Improving footwear to prevent ulcer recurrence in diabetes: Analysis of adherence and pressure reduction
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Chapter 2

THE INTERDEPENDENCY OF PEAK PRESSURE AND PRESSURE-TIME INTEGRAL IN PRESSURE STUDIES ON DIABETIC FOOTWEAR: NO NEED TO REPORT BOTH PARAMETERS

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Roelof Waaijman
Sicco A. Bus
ABSTRACT

**Background:** In plantar pressure studies on diabetic footwear, both the maximum peak pressure (MPP) and peak pressure-time integral (PTI) are often reported. However, specific conclusions for each parameter are not commonly reported, suggesting these parameters may be interchangeable. The aim was to explore the interdependency of MPP and PTI in diabetic patients wearing different types of footwear.

**Methods:** In-shoe plantar pressure was measured in 69 neuropathic diabetic patients who walked in custom made footwear, forefoot offloading shoes, cast shoes, and/or standard footwear. For each of six anatomical foot regions, correlation coefficients were calculated between MPP and PTI. To assess parameter congruency, the percentage of patients showing correlation coefficients > 0.7 or coefficients of variation for both MPP and PTI < 10%, was calculated.

**Results:** Across all footwear conditions, MPP and PTI were highly correlated in the forefoot and midfoot (r > 0.78 in all but one foot region in one footwear condition). Lower correlations coefficients were found in the rearfoot (r = 0.43-0.45). Across regions, between 46% and 87% of patients (mean 72%) showed parameter congruency in the forefoot and midfoot.

**Conclusions:** The results showed that the MPP and PTI are highly interdependent in those foot regions most at risk for plantar ulceration in patients wearing commonly prescribed footwear. Since MPP has been shown to date to be the clinically more relevant parameter of the two, these results suggest that the value of reporting PTI in addition to MPP in the same diabetic footwear study is small.
INTRODUCTION

In-shoe plantar pressure assessment is becoming increasingly popular in both research and clinical practice to evaluate the effects of prescribed footwear in diabetic patients who have a foot ulcer or who are at risk for ulceration. Foot ulcers are a serious problem, with a lifetime prevalence of 15-25% in the diabetic population. These ulcers can lead to infection and lower limb amputation, with 85% of all non-traumatic amputations in diabetes being preceded by a foot ulcer. In the presence of loss of protective sensation due to peripheral neuropathy, the majority of plantar foot ulcers develop as a result of the repetitive action of increased mechanical stress (i.e. pressure) on the foot during ambulation. The goal of prescribed footwear is to lower these pressures in order to heal a plantar foot ulcer or to prevent it from (re)occurring.

In pressure studies on diabetic footwear, often multiple pressure parameters are reported. The maximum peak pressure (MPP) is almost always reported, likely because both in retrospective and prospective studies, diabetic foot ulceration has been associated with the presence of elevated MPP. A significant odds ratio of 3.2 has been found. The peak pressure-time integral (PTI) is also often reported. The PTI has also been associated with foot ulceration, but this association has not yet been demonstrated in a prospective analysis. Recently, a systematic review of the diabetic foot literature from our group showed that in the majority of studies collecting both MPP and PTI data, differences in outcomes between these two parameters were generally small and conclusion were non-specific. Also recently, Keijser et al. found that MPP and PTI were highly interdependent in healthy subjects walking barefoot across a pressure platform. The findings in these studies suggest that these parameters may be interchangeable and the value of reporting both parameters in the same study may be limited.

Because of their suggested relevance in diabetic foot ulceration and their suggested interdependency in previous studies, we chose to further explore the association between MPP and PTI in the diabetic foot. The aim of this study was to assess the degree of interdependency of MPP and PTI in foot pressure analyses of neuropathic diabetic patients wearing different types of offloading footwear. We hypothesized that a strong association between these two pressure parameters would suggest that there is no need to report both parameters in the same footwear study.

METHODS

Subjects

A total 69 diabetic patients at risk for foot ulceration were included in this study (60 males, mean (SD) age 60.7 (8.9) years, mean (SD) diabetes duration 17.7 (14.4) years). All patients had loss of protective sensation due to peripheral neuropathy. This was confirmed by the inability to sense the pressure of a 10g monofilament on the planter hallux, first or fifth metatarsal head or a 25V vibration on the dorsal hallux from a Bio-thesiometer (Bio-Medical Instrument Company, New-bury, OH, USA). Patients had one or more foot deformities, including claw/hammer toes, hallux valgus or rigidus, prominent metatarsal heads, pes cavus, pes planus or Charcot osteoarthropathy, or had
experienced a partial foot amputation. Patients were excluded if they had a current foot ulcer, lower-leg amputation, or if they were unable to walk repeatedly unaided over a distance of 12 m. All patients gave their written informed consent for participation in the study, which was approved by the Local Research Ethics Committee.

