ABSTRACT

BACKGROUND: Since 2006, the Italian National Institute of Health (ISS) has been conducting independent scientific activities to standardize the technical assessment of plantar pressure measurement devices (PMDs).

MATERIAL AND METHODS: On the basis of the ISS results, in 2010 the Pedobarographic Group of the International Foot and Ankle Biomechanics community (i-FAB-PG) promoted a consensus activity about the main technical requirements for the appropriate use of PMDs. The activity relied on a moodle-based online forum, documents exchange, discussions, reviews, meetings and a final survey.

RESULTS: The participation of clinical and technical researchers, users, and manufacturers, contributed to the delivery of the hereby reported recommendations which specifically regard Medical PMDs in the form of platforms.

CONCLUSIONS: The i-FAB-PG community reached overall agreement on the recommendations, with a few minor objections which are reported and commented in the document.

RELEVANCE: The present document, the highest result achievable within a small scientific community, will hopefully represent the starting point of the wider process of establishing official international guidelines or standards, within scientific communities and standardization organizations.

Key words: baropodometry, pressure measurement devices, technical assessment, accuracy, COP estimation.

RIASSUNTO

BACKGROUND: A partire dal 2006, l’Istituto Superiore di Sanità (ISS) ha condotto attività scientifiche indipendenti mirate alla standardizzazione della valutazione tecnica di dispositivi per la misura della pressione plantare (PMDs).

MATERIALI E METODI: A partire dai risultati dell’ISS, nel 2010 il Gruppo Pedobarografico della International Foot and Ankle Biomechanics community (i-FAB-PG) ha lanciato un’attività di consenso relativa ai requisiti tecnici essenziali per un uso appropriato dei PMD. L’attività si è basata su un forum su piattaforma moodle; scambio, discussione e revisione di documenti; incontri finalizzati; verifica finale di accordo.

RISULTATI: La partecipazione di ricercatori, utilizzatori clinici e tecnici, e produttori, ha contribuito alla definizione delle raccomandazioni qui di seguito riportate, che si riferiscono nello specifico a PMD utilizzati in ambito clinico, in forma di piattaforme.

CONCLUSIONI: La comunità i-FAB-PG ha raggiunto un accordo generale sul documento, con solo qualche residua minore obiezione, riportata e commentata nel documento.

RILEvanza: È auspicabile che il documento, che costituisce il massimo risultato raggiungibile all’interno di una piccola comunità scientifica, possa rappresentare il punto di partenza di un più ampio processo per la definizione di linee guida ufficiali e di standard, nell’ambito di società scientifiche e di enti normatori.

Parole chiave: baropodometria, dispositivi di misura di pressione, valutazione tecnica, accuratezza, stima centro di pressione (COP).
INTRODUCTION

Plantar pressure measurement devices (PMDs) are widespread:

- in the biomechanical research, 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 finite element models (FEMs) or in general for biomechanical models;

- in the clinical context, as a support to diagnosis, early detection of pathologies, and monitoring during the treatment of not only orthopaedic diseases, but also degenerative, metabolic and systemic diseases, i.e., diabetes and rheumatoid arthritis;

- as a key instrument for the prescription, design and construction of plantar orthoses, in some cases directly linked to CAD/cAM systems (CAD: computer-aided design; cAM: computer-aided manufacturing), and for the assessment of their efficacy.

Whenever a PMD is used for analysing a patient, it should be referred to as "Medical PMD".

Besides the increasing use of PMDs and the increasing number of peer-reviewed, scientific publications discussing PMDs, the lack of standardisation is clearly evident in terms of both instrumentation and methodologies, which renders any comparison and data sharing very difficult and of uncertain validity. The major difficulties to cope with when discussing about PMD technical performance are related to significant differences in sensor technology, matrix spatial resolution, pressure range, sampling rate, calibration procedures, raw data pre-processing. In addition, critical practical issues interfere with the appropriate use of PMDs, i.e. problems associated with patient behaviour, experimental protocol and data post-processing [1].

At least three fundamental steps have to be followed towards standardisation in the use of PMDs:

1. definition and standardisation of tools and protocols for the technical assessment of PMD hardware performance;
2. definition and standardisation of pressure acquisition protocols;
3. definition and standardisation of data processing and reporting.

