Pilot study: Biomechanical Assessment of the Plantar Pressure Distribution in Healthy Subjects Using the Pressure Platform EcoWalk

Martha Zequera, Oscar Perdomo, Carlos Wilches and Pedro Vizcaya

***Abstract*— Plantar pressure provides useful information to assess the feet's condition. These systems have emerged as popular tools in clinical environment. These systems present errors and no compensation information is presented by the manufacturer, leading to uncertainty in the measurements. Ten healthy subjects, 5 females and 5 males, were recruited. Lateral load distribution, antero-posterior load distribution, average pressure, contact area, force, and peak pressures in 12 plantar regions were recorded. The aims of this study were to assess repeatability of the EcoWalk system and identify the range of pressure values observed in the normal foot. The coefficient of repeatability was less than 4\% for all parameters considered. The peak pressure was found to be repeatable when it was analyzed by region.**

***Index Term*— Pressure sensors, contact area, peak pressures, stability, repeatability.**

I. Introduction

DIABETES mellitus is a disease recognized as a growing global public health problem, considered such as an epidemic by the World Health Organization (WHO) [1]. Nowadays, 347 million people worldwide suffer from this disease. Predictions done by the WHO estimated that the number of diabetic patients will double in 2030 [1, 2]. A substantial increase in the prevalence of type 2 Diabetes has been identified. This group of subjects is at high risk of developing biomechanical alterations of the plantar pressure distribution which, coupled with other complications, including nephropathy, retinopathy, and neuropathy, can generate injuries, foot ulcerations and, if left untreated, leading to foot amputations [3].

The foot is one of the most unique and complex biomechanical structures in nature [4]. Plantar pressure measurements provide useful information to know the normal condition or identify disorders of feet support and load distribution for a suitable gait. The study of plantar pressure in diabetes may contribute to the early diagnosis of injuries that may end in amputation [5]. Several studies were performed on healthy subjects, looking for repeatability, parameters and mathematical relationship between subjects depending on age, size, weight, height and BMI [6-9]. Plantar pressure measurement systems have emerged as popular tools in clinical, ergonomics, and mainly in academic research. But its application is limited due to its high cost, and the lack of information about the reliability of their sensors.

Unfortunately, the commercially available measurement systems are objectionably sensitive to several disturbances, but this aspect is not reported factually in the literature. Some metrological performances of plantar pressure measurement systems showed the presence of bias and random errors (Manufacturer calibration: Pressure range: 50 - 500 kPa, measurement error: -0.6 - 2.7 %, magnitude of the 95% tolerance: 13.5 - 18.7 %; Calibration pressure inside estimated range: measurement error: 1.3 - 5.8 %, magnitude of the 95% tolerance: 1.1 - 14.8 %; Calibration pressure outside estimated range: measurement error: -26.3 - 33.9 %) without calibration information or schemes for error compensation by the manufacturer, which leads to uncertainties in the measurements [10].

EcoWalk system is a relatively new product among the platform pressure measuring devices. Repeatability is one of the elements which may define such dependability [11]. Clinical personal need good repeatability to ensure the best diagnose, basing their judgments on consistent measures [12]. Therefore, the different ranges of normal in-shoe pressure values between healthy and unhealthy people are needed to identify abnormalities.

The aims of this study are to assess the repeatability of the EcoWalk system and identify the range of pressure values observed in the normal foot, for its future contribution to the early diagnosis of biomechanical alterations in diabetic patients in clinical practice, and make a diagnosis more quantitative than qualitative, as is being done.

A methodology to process and compensate the inherent errors was developed, and the results, in normal subjects are presented, for a future study in diabetic patients. Plantar pressure parameters were analyzed: Lateral load distribution (LLD), antero-posterior load distribution (APLD), average pressure (AP), contact area (PA), peak pressures (PP) and force (F). The peak pressure was found to be repeatable when it was analyzed by region.

II. Description

A. Subjects

Ten healthy volunteers were chosen for this study (5 women and 5 men), aged 18 - 27 years and body mass index below 30 (Table I). Subjects were excluded if they presented musculoskeletal injuries or biomechanical alterations, which may affect measurements. Ethical approval was granted by the Ethics Committee for Medical Research of the San Ignacio Hospital. All subjects participating in the study signed a written informed consent.