**Footwear conditions**

Patients were measured in four different types of footwear, all ankle-high modalities commonly prescribed for treatment or prevention of plantar foot ulcers in diabetes. The footwear included custom made therapeutic footwear, a cast shoe (Mabal, Almelo, Netherlands), a forefoot offloading shoe (FOS, Rattenhuber Talus, http://www.rattenhuber.de), and a standard shoe (Pulman, http://www.fld.fr) with flexible outsole and flat insert (Figure 1). Patients wore their therapeutic footwear on both feet. The other footwear conditions were tested on the right foot only (patients wore their own shoe on the left). Not all patients were tested in each footwear condition. A total of 30 patients were tested in the custom made footwear, 24 in the cast shoe, 38 in the forefoot offloading shoe, and 39 in the standard shoe.

![Footwear Conditions](image)

**Figure 1. The four different types of footwear tested in this study: (A) custom made therapeutic footwear, (B) a cast shoe, (C) a forefoot offloading shoe, and (D) a standard shoe.**

**Procedures**

After a baseline assessment, in which data on health history, neuropathy, and foot deformities was collected, patients were tested in one or more footwear conditions in a laboratory setting. Patients were asked to walk at their comfortable speed along a 12 m long walkway. For each footwear condition, several practice trials were used for the patient to familiarize with the procedures and the footwear tested. The walking speed
Interdependency of peak pressure and pressure-time integral was measured using a photocell system and was standardized between walking trials within a footwear condition (maximum variation 10%). In-shoe dynamic plantar pressures were measured at 50 Hz sampling rate using the Pedar-X system (Novel, Munich, Germany). This system comprised a matrix of 99 sensors in 2-mm thick capacitance based flexible insoles which were placed between the foot and the insole of the shoe. Six pairs of wide Pedar insoles were available to accommodate each foot size. All insoles were calibrated following guidelines from the manufacturer. A minimum of 20 midgait steps per foot in multiple walking trials were collected in each footwear condition.

Figure 2. Peak pressure-time curves shown in the left panes and scatter plots of maximum peak pressure (MPP) versus peak pressure-time integral (PTI) shown in the right panes for two foot regions in one subject: the midfoot and metatarsals 2-5. These figures clarify the two different criteria of congruence used for the individual analysis. The midfoot region shows a high correlation coefficient between MPP and PTI ($r > 0.7$). The metatarsals 2-5 region shows a low correlation coefficient ($r < 0.7$), but small coefficients of variation (CV < 10%) for both parameters, indicating a high congruence of peak pressure-time curves from subsequent foot steps.

Data analysis

In-shoe pressure data was analyzed using Novel software. The first and last step of each trial was automatically excluded by the software to eliminate acceleration and deceleration effects. Only the right foot was analyzed. The foot was divided into six anatomical regions using an automated masking procedure: the rearfoot, midfoot, metatarsal 1, metatarsals 2-5, hallux, and lesser toes. For each foot region the maximum peak pressure (MPP) and the peak pressure-time integral (PTI) were calculated. The MPP is the highest measured pressure in any sensor within a region in one foot step. This is the highest value in the peak pressure-time curve of a particular region. The PTI is the time integral of the peak pressure measured in any sensor within the region during one foot
step. This is the area under the peak pressure-time curve of a particular region.

**Statistical analysis**

All statistical analyses were performed using SPSS, version 18.0 and Matlab, version R2010b. Data was analyzed at a patient group level and at an individual patient level. For group level analysis, correlation coefficients were calculated between mean MPP and mean PTI. For normally distributed data, Pearson correlations coefficients were computed. For skewed data, Spearman correlations coefficients were calculated. At the individual patient level, correlation coefficients between MPP and PTI were obtained using the values of each single foot step in a pressure measurement. Higher coefficients reflect more interdependency between parameters. However, low correlation coefficients may incorrectly imply that MPP and PTI are not interdependent (i.e. congruent). This may be the case when the MPP versus PTI scatter plot is concentrated within a small value range, something that is expected from in-shoe pressure measurements in which multiple footsteps are taken by a patient and between-step variability is known to be small (Figure 2). To take this into account, the coefficient of variation (= SD / Mean * 100%) over all footsteps was calculated for both the MPP and PTI. If the coefficient of variation was < 10% in both MPP and PTI, these parameters were considered congruent. If the correlation coefficient between MPP and PTI was > 0.7 the parameters were considered interdependent. These two criteria were named the “criteria of congruence”.

