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Potentialities and Criticalities of Plantar Pressure Measurements in the Study of Foot Biomechanics: Devices, Methodologies and Applications

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1. Introduction

Literally speaking, Biomechanics is the discipline that applies the principles and laws of Mechanics to biological systems. As for the human body and, more specifically, the human foot, biomechanics focuses on the understanding of those laws of the Physics by which the human being moves within the Earth gravitational environment by adopting a bipedal posture and using a complex interfacing structure such as the foot-and-ankle system. Keeping the focus on the most common human displacement activity, i.e., gait, we may state that the main target of a functional gait is to push the body centre of gravity forward. To do that, gait has to deal with a set of forces the body exchanges with the environment – especially with the ground – and with a set of movements which represent both causes and effects of force transmission. A thorough description of the foot biomechanics should then mainly rely on the observation of both kinematic and kinetic variables, namely, i) forces and moments of force external to the body; ii) forces and moments of force internally generated by the musculo-skeletal system; and iii) movements and timing of the movements in terms of linear and angular displacements, linear and angular velocities, linear and angular accelerations of the whole body or of specific body segments. On the other hand, the effects of loading under the sole of the foot in terms of plantar pressure have been reported since the late 1800's; and since the first attempts to measure it, its use has been ever increasing worldwide. In fact, plantar pressure assessment alone is not enough to thoroughly investigate biomechanics – in terms of neither kinematics nor kinetics – being pressure related to the only component of the force vector which is normal to the examined surface. Plantar pressure, however, has great potentialities in the field of Research but even more in Clinics and Podiatry. When compared with other assessment devices typically used in gait analysis, pressure measurement systems are easier to implement and use, less time-consuming and cumbersome to the patient, less expensive than complex gait analysis equipment; measurements are more easily acquired, processed and interpreted, and – last but not least – they are meaningful and effective in the assessment or in the monitoring of any foot or ankle treatment. In the last ten years, a significant increase has been observed in peer-reviewed publications dealing with studies focussed on plantar pressure

measurements. However, despite the great interest of the scientific world in this potentially valuable assessment tool, little evidence has been gathered so far of the effectiveness, appropriateness and generalisability of the plantar pressure measurement methodology. This fact is attributable to several reasons, the most important one being the lack of standardisation. In the following paragraphs, a brief literature overview will be given to better introduce the role pressure measurements have in the scientific and clinical context, but also to better explain how and to what extent the lack of standardisation of instrumentation and procedures has frustrated all researchers' and clinicians' efforts at giving this methodology the role it deserves in the investigation, understanding and management of foot biomechanics.

2. Literature overview

The main source this brief literature overview relies on is the PubMed Web Resource, the specific tool to search in databases of peer-reviewed scientific literature in the biomedical field. PubMed is freely accessible on the web (<http://www.ncbi.nlm.nih.gov/pubmed/>), and its more than 20 million citations for biomedical literature come from MEDLINE – the biomedical database of the U.S. NLM –, life science journals, and online books. This precious free resource has been developed and is maintained by the National Center for Biotechnology Information (NCBI), at the U.S. National Library of Medicine (NLM), located at the National Institutes of Health (NIH).

Search combination	Search date	Total number of publications	Publications in the last ten years	Year of the first publication
„foot“ & „biomechanics“	Jan 17 th , 2011	3975	2132 (54%)	1950
„foot“ & „biomechanics“ & „pressure“	Jan 17 th , 2011	767	470 (61%)	1966
„foot“ & „pressure“	Jan 17 th , 2011	5605	2807 (50%)	1918
„foot pressure“	Jan 17 th , 2011	473	275 (58%)	1980
„foot biomechanics“	Jan 17 th , 2011	58	40 (69%)	1973
„plantar pressure“ or „plantar loading“ or „foot pressure“ or „foot loading“	Jan 17 th , 2011	1124	748 (66%)	1976

Table 1. Publications cited in PubMed resulting from different combinations of search terms that regard foot biomechanics and plantar pressure.

The Author has used a few research combinations just to understand whether and how human plantar pressure measurements are used and associated with the concepts of foot biomechanics and gait. Table 1 briefly indicates the most interesting combinations of search terms, and the main results obtained for each of them up to January 2011 in terms of: i) the overall number of papers found that contain the search terms in all PubMed fields of research; ii) the subset of papers published in the last ten years; iii) the year of the first publication. Table 1 clearly shows that, generally speaking, foot biomechanics is quite a recent field of scientific investigation which is rapidly gaining interest worldwide. All search combinations

proved in fact that at least 50% of the literature is concentrated in the last ten years. With special attention to pressure, it is worth noticing that 20% of all the publications containing “foot” & “biomechanics” also contain “pressure”; the percentage rises to 22% when referred to the last ten years, showing a more frequent association of the concept of “pressure” with the concept of “biomechanics”. As for the great number of publications found for the “foot” & “pressure” combination, it should be noted that some of them do not deal with foot pressure proper, being sometimes focussed on clinical applications and/or on patients with concurrent blood pressure pathologies. Thus, the literature overview was finally focussed on the search combination reported in the last row of Table 1, i.e., „plantar pressure” or „plantar loading” or „foot pressure” or „foot loading”, which turned out to be wide enough and appropriate. From now on, the paper will only deal with this combination of literature research.

As shown in Table 1, the first peer-reviewed publication is quite recent (Gordon, 1976). Actually, the very first paper resulting from the PubMed research is dated 1953 (Cram, 1953), but it is a misprint since the true title is “A sign of sciatic nerve root pressure” rather than “A sign of sciatic nerve foot pressure” as stored in the database, and it has nothing to do with plantar pressure measurement. In about 35 years, 1124 publications have been produced in all, 66% of which in the last ten years. The brief literature overview that follows is based on only 119 publications dated 2010, so as to give an idea of the most recent issues taken into account in this field. Here is a summary of a few interesting observations:

- 86 out of the 119 papers (72% of the total amount) indeed deal with plantar pressure measurements; they have been listed in the Reference section from (Morrison et al, 2010) to (Tessutti et al, 2010).
- Of the 86 publications, 75 (87%) deal with clinical or research applications, while the remaining 11 (13%) address methodological issues. On one hand, this shows the great potential of plantar pressure measurements in the Clinics or in the field of Applied Research; on the other hand, however, the presence of more than 10% of methodological papers may be read as a sign of a moderate but increasing interest towards methodological and standardisation issues. For a more detailed description of Clinical, Sport or Research applications, Table 2 classifies the 86 papers according to the main pathology or issue treated. It is worth highlighting that some pathologies are almost always investigated with the support of plantar pressure measurements – i.e., foot, ankle and hip pathologies, foot surgery, orthosis design and assessment, musculo-skeletal performance –, some do not require pressure measurement investigation as is the case with Parkinson’s disease, a few others are partly investigated by involving pressure measurements and partly only relying on different investigation methods – i.e. balance control, diabetes, gait biomechanics, foot injuries –. As for Diabetes, it should be observed that in the last years most scientific studies on Diabetes and foot biomechanics did rely almost exclusively on plantar pressure measurements, both barefoot and inside prescribed footwear and orthoses. The main reason for this is probably the interest of researchers on the most evident effect of biomechanical alterations, i.e. abnormal peak pressures so often associated with the ulceration process. Only recently has the need been felt for a more complete investigation of biomechanical alterations Diabetes induces in all the structures involved in gait i.e. joints, muscles, tendons, soft tissues, skin, bone, cartilage, peripheral vascular system, motor and sensory nervous system.

- Back to Table 2, it is also extremely important to underline that all 2010 methodological studies are related to pressure measurements.
- With respect to the specific field of application, the 86 papers can be grouped as follows: 69 papers strictly related to the clinical context; 1 to the military environment; 8 to sports; 8 to technology.
- Only 45 out of the 86 publications do report absolute pressure values. This concept is critical indeed, and will be further discussed later on; however, it is worth anticipating that reporting absolute pressure values obtained within a certain study may help understand the appropriateness of the whole methodological setup designed and used in the study, and surely helps researchers to better judge the comparability of his/her own results with those reported in the study.
- As for the technology used in the 86 publications, an increasing interest in wearable devices has been observed with respect to previous years. In detail: in 46 studies a pressure platform was used, i.e. a rigid sensor matrix made integral with the floor; 32 used an in-shoe wearable pressure system; 2 used a custom-made platform purposely designed for pressure and shear measurements; 1 used a footprinting mat; 5 used discrete pressure sensors.
- Still on technology, in a commercial versus prototype pressure devices context, it can be observed that about 60% of the 86 studies used commercial pressure measurement devices. The involved Companies/Products ordered according to a decreasing number of citations are: Novel; Tekscan; Rsscan; Biofoot/IBV(®) in-shoe system; Zebris; Medilogic; Harris footprinting mat; Vista Medical. Only 5 studies described and used prototypes among which a quite new in-shoe prototype of a textile device (Shu L et al, 2010) is worth citing. In the remaining cases, the device was not clearly described, which, together with the lack of absolute pressure values, might represent an obstacle for correct data interpretation and comparison.
- As for the pressure-related parameters used, the situation is quite confusing. Just a few comments to give the reader a rough idea of the need for standardisation, and to well justify the current difficulty in performing proper comparisons among studies:
 - Some “conventional” parameters are frequently cited and used in the papers, e.g., peak pressure, mean pressure, pressure-time integral, peak force, force-time integral, center of pressure, stance period, and symmetry indices, but almost none of the studies describe the way each parameter has been obtained; thus, while some of them are undoubtedly always obtained in the same manner, for others critical differences in the computation algorithm surely lead to different results. Mean pressure is a clear example: its value changes dramatically according to whether it is based on the whole stance period or only on the period of each sensor activation.
 - Meaningful regional masks are used in several papers but they are hardly defined, and even rarer is the detailed description of the algorithm used to select the foot sub-areas.
 - There is an increasing interest towards pressure-derived quantities and novel numerical analysis: while acknowledging the great potential of such computational approach, the risk to obtain poorly comparable results is in this case even greater than when traditional parameters are used, unless comparison is assured and proved with respect to the source datasets. Besides this aspect, derived quantities should be even better described than traditional ones because sometimes their

- clinical association, relevance and meaning are not straightforward for an effective worldwide use.
- The final observation is rather a criticism to the superficial attitude and the lack of attention shown by the main actors of a publication, i.e. authors, reviewers, editors, and even readers: peer-reviewed 2010 publications, similarly to the publications of previous years, sometimes present data that may not be, in any way, related to a properly conducted study. Five examples of dubious measurements are briefly reported below. papers are not clearly cited in order to be respectful with colleagues who did not pay the proper attention while preparing, reviewing or simply reading them. Example 1: according to a study, electronic footprints do not match ink footprints: it is reasonable to hypothesize that the statement came out from comparison with a platform which was not well calibrated or not sensible enough, or even with a very low spatial resolution, but none of these aspects was taken into account in the paper. Example 2: a platform made of resistive sensors is used for static tests lasting more than 30s. Since resistive sensors suffer from hysteresis and creep, their use under static conditions is usually not recommended, unless a preliminary assessment proved that the device can be reliably used for a long loading time. Again, the issue is not discussed in the paper. Example 3: a paper dealing with obese patients ($BMI > 35\text{kg/m}^2$) reported dynamic peak pressures not greater than 250kPa. These values are suspiciously low: for comparison, consider that a paper published in 2001 (Hills AP et al, 2001) reported more than 500kPa of averaged peak pressure values for both men and women. Example 4: a paper reports peak pressures under the forefoot not greater than 35kPa, which is almost impossible: even if the authors meant mean rather than peak pressure – mean being obviously much lower than peak pressure – the result would have been obtained from a person with a body mass of about 35kg standing on a support surface of 100cm^2 , thus greater than the EU size 38 or US size 7. Example 5: a paper deals with pressure measurements obtained with a pressure platform while wearing shoes: this means that the measurements are inconsistent for they refer to the interface between the platform and the sole of the shoe.

