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Review

The value of reporting pressure–time integral data in addition to peak pressure data in studies on the diabetic foot: A systematic review

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ABSTRACT

Background: In plantar pressure studies on the diabetic foot, pressure–time integral data is often analyzed and reported next to peak pressure data, mostly because of its assumed additional value. The aim was to assess this additional value by systematically reviewing the relevant literature.
Methods: The MEDLINE database was searched for original articles that report both pressure–time integral and peak pressure data measured in the diabetic foot. Eligible articles were assessed according to differences in reported results between both parameters, the quality of discussion and specific conclusions drawn on pressure–time integral data, and the added value of the pressure–time integral data.
Findings: All 35 eligible papers described studies on gait. Differences in reported results between parameters were found to be clear, minimal, or absent in 15, 8, and 12 papers, respectively. In 15 papers, the pressure–time integral results were discussed with respect to the peak pressure results, but in only 5 papers the explanation given for reported differences was considered meaningful. Specific conclusions were drawn in 11 papers. Some added value was found in 10 papers, but in all papers one or more limitations to this value applied.
Interpretation: The study findings suggest that the added value of reporting pressure–time integral data is limited. Unless clear benefit can be shown such, as that ulceration can be better predicted using pressure–time integral than using peak pressure data, the reporting of pressure–time integral data seems redundant to express the plantar loading in the diabetic foot.

1. Introduction

Biomechanical factors play an important role in causing chronic foot problems in patients with diabetes mellitus. Elevated dynamic plantar pressures have since long been associated with the development of foot ulcers in patients who have lost protective sensation due to the presence of peripheral neuropathy (Boulton et al., 1983; Veves et al., 1992). These foot ulcers significantly increase the risk for infection and lower-extremity amputation in this patient group (Boulton et al., 2004).

In particular, increased levels of peak pressure in the diabetic foot have been associated with plantar ulceration, in prospective analyses (Frykberg et al., 1998; Pham et al., 2000). Peak pressure is defined as the highest pressure measured in the foot or foot region during gait. As a result, data on peak pressure is almost always reported in articles about studies on foot pressure in the diabetic foot, whether being measured barefoot or inside a shoe or device.

Data on the pressure–time integral is also commonly reported. The pressure–time integral is mostly defined as the area under the peak pressure time curve, although alternative definitions exist. Elevated levels of pressure–time integral have also been associated with plantar ulceration, but to date only in retrospective studies (Stess et al., 1997). Some even consider the pressure–time integral a more relevant parameter than the peak pressure because it incorporates pressure as well as time factors, which are suggested to be important in ulcer formation (Hsi et al., 2002; Sauseng et al., 1999; Soames, 1985; Stess et al., 1997). Evidence for this hypothesis has, however, not been provided to date.

The added value of reporting the pressure–time integral is widely debated (Keijsers et al., 2010; Melai et al., 2011; Waaijman and Bus, 2012). Studies on the diabetic foot often seem to show few differences between peak pressure and pressure–time integral results. Conclusions specific for the pressure–time integral data in these studies seem rarely reported. Furthermore, it is largely unclear how the pressure–time integral is mediated differently than the peak pressure. And finally, justification for the use of pressure–time integral as parameter seems to be provided only sporadically. This questions the need to report both parameters in the same study. To confirm or refute whether these observations are valid, we reviewed the diabetic foot literature. The aim was to systematically review the available research literature on foot pressure studies in the diabetic foot to determine the value of reporting pressure–time integral data in addition to peak pressure data in the same study.

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2. Methods

The MEDLINE database was searched for original research reports of studies on the diabetic foot that report both peak pressure and pressure–time integral data. The search strategy included search terms in the categories diabetes, foot, pressure, and pressure–time integral.

The search string entered in the database was:

((“Diabetes mellitus”[Mesh]) OR (diabetes) OR (diabetic)) AND ((“Foot”[Mesh]) OR (foot) OR (feet)) AND ((“Pressure”[Mesh]) OR (pressure*) OR (load*) OR (pedobarography) OR (“Transducers, Pressure”[MeSH]) OR (“Stress, Mechanical”[Mesh]) OR (Stress*)) AND ((pressure–time) OR (“pressure time”) OR (time–pressure) OR (“time pressure”) OR (pti*) OR (integral*) OR (“pressure load*”) OR (stress-time) OR (“stress time”) OR (stress/time)).

The search was performed on the 1st of October 2011. Studies on healthy subjects or patients with diseases other than diabetes were not considered. Only references in the English language were considered. Tracking of references in included articles was not performed. Both studies on barefoot pressure and in-shoe pressure analysis were included.

