

# Plantar pressure repeatability data analysis for healthy adult based on EMED system

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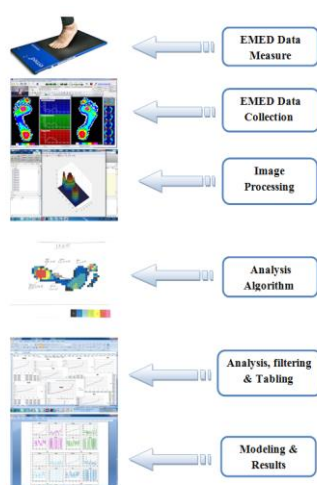
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## Graphical abstract



## Abstract

This paper presents the repeatability data analyses and discusses the selection of the appropriate type of plantar pressure measurements for the EMED system with regards to pressure level values (PLV) over the touch insole area of healthy adults. In this research, a participant with age 28 years old has been chosen as a sample to measure under foot pressure, it is conducted the test 20 times and took part in four types of plantar pressure clinical assessments, dynamic (normal walking), dynamic with load (normal walking, carrying 1.5 kg), static (standing test), and static with load (standing, carrying 1.5 kg). The analysis is implemented using a new approach of recognizing the measurements into 7 different levels of pressure that assigned with 7 colors by considering the image processing algorithm. variance coefficient (VC) check is adopted for the statistical analysis and the selection decision. The results highlighted that the overall pressure levels in dynamic with load category have a better variance as compared with three other categories of plantar pressure on this type of repeatability test. In conclusion, EMED system can be considered as an effective instrument to record plantar foot pressure measurements in such type of analysis.

**Keywords:** Plantar pressure system, EMED, repeatability, variance coefficient

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## INTRODUCTION

Plantar pressure measurements are commonly used in clinical assessments of walking or running function activities of human foot and also in the diagnosis of some diseases such as diabetes (Rosenbaum and Becker 1997), (Deutsch et al. 2008). Some studies have proven that such measurements are useful to identify foot pathology as in (Maetzler, Bochdansky, and Abboud 2010), (De Cock et al. 2006), (Ramanathan et al. 2008), (Vela et al. 1998). During the gait, plantar pressure analysis has interested knowledge on foot deformity and foot loading in diabetic neuropathy (Gurney et al. 2013). Plantar pressure measurement device, EMED system, appears to be capable to collect different parameters such as; peak pressure, mean pressure, and pressure-time integral in adults and podiatric management (Randolph et al. 2000). Currently, no indication exists with regards to the repeatability of the measurements of EMED system to recognize the four types of plantar pressure clinical assessments, dynamic (normal walking), dynamic with load, static (standing test), and static with load. The findings of this paper can support the application of modern insole pressure technologies for future foot diagnosis and gait analysis and to clearly identify foot biomechanical issues. To provide a detailed description on the findings, the paper demonstrates the procedure that

conducted on one subject, which we experimentally found that can be applied same for others.

The accuracy can be defined as the variation between the values of a measurement and the values of a known quantity via a testing process of that instrument (Hsiao, Guan, and Weatherly 2002; Hurkmans et al. 2006). Not only before using a new device, but also when it is intended to conduct new experiment, a validation for the measurements is required about the instruments to determine the repeatability and accuracy of the system (Bland and Altman 2010). The validation process of the measurements for an instrument is also referred as "validity" (Firth et al. 2007; Woodburn and Helliwell 1996). For the gait analysis aspect, calibration benches or systems adopted as a standard tool that are utilized to determine the accurate value or evaluation the measurements of the instrument. Repeatability is another very important feature for an instrument especially for that used in healthy areas, and can be defined as the difference between two or more measurements conducted through the same instrument under the same testing conditions (Hurkmans et al. 2006; Putti et al. 2007; Vidmar and Novak 2009). For the studies, in gait measurement error, usually the authors have also used the "reliability" term to refer for this type of measurement feature (Firth et al. 2007; Kernozek, Lamott, and Dancisak 1996; Low and Dixon 2010; Murphy et al. 2005).

Repeatability and Reliability have been used arbitrarily (Kernozek et al. 1996; Martínez-Nova et al. 2007; Vidmar and Novak 2009).

EMED is a user-friendly device designed for in-shoe monitoring and long-term storage of plantar pressure and spatial-temporal parameters during locomotion, such as gait speed, distance traveled, and stride length and frequency, without the need for a standardized calibration and the constraints of a laboratory setup. One preliminary study (Healy et al. 2012) has already explored the repeatability of the plantar pressures recorded by the EMED. The system was found to be as repeatable as other plantar pressure measurement systems (i.e., F-scan and Pedar). However, the authors assessed only three subjects and no statistical procedure was performed. The authors (Healy et al. 2012) highlighted the need for further investigations to truly understand how accurate and repeatable the plantar pressures measured by EMED are. Another preliminary study assessed the spatial-temporal parameters of the WalkinSense (Castro et al. 2011) at a small sample of 15 participants and found good accuracy and repeatability for these parameters.

In a repeatability study, variability in measurements made on the same subject can be ascribed only to errors in the measurement process itself. When gait analysis devices are assessed, the repeatability between stance phases (within-trial repeatability), between trials (between-trial repeatability), and between days (between-day repeatability) is commonly analyzed. One of the in-shoe plantar pressure devices most frequently used by clinicians and researchers is the Pedar in-shoe system (Novel GmbH, Munich, Germany). This system has been demonstrated to be accurate (Hsiao et al. 2002) and has shown excellent between-trial (Ramanathan et al. 2010) and between-day (Kernozek et al. 1996; Murphy et al. 2005) repeatability. The knowledge of such device attributes (accuracy and repeatability) is of utmost importance before using it in clinical contexts.

