ISTITUTO SUPERIORE DI SANITÀ

Conference

Assessment of pressure measurement devices (PMDs) for their appropriate use in biomechanical research and in the clinical practice

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ABSTRACT BOOK

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Within the ISS research project "Technology assessment of plantar pressure measurement devices (PMDs)" implementation and validation have been conducted of methodology, instrumentation and procedures for the assessment of PMDs main measurement features. The Conference main objectives are: a) to share the main results of the study, especially in terms of technical assessment methodology and experimental setup; b) to formulate and share recommendations for the appropriate use of PMDs; c) to stimulate both the biomechanics research and the clinical environments (Orthopaedics, Diabetology, Medical Podiatry, etc) toward the need for the systematic, on-site technical assessment of PMDs; d) to stimulate PMD manufacturers towards issues like the appropriate calibration of the devices before placing them on the market, and the proper monitoring and maintenance of PMDs; e) to stimulate Notified Bodies - which are responsible for medical device certification and market surveillance - to the correct classification of PMDs on the basis of their intended use.
Keywords: Baropodometry, Appropriateness, Gait analysis, Technical assessment

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Conferenza. Assessment di dispositivi di misura di pressione plantare (PMDs) per un uso appropriato nella ricerca biomeccanica e nella pratica clinica. Istituto Superiore di Sanità. Roma, 10 maggio 2010. Riassunti.
A cura di Claudia Giacomozzi
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Nell'ambito della linea di ricerca ISS "Technology assessment di strumentazione per baropodometria" sono stati messi a punto e validati metodologie, strumentazione e protocolli per la valutazione delle principali caratteristiche metrologiche di dispositivi per baropodometria. Il convegno si prefigge di: a) condividere i principali risultati ottenuti nello studio, soprattutto in termini di metodologia di assessment tecnico e di relativa strumentazione; b) formulare e condividere raccomandazioni per assicurare l'appropriatezza d'uso dei dispositivi; c) stimolare l'attenzione dell'ambiente di ricerca biomeccanica e dei contesti clinici di maggior utilizzo (ortopedia, diabetologia, podologia medica, ecc.) alla necessità di verifica periodica delle caratteristiche metrologiche dei dispositivi; d) sensibilizzare i produttori relativamente agli aspetti di calibrazione appropriata dei dispositivi prima dell'immissione sul mercato, e di monitoraggio e manutenzione periodica dei dispositivi stessi; e) sensibilizzare gli Enti Competenti in materia di certificazione e vigilanza sul mercato di dispositivi medici, ai fini della corretta classificazione dei dispositivi in base al loro utilizzo.
Parole chiave: Baropodometria, Appropriatezza, Analisi del cammino, Assessment tecnico

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Session I

The technical assessment of PMDs

Chairperson:
Aurelio Cappozzo

TECHNICAL ASSESSMENT OF PMDs: STATE OF THE ART, MOTIVATION, OBJECTIVES

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Contrary to kinematic or force measurements, which gait analysis strongly relies on, plantar pressure measurement is hardly considered a meaningful diagnostic tool in clinics; even less consideration is deserved in consolidated research environments to pressure measurement devices (PMDs), although their potential is highly recognized in the specific scientific literature. Reasons for such poor success may be found in a certain lack of accuracy and appropriateness of the existing PMDs. Differences in sensor technology, matrix spatial resolution, pressure range, sampling rate, calibration procedures, raw data post-processing, ageing, lead to significant differences in PMD overall accuracy. Clear examples of these concepts are found in the recent literature. In fact: i) often, not even interesting papers report the acquired absolute pressure values: this point is especially critical, since which is the validity and reliability of the derived or estimated variables the scientific dissertations are based on? ii) significant discrepancies are found among those which report absolute values, even when dealing with same pathology, comparable population samples and comparable experimental setup. As an example, mean peak pressures for toddlers acquired during a period of 5 months after the onset of independent walking, range from 60 to 130 kPa according to different investigations associated with different PMDs. In the field of Diabetes, where very high peak pressures are often developed by Diabetic Neuropathic patients at risk of foot ulceration, variability is even greater, thus preventing from the establishment of reliable risk thresholds, reference databases, evidence for effectiveness of prevention treatment or interventions.

PMDs are also widely diffused in the design and construction of plantar orthoses, and are increasingly used in the field of posturology. Even in these fields the assessment of PMD measurement features is extremely critical, even more critical since for this specific use PMDs fall under the International Regulations for Medical Devices.

From a more technical point of view, very few studies have been published up to now specifically addressing PMD calibration and technical assessment issues; finally, no studies have been found in the Medline database that deal with the technical assessment or comparison of different PMDs.

To overcome this need, in 2006 the Italian National Institute of Health (ISS) approved and conducted a scientific project aimed to design, validate and implement dedicated testing methods for both in-factory and on-the-field PMD assessment. A general-purpose experimental set-up was built, complete and suitable for the assessment of PMDs based on different sensor technology, electronic conditioning and mechanical solutions. Preliminary assessments have been conducted on 5 commercial PMDs.

The study lead to the definition of: i) an appropriate set of instruments and procedures for PMD technical assessment; ii) a minimum set of significant parameters for the technical characterization of the PMD performance; iii) some recommendations to both manufacturers and end users for an appropriate use in clinics and in research context.