Main Pathology/Issue	Number of papers dealing with pressure measurements (% of 86)	Publications dealing with pressure measurements	Number of papers in 2010 -not all dealing with pressure measurements (% of 119)
Ankle pathology	2 (2.3%)	Morrison et al, 2010 Rouhani et al, 2010 a	2 (1.7%)
Anthropology	1 (1.2%)	Hirasaki et al, 2010	3 (2.5%)
Balance control	2 (2.3%)	Hirata et al, 2010 Vuillerme & Boisgontier, 2010	10 (8.4%)
Children	4 (4.6%)	Pau et al, 2010 Bosch et al, 2010 Bosch & Rosenbaum, 2010 Pauk et al, 2010	5 (4.2%)

Main Pathology/Issue	Number of papers dealing with pressure measurements (% of 86)	Publications dealing with pressure measurements	Number of papers in 2010 -not all dealing with pressure measurements (% of 119)
Diabetes	8 (9.3%)	do Carmo Dos Reis et al, 2010 Zequera & Solomonidis, 2010 Cisneros Lde et al, 2010 Hastings et al, 2010 See et al, 2010 Z. Pataky et al, 2010 Chen et al, 2010 Rao et al, 2010	14 (11.8%)
Elderly	1 (1.2%)	Battaglia et al, 2010	1 (0.8%)
Falls	2 (2.3%)	Abu-Faraj et al, 2010 Mickle et al, 2010	2 (1.7%)
Foot injuries	4 (4.6%)	Goffar et al, 2010 Hirschmüller et al, 2010 Schepers et al, 2010 Hetsroni et al, 2010	7 (5.9%)
Foot pathology, anatomy and function	15 (17.4%)	Navarro et al, 2010 Yalçin et al, 2010 Kaipel et al, 2010 Lee et al, 2010 Hyslop et al, 2010 Ribeiro et al, 2010 Mackey et al, 2010 Yavuz et al, 2010 Martínez-Nova et al, 2010 Gu et al, 2010 Barberà i Guillem et al, 2010 Yavuz & Davis, 2010 Nordsiden et al, 2010 Putti et al, 2010 b Menz et al, 2010	17 (14.3%)
Foot surgery	7 (8.1%)	Schuh et al, 2010 a Bayomy et al, 2010 Wagenmann et al, 2010 Yoon et al, 2010 Ellis et al, 2010 Jeans & Karol, 2010 Najafi et al, 2010	7 (5.9%)

Table 2. Part A. 2010 Publications dealing with plantar pressure measurement, classified according to the main pathology or the main issues investigated.

Main Pathology/Issue	Number of papers dealing with pressure measurements (% of 86)	Publications dealing with pressure measurements	Number of papers in 2010 -not all dealing with pressure measurements (% of 119)
Footwear and/or insoles	6 (7.0%)	Hong et al, 2010 Deleu et al, 2010 Stöggel et al, 2010 Schuh et al, 2010 b Tong & Ng, 2010 Queen et al, 2010	7 (5.9%)
Gait strategy/biomechanics	6 (7.0%)	Putti et al, 2010 b Teyhen et al, 2010 C.M. Senanayake & S.M. Senanayake, 2010 a C.M. Senanayake & S.M. Senanayake, 2010 b Rouhani et al, 2010 b M. D'Amico et al, 2010	8 (6.7%)
Knee pathology	4 (4.6%)	Bek et al, 2010 Wang et al, 2010 Lidtke et al, 2010 Aliberti et al, 2010	4 (3.4%)
Lower limb amputees	2 (2.3%)	Kendell et al, 2010 Tura et al, 2010	2 (1.7%)
Lower limb injuries	1 (1.2%)	Kelly et al, 2010	1 (0.8%)
Muscolo-skeletal performance	5 (5.8%)	Braz & Carvalho, 2010 Girard et al, 2010 Stolwijk et al, 2010 No authors, 2010 Tessutti et al, 2010	5 (4.2%)
Postmenopausal women	4 (4.6%)	Monteiro et al, 2010 a Monteiro et al, 2010 b Faria et al, 2010 Monteiro et al, 2010 c	4 (3.4%)
Pregnancy	1 (1.2%)	Karadag-Saygi et al, 2010	1 (0.8%)
NONE (research; methodology;..)	11 (12.8%)	Giacomozzi, 2010 a Natali et al, 2010 Oliveira & Tavares, 2010 Giacomozzi, 2010 b Zammit et al, 2010 Miller, 2010 Ramanathan et al, 2010 Giacomozzi, 2010 c Shu et al, 2010 Chevalier et al, 2010 Keijsers et al, 2010	11 (9.2%)
Total	86 (100%)		119* (100%)

* the list of 2010 papers also included papers - not related to pressure measurements - dealing with: gait rehabilitation (1); ground interfaces (1); obesity (2); Parkinson’s disease (4).

Table 2. Part B. 2010 Publications dealing with plantar pressure measurement, classified according to the main pathology or the main issues investigated.

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. Some proposals have been published and disseminated so far through publications (Giacomozzi C, 2010 a; Giacomozzi C, 2010 b; Giacomozzi C, 2010 c), meetings, on-line forums¹, and an ongoing attempt within the Pedobarographic Group of the International Foot and Ankle Biomechanics Community (i-FAB-PG) for a Consensus Document on the topic. The following paragraphs aim at giving the reader a brief description of the currently available pressure sensor technology, the technical features which mainly interfere with overall PMD performance, some suggestions for implementing an adequate PMD technical assessment.

3.1 Basic concepts on PMD sensor technology

Generally speaking, the measurement of pressure can be obtained with a transducer that quantifies the effect of a force acting perpendicularly to a certain surface. This definition must be clearly kept in mind when investigating foot biomechanics with a PMD because, independently of sensor technology, a pressure sensor alone cannot measure the effect of forces which are not oriented perpendicularly to its surface. Even more important is the concept that, if the sensor surface is not parallel to the ground – as it may happen with in-shoe systems or when the floor is not rigorously horizontal –, the measured quantity is not only, or not completely, related to the vertical component of the Ground Reaction Force (GRF).

Along the years valuable reviews have been delivered on the available sensor technology, novel prototypes, their main features and quality of performance. The first interesting and thorough review was written by Lord in 1981 (Lord M, 1981). Another very good technical review was disseminated by Cobb and Claremont in 1995 (Cobb J, Claremont DJ, 1995): interestingly enough, it also addressed transducers applied to the measurement of shear forces. Albeit highly desirable, none of them have been successfully integrated into commercial pressure measurement systems yet. A further very useful review on the issue of plantar assessment was published in 2000 (Orlin MN, McPoil TG, 2000): it contains not only a thorough review of the available pressure measuring techniques, but also a stimulating discussion on most used parameters and potential clinical applications.

