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Reliability and validity of in-shoe plantar pressure data in diabetic patients: recommendations for use in clinical practice and research

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Background and aims: In-shoe plantar pressure assessment is used more and more to evaluate the effects of therapeutic footwear in diabetic patients. Usually, patients are tested over several walking trials to gain a large number of representative midgait steps from which average pressure pictures are calculated and used for interpretation. However, guidelines on the required number of steps for this purpose are lacking. Too few steps may affect data quality, too much steps may unnecessarily increase patient burden or time spent for data collection and analysis, in particular if multiple measurement sessions are used. Therefore, the aim of this study was to determine the number of steps required for reliable and valid in-shoe pressure data in diabetic patients. **Patients and methods:** Eighteen neuropathic diabetic patients underwent in-shoe plantar pressure assessment (Novel Pedar-X) while wearing therapeutic footwear. Peak pressure, pressure-time integral, contact time, and force-time integral were calculated for each of 6 anatomical foot regions with a minimum of 20 steps per foot. Statistical methods were applied for an incremental number of steps starting with two steps. Intraclass Correlation Coefficients (ICC) were calculated to assess step-to-step reliability. Validity was calculated as a ratio between Limits of Agreement (based on the 95% confidence intervals) and the mean values for 20 steps (=reference protocol) and expressed as Coefficients of Variation (CoV), which were considered acceptable when <10% in all regions. **Results and discussion:** For all parameters and foot regions, only 3 steps per foot were required to obtain excellent reliability (ICC > 0.90). This may be due to the large inter-subject variability present in the results which increases ICC. The CoVs calculated per subject reached levels <10% for all foot regions at 12 steps per foot. This is more than the 8 steps found in healthy subjects, which may be explained by the larger gait variability present in neuropathic patients. Fewer steps were required for the rearfoot than forefoot, which demonstrates the consistency in the loading response at heel strike during gait. **Conclusions:** We recommended to collect 12 midgait steps per foot to obtain reliable and representative in-shoe plantar pressure data in neuropathic diabetic patients wearing therapeutic footwear. These results provide directions in the use of in-shoe plantar pressure analysis for clinical practice and research purposes.

¹Kernozek, TW et al, Foot Ankle Int. 17:204-9, 1996.