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Assessment of the effect of time in the repeatability of the stabilometric parameters in diabetic and non-diabetic subjects during bipedal standing using the LorAn pressure distribution measurement system

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Abstract—**This study was designed to assess the effect of time on the repeatability of the LorAn pressure distribution measurement system, and evaluate the variability of plantar pressure and postural balance, during barefoot standing in diabetic and non-diabetic subjects, for future diabetic foot clinical evaluation. Fourteen subjects were evaluated (8 females, 6 males, 8 non-diabetics and 6 diabetics, age range 30-70 years) and had no musculoskeletal symptoms. Four variables were measured with the platform in the barefoot standing position. Ten measurements were taken using two different techniques for feet and posture positioning, during three sessions, once a week. The MANOVA test confirmed that the platform measurements are reproducible for variables body baricenter (x) and foot baricenter (x) through time, being the coefficients of variation, with a 99% confidence interval, lower than 1.6% for body baricenter (x), and lower than 2.06% for foot baricenter (x), for all studied conditions. For the remaining variables, the results were not stabilized through time, which makes necessary to standardize the measurement protocol that guarantees the repeatability in all variables.**

Keywords: diabetic foot, plantar pressure, postural balance, statistical significance.

I. INTRODUCTION

DIABETES Mellitus consists of a metabolic disorder characterized by multiple chronic complications, and can affect almost every system in the human body [1]. This disease is considered a major public health problem and its prevalence is still increasing worldwide [2]. Diabetic foot is one of the most frequent and severe chronic complications in Diabetes [3]. Multiple factors have been related to ulcer development in these patients, such as peripheral vascular disease, peripheral neuropathy, poor glycaemic control and biomechanical factors [1]. Abnormal pressure patterns can contribute to develop plantar ulceration secondary to peripheral neuropathy. Many studies have been made to determine pressure measurements under different conditions to identify vulnerable areas of the foot and possible orthotic solutions, but the factors which determine these patterns aren't well known, yet [4]-[6]. There are dynamic studies of the foot using in-sole systems [7], as well as barefoot evaluations during walking [4] and static evaluations, using stabilometric platforms [8], in some cases considering dominant and non-dominant leg [9].

The objective of this study is to demonstrate that measurements, in diabetic and non-diabetic subjects, with the LorAn pressure distribution measurement system, and using two techniques, are repeatable along time.

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II. MATERIALS AND METHODS

This study was carried out for assessing the effect of time on the repeatability of the LorAn pressure distribution measurement system and for evaluating the plantar pressure and postural balance variability during barefoot standing position, in diabetic and non-diabetic subjects. Fourteen volunteers (8 females and 6 males, 8 non-diabetics and 6 diabetics) were selected, according to the following criteria: (a) age range: 30-70 years, and (b) with a body mass index inferior to 33. Diabetic subjects were included only if they were on Wagner's grade 0.

Those subjects who experienced osteomuscular injuries, obesity, peripheral neuropathy, vasculopathy or other systemic pathological conditions affecting lower extremities such as multiple sclerosis or intervertebral disc disorders, which could alter the measurements, were excluded. An Informed Consent Form was signed by all subjects, at the time of testing, and approval was obtained from the local Medical Research Ethics Committee.

The measurement system configuration, shown in Fig. 1, was installed at the Department of Electronics of the Pontificia Universidad Javeriana (Bogotá, Colombia). A pressure distribution platform (LorAn Engineering S.R.L., Italy) with a matrix of 48 x 48 resistive sensors and a sampling frequency of 30Hz, using the software *Footchecker 4.0*, was used to collect the percentages of Anterior-Posterior Load Distribution (APLD), Lateral Load Distribution (LLD), Average Pressure (AP), Body Baricenter (BB), Foot Baricenters (FB) during barefoot standing.