Table 1. Mean ± SD results for MPP and PTI expressed for each of the six foot regions and four footwear conditions.

<table>
<thead>
<tr>
<th></th>
<th>Rearfoot</th>
<th>Midfoot</th>
<th>Metatarsal 1</th>
<th>Metatarsal 2-5</th>
<th>Hallux</th>
<th>Lesser toes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MPP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic footwear</td>
<td>193 ± 44</td>
<td>155 ± 44</td>
<td>243 ± 107</td>
<td>264 ± 85</td>
<td>169 ± 104</td>
<td>178 ± 76</td>
</tr>
<tr>
<td>Cast shoe</td>
<td>168 ± 41</td>
<td>111 ± 45</td>
<td>201 ± 65</td>
<td>162 ± 59</td>
<td>172 ± 92</td>
<td>130 ± 71</td>
</tr>
<tr>
<td>Forefoot offloading shoe</td>
<td>248 ± 68</td>
<td>111 ± 30</td>
<td>152 ± 34</td>
<td>134 ± 38</td>
<td>179 ± 122</td>
<td>131 ± 54</td>
</tr>
<tr>
<td>Standard shoe</td>
<td>275 ± 47</td>
<td>99 ± 40</td>
<td>348 ± 95</td>
<td>300 ± 92</td>
<td>244 ± 112</td>
<td>232 ± 90</td>
</tr>
<tr>
<td><strong>PTI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic footwear</td>
<td>76 ± 22</td>
<td>79 ± 18</td>
<td>79 ± 27</td>
<td>99 ± 28</td>
<td>44 ± 24</td>
<td>55 ± 23</td>
</tr>
<tr>
<td>Cast shoe</td>
<td>40 ± 8</td>
<td>39 ± 18</td>
<td>54 ± 22</td>
<td>46 ± 19</td>
<td>40 ± 23</td>
<td>33 ± 15</td>
</tr>
<tr>
<td>Forefoot offloading shoe</td>
<td>61 ± 16</td>
<td>45 ± 20</td>
<td>52 ± 16</td>
<td>52 ± 20</td>
<td>26 ± 20</td>
<td>32 ± 17</td>
</tr>
<tr>
<td>Standard shoe</td>
<td>66 ± 17</td>
<td>33 ± 20</td>
<td>99 ± 38</td>
<td>92 ± 39</td>
<td>50 ± 29</td>
<td>63 ± 32</td>
</tr>
</tbody>
</table>

MPP, maximum peak pressure; PTI, peak pressure-time integral.

**RESULTS**

Mean outcomes for MPP and PTI at group level are shown in Table 1. The correlation
Interdependency of peak pressure and pressure-time integral

Coefficient between MPP and PTI across all regions and footwear conditions was \( r = 0.78 \) (\( P < 0.01 \)). For each region and condition, significant correlation coefficients were found (Table 2). The highest coefficients were found in the forefoot and midfoot (\( r = 0.64 - 0.93 \)), the lowest in the rearfoot (\( r = 0.43 - 0.45 \)). Between footwear conditions, the variation in correlation coefficients was small.

Table 2. Correlation coefficients between MPP and PTI for each of the six foot regions and four footwear conditions.

<table>
<thead>
<tr>
<th></th>
<th>Rearfoot</th>
<th>Midfoot</th>
<th>Metatarsal 1</th>
<th>Metatarsal 2-5</th>
<th>Hallux</th>
<th>Lesser toes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic footwear</td>
<td>0.44*</td>
<td>0.80**</td>
<td>0.85**</td>
<td>0.92**</td>
<td>0.86**</td>
<td>0.82**</td>
</tr>
<tr>
<td>Cast shoe</td>
<td>0.43*</td>
<td>0.93**</td>
<td>0.82**</td>
<td>0.92**</td>
<td>0.90**</td>
<td>0.92**</td>
</tr>
<tr>
<td>Forefoot offloading shoe</td>
<td>0.45**</td>
<td>0.82**</td>
<td>0.64**</td>
<td>0.80**</td>
<td>0.81**</td>
<td>0.78**</td>
</tr>
<tr>
<td>Standard shoe</td>
<td>0.44**</td>
<td>0.90**</td>
<td>0.78**</td>
<td>0.85**</td>
<td>0.81**</td>
<td>0.92**</td>
</tr>
</tbody>
</table>

MPP, maximum peak pressure; PTI, peak pressure-time integral.
* Significantly correlated at \( P<0.05 \).
** Significantly correlated at \( P<0.01 \).

