<tr>
<th></th>
<th>( \beta_0 )</th>
<th>( \beta_{\text{study group}} )</th>
<th>( \beta_{\text{time}} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>PUL&lt;200</td>
<td>130 (5.9)**</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>ROI&gt;200</td>
<td>268 (8.2)**</td>
<td>-64 (10.8)**</td>
<td>-3 (1.4)*</td>
</tr>
</tbody>
</table>

Measured in-shoe peak pressures for are shown both study groups before any modification and for the experimental group after all rounds of modifications. Abbreviations: PUL<200 = all previous ulcer locations with measured peak pressures below 200kPa; ROI>200 = all regions of interest with measured peak pressure above 200 kPa; SD = Standard deviation; SE = Standard Error.

Regression model: Outcome variable = \( \beta_0 + \beta_{\text{study group}} \times \text{study group} + \beta_{\text{time}} \times \text{time} \), in which \( \beta_0 \) = intercept; \( \beta_{\text{study group}} \) = regression slope; study group = control group (0) or experimental group (1); time = follow-up visit (0, 3, 6, 9 and 12 months).

Significance: ns = not significant.
* \( p < 0.05 \), ** \( p < 0.01 \).
insole top cover (20%), softening of material in the insole at the region of interest (16%), the placement of a metatarsal pad or bar (16%), and the adjustment of the pivot point in the outsole roller (6%). Successful offloading was achieved in 51-59% of these regions, dependent on location. At the previous ulcer location with peak pressure <200 kPa, peak pressures could not be further reduced by modifying the footwear (in 60% of cases one round of modification was applied, in 40% the footwear was not modified). None of the outcomes was dependent on type of footwear or participating centre. Excessive build-up of peak pressure in neighbouring regions was present in 2% of cases.

Table 4.3 shows the outcomes for the follow-up pressure analysis. No significant differences were present between the two study groups in patient characteristics and baseline in-shoe pressures. Figure 4.2 shows the course of peak pressure over one year for the two study groups. For this analysis, all regions of interest with a peak pressure >200 kPa were pooled. After modification at entry, the difference between study groups for these pooled regions was significant, and this difference increased over time. Peak pressure reduced significantly over time in the experimental group ($\beta_{\text{time}} = -5 \text{ kPa/follow-up}; 95\% \text{ CI, } -8.6 \text{ to } -0.7; \text{ P < 0.01}$), but not in the control group ($\beta_{\text{time}} = -1 \text{ kPa/follow-up}; 95\% \text{ CI, } -6.6 \text{ to } 3.9; \text{ ns}$). For the previous ulcer location with baseline peak pressure <200 kPa, mean peak pressure did not change significantly over time in either study group. At 3 months follow-up, one round of footwear modifications was applied in 58% of the cases and zero rounds in 28% of cases. At 12 months follow-up, these percentages were 20% and 78%, respectively. Successful offloading was achieved in 64% of the regions of interest with baseline peak pressure >200 kPa after 3 months follow-up and in 81% after 12 months follow-up. In 4 of the 32 control group patients, the footwear was modified in-between visits, at a single occasion during follow-up. None of the outcomes in either group during follow-up was dependent on participating centre.

**DISCUSSION**

This study shows that plantar pressures at high-pressure regions can be reduced to substantial degrees after modifying custom-made footwear based on in-shoe pressure analysis. At the most at-risk foot location, the previous ulcer location, peak pressures above 200kPa were reduced with a mean 23%. However, when peak pressures at the previous ulcer location were below 200 kPa, further pressure reduction proved elusive, suggesting that sufficiently offloaded conditions were already present. Improved offloading was maintained and even further improved over a 12-month follow-up period, and was significantly better that footwear that was not modified based on in-shoe pressure analysis. In only 2% of regions neighbouring the regions of interest, excessive build of pressure was found. In the majority of high-pressure regions (53%), successful offloading was achieved according to
the set criteria, and this improved to 64% after 3 months and to 81% after one year. This provides a valuable objective approach to achieve and preserve better offloading custom-made footwear. Whether this will reduce the risk for pressure-related plantar foot ulcers in patients with diabetes remains to be investigated.