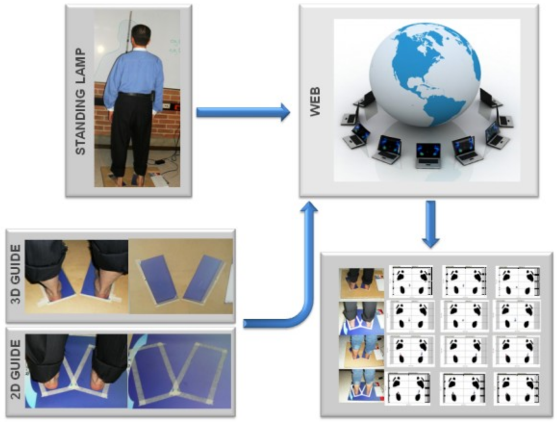


Fig. 1. The study was developing by using the 2D and 3D guides to control foot and body position during the study. A Network system configuration of the pressure measurement system will be implemented in the future through cloud computing.

Two different techniques were used for feet positioning during the test sessions, and a standing lamp was incorporated to draw their silhouettes in front of them in order to control lateral body position. The first method consisted of a 3D wooden frame placed on the platform to control foot and body position, following the anatomical position. The second method consisted of a 2D guide drawn on the platform, following the same geometry of the 3D guide. At the beginning of every session, a calibration procedure was performed by recording reference points using the 3D guide.

A medical doctor examined the subjects, focusing on their feet, before taking the pressure measurements. Subjects were asked to be barefoot, without objects in their pockets and wearing comfortable clothes, in order to prevent inaccurate measurements. Three sessions, held once a week, were carried out at the same time and place for each subject.

Subjects received instructions on how to stand on the platform and proceeded with their first attempt, controlling the position of the feet with both guides. Subjects were required to get on and off the platform at each measurement.

Ten measurements were taken in every session, using the 3D guide. During these ten measurements a research assistant observed and guided subjects, regarding body and feet positions. The same procedure was then followed with the 2D guide. A total of twenty measurements were taken with each subject, in every session.

A MANOVA analysis (Multivariate Analysis of Variance) was carried out with repeated measurements of averages and coefficients of variation for 10 measurements of each one of the seven dependent variables. The foot and the session were considered independent variables within-subjects; the subject's condition, the use of the guide, and measurement position were considered independent variables between-subjects. Only the second level interactions were considered, which led to considering interactions up to the fourth level, when combining between-subjects and within-subjects.

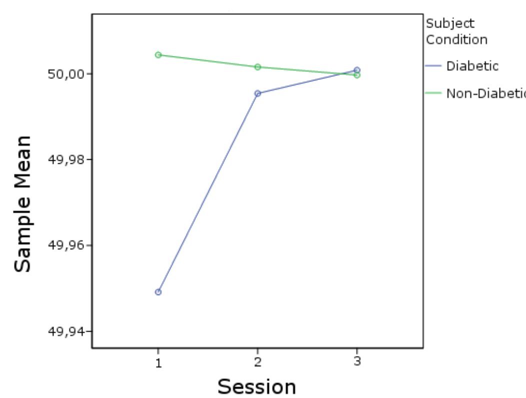
III. Results

Table 1 shows the Wilk's Lambda value, the F approximation and the *p value* of the MANOVA obtained, for averages and coefficients of variation, regarding their relationship with time, and the results for each individual variable for the univariated effects tests within-subjects and between-subjects. The individual tests are corrected using the Huynh-Feldt method, since sphericity was not verified for all the dependent variables. Using α *level* = 1%, significant values are marked in boldface.

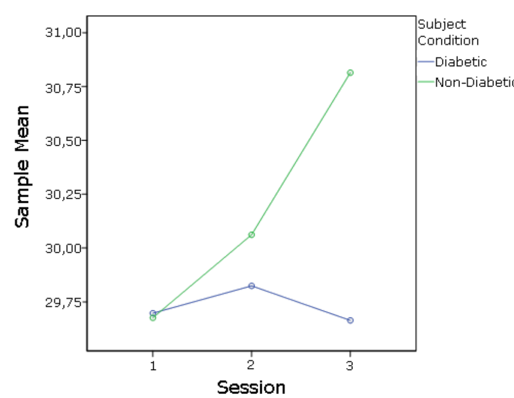
In order to guarantee the reproducibility, it was necessary for the averages to be equal under every condition of the subject through time, regardless of the type of guide used, and for the coefficients of variation to be equal for both guides, or lower for the 3D guide along time.