Right now -at the beginning of 2011- commercial PMDs and most prototypes are still focussed on pure pressure measurements, and are essentially based on optical devices, pneumatic discrete sensors, discrete -or matrices of- resistive sensors, and discrete -or matrices of- capacitive sensors. Worthy of note is a novel textile sensor prototype. Low-cost, semiquantitative pressure measurement solutions are not taken into account here, while they are discussed in (Orlin MN, McPoil TG, 2000). Each of the above sensing solutions will

¹A) The Italian National Institute of Health (ISS) hosts an on-line moodle-based Forum dedicated to PMDs at <http://vcms.iss.it/moodle19/>. Registration is free. Contact c_giacomozzi@yahoo.com for assistance. B) The international community of Foot and Ankle Biomechanics (i-FAB) hosts an on-line moodle-based Forum of the i-FAB Pedobarographic Group at <http://moodle.i-fab.org/>. Free registration is suggested. Contact c_giacomozzi@yahoo.com for assistance.

be briefly described here below, but a first important aspect -which is common to all PMDs with the only exception of optical technology- is **sensor size**. In fact, the smaller the sensor, the higher its sensitivity and its potential to accurately detect localized peak pressures – otherwise underestimated because averaged over the entire surface of a wider sensor. Conversely, the electrical noise of extremely small sensors may increase owing to the necessary greater amplification of the signal, and may thus interfere with sensor accuracy and repeatability. Besides this, the simultaneous electrical management of a very high number of sensors on the same sensor matrix at a high scanning rate might become a critical issue to cope with. For a proper detection of localized peak pressures under the human foot, a linear size of 2-3mm might be reasonable for a sensor, basing this estimation on location and dimension of the metatarsal heads and on the expected local pressure curve.

Brief description of current sensor technologies.

Optical devices

Obviously, they are only aimed at measuring pressures through platforms fixed to the measurement environment, thus this kind of technology is not usable for in-shoe assessment. A good example of an optical pedobarograph – namely the Sheffield pedobarograph – was first described in 1982 (Duckworth T et al, 1982). Basically, the pedobarograph is made of an illuminated glass plate covered with a plastic sheet. When the sheet is pressed on the glass, light scatters and generates a foot image which is captured by a camera at the bottom of the device, and then digitized. Pressure variations are thus measured by quantifying the variations of voltage level in the camera output, which are associated with the variations of intensity of the captured image. It is worth noting here that spatial resolution -further discussed in the following paragraphs as a critical PMD technical feature- is in this case extremely high. The relevance of the use of the optical device in Clinics was reported soon after (Duckworth T et al, 1985), and is still reported in the latest papers (Ramanathan AK et al, 2009).

Pneumatic discrete sensors

A hydrocell-based technology is used within the commercial in-shoe Parotec System. Unlike the optical technology, this one is only used for in-shoe pressure measurements under specific local foot areas. Basically, each sensor is made of a small volume of an incompressible fluid contained in a small polyurethane pack, integral with a microsensor placed just beneath it, and isolated by a thin dielectric foil. An interesting technical paper which analyses some aspects of the performance of the Parotec system was published in 2000 (Chesnin KJ et al, 2000). The paper reports the following relevant technical features: 24 sensors on each insole; pressure range up to 625kPa; pressure resolution 2.5kPa; good accuracy (2%FS); high precision (0.4%FS); negligible hysteresis and drift; very low temperature drift, humidity drift and non-linearity; insole height 3mm; sampling rate 100Hz.

Textile sensor

An interesting novel prototype of a fabric pressure sensor is described in Shu's 2010 paper (Shu L et al, 2010). In brief, each pressure sensor is obtained by fixing a conductive sensing fabric onto a conductive yarn and on a top-bottom conversion layer made of different silicon rubbers. The paper illustrates the main technical features of a prototype insole containing 6 sensors, suggesting it for sports and fitness assessment, i.e.: sampling rate 100Hz; pressure range 0-1000kPa; pressure resolution 1kPa; life-time > 100000 cycles; negligible temperature

and humidity effects; low cost. The height of the insole is not reported in the paper, which might be a relevant issue to be taken into account.

Resistive sensors

One of the two most widely used sensor technologies (the other being the capacitive technology briefly discussed soon after), which may be arranged under the form of arrays of discrete sensors, platforms, or in-shoe systems. Available commercial systems are delivered worldwide by the following Companies: Diagnostic Support (platforms), Imago (platforms), Loran (platforms and in-shoe systems), Medilogic (platforms), Rsscan (platforms), Tekscan (platforms and in-shoe systems), Vista Medical (platforms). There are other brands on the market, but the products are usually made by one of the above Companies. A common functioning principle of the different resistive sensors is that they rely on an electrical current flow whose intensity depends on the pressure exerted on the sensor surface. When the effective contact area of the sensor increases due to pressure, electrical conductivity increases as well, in a roughly linear fashion, within a certain range of pressure. In some cases the change of conductivity is due to a volume effect rather than a contact surface effect, and an elastic deformation takes place in the conductive material. In general, manufacturers have to deal with low-impedance sensors – hence the good performance with respect to noise immunity –, but with some drawbacks such as hysteresis, fast ageing, instability. A special type of resistive devices is also on the market, i.e. long platforms which only act as resistive “contacts” and which are addressed to the measurement of spatial and temporal parameters of gait. Even though some of them – as for example the GaitRite (www.gaitrite.com) – deliver some “pressure” levels rather than only an on-off answer, it is extremely important to keep in mind that they only represent a qualitative output, in no way appropriate for quantitative pressure analysis.

