

COMMENTARY

Performance of plantar pressure measurement devices (PMDs): update on consensus activities

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Summary. A worldwide scientific discussion has been started in 2010 on the need for standardisation, assessment, and delivery of recommendations in the field of plantar pressure distribution measurement at different levels: hardware performance, measuring protocols, data processing, parameters and indicators in diagnosis and therapy. The Italian National Institute of Health (Istituto Superiore di Sanità, ISS) has been conducting for years a scientific project and several activities aimed to design, validate and implement dedicated testing methods and recommendations in the field of pressure measurement devices (PMDs). The present commentary contains a summary of the activities conducted up to now and some future steps which are going to be done at an international level.

Key words: baropodometry, pressure measurement devices, technical assessment, pedography.

The Italian National Institute of Health (Istituto Superiore di Sanità, ISS, Rome, Italy), Department of Technology and Health, has been involved for more than twenty years in the development, assessment and application of instrumentation and methodologies for plantar pressure measurements. On May 10, 2010, ISS organized and hosted the workshop “Assessment of pressure measurement devices (PMDs) for their appropriate use in biomechanical research and in the clinical practice”. A first document was presented at the workshop dealing with methodological issues and some important recommendations to manufacturers and end users of PMDs with special focus on the assessment of PMD hardware performance [1]. On the basis of the general positive feedback from participants to the workshop, a document for a consensus proposal on recommendations and minimum requirements for assessment and appropriateness of PMD hardware

performance has been prepared and submitted to the ESM2010 Scientific Committee¹; the Committee invited ISS to illustrate and discuss the document during a dedicated podium session of the meeting. At the end of the discussion an overall agreement was expressed by the audience on the “need for standardisation in the field of pressure distribution measurement at different levels: hardware performance, measuring protocols, data processing, parameters and indicators in diagnosis and therapy”. Soon after the ESM meeting, ISS activated a moodle-based interactive Forum on PMD hardware performance² where a specific section was dedicated to the ESM consensus proposal: ESM participants who agreed to be registered could find the above material and the proper form to give their suggestions, feedback and their eventual formal agreement to be officially part of the document “Preliminary proposal for consensus”. The activity was closed at the beginning

¹ESM is the acronym for Emed Scientific Meeting, being Emed the capacitive PMD provided by the Company novel gmbh (Munich, Germany; www.novel.de). ESM is a scientific event focussed on foot loading and biomechanics, which takes place every two years, sponsored by the above Company and hosted by important research and clinical centers all over the world. The 2010 ESM was held in Providence (Rhode Island, USA) August 14-17 2010, hosted by the Brown University, The Center for Restorative and Regenerative Medicine, in cooperation with the University of Rhode Island.

²ISS is hosting the moodle-based interactive web page “ISS-PMDs”, which is the ISS forum on hardware performance of plantar pressure measurement devices (PMDs). The page can be found at <http://vcms.iss.it/moodle19>. A free registration is needed to navigate the page, which can be requested by sending an e-mail message with name and affiliation to claudia.giacomozzi@iss.it.

of September, and the proposed document is now available in a draft version in section 3 of the above web Forum ("ESM2010 consensus_v0_confidential.pdf" [2]).

Those who signed the document generally agreed with the methodologies and recommendations proposed by ISS [1]. Main suggestions for changes and integrations are briefly summarised below:

- PMD use and medical device regulation.

PMDs are widely diffuse: *i)* in biomechanical research context, where they are mainly used to acquire kinetic parameters of foot-floor interaction during gait, running and standing, even though few experimental studies are currently conducted to use PMD outputs as input for FEMs and in general for biomechanical models; *ii)* in clinical context, as a support to diagnosis, early detection of pathologies, and monitoring during treatment of orthopaedic diseases as well as degenerative or metabolic or systemic diseases *i.e.* diabetes and rheumatoid arthritis; *iii)* as a key instrument for prescription, design and construction of plantar orthoses, in some cases directly linked to CAD/CAM systems. On the basis of the above intended use, *PMD is recognised as a medical device with measuring function.* Anyway, neither standard procedures nor guidelines have been onset up to now at an international level to assess PMD technical performance, both at the time of their placing on the market and periodically during their lifetime. A suggestion was done that PMDs for specific research goals might be treated differently – from a regulatory point of view – from PMDs addressed to clinical use; in any case, all PMDs should be fully and clearly characterised in terms of their technical specifications.

- Terminology. While pressure measurements are increasingly diffuse in research and in the clinics, great confusion is still present in the used terminology. The confusion is evident even in the definition of the discipline itself: terms like baropodometry, pedobarometry, pedobarography, pedography are currently used. There is a proposal for the adoption of the term pedography, even though a general agreement has not been reached yet. A preliminary discussion and a list of terms which need clarification are reported in [2].

- Standardization and comparability. Pressure measurements should be comparable throughout the world-wide scientific scenario. It is

thus mandatory to reach agreement and consensus on the procedures and criteria to standardise: *i)* the way to assess PMD technical performance and the minimum requirements they have to comply with in order to guarantee the appropriate performance along their whole life time; *ii)* the measuring setup and protocols; *iii)* the data processing, the relevant measured parameters, the algorithms and the way to estimate derived quantities and indicators, the minimum level of significance of parameter changes.

- Co-operation. ISS started the activity to address the keypoint related to PMD technical assessment and performance. Within this specific activity, there is the need for consensus and agreement on common recommendations for tools and procedures for technical assessment of PMDs which should be suitable for application to all commercial PMDs and to prototypes. There is also the need for concerted actions of the scientific communities and PMD manufacturers.

Besides that, there was a suggestion for an overall text editing before a further distribution. Following this precious suggestion, the document is currently under the text editing process and a final version will be soon uploaded on the same web page.

Few further steps have then been done towards a more general consensus activity, briefly:

- a Pedography Group named i-FAB-PG³ has been created and launched at the 2010 meeting of the International Foot and Ankle Biomechanics Community (i-FAB meeting, Seattle, US) under the leadership of T. Pataky, N. Keijsers, C. Giacomozzi, D. Rosenbaum. ISS actively supported the setup of a web, moodle-based Forum for the i-FAB within which a specific Forum is dedicated to the PG consensus activities grouped into three main sections: Technical Assessment, Data Analysis and Applications. The first target of the PG consensus activities will be the presentation of a first approved document at the 2011 ISB meeting (Bruxelles, July 2011);

- at a national level, a collaboration has been started with the technical group of the Italian Society of Movement Analysis in Clinics (SIAMOC) which is addressed towards a "Consensus Conference on Methodologies and Protocols in the field of Gait Analysis"; within this group, ISS will actively participate to the consensus activities in the field of baropodometry, also coordinating the Italian actions with the international i-FAB activities;

- contacts have been established with the UK

³i-FAB is the acronym for the International Foot and Ankle Biomechanics Community, which was officially presented at the 2007 meeting of the International Society of Biomechanics. Relevant information can be found at <http://www.i-fab.org/>.

scientific community which is forming a user group meeting and which is organizing a dedicated meeting on “Clinical applications of foot pressure measurement” (Sheffield, UK, February 3rd, 2011) under the initiative of C. Davenport. ISS will participate to the meeting presenting the past and current consensus activities and looking for a coordinate action with the UK group too.

To conclude, ISS is strongly involved in the above consensus activity. With specific reference to the PMD hardware performance, its moodle page will continue to be a useful working and meeting place for researchers and companies who are deeply interested in PMD technical assessment issues. Meanwhile, a second call for PMD technical assessment has been sent out to Companies, which are positively answering. The web page will keep updated reports on this relevant activity too.

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References

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Conflict of interest statement

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