Custom-made footwear in diabetes: Offloading, usability and ulcer recurrence

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Chapter 3

Offloading effect of therapeutic footwear in patients with diabetic neuropathy at high risk for plantar foot ulceration

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ABSTRACT

Aims
Custom-made therapeutic footwear is often prescribed to patients with diabetic neuropathy, foot deformity and a healed plantar foot ulcer. Offloading these feet is important to prevent ulcer recurrence. The aim was to evaluate the offloading effect of custom-made footwear in these patients.

Methods
In 171 patients with diabetic neuropathy (336 feet) with foot deformity and a recently healed plantar foot ulcer, plantar pressures walking barefoot and inside new custom-made footwear were measured. At the previous ulcer location and at locations of highest barefoot pressure due to the deformity, in-shoe pressures were compared with non-deformed feet. The footwear was considered effective in offloading when in-shoe peak pressure at these locations was <200 kPa.

Results
Mean in-shoe peak pressures ranged between 211 and 308 kPa in feet with forefoot deformity (vs. 191-222 kPa in non-deformed feet) and between 140 and 187 kPa in feet with midfoot deformity (vs. 112 kPa in non-deformed feet). Offloading was effective in 61% of all feet with deformity, 81% of feet with midfoot deformity, 44% of feet with forefoot deformity, and 62% of previous ulcer locations. Inter-subject variability in measured in-shoe plantar pressure was large.

Conclusions
Offloading of custom-made footwear is often not sufficiently achieved in high-risk diabetic feet with deformity. Highest offloading success rates were seen at known high-risk locations such as previous ulcer locations and Charcot feet, the lowest success rates in forefoot deformities. Together with the large inter-subject variability in pressure outcomes, this emphasizes the need for evidence-based prescription and evaluation procedures to assure adequate offloading.
INTRODUCTION

Diabetic foot ulceration imposes a large burden on the patient and the health care system, with increased risk for infection and amputation, lower health-related quality of life, and high treatment costs. In the absence of protective sensation, elevated plantar pressure is causative of plantar foot ulcers, and is strongly associated with foot deformity. Patients with these conditions are often prescribed with custom-made therapeutic footwear. This footwear aims to prevent ulceration by reducing peak pressures at high-risk plantar foot sites through pressure redistribution. Although custom footwear is widely used and assumed to reduce ulcer risk, the scientific evidence is still meagre. Among other factors, this may be related to the lack of knowledge about the offloading effect of this footwear. In clinical practice, footwear evaluation is still heavily based on the experience of the clinical team and a ‘trial-and-error’ approach, using foot ulceration as most informative outcome for footwear success and clinical decision making. Quantitative methods are, however, available to help in footwear evaluation and to improve the interpretation of footwear offloading.

Studies on footwear offloading in high-risk patients with diabetic neuropathy and foot deformity are scarce. One study showed higher in-shoe plantar pressures in a cohort of patients with diabetes and different foot deformities when compared to patients without foot deformity, but this was tested in ‘usual footwear’ that was not further specified and the study did not include a dedicated sample of high-risk patients. A more recent study measured forefoot in-shoe plantar pressures in a group of high-risk patients who remained healed from previous ulceration for a longer period of time while wearing therapeutic footwear, and found a mean peak pressure value of approximately 200 kPa. Although this pressure level should not be interpreted as an individual peak pressure threshold for ulcer-free survival, it may be used as reference to assess success in footwear offloading when an in-shoe pressure measuring device with similar specifications is used.