Capacitive sensors

Their functioning principle is the variation of capacitance induced by a variation of pressure exerted on the sensor surface. The different commercial products use two types of capacitive sensors:

- i. Platforms and in-shoe systems by Novel, and platforms by Zebris use elastomer-based capacitive sensors, thus exploiting the variation of thickness of an elastic dielectric material: the higher the pressure, the smaller the thickness and the higher the capacitance, according to a linear law. In general, manufacturers have to deal with greater difficulties than with resistive sensors to obtain fast measurements, and cope with high impedance, which may entail noise or interference. On the other hand, this kind of sensors show higher stability, lower hysteresis, higher resistance to the deteriorating effects of ageing.
- ii. Platforms by AMCube and Loran use air-based capacitive sensors also known as “touch mode” sensors: air separates the upper part of the capacitor from the lower part, which is covered by a thin dielectric sheet. The whole system is more rigid than with elastomer-based sensors, and usually the range of linear answer is smaller.
- iii. Capacitive technology is also used in the Biofoot in-shoe system by the Institute of Biomechanics of Valencia, Spain (IBV). The system was first described in 2008 (Martínez-Nova A et al, 2008). Its main technical features are: thickness insole 0.7mm; 64 capacitive sensors for each insole; lifetime 3000 steps; pressure range 0-1220kPa; calibration range 0-500kPa; pressure resolution 0.1kPa, measurement uncertainty 10% of calibration range; in-factory calibration; suggested re-calibration after two years. Unfortunately, no further details are available as for the sensor technology they use.

3.2 Basic concepts on PMD technical assessment

Technical assessment of PMD performance is desired, and worldwide claimed to verify appropriateness, reliability and comparability of pressure measurements. It becomes mandatory when such measurements are used for clinical purposes, since in this case the PMD is addressed as a medical device with measuring function, and must comply with specific market regulations. On the other hand, when used in a research or sports context, or if it is a prototype, the device may or may not be considered a medical device – the classification depending on the specific intended use –, but it must always remain safe for users (i.e. minimisation of electrical and mechanical risks, toxicity,...).

PMD performance should be fully characterised in-factory before the device is delivered, or in the research lab in case of prototypes. Owing to ageing effects, however, it is not sufficient to guarantee its appropriate use over time. Thus, the periodic, simplified checking of some technical features should also be implemented on-site, so as to early detect any deterioration of the device entailing the worsening of its measuring performance.

Pressure output of PMDs may significantly differ due to the above-discussed variability in pressure sensor technology, but also due to several equally important factors like the number and arrangement of sensors, the material used to cover, sustain and seal the sensors, the hardware and software used to supply or calibrate the sensors and to acquire data. Thus, PMDs technical performance should be assessed accounting for their final arrangement. In case of in-shoe systems, assessment is even more complex since the devices should also be tested under flexed but repeatable conditions, and with respect to surfaces with adequate elasticity so as to reproduce as much as possible their most frequent working conditions.

With respect to pressure platforms, they may essentially differ for size; thickness; material the mechanical frame is made from; individual sensor technology and performance; individual sensor size; spatial resolution; pressure resolution and range; sampling rate; hardware and software supply and data acquisition equipment. Almost the same holds for in-shoe systems, but for size which is almost always fixed, and for the material of mechanical frame – actually the cover material – which should have specific elastic characteristics and should be appropriate for sealing procedures.

A suitable testing equipment should perform equally well with different sensor technologies and different arrangements. Basically, it should be able to apply a well-controlled and uniform load/pressure over defined PMD areas for a given time period and, in case of dynamic loading, at a controlled and proper rate. Its precision and accuracy should be higher than those expected for the PMD.

The assessment should mainly investigate PMD response in terms of: pressure variability over the whole active area and for the whole pressure range; pressure accuracy; hysteresis; creep and answer stability over short as well as long periods – the latter being mandatory if the device is going to be used for posturographic purposes –; accuracy and repeatability of center of pressure (COP) estimation.

Testing procedures should be properly designed to assess PMDs intended for use in specific scenarios like running, jumping, sprinting, jogging.

More technical details can be found in two 2010 publications (Giacomozzi, 2010 a; Giacomozzi, 2010 b) and on the above on-line forums². Briefly, recommended features of testing equipment for pressure platforms to be used for gait analysis in Clinics (i.e. Medical

² <http://vcms.iss.it/moodle19/>; <http://moodle.i-fab.org/> (see note 1 for explanations)

PMDs) are, at minimum: pressure resolution below 10kPa; force resolution below 1N; spatial positioning re-positioning error lower than 2mm, and sinusoidal loading-unloading cycles applied with a frequency in the range 0.5-1.0Hz.

An example of in-factory testing equipment is widely described together with some suggested testing protocols in (Giacomozzi C, 2010 c): essentially it consists in a wide press machine for delivering pressure steps over the entire PMD surface, and a sensorized, ad hoc testing device which applies controlled static or varying pressure – through pneumatic valves and proper circuitry – as well as force over small active areas.

An example of testing equipment thought for on-site periodic checking is instead described and discussed in (Giacomozzi C, 2010 b). Basically, it consists in a light graduated round table placed on three small pylons, to be used with some weights and a positioning mask. When properly used, the testing device may help to periodically check the accuracy of COP estimation as well as local load and mean pressure under the pylons.

Specific for optical pedobarographs, instead, a very interesting testing equipment and methodology has been described in a 1997 paper with applications to the Sheffield optical pedobarograph (Franks CI, 1997).

4. Pressure measurement protocols and parameters

A wide variety of measurement protocols are currently implemented in the field of plantar pressure assessment, obviously according to the scenario and target of each investigation, e.g., the diagnosis of a pathologic condition, the outcome of a treatment, a patient's monitoring, a footwear/orthosis design and testing, the assessment of a sports performance, a specific study of applied biomechanical research, the identification of reference normative data, and so on. Similarly, there are plenty of pressure-related parameters which are currently considered relevant, some of them directly measured by means of PMDs, some other successively derived or estimated, and, again, the selection of parameters does depend on the final goal of each study. However, there is the need for the identification of some standardisation guidelines -at least to define a few basic parameters and measurement protocols to be taken as reference quantities and reference procedures so as to guarantee the comparability among studies. Moreover, if innovative parameters or measuring conditions were to be compared with some reference parameters and protocols, a better and more correct comprehension would be guaranteed, of new approaches to plantar pressure investigation. The following paragraphs briefly discuss relevant points for both issues.

4.1 Parameters: Traditional and novel ones

With respect to the entire plantar surface of the foot and to the way it is loaded during walking or standing, the following parameters are mostly used and known by the majority of researchers, clinicians and operators in the field:

Peak pressure: For each sensor, it is the highest pressure value experienced during the measurement. It is usually expressed in kPa, even though it is sometimes reported as PSI, N/cm², bar. Software applications associated to PMDs usually deliver a peak pressure map which contains the maximum pressure value reached by each sensor: this represents a spatial rather than a temporal map, since there is no association with the time frame each peak pressure occurs at. There is no confusion or misunderstanding on this parameter, the only doubt is associated with those devices which only deliver relative data rather than absolute values of pressure.