PMDs AS MEDICAL DEVICES: CLASSIFICATION AND CERTIFICATION ISSUES

Mauro Grigioni, Claudia Giacomozzi
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Several controversies raised about certification of PMDs. Basically, the key point for the correct identification of a device and of its certification process is the *intended use* of the device itself as it is stated by the manufacturer. The information summarized here below should help manufacturers and users to better understand the main purpose and application of the PMD they are going to deliver or use.

Definition of medical device. Within EU, Directive 2007/47/ec defines a medical device as "any instrument, apparatus, appliance, software, material or other product, whether used alone or in combination (including accessories and software intended by the manufacturer for diagnostic and/or therapeutic purposes and necessary for proper functioning), intended by the manufacturer to be used in humans for: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, mitigation or compensation for an injury or handicap; investigation, replacement or modification of anatomy or of a physiological process; control of conception; the device has not to apply the principal intended action by using pharmacological or immunological means or through metabolic processes, but its function may be assisted by such means". Similar definition is given by the U.S. Food and Drug Administration (FDA), and by the Canadian Food and Drugs Act.

Certification. In EU, all medical devices must be identified with the CE mark. CE mark is also required by: EU Candidate Member States; Norway, Iceland and Liechtenstein; Switzerland. In US, medical devices can enter the market only after FDA controls and approval. The same is for Canada and Japan. Often, medical devices which already has the CE mark are facilitated in their certification process within non-EU countries. The complexity of the certification process depends on the classification of the medical device.

Classification. It is the sole responsibility of the manufacturer to classify his devices as per european regulation. Clinical evidence of a manufacturer's classification must be provided. Any medical device classification made by a manufacturer can be contested by a European Notified Body. Medical devices that are not classified or are determined to be improperly classified are forbidden to entry or removed from the European Market. Classes are established in accordance with the potential risk to the patient. Basically: *high risk* devices are life supports, critical monitoring, energy emitting and other devices whose failure or misuse is reasonably likely to seriously injure patient or staff; *medium risk* devices include many diagnostic instruments whose misuse, failure or absence with no replacement available would have a significant impact on patient care, but would not be likely to cause direct serious injury; *low risk* devices are those whose failure or misuse is unlikely to result in serious consequences. Regarding PMDs, their appropriate classification is especially relevant when a diagnosis is used to define a subsequent treatment. PMDs currently on the market seem to be not uniformly classified. Examples of classification rules and application will be given to highlight the specificity of this medical device.

PRESSURE SENSOR TECHNOLOGY

Antonello Fadda
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Pressure sensors are based on a variety of technologies but, as plantar pressure measurement is considered, the choice is reduced to only two fundamental types: resistive and capacitive. Resistive sensors may exist in different types, but all share a common feature: an electrical current flow is modulated by the pressure exerted on the sensor surface. Usually the physical mechanism involved is that of contact resistance, as in devices commercially known as FSR (Force Sensing Resistor). Due to small-scale deformations of the contact surfaces effective contact area increase, causing an increase of electrical conductivity, that is roughly linear in a given range of pressure. Border effects are an important issue and geometry of sensor is used by designers to gain control over sensor characteristics, besides the initial choice of materials. A different type of resistive sensor is based on a volume effect, as opposed to the surface effect of the former one. Here conductive particles are dispersed in a polymeric matrix and the elastic deformation of the material results in an increase of volume conductibility. The "resistance" of resistive sensors is actually a non linear V-I relationship and only small voltages must be used to stay in a linear region. It is possible to realize large resistive arrays driven by a relatively simple electronics, as resistance variations are simply detected by routing small direct voltages to the sensors. The typical low impedance of the sensor also makes it easy to obtain a good noise immunity of measurements.

Conventional capacitive sensors are based on the variation of thickness of an elastic material forming the dielectric layer of a small plane capacitor. As capacitance depends on the inverse of thickness an increase of pressure produce a proportional increase of capacitance, with a linear law. Border effects and mechanical problems may give rise to disturbances of such an ideal behavior. Fast measurement of capacitance is not as easy as that of resistance, as only time-varying test signals may be used. Small capacitors are high impedance devices, and care must be taken in the design of electronics, to avoid noise and interference problems.

A variation of the capacitive concept is that of "touch mode" sensors. Here the upper plate of the capacitor, especially designed to this purpose, is inflected by external pressure and is allowed to move in an air gap and touch the bottom plate, that is covered by a thin dielectric layer. At this point contact surface, and capacity, will increase as pressure increase. In our laboratories pressure sensors are tested to evaluate characteristic that are considered important in biomedical application. Besides the fundamental procedures of range calibration, linearity, hysteresis and creep test, we also performed dynamical studies, to assess the frequency response of resistive sensors and make a more complete model to be used in precision instrumentation.

Finally it is worth to mention that the performance of a PMD is determined not only by sensor technology, but is the result of many factors, as mechanical assembling, matrix scanning electronics, data transfer protocol.