As shown in Table 1, only variables BBx and FBx has similar averages through time with the use of 2D or 3D guide and position (anterior or posterior foot position), so their measure is robust and only varies due to the subject conditions (presence of diabetes or foot used). In the other variables there are significant effects of time. This effect of the session requires a more detailed analysis.

Fig. 2 presents the effect in variables LLD and AP in which diabetic subjects are reaching to non-diabetic subjects; in contrast, for variables BBy and FBy the two conditions start at the same value, but non-diabetic subjects increase, getting apart from the diabetic subjects.



(a)



(b)

Fig. 2. MANOVA analysis and univariate effects test for averages (a) in LLD. (b) in BBy.

TABLE I
RESULTS OF THE MANOVA ANALYSIS AND THE UNIVARIATE EFFECTS TESTS

MANOVA Test	Variable	MANOVA			Univariate Effects Tests						
		Wilk's Lambda	F value	p - value	APLD	LLD	AP	BBx	BBy	FBx	FBy
Averages	Ss	0,81	10,70	**<0,01**	1,00	0,02	**<0,01**	0,76	**<0,01**	0,09	**<0,01**
	Ss * N-D	0,84	13,04	**<0,01**	1,00	**<0,01**	**<0,01**	0,01	**<0,01**	0,59	**<0,01**
	Ss * N-D * pos	0,60	3,86	**<0,01**	**<0,01**	1,00	1,00	1,00	1,00	1,00	1,00
	Ss * N-D * tech	0,56	3,32	**<0,01**	1,00	0,02	0,81	0,73	0,72	0,62	0,68
	Ss * ft	0,49	3,91	**<0,01**	0,86	0,78	0,04	N/A	N/A	0,03	0,53
	Ss * ft * N-D	0,58	5,57	**<0,01**	0,02	**<0,01**	**<0,01**	N/A	N/A	0,38	**<0,01**
	Ss * ft * N-D * pos	0,31	1,80	0,09	0,01	1,00	1,00	N/A	N/A	1,00	1,00
	Ss * ft * N-D * tech	0,16	0,79	0,64	0,83	0,72	0,49	N/A	N/A	0,39	0,71
	Ss * ft * pos	0,01	0,04	1,00	0,92	1,00	1,00	N/A	N/A	1,00	1,00
	Ss * ft * tech	0,30	1,75	0,10	0,51	0,31	0,76	N/A	N/A	0,24	0,03
	Ss * ft * tech * pos	0,06	0,27	0,98	0,51	1,00	1,00	N/A	N/A	1,00	1,00
	Ss * pos	0,50	2,59	0,01	**<0,01**	1,00	1,00	1,00	1,00	1,00	1,00
	Ss * tech	0,52	2,81	**<0,01**	1,00	**<0,01**	0,05	0,57	0,13	0,65	0,17
	Ss * tech * pos	0,01	0,03	1,00	0,71	1,00	1,00	1,00	1,00	1,00	1,00
Coefficients of Variation	Ss	0,18	11,72	**<0,01**	0,26	**<0,01**	**<0,01**	**<0,01**	0,05	0,24	0,07
	Ss * N-D	0,21	9,84	**<0,01**	**<0,01**	0,48	0,25	0,05	0,01	0,05	**<0,01**
	Ss * N-D * pos	0,89	0,31	0,99	0,43	1,00	1,00	1,00	1,00	1,00	1,00
	Ss * N-D * tech	0,70	1,10	0,39	0,57	0,97	0,10	0,59	0,25	0,16	0,15
	Ss * ft	0,67	1,97	0,06	0,05	0,14	0,11	N/A	N/A	0,15	0,13
	Ss * ft * N-D	0,49	4,21	**<0,01**	0,03	**<0,01**	0,10	N/A	N/A	0,17	0,09
	Ss * ft * N-D * pos	0,93	0,31	0,97	0,44	1,00	1,00	N/A	N/A	1,00	1,00
	Ss * ft * N-D * tech	0,47	4,54	**<0,01**	0,05	0,03	**<0,01**	N/A	N/A	0,07	0,10
	Ss * ft * pos	1,00	0,00	1,00	1,00	1,00	1,00	N/A	N/A	1,00	1,00
	Ss * ft * tech	0,43	5,31	**<0,01**	0,38	**<0,01**	0,14	N/A	N/A	0,10	0,08
	Ss * ft * tech * pos	0,89	0,51	0,88	0,26	1,00	1,00	N/A	N/A	1,00	1,00
	Ss * pos	0,91	0,26	1,00	0,60	1,00	1,00	1,00	1,00	1,00	1,00
	Ss * tech	0,56	2,01	0,05	0,61	0,66	0,15	0,71	0,31	0,11	0,22
	Ss * tech * pos	0,99	0,03	1,00	0,90	1,00	1,00	1,00	1,00	1,00	1,00