TABLE I
PATIENT CHARACTERISTICS

	Age (years)	Weight (Kg)	Height (m)	BMI (Kg/m^2)
Mean	24.3	63.26	1.64	23.35
SD	3.43	10.23	0.09	2.92

B. Equipment

The measurement system consisted on 5 components: the pressure platform EcoWalk (Ecosanit, Anghiari, Arezzo, Italy), the software EcoFoot 4.0, a handrail, a reference frame, and digital weight scale.

The pressure platform EcoWalk is composed by 2304 resistive sensors, arranged in a matrix of 48 × 48 sensors (1 sensor/cm^2), and a sample rate of 30 Hz. EcoFoot 4.0 software was used to measure: lateral load distribution (LLD), anteroposterior load distribution (APLD), average pressure (AP), contact area (PA), force (F), and peak pressures (PP).

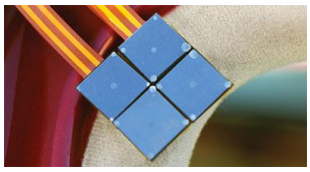

Fig. 1. Force sensing array.

The handrail was given to help the subjects to keep their balance during the measurement, but without affecting the pressure measured. The purpose of the reference frame is to maintain the feet in an anatomical position during measurements, with a foot stance angle of 19, relative to the longitudinal axis (Figure 2). Previous studies revealed that a reference frame allows greater repeatability of pressure measurements [13].

C. Protocol

For recruitment, a doctor performed a comprehensive physical exam of the participants, assessing the state of their feet, and selecting those who didn't present musculoskeletal injuries or biomechanical alterations. The subjects approved were asked to be barefoot, with their pockets empty, jewelry and watches removed, and wearing comfortable clothes, in order to avoid changes in the measurement.

Each subject was measured 30 times with a technique for controlling the position of their feet, using the reference frame. The technique consisted on positioning the feet using the

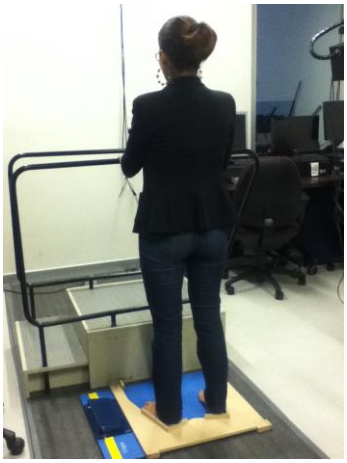

Fig. 2. Subject on the pressure platform.

frame, and removing it before measuring the plantar pressure, to avoid noise caused by the presence of the frame on the platform.

The measurement process was supervised by the research group staff, who guided the accommodation of the feet of the subject and body position.

D. Data Measured

The pressure platform EcoWalk measures plantar pressure distribution, capturing the pressure at each sensor for calculating the different parameters. LLD indicates the percentage of load on each foot; APLD is percentage of load in rearfoot and forefoot; AP is the average pressure on each foot; CA are the count of all sensors activated on each foot, since the sensor area is 1 cm^2; F is the force calculated from the sum of pressures on each sensor on each foot (1).

$$F = \sum P_{sensor} \cdot CA \quad (1)$$

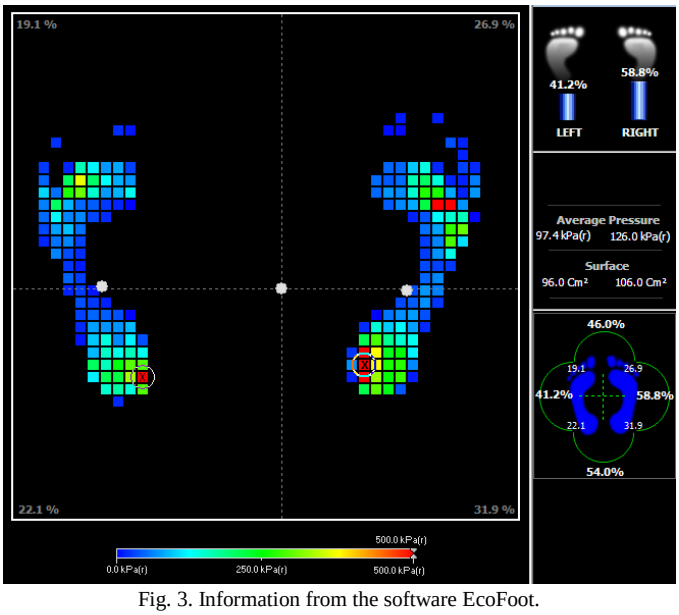

Fig. 3. Information from the software EcoFoot.

