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

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Chapter 2

Twelve steps per foot are recommended for valid and reliable in-shoe plantar pressure data in neuropathic diabetic patients wearing custom made footwear


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Chapter 2

ABSTRACT

Background
Dynamic in-shoe plantar pressure assessment is used both in research and clinical practice to evaluate therapeutic footwear interventions in neuropathic diabetic patients. The aim was to determine the required number of footsteps for reliable and valid in-shoe plantar pressure data in these patients.

Methods
In 30 neuropathic diabetic patients wearing custom–made therapeutic footwear, in-shoe plantar pressures were measured for a minimum of 20 midgait walking steps per foot. For each incremental number of steps and for each of six anatomical regions per foot, peak pressure, pressure-time integral, contact area, contact time, and force-time integral were calculated. Reliability was assessed by calculating intraclass correlation coefficients. Validity was assessed by calculating the coefficient of variation between each n-step protocol and the 20-step reference protocol based on limits of agreement analysis. Data was considered reliable with intraclass correlation coefficients >0.90 and valid with coefficients of variation <10%.

Findings
Three steps per foot were required to obtain reliable data for each foot region and parameter. Depending on the parameter, between 7 and 17 steps per foot were required to obtain valid data. With the exception of deviant outcomes in three forefoot regions for force-time integral, overall 12 steps per foot were required for valid data.

Interpretation
For neuropathic diabetic patients wearing custom-made therapeutic footwear, 12 midgait steps per foot are required to obtain valid and reliable in-shoe plantar pressure data. This provides directions for the use of in-shoe plantar pressure analysis in research and clinical practice in this patient group.
INTRODUCTION

In-shoe dynamic plantar foot pressure assessment is used more and more in research and clinical practice to evaluate the efficacy of therapeutic footwear prescriptions in diabetic patients with peripheral neuropathy. Elevated plantar foot pressure is a causative factor of foot ulceration in these patients \(^1,^2\), and foot ulceration is an important precursor of infection and amputation \(^3\). To reduce the risk of ulceration, therapeutic footwear is commonly prescribed. This footwear primarily acts to redistribute plantar pressures on the foot and relieve pressure in regions at risk for ulceration \(^4,^5\). To adequately assess the efficacy of therapeutic footwear interventions, one has to rely on representative and reliable in-shoe plantar pressure data.

To obtain such a representative (i.e. valid) and reliable estimate of the true in-shoe plantar pressures, data from multiple footsteps are generally collected, often in multiple walking trials. However, the precise number of collected steps per foot is often not reported and may vary considerably, from as few as three steps \(^6\) to as many as 30-40 steps \(^7\). Too few collected footsteps may compromise data quality. Too many collected footsteps may fatigue patients, in particular with repeated measurements or multiple conditions tested and will increase data collection and analysis time. Guidelines for the required number of footsteps for valid and reliable in-shoe plantar pressure data in neuropathic diabetic patients currently do not exist.

The only study we found on this topic assessed healthy subjects and found that eight steps per foot were required to obtain reliable in-shoe plantar pressure data \(^8\). However, this study assessed only data reliability, not data validity, assessments were at the group level, and subjects were tested in standard footwear on a treadmill at controlled speeds. This limits the extrapolation of these findings to individual diabetic patients of which many have abnormalities in foot structure, gait, or balance \(^9\)\(^-\)\(^11\), and who are generally tested in a clinical setting wearing therapeutic footwear and walking overground at comfortable speeds.

The above considerations suggest that specific guidelines for the required number of footsteps for valid and reliable in-shoe pressure data in neuropathic diabetic patients are needed to help direct clinical practice and research toward proper use of in-shoe plantar pressure analysis. Therefore, the aim of this study was to determine the number of footsteps required to obtain valid and reliable in-shoe plantar pressure data in neuropathic diabetic patients wearing custom-made footwear. For this analysis, we focused on the most commonly reported pressure parameters in diabetic footwear studies.
Chapter 2