PMD TECHNICAL ASSESSMENT: ISS METHODOLOGY AND RECOMMENDATIONS

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The ISS methodology for technical assessment of pressure measurement devices (PMDs) comes from the following basic concepts: i) high accuracy of pressure measurements is achieved only if sensors are wholly characterized in terms of range, linearity, hysteresis, ageing,..; while isolated sensor characterization should be done by the manufacturer, the here intended technical assessment rather takes into account each and every "contribution" to the sensor response within the final product (i.e. sensor arrangement, eventual cross-talk, mechanical or electronic constraints, algorithms,…); thus, the assessment set-up should be designed to test the PMD in its final commercial arrangement; ii) pressure transducers commercially used for PMDs are arranged as discrete sensors or in bi-dimensional arrays, and can exploit capacitive or resistive properties. A general purpose test device should allow the assessment of both single sensors and complete platforms of different sizes, spatial resolutions and temporal resolutions; iii) calibration and testing procedures entail pressure sensors to be subjected to a known pressure. Each sensor has an active area that is to be uniformly loaded. This requirement is easily met if the calibration device directly generates a pressure, whereas if a force is generated its uniform distribution over the sensitive area is not easily guaranteed; iv) besides single sensor characterization in terms of pressure response, the assessment of accuracy in center of pressure (COP) estimation over the assembled sensor matrix is also mandatory, since eventual cross-talk, electrical interferences or mechanical construction issues might affect COP accuracy. To this purpose, the simultaneous application of known forces over at least two small areas may represent a reliable and accurate way to assess measured vs calculated COP position; v) calibration and test procedure targets are different in factory and on the field. In factory the sensor response has to be wholly characterized, which requires the application of accurate and varying pressure/time profiles. On the field spot-checks are mainly needed since an easy, fast procedure is sought for.

ISS thus proposes a PMD assessment set-up made of: i) a valuable pneumatic calibration device based on a pneumatic circuit including an on-off valve and a proportional valve for the application of pressure in the range 0-700kPa under static and dynamic conditions over a small squared area, in the frequency range 0.5-1Hz; the device allows the assessment of local accuracy and precision, hysteresis, creep; ii) a special tool – associated with the above device - to apply a known vertical force through 3 round supports of a graduated round table, to assess accuracy and precision of COP estimation. Correctness of table position is assured by an ad hoc positioning system; iii) a membrane-based press machine to apply static steps of pressure in the range 0-1200kPa to simultaneously assess sensor accuracy over the whole PMD surface in all those PMDs which allow for the simultaneous loading of their entire surface.

Recommendations will also be formulated about the minimum technical requirements a PMD should have to be reliably used in the field of gait analysis and for stabilometric tests.

Session II

PMDs: role, management and assessment in biomechanical research and in the clinical practice

Chairperson
Claudia Giacomozzi

EXPERIENCE AND FEEDBACK FROM THE UNIVERSITY OF ROME FORO ITALICO

Aurelio Cappozzo
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Prior to the pressure measurement devices, the force plate was invented. The six component dynamometers called force plates are indispensable measurement instruments in a movement analysis laboratory. They provide the time history of the resultant load exchanged, for instance, between foot and floor during the execution of physical exercise. This resultant load is represented by a vector force, the line of action of which passes through an arbitrarily defined reduction point, and a vector couple. The scalar components of these vectors are measured relative to an arbitrarily defined orthogonal system of axes. The n electrical signals provided by the instrument, where n depends on the sensor technology used, are multiplied by an nx6 matrix of calibration parameters thus obtaining the six above-mentioned vector elements in their respective mechanical units. This operation entails the normally accepted, but still disputable, hypothesis of linear relationship between the operand vectors. While solving the inverse dynamic problem during biped locomotion, the knowledge of foot-to-floor load is indispensable when both feet are in contact with the ground (mechanically indeterminate system). Strictly speaking, during single support, it is a redundant piece of information, but, as such, it provides a very appreciable contribution to accuracy. Since the force plate can apply to the foot only a friction couple about an axis orthogonal to its surface, there must exist a reduction point for which any other couple component is nil. When this point is chosen for the representation of the measured resultant load, the couple is named "free torque" ("free couple" would be a more rigorous expression, but it is not used in the present context) and the mentioned point is named centre of pressure (CoP) as a consequence of the fact that the resultant of the orthogonal components of the distributed forces acting on the foot sole passes through that point. Although the position of this point at a given instant during movement depends on a plethora of different aspects of the motor task, i.e. both position and acceleration of the body centre of mass, as well as the angular acceleration of all body segments, it is extensively used both for foot mechanics and for whole body motor capacity assessment.

Having said this, it appears evident that, in a movement analysis laboratory, the accuracy of this instrument is crucial and the disastrous effects that diminished accuracy may have on the end results of the analysis are thoroughly illustrated in the literature. As is the case with all measuring instruments, accuracy depends on the calibration model and on the estimate of the relevant parameters. Taking for granted that the former factor does not change during the operative life of the instrument, there is ample evidence that the calibration parameters do vary. Therefore, good practice would require that a force plate be regularly submitted to a spot check and, when this provides a negative response, to recalibration. However, this rule is overlooked most of the time and sustainable techniques for implementing it are not easily available.

EXPERIENCE AND FEEDBACK FROM LIVERPOOL UNIVERSITY

Paolo Caravaggi (a), Todd Pataki (b)
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Pressure plates are regularly employed at PREMOG (Primate Evolution & Morphology Group, Liverpool University) for several biomechanics investigations. Over the last four years, two 0.5m and 1m Footscan 3D systems (RSscan, Olen, Belgium) have been used to assess pedobarographic correlations with different gait parameters. One of the main lines of research of PREMOG is the study of the relationship between lower limb kinematics and pressure data during barefoot walking on different substrates. Since footprints represent the oldest evidence of how our ancestors used to walk, it is of great interest to study how foot pressure and kinematics are related to footprints. Multibody and FE dynamic models are currently being implemented to investigate the mechanics of footprint formation in order to shed some light on this interesting subject.