It is currently unclear to what extent custom-made footwear for these high-risk patients with diabetic neuropathy and foot deformity meets this criterion. Therefore, the aim of this observational study was to investigate to what extent offloading by means of custom-made footwear results in peak plantar pressures below 200 kPa in at-risk foot areas affected by foot deformity in patients with diabetic neuropathy and a history of plantar foot ulceration. Furthermore, the study aimed to assess determinants of in-shoe offloading success. We hypothesized to find insufficient overall offloading success rates (i.e. < 80%), based on the high ulcer recurrence rates still found in patients with diabetes, and the lowest success rates (i.e. highest in-shoe peak pressures) in feet with the most severe foot deformities.
Subjects
A total of 171 consecutive patients with diabetic neuropathy (contributing 336 feet), who presented at the outpatient diabetic foot clinics of 10 Dutch hospitals between January 2008 and October 2010 and fulfilled the inclusion criteria, participated in this study. The study was part of the DIAFOS trial (trial register ID NTR1091)*. Baseline patient characteristics are shown in Table 3.1. All patients had a healed plantar foot ulcer within 18 months prior to the assessment. Loss of protective sensation due to neuropathy was verified by the inability to sense the pressure of a 10g Semmes-Weinstein monofilament at one or more of three plantar foot sites tested: hallux, first metatarsal head, and fifth metatarsal head, or the vibration of >25 Volt measured at the dorsal hallux using a Bio-thesiometer (Bio-Medical Instrument Company, Newbury, Ohio) 6. Patients were excluded when they were unable to walk unaided for 100m or when they had bilateral amputation proximal to the metatarsal bones. Written informed consent was obtained from each patient prior to the start of the study and all procedures were approved by the medical ethics committee of the Academic Medical Center in Amsterdam, the Netherlands.

Foot deformity
Each foot was physically examined by one of three trained researchers (MA, RW, or RK) for presence of deformity. Additionally, photographs of each foot were taken in a loaded and unloaded position using a standardized protocol. These photographs were assessed for presence of deformity and forefoot amputation level (i.e. digit, ray, or transmetatarsal) by two teams of two trained observers who reached consensus on outcome. The presence of deformity was primarily diagnosed based on photographic assessments, except for prominent metatarsal heads and limited joint mobility, which were diagnosed based on the physical examination. Hallux valgus was defined as lateral deviation of the hallux with respect to the first metatarsal bone, hammer toes as hyperflexed inter-phalangeal joints with plantar floor contact of the top of the toes in a loaded position, claw toes as hyperextended metatarso-phalangeal joints with hyperflexed inter-phalangeal joints, pes cavus as a high medial foot arch, pes planus as a flattened medial foot arch, prominent metatarsal heads as palpable bony prominences, and Charcot foot as visible dislocation of the midfoot joints, in some cases resulting in a rocker bottom deformity. The presence of Charcot foot and the level of amputation were verified in the medical file of the patient. Range of motion in the first metatarso-phalangeal joint was measured using goniometry in a supine position and limited joint mobility was considered present when the range of motion was smaller than one standard deviation below the mean of all feet. Finally, feet without foot deformity were labelled as non-deformed feet.
Footwear
All patients were prescribed with new therapeutic footwear, which included fully customized footwear (i.e. custom insoles in custom-made shoes, N=146) or semi-customized footwear (i.e. custom insoles in extra-depth shoes, N=25). In each of the 10 participating centres, footwear was prescribed by a rehabilitation specialist and manufactured by an orthopaedic shoe technician, both with minimally 4 years of experience in diabetic foot treatment. Shoe lasts were generally created from plaster cast or from foam impressions with geometrical foot measures. Blueprints were used to specify at-risk regions to be targeted. Although not enforced by any protocol, footwear design mostly followed the Delphi-based algorithm published by Dahmen et al. Custom insoles consisted of multi-layered materials, mostly with a cork base added with micro-cork and a midlayer of ethylene vinyl acetate based multiform. Local softening in the insole was frequently added and corrective elements (e.g. metatarsal pad or bar), were occasionally incorporated. The insoles were finished with a leather, PPT (Langer, Inc., Deer Park, New York, USA) or Plastazote (Zotefoams plc, Croydon, UK) top cover. Shoe outsoles mainly consisted of stiffened rubber or Poron and a roller configuration.

Instrumentation
Barefoot dynamic plantar pressures were measured using an EMED-X platform (Novel GmbH, Munich, Germany) which consists of capacitance-based sensors in a spatial resolution of 4 sensors per cm² that were sampled at 70 Hz. In-shoe dynamic plantar pressure was measured using the Pedar-X system from Novel. This system comprises flexible 2 mm thick insoles, available in different length and width sizes, containing a matrix of 99 capacitance-based sensors in a spatial resolution of approximately 2 sensors per cm², with each sensor sampling at 50 Hz. The insoles were placed inside the shoe between the sock and insole. Each insole was calibrated prior to data collection according to the manufacturer’s specifications.