For the measuring of PP, the maximum pressure value, it was considered to use a regional analysis rather than a global analysis, because the global PP of the foot is highly variable

between measurements. For the regional segmentation, it was used a mask of 12 regions, based on the division developed by Periyasamy [14] and expanded to consider the 5 metatarsal heads.

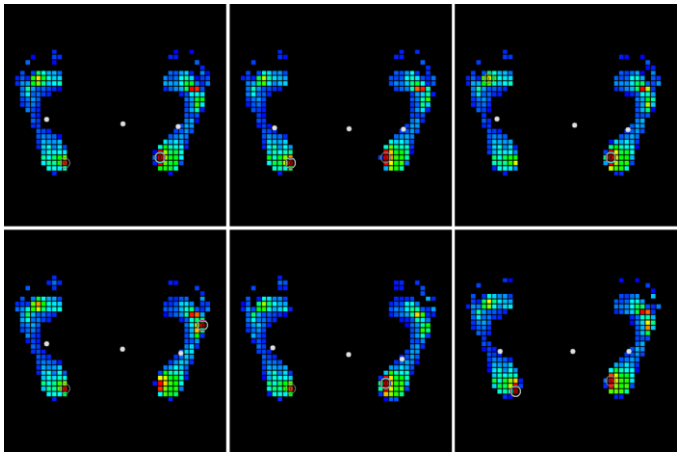

Fig. 4. Pressure distribution of one subject - variation of peak pressure between measurements, in the fifth metatarsal head.

The 12 regions analyzed were: heel (H1 and H2), midfoot (M3 and M4), forefoot (MTH5 - MTH9), first toe (T10), second toe (T11), and lesser toes (T12) (Figure 5).

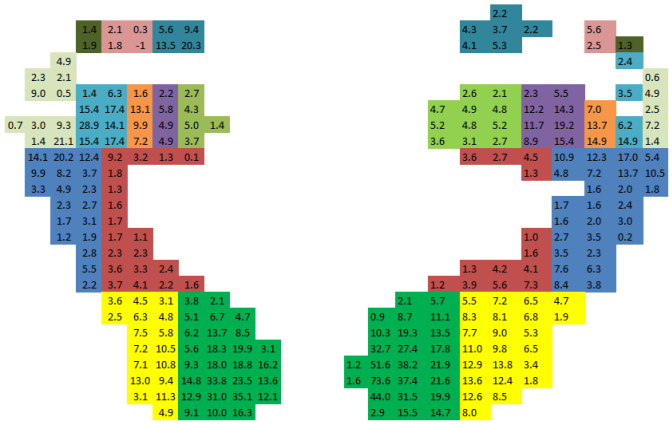

Fig. 5. Division of foot into 12 regions of interest after processing the plantar pressure data.

E. Data Processing

After measuring the 10 subjects, each measurement (300 measurements in total) was processed to calculate CA, F and PP; while LLD, APLD and AP were given by the software. On each variable, a statistical analysis was carried out in order to assess its performance and those with lower variability within-subjects were selected. These variables are the main parameters in order to choose the most significant measurements from each subject.

F. Statistical Analysis

A statistical analysis was performed using the software SPSS, in which mean, median, mode, variance and standard deviation (SD) were obtained, with independent variables being gender, foot, and position (anterior or posterior).

For PP, the statistical analysis was carried out in order to obtain mean and standard deviation in ten subjects and for each plantar region.

III. Results

The set of signals obtained during the study in ten healthy subjects were analyzed using parametric statistical and nonparametric methods with MATLAB software. A significant difference was found within-subject comparison between different parameters under study.

The statistical analysis showed a significant response between subjects with different gender and type of foot analyzed, which is an expected response according to the literature.

The results of mean, standard deviation (SD) and variance, for the lateral load distribution are presented in table II. The SD and variance are the same for both feet because the percentage of distribution for one foot is: $\%LLD_L$ = 100%-%LLDR. This parameter presented a low SD between measurements within-subjects.