Session (Ss), subject condition: diabetic – non-diabetic (N-D), Position: Anterior - Posterior (pos), Use of guide (tech), Foot (ft).

Variable APLD presents a nonlinear mix effect with time.

In Table 1, coefficients of variation are also shown, where is possible to observe that the effect of sessions is noteworthy. Session had a significant effect in 5 of 7 variables, alone or in interaction.

In variables LLD and BBx, the coefficient of variation decreased with session. In variable LLD a triple interaction with session is also shown, in which the left foot of the diabetic group decreased their coefficient of variation more quickly.

In Fig. 3 is shown that variable APLD does not present a main effect with the session, but has interactions: non-diabetic subjects decreased their coefficient of variation along time, while diabetic subjects increased it, reaching the initial value of non-diabetics.

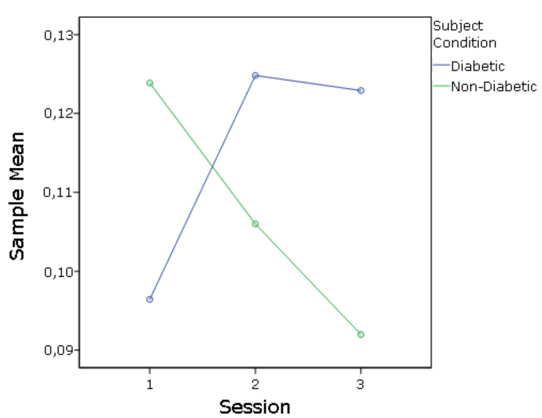


Fig. 3. MANOVA analysis and univariate effects test for coefficient of variation in APLD.

In variable FBy, non-diabetic subjects kept low their coefficient of variation through sessions, while diabetics presented an inverse U-shape result.

IV. DISCUSSION

The variables BBx and FBx presented low coefficients of variation, showing that the method used for lateral body position control was effective.

For variables LLD and AP, the results were equaling over time, as the sessions were developing, leading to the conclusion that subjects were adapting to the guides, manifesting what is known as a *learning curve*.

Table 1 reviews significant differences in averages and coefficients of variation due to session, in particular in interaction with diabetic condition. Variables APLD, BBy and FBy present behaviors in which the lack of antero-posterior postural control is manifested, indicating that the methodology needs to be refined.

In Table 1, other effects are evidenced related with the subject's conditions and the foot. Even though these are not part of this article's objective, it is important to emphasize that there are relevant differences in the average and coefficient of variation due to the particular foot used, which support the need for a better methodology.

V. Conclusion

With the obtained results using the guides, the measurements with the platform are repeatable for variables BBx and FBx over time.

In variables LLD, AP, APLD, BBy and FBy are not repeatable due to the effect of the lack of antero-posterior postural control, indicating that the methodology used needs to be refined in future studies.

For future works, a larger sample size should be used in order to completely demonstrate the repeatability, along with more repetitions, in controlled conditions, with more sessions for taking measurements and a more rigorous protocol.

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