Procedures
For barefoot pressure assessment, at least 4 walking trials were collected per subject using a 2-step approach to the platform. In-shoe plantar pressure was assessed while walking repeatedly along a walkway of minimally 10 meter length. It was assured that pressures from at least 12 midgait steps per foot were collected. Patients walked at a self-selected comfortable speed, which was measured using a stopwatch, and was controlled between trials (± 5% variation allowed). All patients wore thin seamless socks which were provided during the measurements.
Novel multimask software (Version 13.3.65) was used to analyze the pressure data. Footsteps showing major deviances in the ground reaction force curves were removed manually. For both the barefoot and in-shoe pressure distribution diagrams, masks were created per foot to divide the foot into 10 anatomical regions: lateral and medial heel, lateral and medial midfoot, metatarsal 1, metatarsal 2/3, metatarsal 4/5, hallux, toes 2/3, and toes 4/5. Additionally, the previous ulcer location was masked. For each region, the mean peak pressure over the multiple steps per foot was calculated.

All feet were grouped according to type of deformity (claw toes, hallux valgus, Charcot foot, etc). For each deformity group, one region-of-interest was defined based on where the mean measured barefoot peak pressure in that group was highest and therefore considered most at risk for ulceration. Such a region-of-interest could cover one or two anatomical regions, such as metatarsal heads 2-5 in the case of claw toes (Table 3.2). In each group of feet with a particular deformity, other deformities could be present as long as these other deformities did not have the same region-of-interest as the primary deformity. This means that feet with multiple deformities could be included in more than one deformity group. Per deformity, footwear offloading was assessed only at the region-of-interest. Additionally, footwear offloading was assessed in all patients at the previous ulcer location.

Footwear offloading was assessed in three ways. First, in-shoe peak pressure was compared between each deformity group and the no-deformity group. Secondly, the relative peak

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**Table 3.1. Baseline patient’s characteristics and walking speed for in-shoe pressure measurement.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>171</td>
</tr>
<tr>
<td>Number of (non-amputated) feet</td>
<td>336</td>
</tr>
<tr>
<td>Gender (male / female)</td>
<td>140 / 31</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.8 (10.2)</td>
</tr>
<tr>
<td>Diabetes type (Type 1 / Type 2)</td>
<td>49 / 122</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>14.0 (10.0 – 27.5)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>30.9 (6.0)</td>
</tr>
<tr>
<td>HbA1C (mmol/mol)</td>
<td>64 (42)</td>
</tr>
<tr>
<td>HbA1C (%)</td>
<td>7.6 (1.4)</td>
</tr>
<tr>
<td>Vibration perception threshold (V)</td>
<td>45 (11)</td>
</tr>
<tr>
<td>Walking speed (m/s)</td>
<td>1.03 (0.28)</td>
</tr>
</tbody>
</table>

*Data are expressed as N, mean (SD) or median (inter-quartile range).*
pressure reduction between in-shoe and barefoot was calculated for each deformity group and the no-deformity group. Third, the percentage of cases with in-shoe peak pressure below 200kPa (defining success in offloading) was calculated, based on a previous report indicating a 200kPa threshold as effective for ulcer-free survival in the forefoot. Offloading success scores were considered insufficient when this percentage was lower than 80%, and sufficient when above 80%.

**Statistical analysis**

Statistical analyses were carried out using PASW statistics version 18 (SPSS inc., Chicago, USA), and if not specified otherwise, a significance level $p < 0.05$ was used. Independent sample t-tests were used to compare in-shoe peak pressure between each deformity group and the no-deformity group. Pearson correlation coefficients were calculated to determine the association between barefoot and in-shoe peak pressure at the previous ulcer location. Between participating centres, differences in in-shoe plantar pressures were assessed with one-way analysis of variance and post-hoc testing, while differences in offloading success were assessed with Kruskal-Wallis tests. Univariate logistic regression analyses of offloading success at the previous ulcer location were performed including the variables: vibration perception threshold, body mass index, type of foot deformity, barefoot peak pressure, walking speed, type of footwear, and participating centre ($p < 0.10$). Significant factors were included in a multivariate logistic regression model in a backwards stepwise fashion.