Mean pressure: For each sensor, it is the pressure value averaged over the measurement period. Measurement units are the same as for peak pressure. Two approaches may be followed to compute this parameter: averaging pressure over the entire measurement time period or only over the time period the specific sensor had been loaded, which may be much shorter than the entire duration of the test. Thus, in order to avoid interpretation mistakes, the computation algorithm should be clearly stated. Mean pressure output is usually delivered in the form of spatial maps.

Peak pressure curve (usually known as PPC): For the entire measurement surface, it represents the time process of the instantaneous maximum pressure value along the entire measurement period. In an x-y Cartesian graph, the horizontal axis x represents the time process expressed in absolute values (usually s or ms) or as percentage of the whole stance phase, while the y axis represents the instantaneous peak pressure expressed in absolute pressure units (kPa is recommended). Unlike the peak pressure map, this plot contains temporal information while it does not associate such information to the different areas of the plantar surface which instantaneously registers the highest pressure. PPC curve smoothing depends on PMD sampling rate and on eventual smoothing algorithms.

Force curve: Similarly to PPC, it represents the time evolution of the instantaneous value of the vertical component of the GRF. Absolute force values are expressed in N; for inter-subject comparisons, force is normalised to each subject's body weight, and thus expressed as %N or %b.w. This parameter is especially relevant for assessment issues, since the curve can be directly compared with the corresponding curve obtained with a standard force platform.

Pressure-time integral or impulse (usually indicated as PTI): It represents the area under PPC. If peak pressure is expressed in kPa, PTI should be expressed as kPa*s. Great differences might be found in the final PTI value due to the specific computation algorithm and to the PMD sampling rate, which must therefore be clearly stated. Just to explain the concept, if PTI is calculated as the sum of the products of instantaneous pressure by sampling interval, the final value will be much more accurate when using higher sampling rates.

Force-time integral or impulse (usually indicated as FTI): Similarly to PTI, this parameter is obtained by calculating the area under the force curve and is usually expressed as N*s or %N*s. As for PTI, computation procedures should be clearly stated.

Contact area: It is the instantaneous value of loaded PMD area. It is usually expressed in cm², and a curve similar to PPC is usually plotted to show contact area evolution along the measurement period. Differences in the estimated area are mainly due to PMD spatial resolution, sensor size and pressure threshold. Thus, proper information should be delivered together with this parameter.

COP trajectory: Represented by a two-dimensional array formed by the instantaneous COP coordinates, it is usually expressed in cm or PMD pixel units, for the whole measurement period. Again, differences may be found due to PMD spatial resolution, which must be clearly stated. A clear statement of the reference coordinate system used must be given too. In case of posturographic analyses, when parameters like COP sway or area or frequency content are of great interest, PMD sampling rate and frequency response may significantly affect the final COP values.

Besides the above parameters, other interesting indicators are used in specific pressure-related studies, as is for specific pressure gradients (Mueller MJ et al, 2008) or indicators

related to COP velocity or acceleration (Wang Y, Watanabe K, 2008). Novel computational approaches have been tried, validated and used in recent publications dealing with neural networks (Betker AL et al, 2005), fuzzy logics (Senanayake CM, Senanayake SM, 2010 a), cluster analysis (Giacomozzi C., Martelli F, 2006), finite element models (Shiang TY, 1997; Petre M et al, 2008; Gu YD et al, 2010; Chen WM et al, 2010), image processing techniques (Pataky TC et al, 2009; Oliveira FP, Tavares JM, 2010) and so on. Usually, the inputs of such models are represented by the above traditional parameters, their reliability strongly relying on the quality and reliability of raw data. For all these interesting new approaches, proper background knowledge and details should be delivered to readers and potential users so that they may deeply understand the meaning, clinical relevance and applicability, limitations, potential, and proper field of application of each new pressure-related parameter.

Proposals for innovative parameters: pressure-integral map, actual mean pressure map, loading time map.

Pressure-integral map: the computation of PTI as the area under PPC is a useful parameter, but it is not able to discriminate those areas of the plantar surface which undergo higher, prolonged and more dangerous loading, i.e., it does not contain spatial information. Moreover, it is associated with an ideal sensor which is loaded with the instantaneous maximum pressure for the entire measurement period: being this almost impossible in dynamic measurement, the final PTI value almost always represents an overestimation even with respect to the most “stressed” region of the foot (conversely, PTI values represent a good estimation of the true local impulse in the case of a regional analysis, as will be described in the following paragraph). The proposed Pressure-integral maps should rather request the calculation of the ‘local’ PTI for each activated sensor. As for peak pressure maps, pressure-integral maps would contain temporal besides spatial loading information and might indeed have a high clinical relevance.

Actual mean pressure map: while most of the current PMD softwares deliver mean pressure maps which result from averaging pressure values over the whole measurement period, the actual mean pressure map should contain values averaged only over the time frame of each sensor activation. This may render the map more helpful in detecting those areas loaded for a limited amount of time, but with a potentially dangerous mean load.

Loading time map: this is again an attempt to add temporal to spatial information on load distribution. In this case, a previous agreement is needed on the definition of a certain number and duration of contact phases. As a suggestion, the conventional contact phases might be used, i.e. initial contact and loading response (initial 16% of stance), midstance (successive 32% of stance), propulsion (successive 33% of stance) and push-off (remaining 19% of stance) (Vaughan CL et al, 1999). If different colours are associated with the different phases, and with the persistence of loading across several phases, a specific colour – and a specific numeric value – may be associated to each activated sensor on a spatial-temporal map.