METHODS

Subjects
Thirty neuropathic diabetic patients (22 males, 8 females, mean (SD) age 58.5 (10.9) years, mean body mass index (BMI) 31.5 (7.5)) who were at risk for plantar foot ulceration participated in the study. Mean time since diabetes onset was 25.2 (16.9) years. Twelve patients had diabetes type 1, 18 patients had diabetes type 2. All patients had peripheral neuropathy, indicated by a loss of protective sensation in the foot through the inability to sense the 10g Semmes-Weinstein monofilament at three plantar foot sites tested (hallux, first metatarsal head, and fifth metatarsal head). Each patient presented with one or more foot deformities which were assessed clinically. These deformities included hammer/claw toes, pes cavus, prominent metatarsal heads, limited joint mobility at the first metatarsal-phalangeal joint, and hallux valgus. Subjects had to be able to walk unaided for a distance of at least 100m. Patients with non-diabetic causes of neurological deficit or lower extremity amputation were excluded. Written informed consent was obtained prior to the start of the study. All procedures were approved by the medical ethics committee of the University of Amsterdam Medical Centre.

Instrumentation
In-shoe dynamic plantar pressure was measured using the Novel Pedar-X system (Novel GmbH, Munich, Germany). The system comprises flexible 2mm thick insoles with a matrix of 99 capacitance-based sensors each sampling at 50Hz, which were placed in the shoes between the sock and insert. The measurement insoles are attached by leads to a data logger worn by the subject on a waist belt. Data was transmitted through a wireless Bluetooth connection to a laptop computer on which the data was stored. In-shoe plantar pressure was measured within a range of 20 to 600 kPa. Six different pairs of wide Pedar insoles were available to accommodate each foot size. Before data collection, each pair of insoles was calibrated according to the manufacturer’s specifications.

Footwear
Patients wore newly-prescribed therapeutic footwear, which included fully customized footwear (orthopedic footwear), or custom molded inserts worn in extra-depth shoes (semi-orthopedic footwear).

Procedures
Before pressure assessment, a ‘zero-calibration’ was performed by unloading each measurement insole while the patient wore shoes. In-shoe plantar pressure was assessed while walking in multiple trials along a 12m walkway in a laboratory setting. Prior to the collection
of data, subjects performed two practice walking trials. Subjects walked at a self-selected comfortable speed, which was controlled during subsequent trials (± 5% variation allowed). Walking speed was measured using a photocell system. It was assured that in-shoe pressures from a minimum of 20 midgait steps per foot were collected.

**Data analysis**

Software from Novel was used to analyze the in-shoe pressure data. The first and last footstep of each walking trial was removed automatically by the software to avoid acceleration and deceleration effects on the data. Additionally, footsteps showing sensor errors or major deviations in the ground reaction force curves were removed manually. Masks were used to divide the foot into six anatomical regions per foot: heel, midfoot, 1st metatarsal, 2nd to 5th (lesser) metatarsals, hallux and 2nd to 5th (lesser) toes. For each incremental number of footsteps and for each foot region, mean values for the 30 subjects for peak pressure, pressure-time integral, contact area, contact time, and force-time integral were calculated. These five parameters were chosen because they are the most commonly reported parameters in pressure studies on diabetic footwear. Peak pressure and pressure-time integral are clinically most relevant, whereas force-time integral is biomechanically relevant in showing the mechanism of action in load (re-)distribution of footwear interventions. The first 20 clean midgait steps per foot were selected for data analysis. The condition with 20 footsteps was used as *reference step protocol* for statistical analysis. Each condition with an incremental number of footsteps, starting with two and finishing with 19, was defined as *n-step protocol*. The left and right feet were assessed separately.

**Statistical analysis**

Statistical analysis was carried out using SPSS statistical software (Version 18.0). To determine the number of footsteps required for reliable in-shoe pressure data, Intraclass Correlation Coefficients (ICC) were calculated per pressure parameter and foot region, for each incremental number of footsteps between two and 19 in comparison with the reference step protocol. An ICC > 0.90 was considered indicative of excellent reliability. To determine the number of footsteps required for valid in-shoe pressure data, limits of agreement analysis was performed in order to take into account inter-individual differences in gait variability and pressure recordings. First, for each pressure parameter and foot region, mean differences between values of each n-step protocol and the reference step protocol were calculated per subject. Ninety-five percent limits of agreement of these mean differences were then calculated per n-step protocol (Formula 1). Subsequently, a coefficient of variation was calculated between the 95% limits of agreement interval and the mean value for the 20-step reference protocol (Formula 2). Data was considered valid when this coefficient of variation was smaller than 10%. Overall, in-shoe plantar pressure data was considered
valid and reliable in this study when for all five pressure parameters and for all foot regions the criteria for valid and reliable data were reached.