![Figure 3.1](image)

**Figure 3.1.** Histogram showing the barefoot peak pressure (grey bars) and in-shoe peak pressures (black bars) at the previous ulcer location for each of the 147 subjects with a non-amputated previous ulcer location. The horizontal dashed line represents the 200kPa threshold used to define offloading success in this study. Data are ranked by measured in-shoe peak pressure. In 17 cases (12%), the peak pressure saturation level of the EMED platform (1275kPa) was reached.
<table>
<thead>
<tr>
<th>Type of deformity</th>
<th>Number of feet</th>
<th>Barefoot peak pressure (kPa)</th>
<th>In-shoe peak pressure (kPa)</th>
<th>Relative peak pressure reduction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Deformity</td>
<td>No deformity</td>
<td>Region-of-interest</td>
<td>Deformity</td>
</tr>
<tr>
<td>Hallux valgus</td>
<td>41</td>
<td>74</td>
<td>MT1</td>
<td>637 (334)</td>
</tr>
<tr>
<td>Hammer toes</td>
<td>65</td>
<td>74</td>
<td>Toes</td>
<td>393 (231)</td>
</tr>
<tr>
<td>Claw toes</td>
<td>57</td>
<td>74</td>
<td>MT2-5</td>
<td>840 (304)</td>
</tr>
<tr>
<td>+ Prominent MTHs</td>
<td>16</td>
<td>74</td>
<td>MTs</td>
<td>1050 (211)</td>
</tr>
<tr>
<td>+ Pes cavus</td>
<td>13</td>
<td>74</td>
<td>MTs</td>
<td>949 (284)</td>
</tr>
<tr>
<td>Prominent MTH</td>
<td>38</td>
<td>74</td>
<td>MTs</td>
<td>969 (245)</td>
</tr>
<tr>
<td>Pes planus</td>
<td>63</td>
<td>74</td>
<td>Midfoot</td>
<td>278 (237)</td>
</tr>
<tr>
<td>Pes cavus</td>
<td>10</td>
<td>74</td>
<td>MTs</td>
<td>661 (417)</td>
</tr>
<tr>
<td>Charcot feet</td>
<td>24</td>
<td>74</td>
<td>Midfoot</td>
<td>722 (481)</td>
</tr>
<tr>
<td>Hallux amputation</td>
<td>10</td>
<td>74</td>
<td>MTs</td>
<td>862 (388)</td>
</tr>
<tr>
<td>Lesser toe amputation</td>
<td>16</td>
<td>74</td>
<td>MTs</td>
<td>861 (328)</td>
</tr>
<tr>
<td>(Trans) MT amputation</td>
<td>19</td>
<td>74</td>
<td>Midfoot</td>
<td>401 (391)</td>
</tr>
<tr>
<td>LJM (1st MTPj)</td>
<td>41</td>
<td>59*</td>
<td>MT1</td>
<td>629 (361)</td>
</tr>
<tr>
<td>Previous ulcer ‡</td>
<td>147†</td>
<td>N/A</td>
<td>Previous ulcer site ‡</td>
<td>729 (393)</td>
</tr>
</tbody>
</table>

Data are expressed as N, mean (SD), or as percentage reduction between barefoot and in-shoe peak pressure. MTH = metatarsal head; MT = metatarsal, LJM = limited joint mobility; MTPj = metatarsal-phalangeal joint.

* Feet without LJM in accordance with the definition of LJM given in the methods section.

† In the feet of 171 patients, 20 previous ulcer sites were amputated. Four patients were not able to successfully perform barefoot plantar pressure measurement and were therefore excluded from this analysis.

‡ Anatomical locations of the previous ulcers were: hallux (N = 34), toes 2/3 (N = 23), toes 4/5 (N = 2), MT1 (N = 39), MT2/3 (N = 20), MT4/5 (N = 17), medial midfoot (N = 5), lateral midfoot (N = 2), MT base (N = 4) and heel (N = 1). N/A = not applicable.
RESULTS

The highest mean barefoot and in-shoe peak pressures were found in feet with claw toes and prominent metatarsal heads (Table 3.2). In-shoe peak pressures at the region-of-interest varied between 29 and 596 kPa across all feet. All deformities showed higher in-shoe peak pressures when compared to non-deformed feet, but these differences were only significant in hammer toes, claw toes + prominent metatarsal heads, pes planus, Charcot feet, and metatarsal amputation.