Table 3. Percentage of patients that reached the criteria of congruence for MPP and PTI expressed in each of the six foot regions and four footwear conditions.

<table>
<thead>
<tr>
<th></th>
<th>Rearfoot</th>
<th>Midfoot</th>
<th>Metatarsal 1</th>
<th>Metatarsal 2-5</th>
<th>Hallux</th>
<th>Lesser toes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criterion 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic footwear</td>
<td>63%</td>
<td>13%</td>
<td>17%</td>
<td>30%</td>
<td>3%</td>
<td>30%</td>
</tr>
<tr>
<td>Cast shoe</td>
<td>29%</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>4%</td>
</tr>
<tr>
<td>Forefoot offloading shoe</td>
<td>37%</td>
<td>32%</td>
<td>16%</td>
<td>42%</td>
<td>3%</td>
<td>8%</td>
</tr>
<tr>
<td>Standard shoe</td>
<td>28%</td>
<td>5%</td>
<td>21%</td>
<td>41%</td>
<td>5%</td>
<td>21%</td>
</tr>
</tbody>
</table>

| **Criterion 2**        |          |         |              |                |        |             |
| Therapeutic footwear   | 20%      | 77%     | 73%          | 47%            | 67%    | 43%         |
| Cast shoe              | 8%       | 71%     | 79%          | 46%            | 75%    | 54%         |
| Forefoot offloading shoe| 21%      | 58%     | 74%          | 29%            | 84%    | 74%         |
| Standard shoe          | 18%      | 62%     | 54%          | 31%            | 67%    | 44%         |

| **Criterion 1 or 2**   |          |         |              |                |        |             |
| Therapeutic footwear   | 83%      | 83%     | 87%          | 70%            | 67%    | 63%         |
| Cast shoe              | 38%      | 75%     | 79%          | 46%            | 75%    | 58%         |
| Forefoot offloading shoe| 55%      | 79%     | 84%          | 66%            | 87%    | 76%         |
| Standard shoe          | 44%      | 67%     | 69%          | 69%            | 69%    | 62%         |

MPP, maximum peak pressure; PTI, peak pressure-time integral.
* Criterion 1: coefficients of variation in both MPP and PTI < 10%.
** Criterion 2: correlation coefficient between MPP and PTI > 0.7.

Results from the individual patient analysis are shown in Table 3. The percentage of
patients fulfilling the ‘criteria of congruence’ ranged from 38% to 87% across regions and conditions. Higher percentages were found in the forefoot and midfoot than in the rearfoot. For the forefoot and midfoot, most patients fulfilled the criteria of congruence based on a calculated correlation coefficient between MPP and PTI of >0.7. For the rearfoot, more patients fulfilled the criteria based on small coefficients of variation (<10%) found in both parameters.

DISCUSSION

The in-shoe pressure results show that the MPP and PTI are highly interdependent in the four different types of footwear tested in these high-risk diabetic patients. Strong interdependency was found, both at the group and individual patient level, in those regions that are most at risk for plantar ulceration (forefoot and midfoot). At group level, correlation coefficients between MPP and PTI ranged from 0.64 to 0.93 across foot regions and conditions (from 0.78 to 0.93 if the metatarsal 1 region in the forefoot offloading shoe was left out). At the individual patient level, parameter congruency varied across the same regions and conditions between 46% and 83% (mean 72%). Between subjects, these data suggest a high degree of similarity in the shape of the peak pressure-time curves, which may differ only in amplitude and time of contact. Within subjects, the results suggest a high reproducibility of the peak pressure-time curves. These findings suggest that the MPP and PTI are interchangeable parameters and therefore do not seem to have a mutual additional value in the same footwear study.

The interdependency of MPP and PTI found in this study is in agreement with findings from recent reports. Our own systematic review of the diabetic foot literature showed that the majority of studies found no or only minimal differences in the pattern and significance of outcomes between reported MPP and PTI data\textsuperscript{11}. Specific conclusions for each parameter were drawn in a minority of papers. A recent study on dynamic barefoot pressures measured in healthy subjects also showed a strong interdependency between measured MPP and PTI ($r = 0.78$; same value as in current study)\textsuperscript{12}. The findings in these previous studies add to the conclusion that the value of reporting one parameter in addition to the other is small.