Formal PMD assessment has never been conducted at our lab. Small pilot studies with control objects of known mass and surface areas are periodically conducted, but these serve mainly as a system check, to make sure that recorded values are approximately correct. No systematic study across the range of physiological pressure ranges has been conducted. No dynamic assessment has been conducted. To a large extent, we have trusted the manufacturer and our pilot studies.

However, our lab exclusively uses RSscan's dynamic calibration protocol ("Footscan 3D") via a Kistler force plate to ensure that total pressure is equivalent to the measured vertical ground reaction force. We have noticed that this protocol tends to introduce non-physiological step-like changes in pressure time series data, but since most of our analysis uses spatial summaries like peak pressure and pressure integral, we have not been too concerned with these high-frequency problems.

Our lab is not equipped with any instrument and/or test protocol to assess reliability. Although the pressure plates haven't been used for clinical applications and/or to measure absolute values of pressure, we often questioned whether the collected data could be biased by the state/condition of the plates. Our experience suggests that, over time, degradation of the plate cover-layer and dirty sensors result in loss of sensitivity. As recommended by the manufacturer we periodically seek maintenance when we (qualitatively) observe associated signal problems. However the company provides neither maintenance certificates nor details regarding the methodology/tests employed in maintenance, including especially sensor reliability and measurement error.

Despite being satisfied with the system overall, we strongly believe that greater technical transparency would promote user satisfaction and higher quality of research.

EXPERIENCE AND FEEDBACK FROM GHENT UNIVERSITY

Dirk De Clercq, Veerle Segers
Laboratory for Movement Analysis, Department for Movement and Sport Sciences, Faculty of Medicine and Health Sciences, Ghent University, Ghent, Belgium

Plantar pressure measurements in biomechanics of running. Plantar pressure measurements are used for two decades in our research on biomechanics of running. These measurements were carried out with different Footscan® systems (measurement frequency 100 Hz or more) in combination with recordings of the ground reaction forces by means of a force plate.

In an early study on running with and without shoes by non habitual barefoot runners, running at velocities well above their preferred jogging pace, a somewhat flatter foot placement was found in the barefoot condition.

A next step in unravelling the running gait pattern was investigating the temporal characteristics of the barefoot foot unroll pattern in a large sample of injury free young sports active people running at sub-maximal speed. Using cluster analysis four subgroups were identified and it was demonstrated that tracking the COP is useful in the study of the foot unroll.

The prospective study by Willems et al. identified gait related biomechanical risk factors for exercise related lower leg pain. Several plantar pressure variables aligned with variables from 3D kinematics and were between the most discriminating between injured and non-injured runners.

Recently a large dataset on healthy subjects walking and running in barefoot and shod condition over the plantar pressure plate was obtained. Comparisons of the plantar pressures by means of he pedobarographic statistical parametric mapping technique developed by Todd Pataky. This was done for both locomotion modes with and without shoes. Results from the latter comparison will be presented at the symposium.

Disclosures: D. De Clercq was in 2003-2004 involved in the IWT/30405 - Project (Flemish government agency for Innovation by Science and Technology) on "Optimization of the RSscan plantar pressure measurement system".

EXPERIENCE AND FEEDBACK FROM REHABILITATION INSTITUTE S. STEFANO, ITALY

Moreno D'Amico (a,b), Pietro Roncoletta (b), Massimo Vallasciani (a)
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(b) Bioengineering and Biomedicine Company Srl, S. Giovanni Teatino, Chieti

Baropodographic measurements and averaging in locomotion and postural analysis. The use of quantitative baropodography measurements, either by means of pressure sensing foot insoles or floor mats/platforms, is quickly increasing in clinical and research fields for the analysis of a wide variety of foot and ankle disorders. The study of underfoot load distribution is very important to determine posture balance and compensatory strategies in the body system, given the strict link between the forces generated through the feet during locomotion or in static posture and forces exerted on all the body and in particular on spine The intrinsic variability connected to posture, gait or to any other motor task (both normal and pathological one), implies the necessity to approach biomechanics of movement in terms of the identification of an average behaviour and a band of variability around this latter. This concept is the basis of the general approach our group is working on since many years to establish a set of general algorithms and mathematical/statistical tools for the quantitative study of movement and posture. Underfoot pressure maps measurements allow to identify foot/floor interaction and foot mechanics from which it is possible to study upper level biomechanical behaviour during locomotion and orthostasis. Unluckily, pressure maps measurement systems do not allow to collect shear forces, so the optimal condition in some cases would be to simultaneously record data from both baropodographic systems and 3D force platforms. Kinematics measurements complete the necessary information when a full posture and movement analysis is to be performed. Multi-factorial approach is the term used to express the necessity to perform biomechanical analysis by collecting sets of different variables from several measurement devices and to elaborate them within a well established framework. The aim of this paper is to present the necessary methodological approach we had to develop in order to integrate baropodographic measurements into the above mentioned general framework including the original mathematical-statistical procedures to consider average behaviour i.e. to assess the full Mean Gait Cycle from a set of multiple walk trials. Anyway in many cases baropodographic measurements could represent a sufficient source of information to perform a well established clinical evaluation of subject conditions. Clinical examples both in orthopaedic and in neurological fields will be fully explained in order to describe practical clinical application of such a methodology. Criticism about accuracy and precision of Pressure Measurement Devices applied to Clinics will be discussed.