The relative peak pressure reduction from barefoot to in-shoe peak pressure was higher for deformed feet (50% - 76%) than for non-deformed feet (14% – 66%) (Table 3.2). At the previous ulcer location, the relative peak pressure reduction was 85% (range: -49% to +98% across 147 cases) (Figure 3.1). The correlation coefficient between barefoot and in-shoe peak pressure was 0.528 at the previous ulcer location ($p < 0.001$).

Offloading success scores are shown in Table 3.3. Overall, 61% of all feet with deformity showed successful offloading. At the previous ulcer location, successful offloading was found in 62% of the cases. Lower scores were present for foot deformities with the metatarsals as region-of-interest (11% - 60%) than for deformities with the midfoot (67% - 91%) or toes (95%) as region-of-interest. In 24% of the feet, successful offloading was found for the whole foot (i.e. in all forefoot and midfoot regions peak pressure was <200kPa). Between participating centres (included patients: 5 to 26), mean in-shoe plantar pressures at the previous ulcer location ranged between 143 kPa and 260 kPa, and was significantly different ($p = 0.018$). Offloading success ranged between 31% and 86%, and was also significantly different ($p = 0.009$).

The univariate regression analyses of successful offloading showed that barefoot plantar pressure and participating centre were the only significant factors. Both these factors remained significant in the multivariate logistic regression model, with OR 0.805 per 100kPa barefoot peak pressure (95% CI: 0.728 – 0.889, $p < 0.001$) and OR 0.866 for participating centre (95% CI: 0.763 – 0.983, $p = 0.026$).

DISCUSSION

In this study, the extent to which custom-made footwear offloads the foot was assessed in a group of 171 high-risk patients with diabetic neuropathy and specified to the type of foot deformity these patients had. The results show that the majority of feet with deformity had significantly higher in-shoe peak pressures when compared to non-deformed feet. More than one third of feet was not adequately offloaded by the custom-made footwear, which confirms our hypothesis. Offloading success was highest in feet with known high-risk target
locations, such as the previous ulcer location, Charcot deformity, and amputation at metatarsal level (16% - 38% of cases with in-shoe peak pressure >200kPa). Offloading success was lowest in cases where the metatarsal region was the region-of-interest (40% - 89% of cases with in-shoe peak pressure >200kPa). These outcomes suggest that improvement in footwear design is required and should focus most on those deformities that affect pressure in the metatarsal region. Additionally, large inter-individual differences were found in footwear offloading: measured in-shoe pressures at the region-of-interest were as low as 29kPa and as high as 596kPa. Prescription and manufacturing of the footwear in this study was not based on evidence-based guidelines, as these do not exist. These outcomes emphasize the need for such guidelines as well as quantitative evaluation approaches, to better identify increased pressure locations in individual feet and to assure sufficient offloading in high-risk patients.

Offloading success scores were variable across deformities. They were lowest in deformities affecting the forefoot, in particular in feet with claw toes (11% - 39%), which are prevalent in the diabetic population. These results support earlier findings from Ahroni et al. who...
showed that in-shoe plantar pressures were highest in patients with diabetic neuropathy who had claw toes and prominent metatarsal heads. The offloading success scores were insufficient in feet with these deformities, despite that the percentage pressure reduction between barefoot and in-shoe peak pressure was among the highest in the study (71% - 76%). Apparently, claw toe deformity represents a high-risk condition that can be substantially off-loaded using custom-made footwear, but still requires more specific attention in footwear prescription to achieve lower absolute peak pressure levels.