TABLE II
RESULTS OF LATERAL DISTRIBUTION

Subjects		Load Left foot (%)	Load Right foot (%)
1	Mean	50.89462	49.10538
	SD	1.61847	1.61847
	Varianza	2.619	2.619
2	Mean	48.23865	51.76135
	SD	2.16097	2.16097
	Varianza	4.67	4.67
3	Mean	48.2085	51.79151
	SD	2.66356	2.66356
	Varianza	7.095	7.095
4	Mean	41.89974	58.10027
	SD	1.33445	1.33445
	Varianza	1.781	1.781
5	Mean	45.39824	54.60176
	SD	2.21186	2.21186
	Varianza	4.892	4.892
6	Mean	41.50172	58.49829
	SD	2.45575	2.45575
	Varianza	6.031	6.031
7	Mean	45.8069	54.1931
	SD	2.30707	2.30707
	Varianza	5.323	5.323
8	Mean	43.53253	56.46747
	SD	2.2667	2.2667
	Varianza	5.138	5.138
9	Mean	45.25661	54.74339
	SD	2.58929	2.58929
	Varianza	6.704	6.704
10	Mean	47.52509	52.47491
	SD	1.67684	1.67684
	Varianza	2.812	2.812
Total	Mean	45.82626	54.17374
	SD	3.54785	3.54785
	Varianza	12.587	12.587

In Figure 6 is shown F in the ten subjects studied, the values presented an abnormal distribution in within-subject and between-subject. A larger variance and a tendency to a non-

normal data, it can be modeled and represented such as a skewed distribution.

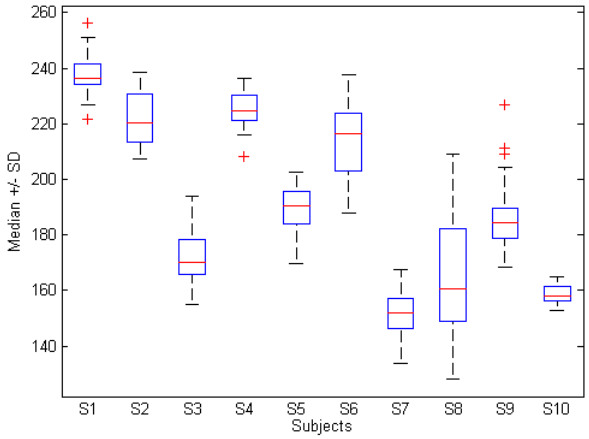

Fig. 6. Subjects vs Force.

In Figure 7 is shown CA in the ten subjects. It was observed that there is less variance, which leads to a more consistent data within a smaller range. Statistical tests showed that the distribution was normal because the mean, median and mode were approximately equal.

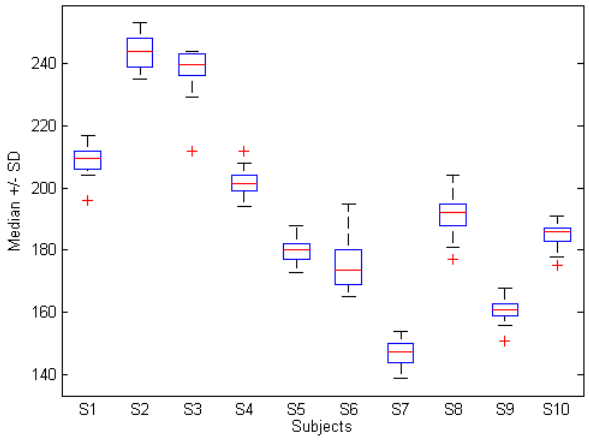

Fig. 7. Subjects vs Contact Area.

For PP, figure 8 presents the mean and standard deviation of the peaks in each region for one subject. And in figure 9 is shown the mean and standard deviation of the peaks for the ten subjects in the region Forefoot5 (MTH5).

IV. Discussion

The process of region segmentation (Figure 5) was not the best due to sensor size, shape and foot position. Although the regions were segmented based on foot anthropometry, they had to be adapted to the geometry of the pressure distribution.

The repeatability of the EcoWalk system was assessed in ten healthy subjects. It was identified the range of pressure values and contact area for different age, foot size, weight, height and BMI. The coefficient of repeatability (CR) for the contact area parameter was less than 4% for all the ten subjects.