EXPERIENCE AND FEEDBACK FROM UNIVERSITY OF MUENSTER, GERMANY

Dieter Rosenbaum
Motion Analysis Laboratory, Orthopaedic Department, University Hospital Muenster, Germany

Plantar pressure measurements in lcinical and research applications. Plantar pressure measurements are an established tool that is regularly used for clinical applications in patients of the Orthopaedic as well as the Traumatology Dept of the University Hospital. Due to the fact that patients are often seen repeatedly, i.e. before and after surgery or in the course of the disease or healing process, it is important that the measurements provide a sufficient repeatability with respect to the measurement parameters that are being used for evaluation purposes. In order to assess basic foot function we rely on the information obtained with a pressure distribution platform (EMED X or ST by Novel) that is being used for measurements of barefoot walking at self-selected speed. The standard procedure requires - after a customization period - repeated measurements until at least 5 valid trials of each foot are stored for further analyses. In single patients, the data are used to generate a standard clinical report that can be fed back to the physician. Specifically, the visual impressions (usually an averaged maximum pressure picture) as well as some regionally evaluated parameters (usually obtained with a mask for 10 foot regions) provide sufficiently detailed information. However, this information will be completed with a short summary of the key characteristics and the main findings. They are also used for designing customized orthotics when this appears to be indicated. In-shoe pressure measurements are used to assess the interaction between the foot and footwear, i.e. shoes and/or orthotics. Here we use capacitive insoles (PEDAR by Novel) that are available in various sizes with a range from children's to adults' sizes. Multiple steps can be performed in the lab or even outside and are stored for each shoe/insole condition for later comparisons that help to assess their characteristics and appropriateness with respect to distributing or shifting the load and off-loading highly-loaded or painful areas of the foot. For research purposes, these individual analyses are not performed because the single subjects will be collected in the data base that is being used for some kind of group evaluation in order to describe the average characteristics of a patient population e.g. with a specific foot deformity or surgical treatment. In all instances, great care will be taken to make sure that the subject is walking with a most natural gait pattern. Furthermore, the boundary conditions will be controlled or monitored as far as possible. Therefore, factors like length of approach, number of steps, gait speed will be documented as far as possible. In summary, pressure distribution measurements are a valuable and regularly used tool for clinical and research purposes with respect to foot (dys)function.

EXPERIENCE AND FEEDBACK FROM THE NUFFIELD ORTHOPAEDIC CENTRE, OXFORD, UK

Julie Stebbins
Oxford Gait Laboratory, Nuffield Orthopaedic Centre, Oxford, UK

Plantar pressure assessment at the Oxford Gait Laboratory. We currently assess approximately 350 patients per year in the Oxford Gait Laboratory. Eighty percent of our patients are children. Cerebral Palsy makes up the majority of the clinical population (~60% of patients). We routinely perform pedobarograph assessment on patients with clubfoot, cerebral palsy, and any other patients referred with a specific question related to foot deformity and/or orthotic prescription. We use this information to guide treatment (surgical, orthotic, and physiotherapy) and also to assess treatment outcomes. We also use the information to gauge change in the foot loading patterns over time, to determine if this is improving, deteriorating or remaining unchanged.

We measure plantar pressure using an Emed (Novel) pressure plate, at the same time as collecting multi-segment foot kinematic data from our Vicon MX system. We then use the markers on the foot to sub-divide the footprint into five different regions (medial heel, lateral heel, midfoot, medial forefoot and lateral forefoot) by projecting the x and y co-ordinates vertically onto the footprint. We report peak force in each of the five sub-areas over the entire stance phase, and compare the findings to average data collected from a reference population. We are currently working to develop this further and compare this method of footprint sub-division to more conventional methods.

In addition, we are working on correlating the findings from the multi-segment foot kinematics (peak and average values) with the peak pressure distribution during both static stance, as well as walking (mid-stance). We have assessed this relationship in children with hemiplegic cerebral palsy, as well as club foot, with interesting results. The relationship between kinematics of the foot and loading under the foot is not necessarily intuitive, which illustrates the lack of understanding of how the foot behaves when deformity is present. For example, the hindfoot may be in a valgus alignment, but not necessarily exhibit loading under the medial aspect. Similarly, loading under the medial hindfoot does not necessarily imply valgus alignment. Both pieces of information are necessary to correctly interpret the data. We have found it helpful to report combined information about foot motion and loading, to provide a complete, biomechanical assessment of foot, and provide more accurate and precise information to clinicians.

EXPERIENCE AND FEEDBACK FROM TOR VERGATA UNIVERSITY HOSPITAL, ITALY

Luigi Uccioli (a), Claudia Giacomozzi (b)
(a) Department of Internal Medicine, Tor Vergata University, Rome, Italy
(b) Department of Technology and Health, Istituto Superiore di Sanità, Rome, Italy

Within the Internal Medicine Dept of the Tor Vergata University Hospital a highly qualified service has been set up several years ago for the management of Diabetes and pathology-related foot damages. The co-operation with ISS - started in 1998 - allowed the conduction of serious and relevant research in the field of the biomechanics of the Diabetic foot. The instrumentation ISS delivered for the clinical investigations was specifically tailored for the main target of each study, the clinical investigation environment, the accuracy needed for each parameter of interest. Main studies - all focussed on Diabetic patients with and without neuropathy - and relevant measurement setup are briefly summarized here below:

- alteration of foot-floor interaction: the study was conducted with an integrated piezo-dynamometric platform made of a commercial force platform and a pressure resistive matrix purposely constructed and calibrated at ISS; algorithms for the estimation of local shear forces were also applied; the study lead to the identification of significant alteration of the medio-lateral shear force under the metatarsals of neuropathic patients;
- muscle performance and ankle joint mobility: the ISS delivered a prototype of a 3D dynamometer, balanced to allow patients to perform ankle movements in selected planes, and calibrated to accurately measure 3D moments of force around the ankle-complex under controlled isometric conditions; a significant decrease of muscle performance was found in presence of neuropathy, especially in ankle dorsal flexors, together with a 3D progressive reduction of ankle mobility;
- setup for fast screening of patients at risk of ulceration: the use of an accurate capacitive pressure platform allowed to measure and reliably use a single specific kinetic parameter, the Peak Pressure Curve (PPC); cluster analysis applied to more than 100 PPCs allowed us to build up a fast sensitive screening test;
- assessment of efficacy of plantar orthoses: accurate capacitive plantar insoles were used; special effort was done to find the most suitable testing protocol and reference measurements at baseline; the instrumental assessment is now part of the testing and approval phase of the orthoses, and it is used whenever clinicians have doubts about the need for change or replacement of the preventive treatment.

Further studies are still in progress in this field, the most interesting of which dealing with an attempt to recover foot mobility of neuropathic patients through home-based physical exercises.

EXPERIENCE AND FEEDBACK FROM THE UNIVERSITY OF WASHINGTON, SEATTLE, USA

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Pressure measurement - The need for standardization and calibration. There are, in my opinion, two major issues that need to be addressed before pressure distribution measurement can become used in a clinical context on a more routine basis. These are: 1) Direct linkage between the measurement and clinical outcomes and; 2) The adoption of industry-wide standardization and traceable calibration. This presentation will make passing reference to the first topic but focus on the second of these issues which is central to the goals of the current workshop. An appropriate comparison of the current situation regarding plantar pressure measurement is an analogy with the measurement of blood pressure. Certainly, clinical decisions are made based on blood pressure measurement in the area of detection and treatment of hypertension and other cardiovascular diseases. As access to blood pressure measurements outside the clinic has grown (in the home, in supermarkets etc.) and as automated devices for blood pressure measurement have proliferated, groups such as American Association for the Advancement of Medical Instrumentation (http://www.aami.org/) and the European Society of Hypertension (ESH http://www.eshonline.org/) have led the way towards the development of standards for accuracy and utilization. These organizations have developed a system of evaluation where devices must meet certain accuracy standards to be recommended. Interestingly, the ESH has lamented the power of this approach noting that one of the most popular automated blood pressure monitors continues to be used in clinical practice and hypertension research despite a number of reports of its inaccuracy. The problem faced by the clinician or researcher who wishes to use plantar pressure measurement is similar, but somewhat more complicated, that that of a clinician who measures blood pressure. The user wants a plantar pressure measurement system to be accurate not only on an initial reading, but also to be accurate over time as the characteristics of the patient or the measurement interface change. Comparison to the literature is a frequent requirement and this implies that different systems produce similar results under similar conditions. Moreover, a frequent requirement is to assess how the pressure under a barefoot is altered by footwear. Very few of the foregoing questions can be reliably answered at the present time because of lack of technical standardization and calibration. A solution to the issues discussed above may be for one of the emerging societies or interest groups (such as i-FAB www.i-fab.org or its Pedobarography Group http://www.i-fab.org/i-FAB-PG/) to engage the American Association for the Advancement of Medical Instrumentation in order to set standards that can be used to provide guidance to users. This would be of great benefit to the field and could lead to significantly more utilization of plantar pressure measurement in the clinical domain.

Session III

Compliance with PMD technical assessment: the point of view of the manufacturers

Chairperson
Antonello Fadda

PMD MANAGEMENT AT AMCUBE

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High reliability of a capacitive pressure sensor plate. The use of plantar pressure measurement devices (PMDs) has been key for diagnosis, management and prevention of pressure-related foot problems. Today PMDs are used for the population at large under both static and dynamic conditions. At the beginning of the project, we wanted to make a PMD as a diagnostic tool for podiatrists. Podiatrists want a highly reliable, accurate, low-priced, easy-to-use product. At the same time, we intended to design a product with high performances, suitable for scientific research in biomechanics. Different types of sensors exist to measure the pressure: resistive, piezoelectric or capacitive... As a wide range of pressure can be applied under the foot, the instrument must be capable to measure the whole range. Indeed, under static conditions, applied pressures range between 2 and 100 kPa; under dynamic conditions, pressures can increase up to 900 kPa or more for some pathological cases. We thus wanted to develop a product that could be used for both static and dynamic analysis and that would not need too much maintenance. After thorough research, we chose the capacitive sensor because it allows wide range pressure measurements, and enables the operator to measure absolute pressure with high accuracy without knowing the patient's weight. We designed and constructed a sensor plate with 2 capacitive sensors by square centimeter and an active area of 49x49 cm. Surface and thickness are very important to obtain a natural step, so our plate is very thin: 5 mm. Very light and easily protable, it is powered only by USB, so it needs only one connection wire. As for price, our product is one of the cheapest on the market. We also offer a smaller plate with the same level of perfomance and sold at a reduced price. Thanks to the capacitive sensor and the applied calibration, the plate can perform measurements both under dynamic and static conditions. Moreover, this plate requires only one calibration, the customer can be sure of the analysis results even after thousands of uses. We will show that even after years of use and thousands of analysis, the results of the pressure measurements are the same roughlty 5%. This is possible thanks to the design of the capacitive sensor: coplanar geometry and the use of air as dielectric. Another advantage is that even after more than 20 minutes under pressure, the measured values do not change. The results presented by Claudia Giacomozzi in the article untitled "Appropriateness of plantar pressure measurement devices in a research context: a comparative technical assessment." are very interesting for us and show our product has very good rate at low/medium pressure. Our Research and Development Department is working to have better calibration at very high pressures.