The presence of a step or trial effect in the data (values increasing or decreasing with an incremental number of footsteps) was tested for each foot region and for each parameter. For this purpose, average values of the 30 subjects for each incremental number of footsteps were plotted. From these plots, linear regression coefficients were calculated and tested for statistical significance ($P < 0.05$). Additionally, ANOVA repeated measures and post-hoc analysis was used to compare the averaged values between each of four blocks of five subsequent footsteps ($P < 0.05$).

RESULTS

Between two and five walking trials on the 12m walkway were required to obtain a minimum number of 20 left and right midgait footsteps in each subject. Six footsteps of six different patients showing sensor errors in the pressure recordings were removed manually. The mean (SD) walking speed of the subjects was 1.1 (0.2) m/s. Mean values and standard deviations for each parameter per foot region based on the 20-step reference protocol are shown in Table 2.1. In the analysis of a step or trial effect, none of the regression coefficients was statistically significant. Additionally, no significant differences were found between the average values for the four blocks of five footsteps, with the exception of contact time measured in the lesser metatarsal region. This means that there was no step or trial effect present in the data.

Three steps per foot were required to obtain excellent reliability scores (ICC > 0.90) in each foot region for all pressure parameters (Table 2.2). For assessment of data validity, the coefficients of variation gradually decreased when adding more footsteps to the calculation (Figure 2.1). The number of footsteps required to reach coefficients of variation below 10% per foot region and parameter are shown in Table 2.3. For peak pressure, pressure-time integral, contact area, contact time, and force-time integral, the required number of steps per foot
for all foot regions together was 12, 11, 9, 7, and 17, respectively. More footsteps were generally required in the right foot compared to the left foot and in the forefoot compared to the rearfoot.

In the right forefoot, a deviant number of 15, 16, and 17 footsteps were required to obtain valid force-time integral data in the lesser toes, hallux, and first metatarsal regions, respectively. The data for these foot regions showed outliers in three out of thirty patients. No specific disease characteristics were present in these patients that may explain these deviant outcomes. The decline of the coefficients of variation in these regions with increasing number of footsteps reached a plateau between 10 and 16 footsteps for force-time integral that was more significant than for the other parameters (Figure 2.1E). As a result, minor changes in the coefficient of variation may give larger changes in the number of required footsteps, which may explain the higher number of footsteps required for force-time integral in these three regions.

With the exception of force-time integral values in these three forefoot regions of the right foot, 12 steps per foot were required to obtain valid and reliable data for all pressure parameters in all regions of both feet.
Table 2.2. *Intraclass correlation coefficients per foot region for each pressure parameter shown for the 2-step and 3-step protocols.*

|                  | Left foot | | | | | | | | Right foot | | | | | |
|------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                  | Heel      | Midfoot | Metatarsal 1 | Metatarsals 2-5 | Hallux | Toes 2-5 | Heel | Midfoot | Metatarsal 1 | Metatarsals 2-5 | Hallux | Toes 2-5 |
| **Peak pressure**|           |         |             |              |        |           |      |         |             |              |        |           |
| 2-step protocol  | 0.98      | 0.98    | 0.97        | 0.98          | 0.97   | 0.99      | 0.98 | 0.95    | 0.93        | 0.98          | 0.95   | 0.97      |
| 3-step protocol  | 0.99      | 0.98    | 0.98        | 0.99          | 0.98   | 0.98      | 0.98 | 0.96    | 0.96        | 0.99          | 0.96   | 0.98      |
| **Pressure-time integral** | | | | | | | | | | | | | | | | |
| 2-step protocol  | 0.97      | 0.97    | 0.95        | 0.95          | 0.96   | 0.96      | 0.95 | 0.97    | 0.89        | 0.98          | 0.93   | 0.97      |
| 3-step protocol  | 0.98      | 0.97    | 0.96        | 0.97          | 0.97   | 0.97      | 0.97 | 0.94    | 0.98        | 0.98          | 0.95   | 0.98      |
| **Contact area** |           |         |             |              |        |           |      |         |             |              |        |           |
| 2-step protocol  | 0.99      | 0.98    | 0.95        | 0.99          | 0.99   | 0.98      | 0.99 | 0.98    | 0.96        | 0.98          | 0.99   | 0.98      |
| 3-step protocol  | 1.00      | 0.98    | 0.96        | 0.99          | 0.99   | 0.98      | 0.99 | 0.98    | 0.98        | 0.99          | 0.97   | 0.98      |
| **Contact time** |           |         |             |              |        |           |      |         |             |              |        |           |
| 2-step protocol  | 0.96      | 0.97    | 0.98        | 0.98          | 0.88   | 0.95      | 0.95 | 0.96    | 0.88        | 0.97          | 0.94   | 0.94      |
| 3-step protocol  | 0.98      | 0.97    | 0.99        | 0.98          | 0.95   | 0.97      | 0.96 | 0.97    | 0.92        | 0.97          | 0.94   | 0.95      |
| **Force-time integral** | | | | | | | | | | | | | | | | |
| 2-step protocol  | 0.95      | 0.98    | 0.93        | 0.96          | 0.97   | 0.95      | 0.92 | 0.98    | 0.90        | 0.97          | 0.97   | 0.93      |
| 3-step protocol  | 0.97      | 0.99    | 0.95        | 0.98          | 0.98   | 0.97      | 0.96 | 0.99    | 0.94        | 0.98          | 0.98   | 0.96      |
Table 2.3. Number of steps required to obtain coefficients of variation <10% per foot region and parameter. Underlined numbers represent the highest number of required steps per parameter.