Lateral load distribution presented a low SD, showing that the reference frame is effective for controlling foot position and reducing instability of the subjects. This is important in

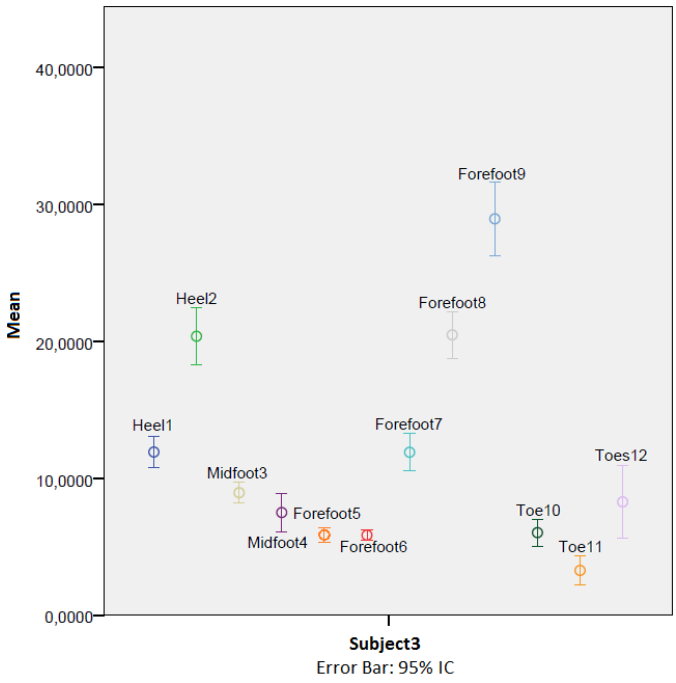

Fig. 8. Peak pressures in 12 regions of interest for one subject, for left foot.

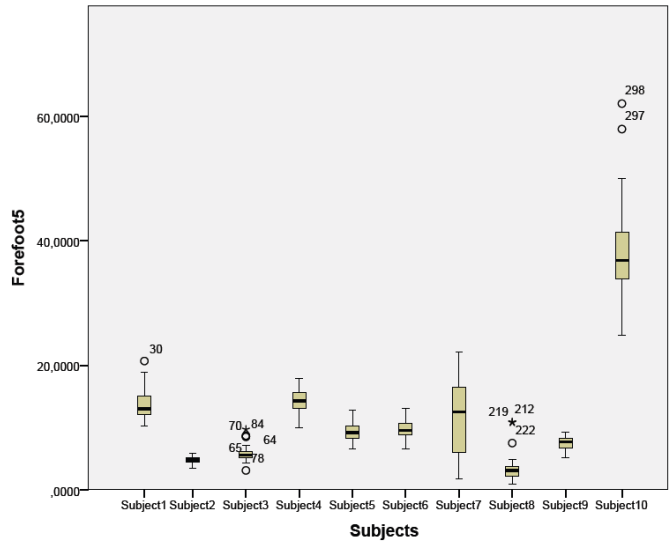

Fig. 9. Peak pressures for 10 subjects in the region Forefoot5, for left foot. ★,○: atypical data.

order to obtain low variation between measurements within-subjects.

For peak pressure in one subject (Figure 8), the region T12 presented a high SD, because not in all measurements the platform measured pressure in the lesser toes. For the region MTH9, located below region T12, presented high SD, due to variations in the area assigned to this region by the segmentation algorithm. This change caused that in some measurements the peak was in this region and in other measures in the adjacent region (MTH8). The lower SD values were in regions H1, M3, MTH5 and MTH6, which are important regions for stance support of the subject.

In figure 9, the peak pressures for 10 subjects are presented, measured in the region MTH5 as one of the main regions for

support. For this area, subjects presented low mean and SD values, except for subjects 7 and 10, which they had unidentified biomechanical alterations, which caused the anomalous results.

According to [6]–[8], the repeatability can be estimated through mathematical and statistical analysis of the parameters involved in the measurements of the pressure plantar system. The contact area and peak pressure can be relevant parameters for objectively choosing the most representative sample in a set of measurements.

The need of a metrological performance of the available measurement systems by manufactures have to be reported. The presence of bias and random errors with an appropriate calibration information or schemes for error compensation, lead to a comprehensively knowledge of the uncertainty allowing accuracy in the measurements.

It's necessary to increase the number of subjects in future studies, to ensure statistical validation, in healthy subjects and patients with diabetic foot in the first stages of the pathology, for a future implementation of this methodology in a clinic environment.

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