The present document only deals with the first step. More specifically, it constitutes the final output of a dedicated consensus Activity ("Agreement on PMD hardware performance"), which has been conducted by the Pedobarographic Group (i-FAB-PG) of the International Foot and Ankle Biomechanics community (moodle.i-fab.org). Before the community reaches full agreement, just a few minor questions remain to be discussed, mostly related to specific aspects raised by some manufacturers. These aspects are fully reported and commented in the document.

All the statements, recommendations, technical and methodological suggestions hereby reported are the result of: i) preliminary activities at the ISS regarding this specific issue [2, 3]; ii) online activities within the i-FAB-PG moodle-based forum; iii) background/working material found in the literature [2-18]; iv) document revision, and final on-line survey.

The content of this final i-FAB-PG Consensus Document addresses PMDs, in the form of PLATFORMS intended to be used as Medical PMD for barefoot walking analysis and, optionally, for stabilometric analysis. It may also be applied to different sensor arrangements - e.g., wearable or flexible equipment - to perform a partial assessment with the sensor horizontally placed on a plane. In any case, further specification and agreement is needed for sensor performance assessment under flexed conditions.

The i-FAB-PG Consensus Document should be seen in terms of pure scientific consensus, obtained through the joint effort of researchers and manufacturers. The manufacturers and users who will agree to follow the recommendations contained in the document will do so on a purely voluntary basis, without any regulatory constraint. In fact, even though the recommendations are in agreement with the requirements of EU Directives for Medical Devices, - i.e. they aim at preserving the safety of users and the achievement of the intended use - in no case do they constitute an instrument by which to claim compliance, or demonstrate lack of compliance, with the EU Regulations.

Finally, the present i-FAB-PG Consensus Document, which represents the highest result achievable within the above scientific community, aims to be a starting point for the onset of the complex process of defining official international guidelines and standards, which are expected by wider scientific societies and international standardization organizations.

MATERIALS AND METHODS

Sequence of actions towards consensus

Since 2006, the Department of Technology and Health of ISS, the Italian National Institute of Health, has been conducting a scientific project and several related activities aimed to design, validate and implement dedicated testing methods and recommendations for PMD technical assessment [2, 4].

In 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" [5]. A first proposal document was presented at the workshop, dealing with methodological issues and some
Some specific on-line activities were activated for limited time periods, which are briefly summarised here below:

- From January 28th - February 11th 2011. A daily open online discussion was "tutored" on the Consensus Document Draft0: it was a constructive phase of the consensus process, even though there was not a true daily on-line discussion among participants for most of them preferred an off-line way of contributing.

- From March 1st - June 9th 2011. The revised Draft1 of the Consensus Document was uploaded and open for comments through the page. As no relevant comments were posted, the Final Document was written with only few minor editorial changes.

- June 10th - July 5th 2011. The Final complete Consensus Document was uploaded and remained available for comments until its discussion during the i-FAB-PG general meeting in Brussels (July 5th, 2011), open to all ISB participants;

- From July 6th - July 31st 2011. The Final Survey was launched and kept open to ask for a Final Agreement on the Final Consensus Document; quick questions were delivered to ask whether participants had any residual objection regarding each Table in particular or the entire Document as a whole.

For the general revision procedure, the concept was followed of taking into account each general comment providing a good explanation, contributed at any stage of the revision process, and with a general applicability to Medical PMDs. Each revision was shared and agreed by the PG leaders - i.e. the authors of the present Document - before dissemination. More in detail:

- From Draft0 to Draft1. Seventeen users actively navigated the page during the period; 5 researchers and 3 manufacturers sent back their comments; some other researchers and manufacturers sent their informal comments through private email to activity leaders. None of the points suggested in Draft0 was rebutted; few points were raised for clarification, and proper explanations were added at the beginning or in the core of Draft1; other points were added as suggested by participants. comments were not added to the document when they were too specific or regarded the performance of specific commercial products. In any case, individual answers were sent to each participant if specifically requested;