<table>
<thead>
<tr>
<th></th>
<th>Left foot</th>
<th>Right foot</th>
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<tbody>
<tr>
<td></td>
<td>Heel</td>
<td>Midfoot</td>
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<tr>
<td>Peak pressure</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Pressure-time integral</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Contact area</td>
<td>2</td>
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<tr>
<td>Contact time</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Force-time integral</td>
<td>10</td>
<td>8</td>
</tr>
</tbody>
</table>
Figure 2.1. Coefficients of variation shown as a function of the number of footsteps. Data are presented as an average (+ 2 SDs) of all 12 foot regions. Curves are shown for (A) peak pressure, (B) pressure-time integral, (C) contact area, (D) contact time, and (E) force-time integral. The dotted vertical lines define the number of steps where the coefficients of variation were smaller than 0.10 (10%) in all 12 regions.
DISCUSSION

The aim of this study was to determine the required number of footsteps for valid and reliable in-shoe plantar pressure data in neuropathic diabetic patients wearing custom-made therapeutic footwear. For this analysis, we chose to select the five most commonly reported parameters in diabetic footwear studies. The results showed that only three steps per foot were required in these patients to obtain highly reliable data. To obtain valid in-shoe pressure data, between 7 and 17 steps per foot were required, depending on the parameter of interest. With the exception of some deviant outcomes for force-time integral, this study showed that 12 steps per foot were required to obtain both valid and reliable in-shoe pressure data in all parameters. Based on these results, we recommend that 12 midgait steps per foot are collected when in-shoe plantar pressure measurements are performed to evaluate custom-made therapeutic footwear in neuropathic diabetic patients who are at risk for ulceration.

Within only three steps per foot, ICCs reached levels above 0.90 indicating excellent reliability of the in-shoe plantar pressure data. This is not surprising considering the consistency people tend to show from step-to-step in level walking, resulting in only small differences in pressure and time parameters between subsequent steps. However, ICC calculations have the disadvantage that they are influenced by inter-subject variability, which was large in this study as the standard deviations of the mean outcomes in Table 2.1 show. Furthermore, ICC scores provide information at group level, not at the individual patient level. We aimed to provide recommendations on the use of in-shoe plantar pressure analysis in individual patients, as this seems more relevant for clinical practice. Therefore, a limits of agreement analysis was applied. This analysis showed that for contact time and contact area fewer footsteps were required to obtain valid data than for the pressure parameters, likely because they are not influenced by individual sensor values, giving more consistent step-to-step outcomes. The lower coefficients of variation (SD/mean) for these parameters shown in Table 2.1 also indicate this. Nevertheless, among the selected parameters, peak pressure is the most commonly reported and clinically most relevant parameter in assessment of the diabetic foot. Therefore, the results for peak pressure were leading in the recommendations made.