Two reviewers independently assessed references by title and abstract to include only those articles on the diabetic foot that reported both peak pressure and pressure–time integral data. Assessment outcomes were discussed between reviewers and a final decision regarding eligibility was made. Full-paper copies of eligible articles were retrieved. These articles were assessed independently by both reviewers. Data on type and number of patients tested, primary assessment in the study (e.g. comparison between subject groups or between footwear conditions), type of pressure measurement (barefoot or in-shoe), and pressure measurement system and specifications were extracted.

Each article was subsequently assessed based on five items (Table 1). Extracted data and outcomes on these five items were summarized in a table. Differences between reported data on peak pressure and pressure–time integral (item 1) were evaluated based on a) the number of significant differences found in the study for each parameter, b) the significance levels of differences found, and c) the pattern of results. Item a) and b) may be different between parameters when multiple subject groups, footwear conditions, or foot regions are compared. For example, forefoot peak pressure may be significantly different between patients with a previous foot ulcer and those without, while the pressure–time integral is not. Differences in the pattern of results between parameters may be present in the distribution of results across different foot regions or footwear conditions. For example, measured peak pressure in a group of subjects may be highest in the medial forefoot, while the pressure–time integral is highest in the lateral forefoot. Outcomes on the first item were scored as “no”, meaning that differences between parameters were neither present in significance nor in pattern; “minimal”, meaning that differences were present in either significance or pattern; and “clear”, meaning that differences were present in both significance and pattern.

Items two to five were scored in a binary fashion (“yes” or “no”) and were considered important to show the value and meaning of reporting the pressure–time integral. These items included whether or not the pressure–time integral results were discussed by the authors (item 2, 3a), a meaningful explanation of the (lack of) differences found between results on both parameters was given (item 3b), and specific conclusions on pressure–time integral data were drawn by the authors, or could be drawn by the reviewers (item 4). An explanation was considered meaningful (item 3b) when authors further interpreted underlying data, used quantitative data from other studies, or provided a clear theoretical framework to explain the (lack of) differences found between pressure parameters. The added value of reported pressure–time integral data (item 5) was generally based on scores on items 1 to 4. If all these items were scored with “clear” or “yes”, this generally resulted in a “yes” for added value in most other cases in a “no”.

Independently obtained outcomes for each reviewed article were discussed between both reviewers and a final decision on outcome was made. Descriptive statistics were used to analyze the data.

Table 1
Scoring items used in the assessment of each eligible article.

Item no.		Description
1		Were differences found between reported data on peak pressure and pressure–time integral?
2		Were the results on pressure–time integral discussed in the discussion section of the article?
3	a	Were the results on pressure–time integral discussed and explained in comparison to the results on peak pressure?
	b	If so, was the explanation for (the lack of) differences found meaningful?
4	a	Were specific conclusions drawn by the authors based on the pressure–time integral results?
	b	Could specific conclusions be drawn by the reviewer based on the pressure–time integral results?
5		Did the reporting of pressure–time integral data have added value to the reporting of peak pressure data?

3. Results

A total of 58 references were identified in the MEDLINE database search. After assessing for title and abstract, 35 original articles were found eligible for full paper review. All articles described studies in which plantar pressure was measured during gait. Study characteristics are summarized in Table 2. The majority of papers reported on in-shoe pressure studies (n = 20) and on the comparison between different subject groups (n = 16). The most commonly used pressure measurement systems were the emed and pedar from Novel (Munich, Germany) (n = 23).

Table 2 shows per article reviewed the scores on the five items. Fifteen studies showed clear differences between reported data on peak pressure and pressure–time integral, 8 found minimal differences, and 12 found no differences. In 28 articles, the pressure–time integral results were discussed. In 15 papers, these results were discussed in comparison with the peak pressure results. Five of these 15 papers provided meaningful explanations for the differences found between pressure–time integral and peak pressure results.

Specific conclusions on reported pressure–time integral data were drawn by the authors in 11 articles. The reviewers drew specific conclusions in 14 articles. In 10 articles, the pressure–time integral data was considered to have some value in addition to the peak pressure data, but for all, one or more limitations to this added value applied.

4. Discussion

The majority of papers (57%) reported minimal or no differences between peak pressure and pressure–time integral results. Thus, significant results and patterns in the peak pressure data were mostly mimicked in the pressure–time integral data. Only 15 of 35 papers discussed the pressure–time integral results in comparison to the peak pressure results, and in only 5 of these 15 papers the explanation given for (the lack of) differences in results between both parameters was considered meaningful by the reviewers. This outcome does not sufficiently improve our understanding of the use of the pressure–time integral as a pressure parameter. Specific conclusions and added value based on pressure–time integral data were found in a minority of papers (~30%), and in all papers limitations to this added value were identified. These outcomes generally do not support the reporting of both pressure parameters in the same diabetic foot study.

Limitations to the added value of pressure-time integral data were as follows. First, the added value accounted only for the heel region