4.2 Regional parameters: potentialities of different methodological approaches

Regional analysis of plantar pressure maps and parameters is commonly used, and most of the more recent publications do implement procedures and algorithms to identify specific regions of the plantar surface of the foot. Great potential should be recognised to regional analysis, since it allows to focus on specific areas of interest and to better quantify local alterations of biomechanical parameters. This is particularly important when the

effectiveness of a surgical or orthotic treatment has to be exactly quantified. However, what has been discussed in the previous paragraphs with respect to PMD variability of response, lack of standardisation and risk for misleading or missing comparisons, is here amplified, and even greater attention must be paid when designing, implementing and reporting plantar pressure investigations. The increased difficulties, in fact, are essentially due to the variability of the criteria for defining plantar regions, and to the percentual increased weight of computational errors related to smaller areas of interest. While the latter can only be minimised by better characterising PMD technical performance as already pointed out in previous paragraphs, it is interesting here to focus on the criticalities of the regionalisation procedures. Basically, two main approaches are currently followed to identify foot regions: one exploits the geometry of the footprint and the background knowledge of the anatomical structure of the foot; the other uses the information coming straight from the anatomy of the analysed foot.

Geometry-based approach: each and every selection method based on the acquired footprint does start from the longitudinal bisection of the footprint, which is usually computed from: i) the bisecting line of the foot; ii) the line going from the center of the heel to the second toe; iii) the midline of the rectangular box which contains the footprint. As a second step, the transversal selection of the main foot regions with respect to the longitudinal axis of the footprint is usually done by using lines which are perpendicular to it, and roughly located in correspondence with anatomical structures such as the Lisfranc or the Chopart line or the projection of the ankle joint axis, or structures that represent specific percentages of the footprint length. As a successive step in the regionalisation process, toes and individual metatarsal areas are identified on the basis of least square error algorithms, anatomically related assumptions, or other specific criteria. While, as already said, almost all 2010 published studies rely on regional analysis, none of them describe the way regions have been obtained. Sometimes, algorithms are known within a certain community, i.e. groups of researchers who are using the same commercial product. In any case, no procedure for footprint regionalisation has been “standardised” so far. Therefore, in order to avoid misleading conclusions it is mandatory that selection criteria are clearly described in the papers. With discrete sensors the regionalisation phase can be simplified, since they are indeed positioned under well-defined anatomical locations, thus variability in the final outcome of regional analysis will be mainly related to variability in sensor positioning.

Anatomy-based approach: this quite complex approach calls for the simultaneous use of a PMD and a kinematics measurement system to acquire instantaneous positions of foot anatomical landmarks, which are then projected onto the footprint and used for the anatomically-based region selection. This approach greatly improves the reliability of regional analysis in case footprints are not complete or strongly altered by the pathology. Dedicated algorithms must be designed and implemented to properly use the kinematic foot model, superimpose all the involved reference systems, and project the anatomical landmarks. Up to now, the anatomical masking approach has been applied to a prototype pressure platform and dedicated integration software by the Italian National Institute of Health together with a five-segment foot model by Istituti Ortopedici Rizzoli (Giacomozzi C et al, 2000; Stebbins JA et al, 2005), and to Novel platforms and dedicated integration software together with the Oxford Foot Model (Giacomozzi C et al, 2010). A further methodological study based on a Tekscan platform (Miller AL, 2010) only dealt with reference system integration issues.

4.3 Thoughts on protocols

Human walking and standing show intrinsic variability due to the high number of variables which play a role in the gait biomechanical model. In particular, the instantaneous pressure distribution obtained while interacting with the ground suffers from even greater variability due to fast local adjustments of the whole system while bearing and transferring load. The best approach to assess foot biomechanics through reliable and reproducible pressure measurements should therefore be based on the characterisation and control, as complete as possible, of measurement conditions. Here below a limited – certainly not exhaustive - list of concepts and suggestions is given, which should be taken into account to render investigations reliable and reproducible. Most concepts are equally applicable to both platforms and in-shoe systems when performing dynamic gait analysis; system-specific issues, and issues only related to posturographic analysis are identified separately.

- **Measurement environment:** environment conditions should always be controlled and described in order to render measurements reproducible. Any change introduced in a “standard” measurement environment should be well characterised and described: it may have relevant impact on pressure measurements. Barefoot gait analysis focussed on level walking is usually performed in a laboratory environment with good control of light, noise, temperature and humidity; the platform is inserted flush in a comfortable walking pattern, parallel and integral to the ground (patients should not be aware of the exact position of the platform); the walkway is large and long enough to guarantee the performance of a certain number of “at-regimen” steps. Walkways usually consist of quite rigid surfaces; wherever soft carpets are used, even though they do not cover the platform, it must be clearly stated in the study. It may happen that thin portable pressure platforms are placed over soft carpets rather than directly on the floor: this unstable installation should always be avoided and, in any case, it surely entails some alteration in platform performance. When in-shoe systems are used, the measurement scenario may be more varied, and must definitely be described as for: i) the environment itself (a laboratory context, a room or a place into a clinic, outdoors, ...); ii) the walkway (a level hard/soft surface, a slope, stairs, a treadmill, ...).
- **Number and kind of steps:** owing to gait variability, pressure parameters cannot be calculated over one step only; a certain number of steps are thus necessary to perform stable and reliable averages. A study published in 1996 showed that data averaged over 12 steps have quite an adequate standard deviation, which improved only slightly by increasing the number of steps (Macellari V, Giacomozzi C, 1996); however, this number of steps might be indeed too high to be obtained in a clinical context, especially with compromised patients. Five or six is the usual number of steps to obtain mean values of pressure quantities acquired through a platform; more steps are used in case of in-shoe systems, since they are acquired quite easily and the acquisition process is less time consuming. As for which step is to be included in the analysis, standardised approaches with pressure platforms commonly take into account the first, the second, or the third step: the three approaches may be valid, the choice mainly depending on the measurement environment and the main target of the investigation. With in-shoe systems, it is quite common to discard the initial and last steps and to average data over a fixed number of central steps (usually 5-10 steps for each foot).
- **Assessment tasks:** according to the target of the investigation, patients or volunteers are asked to perform specific locomotor tasks (posturographic tasks are briefly discussed as the last point of this list). With the only reference to platform-based gait

analysis during walking, some “requirements” of the measurement protocol are already worldwide agreed upon, i.e.: patients have to be tested barefoot, with arms moving freely along the body; they should become acquainted with the task before acquiring data; artefacts due to sudden noise, light or movements of people should be avoided; patients should look straight ahead, walk naturally and avoid looking at their feet; overtly altered trials must be discarded. As for walking speed, two main approaches are followed: i) the patient has to keep a fixed progression speed– usually with the help of a metronome –; ii) the patient walks at a self-selected speed. Changes in the measurement protocol should be clearly described, as is for example for purposely faster or slower walk, walk on treadmill, dual tasks such as cognitive, acoustic or visual tasks requested during walking. When an in-shoe system is used, changes from the above protocol are frequent: variation in progression speed, true and proper modification of the gait path – i.e. non straight paths, slopes, stairs, treadmill, etc.