Many patients in this study had severely complicated feet, which is illustrated by the high barefoot peak pressures measured, in several cases even saturating the pressure platform at 1275kPa. Quite remarkably, however, and in contrast with our hypothesis, the foot conditions that are generally considered as highest-risk showed the highest offloading success rates by the footwear. This includes the previous ulcer location, Charcot feet, and feet with (trans-)metatarsal amputation (62% - 84% effective footwear). In Charcot feet (N=24) and feet with (trans-)metatarsal amputation (N=19), in-shoe peak pressure at the region-of-interest (midfoot) was significantly higher than in non-deformed feet. This was expected because the midfoot is not a heavily loaded area in a normally structured foot. However, the relative pressure reduction between barefoot and in-shoe was substantial, in particular in Charcot feet (74%) and the previous ulcer location (84%). Maybe, footwear prescribers and manufacturers focus on the most severe foot conditions, which are relatively easy to identify, and use more, or more effective footwear designs and materials than for less severe conditions. Consequently, more successful offloading was achieved compared to the less severe foot conditions or less obvious at-risk locations. Although it is not certain that a 200kPa threshold defined for the forefoot also applies to the midfoot, or that the midfoot requires a lower threshold, the data shows that custom-made footwear was most effective in offloading the most severe foot conditions. However, such a focus on clinically identifiable regions may distract from identifying other regions with high pressures that would not be targeted without data on in-shoe pressure. We therefore argue that quantitative methods, such as in-shoe plantar pressure measurement, are essential to identify all risk locations under the foot to be targeted in footwear design and manufacturing.

The logistic regression analysis showed only two significant contributors to successful offloading, namely low barefoot peak pressure and participating centre. The effect of barefoot peak pressure is in line with the significant association found between barefoot and in-shoe peak pressure. The effect of participating centre may point to different standards and quality in footwear prescription and manufacturing. One should realize though that the case load of patients (both in number and in severity of condition) may be quite different between centres, which can affect the pressure differences found between centres. Despite being significant contributors, both odds ratios were close to one, which undermines their predictive power. Apparently, success in footwear offloading is difficult to predict. This
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seems typical for diabetic footwear studies, where significant group effects are often found, but inter-individual variability is large, therefore limiting predictability of outcomes. Also in the study by Owings et al., the range of in-shoe pressures measured across patients was large. The lack of available evidence-based approaches in footwear prescription and manufacturing may explain (part of) this variability. The use of more quantitative, computer-driven, approaches, such as 3D foot scanning, barefoot pressure measurement and CAD-CAM, can result in better offloading compared to traditional methods. But, as shown in the current study and by Owings et al., barefoot peak pressures do not accurately predict in-shoe peak pressures. Therefore, the measurement of in-shoe plantar pressures is needed to evaluate the offloading success of custom-made footwear. These measurements can guide modifications to the patients’ footwear to further improve its offloading properties, which reduces variability in outcome. Furthermore, differences in offloading success between centres with a similar case load of patients should lead to improvement of standards and quality of footwear prescription in all centres based on this type of quantitative assessment. Whether the use of these methods prevents ulceration in the diabetic foot remains to be investigated and is a focus of interest in our own DIAFOS trial.

Some limitations apply to this study. First, the in-shoe peak pressure reference value of 200kPa is not an evidence-based absolute threshold level that predicts ulceration or ulcer-free survival. The threshold should be seen as an indicator for proper offloading until a more appropriate evidence-based threshold level is defined. Because offloading success rate is based on this threshold, the same applies to the use of the 80% reference value to classify offloading success rate as sufficient or insufficient. Secondly, the results may be specific for the practice, experience, skills, type of footwear, and materials used in the participating centres from which patients were recruited. Outcomes may be different in other settings. However, our recruitment of patients from multiple centres does improve the external validity of the findings. Nevertheless, future studies should focus on establishing evidence-based guidelines for footwear prescription and manufacturing that may further improve consistency of results.

CONCLUSION

The results of this study show that offloading is often not sufficiently achieved in the high-risk diabetic foot with deformity. The highest offloading success rates were found in feet with known high-risk locations such as the previous ulcer location, Charcot feet, and feet with amputation at the metatarsal level. The lowest offloading success rates were found in foot deformities that have their pressure-increasing effect at the metatarsal region. Together with the high inter-subject variability in in-shoe pressure outcomes, this emphasizes the need for more evidence-based prescription and manufacturing protocols and quanti-
Offloading effect of therapeutic footwear

tative evaluation approaches to better identify increased pressure locations in individual feet and to assure adequate offloading of custom-made footwear in patients with diabetic neuropathy.
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