The lowest correlation coefficients were found in the rearfoot. Also the percentage of subjects showing high parameter congruence was lowest in the rearfoot. Similar findings were reported by Keijzers et al. for measured barefoot pressure in healthy subjects\textsuperscript{12}. Lower correlation coefficients in the rearfoot may be explained by a smaller variability in measured MPP and PTI found between subjects in the rearfoot than in other regions (Table 1). Less scattered data generally leads to lower correlation coefficients. Also, differences in the shape of the normalized peak pressure-time curves may explain these results. Visual inspection of these curves showed more variability in shape for the rearfoot than for the other regions, particularly during mid stance and terminal stance, suggesting that the rollover dynamics of the foot may play a role. Nevertheless, the clinical relevance of finding lower correlation coefficients in the rearfoot is not very high, because pressure related plantar ulcers are rare in this region\textsuperscript{2}. In cases where the measurement of rearfoot pressures is important, calculating both the MPP and PTI may give a more valuable description.
Four different types of footwear were tested in this study to be representative of the range of footwear conditions commonly prescribed to diabetic patients. Two types of custom made and two types of prefabricated shoes were included. Small differences for calculated correlation coefficients and percentages of parameter congruency were found between footwear conditions. This suggests that the interdependency of MPP and PTI is not affected by the type of footwear. Based on these results, we may further speculate that the different design principles incorporated in the tested footwear, such as custom molding, total contact, rocker bottom, and negative heel outsole, do not influence MPP or PTI in such a different way that specific conclusions would be expected. Future pressure studies on the effects of footwear modifications are needed to confirm or refute these hypotheses.

Based on the current and previous findings, it seems difficult to determine in which way the PTI may be mediated differently than the MPP. Some factors such as the size of a masked foot region or the speed of walking may play a role. Within one masked region, more than one anatomical structure (e.g. multiple metatarsal heads) can be loaded. This could affect PTI more than MPP, because only for the calculation of PTI multiple sensors within one mask may contribute. With smaller masks, the interdependency between MPP and PTI has been shown to be stronger\(^2\). Speed of walking affects MPP and PTI differently, in particular at low speeds\(^{14,15}\). With decreased walking speed, the MPP decreases in a linear fashion, whereas the PTI increases in a non-linear fashion\(^{15}\). This is not an issue when walking speed is controlled or standardized between tested conditions. However, it may be important when treatment methods enforce a significant decrease in walking speed, such as with the use of a total contact cast for treating plantar foot ulcers in diabetes. In such cases, different conclusions may be drawn based on the PTI data than on the MPP data. More research is needed to determine how these parameters may be influenced differently and how such a difference should be interpreted.

The MPP has been shown in both retrospective and prospective studies to be predictive of foot ulceration in diabetes\(^{3-6}\). Although the PTI has been suggested by several authors to be associated with diabetic foot ulceration, its clinical value has not been proven in prospective analyses. Therefore, we may consider the PTI as the redundant parameter of the two. More practical reasons for preferring the MPP instead of the PTI is that the MPP is more comprehensible, and it is directly interpretable on-screen during measurement. Therefore, until studies demonstrate that the PTI is similarly or more predictive of ulceration than the MPP, it seems sufficient to report only MPP data in diabetic footwear studies.

A limitation of the study was that the cut-off levels to define a high correlation coefficient or a good congruency between MPP and PTI were arbitrarily chosen. We considered a correlation coefficient above 0.7 as high because ~50% or more of the variance in one parameter would be explained by the other. The cut-off level of 10% to define small coefficients of variations was based on common sense rather than scientific deduction. Such a percentage indicates a concentrated cloud of dots in the MPP versus PTI scatter plot that may illustrate the congruency between parameters. With a different cut-off level chosen, outcomes may have been different, but conclusions likely would have been similar. Another limitation of the study may be that the results are specific
for the calculation method for PTI as defined by the measurement system used in this study (i.e., area under the peak pressure-time curve). Different calculation methods may lead to different results and potentially to different conclusions on the added value of using the PTI. Also as part of a composite parameter, such as in the calculation of daily cumulative tissue stress, the value of PTI may be interpreted differently. Additionally, the shape of the peak pressure-time curve that determines the PTI has been shown to distinguish patients with different levels of foot impairment. Despite the presence of these different calculation methods and uses of the PTI, the way it is used and analyzed in the current study is the most commonly reported and, therefore, the most representative method to include.

CONCLUSION
This foot pressure study showed a high interdependency and congruency between the two most reported pressure parameters, the MPP and the PTI, when measured in neuropathic diabetic patients wearing commonly prescribed diabetic footwear. This interdependency was strongest in the foot regions most prone to pressure-related ulcers and was independent of type of footwear tested. These results suggest that the MPP and PTI are interchangeable and that outcomes on each parameter will likely lead to similar conclusions. Until the moment that prospective studies show that the PTI is a better or equally good predictor of diabetic foot ulceration as the MPP, the value of reporting the PTI in addition to the MPP in the same diabetic footwear study seems small.
REFERENCES