- From Draft1 to the Final Document. No comments were posted on the i-FAB-PG Forum; another positive answer was received through the ISS PMD Forum from another manufacturer who requested no changes at all. Only minor editorial changes were shared among the PG leaders, and implemented in the Revised version, which was presented at the i-FAB-PG meeting on July 5th 2011 and uploaded to the Forum for the Final Survey;

- From Final Document to i-FAB-PG Consensus Document on PMD Technical Assessment - i.e. the present Document -. Ten comments were received in all, with 3 containing suggestions for further specifications rather than changes. As for the remaining comments, they mainly regarded commercial experiences from Manufacturers: a short explanation accounts for them in the consensus Tables. Whenever high-level specifications led to disagreement/discussions deserving further investigation, a more general level was maintained for this final Consensus Document with respect to the working documents, whose validity had been implicitly
RESULTS

The i-FAB-PG consensus document

The outcomes of the described consensus activity have been collected in eight tables. Briefly: Table 1 resumes the basic principles over which agreement has been reached, and which represent the basis for the PMD technical assessment approach; Table 2 describes the parameters which should be included in the minimum set of parameters to be assessed in factory; Table 3 reports the technical requirements a proper test system should have to deliver the parameters listed in Table 2; Table 4 deals with a suggestion for implementing in factory testing protocols; Table 5 gives some recommendations in terms of minimum requirements for Medical PMDs addressed to barefoot gait analysis; Table 6 contains a proposal for the Manufacturer's technical report to be associated with the commercial PMD; Table 7 deals with on-site, periodical assessment of PMDs; Table 8 contains a sort of checklist for Authors, Reviewers and Editors to properly judge the consistency of data scientific papers rely on. In each Table comments and explanations are reported when a full agreement had not been reached with respect to the specific point.

DISCUSSION AND CONCLUSIONS

The i-FAB-PG Consensus Document hereby reported is the first attempt of a Scientific community at having users and manufacturers work together for the definition of recommendations to standardise the assessment of PMD hardware performance. Notwithstanding the effort and the time devoted to discussing and finding agreement on several issues, and the valuable results obtained up to now, the Document should still be reckoned as a merely scientific initiative of only a part of the entire world scientific community involved in PMD research and applications.

At a more general level, at least another three project lines should stem from this first experience, namely:

- the preparation of official guidelines as a result of a worldwide consensus activity. ISS is deeply involved in the formulation of official guidelines at national level in the field of Public Health, and is thus ready to start and lead such an initiative at the International level. The process should be based on an active collaboration with the dedicated scientific societies all over the world; the activities ISS is conducting within the Italian Society of Movement Analysis in clinics (SIAMOC) already represents a first step in this direction. Equally important in this sense are all the dissemination activities aimed at sharing a deeper knowledge of PMDs technology, potentialities and criticalities with users at different levels and in different scenarios;

- the definition of a clearer regulatory scenario: an issue of particular relevance in clinical environments, where PMDs are to be intended as Medical Devices. ISS has already started a regulatory activity in this direction within the Italian Institutes for Standards, for the submission of a PMD-specific Standard; hopefully, this activity will be eventually taken to the European level;

- continuous research and technology development to design and validate innovative and valuable methods and instruments for PMD testing, both on the bench and in the field;

After this Consensus Document, i-FAB-PG will hopefully continue the discussion and investigation of the other issues relevant to the appropriate use of PMDs: those strictly related to measurement protocols, and data extraction and interpretation.

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Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study. Manufacturers’ indications and suggestions have been taken into account only when based on a strong scientific rationale, and having general applicability.

References

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3. Pressure measurement devices (PMDs): Technical and performance issues. In 2010 great attention was paid to the technical aspects of plantar pressure measurement. Awareness is growing in the scientific environment about the key point: in order to render pressure measurements appropriate, comparable, meaningful and effective, the process towards standardisation has to start with the assessment of the technical performance of the pressure measurement devices (PMDs) through which pressure is quantified. Technical assessment of PMD performance is desired, and worldwide claimed to verify appropriateness, reliability and comparability of pressure measurements. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is an initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration. The mission of the ICH is to promote public health by achieving greater harmonisation through the development of technical Guidelines and requirements for pharmaceutical product registration. Performance evaluation: Review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations. Regulatory Authority (RA): A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (Source – EU-Canada MRA). In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.