The offloading results at entry confirm recent findings from a similar but smaller study 12. This study reported a mean 30% peak pressure relief after footwear modification and a 100% success rate using similar criteria. The lower current success rates may be because more regions of interest per foot were selected. This may have reduced the chance for success in each region of interest, because of pressure redistribution effects or because a certain region was given priority for clinical reasons. In 63% of the failed offloading attempts, the maximum 3 rounds of modifications were not used. This may have been caused by time constraints in busy outpatient clinic or by the fear for increasing pressure in an already offloaded region. This adds to the lower success rate in the current study. These factors may also explain the lower mean number of modification rounds in the current study (1.4) compared to the previous study (1.8). Nevertheless, both studies lead to the conclusion that in-shoe pressure analysis is a valuable tool to achieve better offloading footwear.

During follow-up, in-shoe peak pressures were further reduced by modifying the footwear. Fewer rounds of modifications were needed at each subsequent follow-up visit. The ‘saw tooth’ pattern of peak pressure change in the first 6 months (Figure 4.2), showed that improved results could not be preserved in the short run without further modification of the footwear. These results support the long-term pressure monitoring at 3-monthly intervals. At each follow-up stage, in-shoe peak pressures were significantly lower in the experimental group than in the control group, in which peak pressures did not change over 12 months time. Wear and tear of the footwear was expected to increase peak pressures over time in the control group 22, 23, despite that results on this aspect are still inconclusive 14, 24. Clearly, more research on the mechanisms of in-shoe pressure change, or the lack thereof, over time is required to better clarify the follow-up pressure results in this study.

The majority of previous ulcer locations (64%) showed baseline peak pressures below 200 kPa, and by modifying the footwear further pressure-relief was not possible. The mean measured in-shoe peak pressure of 127 kPa was low. This suggests that for these locations the footwear was already sufficiently offloaded, maybe by being an important and clear target in footwear design. In contrast, in 85 patients, 229 regions of interest with peak pressures >200 kPa were identified, among which many less clear targets, supporting the use of objective evaluation tools. Risk for ulceration may be increased at these high-pressure locations 20, 25. Therefore, offloading was considered insufficient and in need for improvement in these cases. The lack of a structured and evidence-based protocol for footwear design and manufacturing may be an underlying cause. Footwear prescription and evaluation is in
many ways still more an art than a science, which may introduce variability in design and in efficacy of footwear prescriptions \textsuperscript{10,26}. Better offloading can be achieved with the use of quantitative computer-assisted approaches in footwear design and manufacturing, which may reduce variability \textsuperscript{27}. Still, an individual-based approach in footwear evaluation seems necessary. The current approach can be helpful in this regard, and seems to be independent of the clinical team (albeit having ample experience) and type of custom-made footwear used, which improves external validity.

This study was limited in some aspects. First, data on ulcer recurrence rates were not available for this study. Therefore offloading success could not be associated with ulcer recurrence data. Success criteria were based on common sense and indications of clinically relevant pressure reduction that may prevent ulcer recurrence \textsuperscript{20,28}. Future studies, such as our DIAFOS trial, should confirm if using such criteria can prevent plantar foot ulcer recurrence. Secondly, successful offloading did not necessarily imply optimal footwear. Further modification or other footwear designs may have further reduced pressure. However, our goal was to test a clinically feasible approach, and therefore the number of modification rounds was limited to three. Finally, we did not use standardized protocols for modifying the footwear, since guidelines are lacking. This could affect the reproducibility of the results. Future investigations should focus on developing evidence-based guidelines for effective footwear designs and modifications.

In conclusion, we found that the majority of high-risk regions, whether predictable or not from foot screening, can be offloaded to a substantial degree using in-shoe plantar pressure analysis as guidance tool for modifying custom-made footwear. These improved conditions could be maintained and even further improved over time using the same approach. This provides a useful objective approach for clinical practice to achieve and preserve better offloading footwear that may reduce the risk for pressure-related plantar foot ulcers in patients with a diabetic foot.
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