PDM MANAGEMENT AT NOVEL

Peter Seitz, Axel Kalpen
NOVEL gmbh, Munich, Germany

Many clinicians daily assess the dynamic pressure distribution of the patient's foot and make clinical decisions based on this data. Accurate and reliable pressure information is indispensible for the clinician to decide for appropriate treatment. Depending on the loading pattern of the foot and the pathology of the patient the local pressure values of the foot can reach up to 1.2 MPa, or even higher. The actual value of local pressure is extremely important in patients with pathologies such as the diabetic foot. Therefore, it is necessary that every sensor within a pressure system displays the accurate, absolute pressure value. To provide clinicians and researchers with accurate pressure distribution data novel has offered high quality emed® pressure platform systems since 1984. Each system contains individually calibrated, accurate, reliable capacitive sensors. Any sensor used for pressure distribution measurement is deformed by applied pressure therefore a well defined spring balance element inside the sensor is required. This deformation is translated into an electric signal. To get accurate and reliable results it is very important that the deformation of the sensor is reproducible and stable over a long period of time. The loading should be reversible during off-loading, resulting in a small hysteresis. To meet these requirements novel uses unique elastic materials as a spring balance element inside the pressure sensors. An exceptional calibration procedure using the patented trublu® calibration system was developed to define the relationship between the applied pressure and the displayed sensor signal. Each individual sensor is calibrated throughout the entire pressure range. This results in accuracy better than +/-5% for pressure values up to 1.25 MPa. The hysteresis of the novel emed® systems is less than 3%. For more detailed results see reference. Based on the local pressure values, local and total forces can be calculated from the loaded areas and the applied pressure. Since the sensor properties may change slightly over time, calibration must be checked periodically. It is recommended to do this at least once a year. This assessment is offered from novel as a service for its users. Also, the user should periodically perform some simple tests to check the calibration. Subjects should be asked to stand with one foot on the platform. Without revealing the subject's bodyweight to the system, the emed platform will display the subject's bodyweight, within 5%. However, the only way to determine the exact accuracy of each individual sensor it is indispensible to use the trublu® calibration system. Pedography systems used in clinical routine are regulated according to the Medical Device Directive Law of the European Community. They are Confirmed Medical Products Class I with measuring function (Im) and have to strictly follow the official specified conformity assessment. An official Notified Body, such as ISS or TUEV is required, to approve the quality standards for the measuring function. All emed® platform systems are produced with the approval by a Notified Body and documented by a valid CE Certificate. Systems without this approval may not be distributed in the Common Market.

PMD MANAGEMENT AT RSscan

Jean-Pierre Wilssens
RSscan International, Olen, Belgium

RSscan International is the manufacturer of the footscan system, developed in 1994, our system uses resistive technology and distinguishes ourselves from our competitors through the combination of with higher frequencies (500 Hz) and larger systems (up to 2m long). One of the other big advantages of the footscan system is that the 2m plate allows for running or sprinting measurements. Although clinical use also benefits from the 2m lengthy plate since no one- or two-step method is necessary, and pressure data can be captured while patients walk naturally without targeting the plate. In the past ten years there have been various (PhD) studies where the footscan system was used for gait analysis on a variety of topics such as: i) running and exercise related injuries; ii) evolution of primates and veterinary research; iii) toddlers, diabetic patients and amputees; iv) pressure measurement analysis and modeling; v) balance and coordination. Several of these studies have received international recognition: i) Dr. Willems studies found that pressure measurements are strong predictors for exercise related lower leg pain. It should be emphasized that the parameters with the highest predictive values require the high frequency of the footscan system (500 Hz); ii) Dr. D'Août's anthropological studies showed how the footscan system can be used to assess the effect of footwear on the feet. This shows the footscan systems ability to review differences in morphology and functionality; iii) Dr. Franklyn-Miller used to footscan to prescribe (D3D) inlays and reduced the injury rate by 66% in a (high risk) group of military trainees. These results show how the footscan system can be used to diagnose pathologies and prescribe medical interventions. Although footscan has been successfully used by scientist, we are always trying to improve the footscan system. We currently calibrate our system by dynamically loading each individual sensor using an instrumented pressure rod with an integrated force cell. This allows us to simulate the foot's dynamic range of loading. The footscan systems are capable of measuring at very high frequencies thanks to our patented technology. However, this technology is limited to foot-sized surfaces and does not allow loading of the entire plate's surface. Therefore the sandwiching calibration method, generally used by our competitors, is not suitable for the footscan system. Furthermore, this calibration method is not representative for the footscan systems intended use, which further emphasized by the fact that many pathologies are characterized by rapid movements, such as clap feet in diabetic patients or rapid (over) pronation in runners. Finally, we recommend our scientific users to dynamically calibrate the footscan system using our patented technology in combination with our 3D box and a force plate.