This priority given in the interpretation to peak pressure was also one of the reasons to exclude the deviant results on force-time integral in three right forefoot regions in the recommendations made. Another reason was that the coefficient of variation for force-time integral across the range of 10-16 footsteps only showed a minimal change (Figure 2.1E), suggesting that the coefficients at 12 footsteps were quite similar to those of the other pressure parameters. This indicates that the deviant results on force-time integral had no significant impact on the overall study findings. Probably for the same reason, differences
were found in the required numbers of steps between the left and right feet (Table 2.3). Although these differences were sometimes large, for example for contact area in the hallux region (2 footsteps required for the left foot, 9 for the right foot), the coefficients of variations at these step numbers were not very different between left and right. Moreover, left-right differences for the primary parameter, peak pressure, were small. Therefore, no specific conclusion should be drawn from the discrepancies between the left and right foot.

The results indicate that more footsteps are required to obtain reliable and valid in-shoe plantar pressure data in neuropathic diabetic patients than to obtain reliable data in healthy subjects (8 steps per foot)\(^8\). However, the current study showed reliable data after only 3 steps per foot, but valid data after 12 steps per foot. Kernozek et al. did not report on an individual patient-based validity analysis. Furthermore, data collection methods were different between studies: treadmill walking at a controlled speed versus overground walking at a comfortable speed. Finally, neuropathic patients are generally different from healthy subjects in presence of foot deformity, gait and balance abnormalities, and footwear use, which may also affect in-shoe pressure data consistency in a different way\(^9,10\). Therefore, a valid comparison between these two studies is not possible.

Most gait laboratories are confined in space. Therefore, data from multiple walking trials are often collected to obtain a representative number of steps per foot for data analysis. In this case, speed of walking has to be standardised between trials, where some trials may be excluded because speed is outside the set range. Furthermore, data from multiple walking trials needs further processing to obtain an ensemble average for all footsteps. Efficiency of data collection and analysis would improve if only one walking trial containing 12 steps per foot would be collected. This would require a setting for unobtrusive walking along a straight path of about 25 meters, and a mobile and telemetric system that can measure over such a distance. Because a step or trial effect was not shown in this study, such an effect also seems unlikely in a longer walking trial of 25 meters.

A few limitations apply to this study. First, the criterion level of 10\% for the calculated coefficient of variation and the use of 20 footsteps as reference protocol were arbitrarily chosen. Different choices may have resulted in different outcomes. However, as Figure 2.1 shows for the pressure parameters, the decline in coefficient of variation curves reached some kind of plateau at a level of approximately 10\% between 10 and 15 footsteps. Therefore, in hindsight, the 10\% criterion level and the 20-step reference protocol seem to be adequately chosen. Secondly, an age-matched healthy control group was not included which limits the assessment of the specific effect of diabetic neuropathy on data reliability and validity. Such an assessment was, however, beyond the scope of this study, in which we primarily aimed to establish recommendations for testing individual neuropathic diabetic patients in a clinical setting. Further research is needed to compare patients with healthy subjects. Finally, the
outcomes are specific for high-risk diabetic patients being tested in custom-made footwear. Although the data may be externally valid for other subgroups of patients (e.g. non-neuropathic, wearing standard footwear, or with active ulceration offloaded unilaterally), this can not be determined from the current study. Nevertheless, in-shoe plantar pressure analysis seems most relevant for evaluating therapeutic footwear in high-risk neuropathic patients for preventative purposes.

**CONCLUSION**

This study showed that 12 midgait steps per foot were required to obtain reliable and valid in-shoe dynamic plantar pressure data in neuropathic diabetic patients wearing custom-made therapeutic footwear. This finding provides directions for the use of in-shoe plantar pressure assessment for clinical practice and research purposes. Furthermore, the results contribute to the standardization of protocols on foot pressure measurements, a topic that has gained recent interest within the International Foot and Ankle Biomechanics community (www.i-fab.org).

Based on the study findings, we recommend that 12 midgait steps per foot are collected when dynamic in-shoe plantar pressures are measured in neuropathic diabetic patients wearing custom-made therapeutic footwear. If space and equipment allows, data is preferably collected within one walking trial to improve efficiency. There may be reasons to collect more than 12 steps per foot, for example to improve statistical power. However, we suggest that this is considered in relation to need, possible patient burden, and efficiency. We further recommend that authors report the (minimal) number of footsteps collected for in-shoe plantar pressure analysis.
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