- **Specific in-shoe system assessment requirements:** one of the most challenging targets of PMD measurement standardisation is the identification of a reference measurement protocol to be used with in-shoe systems. As a point of fact, these systems are only used in conjunction with an interface between the foot and the floor – i.e. the footwear – which not only modifies and interferes with pressure measurement from a technical point of view, but significantly alters gait as well. For both reasons it is not possible to use barefoot measurement as a reference: rather, it would be useful to standardise the footwear to be used for reference measurements. This is usually done in individual studies, i.e., each research group identifies and uses the measurement conditions and the footwear which are considered the most suitable in terms of feasibility, reproducibility, patient’s wearing and equipment burden, allowed gait pattern. Most common in-shoe reference measurements are performed while wearing special socks (with no shoes on), sandals, or a well defined type of sports shoes.
- **Posturographic assessment:** standard measurement protocols do exist even though they are usually implemented with force, rather than pressure, platforms. These protocols account for several aspects, i.e., foot position, patient’s position and behaviour, platform position and environment, task duration, etc. (Kapteyn TS et al, 1983). Any deviation from the standardised measurement conditions should thus be clearly described and motivated.

4.4 The role of pressure data processing

This issue is of special relevance in the field of plantar pressure measurements, being the third critical factor, together with PMD technical performance and measurement protocols, to be taken into account in the standardisation process. Several controversies are currently open in the scientific world as for the proper way to process pressure raw data. At the same time, the lack of relevant processing details in some PMD commercial softwares and in the scientific literature renders any description of the state of the art quite complex. The issue will be widely discussed in the i-FAB-PG in the next future, and the eventual agreement on standardised proposals will be shared with the scientific community. As for the discussion on the topic in the present document, the author is here only contributing with two very general, but basic, suggestions. The first is the strong recommendation to clearly describe each and every step of the data processing that takes from pressure raw data to derived parameters: this description is mandatory to render researchers aware of whether, and to what extent, some datasets may be compared with those extracted from their own studies.

The second is a suggestion to a proper selection and use of statistical analysis: in fact, most investigations strongly rely on parametric statistics, i.e., data are usually reported and analysed in terms of mean values and standard deviations. It is not infrequent, however, that the number of samples used and/or of experiments conducted in the study is too small to guarantee the normal distribution of the measured quantities, as is mandatory for a correct use of parametric statistics. In some cases non-parametric statistics are more suitable to describe and interpret datasets, and to infer on the relevance of differences among populations or treatments.

5. Conclusions

Plantar pressure measurements do have a great potential to support the study of foot biomechanics both in a research context and in the clinic. The literature overview reported hereby, even though it only focusses on the 2010 peer-reviewed publications indexed in PubMed, clearly shows that PMD measurements are increasingly used – alone or in conjunction with other kinetic/kinematic parameters – to deeply investigate clinical outcomes of surgical interventions, rehabilitation treatments, preventive actions, disease evolution, as well as to implement new biomechanical models or validate novel methodological approaches. Even though PMDs have been used for several years now, criticalities are still present, which still prevent the complete exploitation of all their potentialities. In the sequence from the design and construction of a PMD to its use on the field, such criticalities may be identified as: i) lack of standardisation of the procedures to assess and compare PMDs technical performance; ii) lack of comparability of measurement protocols; iii) lack of standardisation of the definition and use of data processing procedures. The scientific community is currently demonstrating increasing interest in the above issues. With respect to the first one, attempts towards consensus agreement have already been started in 2010 and are currently implemented within international scientific communities; basic concepts and preliminary recommendations have been described and discussed in the present document. As for the second issue, a short overview of the main measurement parameters and protocols has been reported, along with some suggestions to parameters which might be relevant and meaningful especially in the clinic. The last issue is still at a preliminary discussion phase, and only two basic suggestions have been briefly given in the document, which mainly point to the importance of a clear description of processing procedures and to the proper identification of statistical analysis tools.

Fast advances in technology as well as in computational mechanics are already showing new promising scenarios for the investigation of foot biomechanics, where pressure measurements might become more reliable and suitable (as might be the case with more flexible, wearable textile sensors), and successfully integrated with local friction and shear measurements -at the foot-floor or the foot-insole interface-, reliable low-cost kinematics systems, and 3D dynamic FE models.

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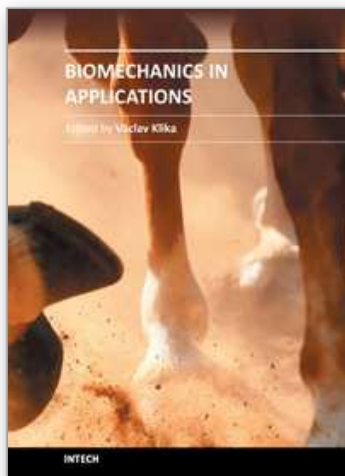
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During last couple of years there has been an increasing recognition that problems arising in biology or related to medicine really need a multidisciplinary approach. For this reason some special branches of both applied theoretical physics and mathematics have recently emerged such as biomechanics, mechanobiology, mathematical biology, biothermodynamics. The Biomechanics in Application is focusing on experimental praxis and clinical findings. The first section is devoted to Injury and clinical biomechanics including overview of the biomechanics of musculoskeletal injury, distraction osteogenesis in mandible, or consequences of drilling. The next section is on Spine biomechanics with biomechanical models for upper limb after spinal cord injury and an animal model looking at changes occurring as a consequence of spinal cord injury. Section Musculoskeletal Biomechanics includes the chapter which is devoted to dynamical stability of lumbo-pelvi-femoral complex which involves analysis of relationship among appropriate anatomical structures in this region. The fourth section is on Human and Animal Biomechanics with contributions from foot biomechanics and chewing rhythms in mammals, or adaptations of bats. The last section, Sport Biomechanics, is discussing various measurement techniques for assessment and analysis of movement and two applications in swimming.

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