PMD MANAGEMENT AT LORAN

Gabriele Casadio
LORAN Engineering, Bologna, Italy

Education and training in the field of plantar pressure measurement. The use of pressure platforms to detect the plantar pressure is a topic that has been investigated for a long time since the early 90's. There are many theories proposed in the use of these systems as to use for automated diagnosis of diseases of the foot, finding the parameters for the definition of particular diseases, aid in evaluating the analysis of the foot, creating computerized orthotics etc.

Since we started working on this market, more than 20 years ago, with the design of early systems made in Italy at a business level the most problems encountered were:

- the availability, or the production of pressure sensors in a matrix format that were accurate, repeatable and cheap;
- training of personnel who could not use the systems so as to understand and interpret correctly the results.

In recent years we realized that if from one part the realization of sensors with the required characteristics was a problem from the other the widespread use of these systems is often dictated by a factor of "fashion" or by an imposed necessity rather than any real use of the system in its completeness of results. Many users will continue, even today, to use the platforms as mere device to acquire images to be delivered to the patient instead of an assessment with classic Podoscope. Few percentage are the realities, both public and private, that actually use the systems as an aid in diagnosis.

We believe that, in general, the real problem is the training of specialized personnel that should use this type of equipment.

For greater clarity, we consider that these devices should be divided into two broad categories:

- systems which function as evaluation of pressure plantar distributions;
- systems with function of measuring plantar pressures.

The first must ensure repeatability, ability to clear identification of areas at different pressures, speed of acquisition sufficient to guarantee a minimum of dynamic images to rebuild the kind of jstep, powerful and user friendly software. The second, in addition to the previous characteristics, must ensure accuracy in measuring of pressure, repeatable and verifiable with validated systems. The two real objectives to be pursued, in our view, should therefore be to define the minimum parameters that a system must insure and attestation of specialization for the users. Loran currently proposed systems that are identified in the first category with different technology sensors, seeking to ensure good repeatability and controls for uniformity of response. The systems are tested with an equipment that we manufacture that controls the pressure exerted on a surface known and based on the tests are verified correction files.

PMD MANAGEMENT AT TEKSCAN

Norman Murphy
Consultant Director Product and Market Research and Development, Medical Group, Tekscan, Inc., South Boston, MA, USA

The Tekscan MatScan floor mat system: a review. This presentation discusses the methods and guidelines recommended by Tekscan to deliver accurate, repeatable and reliable measurements when using the MatScan® Floor Mat System. A parallel is also made with the ISS (Istituto Superiore di Sanità) Matscan study, to explain how following such guidelines further improves outcomes. Tekscan believes that the study by ISS on PDMs is extremely important. This study will help clarify the relevancy of the available PMDs, and establish common guidelines for performing accurate quantitative baropodometric measurements and analysis. Regarding the study by ISS on the MatScan, Tekscan has reproduced similar results. Tekscan used a similar technical assessment approach as ISS. In addition, Tekscan has developed new methods and guidelines for appropriate and optimal use of the MatScan. The application of these methods and guidelines ensure improved sensor measurement accuracy, performance and ease of use. Variation exists between the individual sensing elements of the matrix-based PMD sensors. The MatScan sensor is no exception. The clinical community has a higher tolerance for such variations in PDM sensors, and these are accepted in the majority of clinical applications. However, for applications under scientific rigor, such as in research and development, Tekscan recommends the use of an equilibrator (air bladder) device to assess, optimize and maximize sensor uniformity and performance. Tests of individual sensing element outputs and overall sensor output distribution should be performed with a fully-equilibrated sensor. Tekscan provides a commercially available equilibrator device for use with the MatScan. Tekscan also recommends and provides equilibration procedures to significantly reduce the sensel to sensel variation, if present. An air bladder equilibration of the MatScan sensor is applicable when two main conditions are met: 1) sensor-bladder stabilization occurs after sufficient settling time; and 2) trapped air within the senor is allowed to escape (vent). Of importance, Tekscan does not recommend the use of an equilibrator device to calibrate the MatScan sensor, or to conduct dynamic testing. Lastly, Tekscan conducts research testing to improve the existing calibration procedures, and to develop functional and practical calibration routines. Along with these calibration enhancements, Tekscan provides and recommends guidelines for optimal use. To set the criteria for the research and clinical testing, calibration procedures results are compared to force plate measurements. Force plates are considered to be the gold-standard in the industry. Since the study by ISS, Tekscan has introduced two new calibration procedures to the commercial market. These new calibration procedures improve MatScan sensor measurement accuracy and ease of use. These new calibration methods account for time-based compensations that occur during dynamic events. They also significantly improve sensor output accuracy by reducing hysteresis. For optimal performance of the MatScan System, Tekscan recommends that the calibration conditions mimic the events being recorded.

PMD MANAGEMENT AT ZEBRIS

Roberto Mariani
Italian Official Importer of Zebris Medical GmbH, Isny, Germany

Zebris PMDs rely on capacitive, elastomer-based sensor technology; main technical features of the platforms are: accuracy ±5% (FS); hysteresis <3% (FS); measurement range 1-120 N/cm²; sampling rate up to 120 Hz (optional 240 Hz).

The presentation at the ISS event will mainly deal with:

- introduction to the Zebris Medical GmbH company facts at 2010;
- technical data of the FDM series (from the little portable platform to the big treadmill FDM-THQ);
- method and materials from the construction processes at Zebris.

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