In short analysis, not many researches addresses the accuracy and the tools to achieve that, especially on the plantar pressures analyzer (EMED), also, it is not clear how many times we need for the reading to consider. The acquisition of these plantar parameters is affected by some of technical and theoretical parameters. A summary of noteworthy contributions of plantar pressure repeatability test for healthy persons can be seen in Appendix A. Therefore, a lack of information becomes a barrier for adopting this configuration for the instrument in research and clinical contexts. Thus, the aim of this work is to indicate the suitable one among four categories include; Dynamic (normal walking), Dynamic with load (normal walking, carrying 1.5 Kg), Static (Standing test), and Static with load (Standing, carrying 1.5 Kg). This evaluation is assessed according to the repeatability test that performed by the EMED system. The values stored by EMED measuring typical gait in an adult population are also presented. We hypothesized that the plantar pressure parameters recorded by EMED would be accurate and repeatable for such analysis.

**MATERIALS AND METHOD**

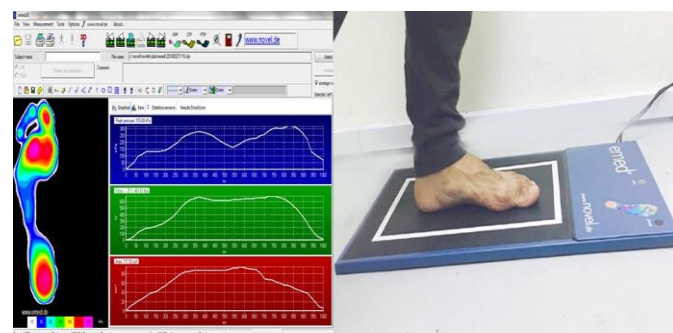


Fig.1. Experimental setup during the test.

Twenty-eight years old healthy young man participant, his body mass is 64 kg, was recruited. The subject had no history of neurological diseases, and was free from foot or ankle pathology. The participant was tested four times within 2 hours day interval. In the four sessions,

the subject carried out the four different conditions; dynamic (normal walking), dynamic with load (normal walking, carrying 1.5 kg), static (standing test), and static with load (standing, carrying 1.5kg). The EMED system was completely arranged according to the instructions provided by EMED manufacturer (Graf 1993). (Graf 1993). Fig. 1. shows the measurements set up.

**Data analysis**

The repeatability has been defined as the ability of an instrument for measuring same values for the repeated measures over the same conditions of a particular experimental which indicating the same parameters of the quantity being measured (identical sample) and taken by the same subjects under the same equipment and conditions (Wieggers and Beatty 2013), (Bircher et al. 1994). Therefore, under the EMED plantar pressure system, and the same subject, measurements were implemented within the same environment. The outcome of the measurements can be summarized in Fig. 2.

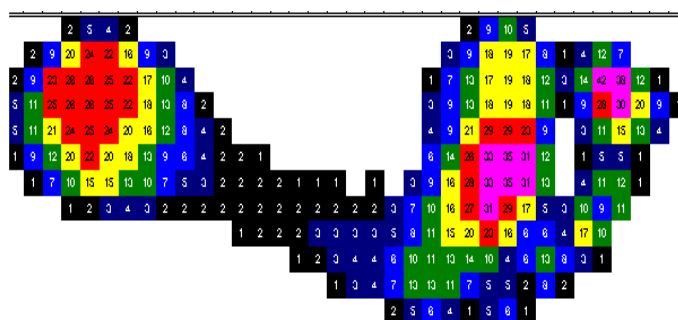


Fig. 2. Typical recording of plantar pressure using the EMED system.

**Image processing**

The data initially obtained from EMED have been organized, classified, and processed for analysis towards modelling. Some preliminary arrangements have been carried out on the foot planter data. For instance, these may involve placing data into rows and columns in a table format as a structured data for further analysis, this work used the Microsoft Excel facilities for the data tabling and MATLAB code editor for the process and analysis.

Relationships were explored among the peak and the mean plantar pressure measurements as classified by the image processing algorithm in which pressure over the insole area have been divided into 7 levels. The image processing program has been designed to implement several processes on the images that attained from the EMED tests so as to get the suitable interpretation of the image that shows the pressure distribution over the insole plantar for further analysis, as can be described in the flowchart of Fig. 3.

The image captured by EMED is conveyed to the computer by custom MATLAB software developed for this purpose. The algorithm of image processing starts by creating a mask to segment only the feet of the acquired image, hence, take out the background. Then, resizing the image to reduce the pixel values so that the processing will be faster and the singular value decomposition (SVD) value will be limited. The resizing to suitable resolution is essential because over-resized will make the image broke. Based on a particular threshold, shown later in Table 1, the algorithm converts the image from RGB into Index image format to be able to specify the values of the pressure levels, which represented by different colors, each color refers to a specific range of values. All the analysis based on the quantitative tables created by the image processing algorithm and the seven level ranges, plantar pressure ranges (PPR) of the pressure over the insole area have been described in Table 1.

As shown above in Table 1, Level 7, denotes by magenta color, represents the highest peak pressure range (>300kPa) over the plantar touch area, while Level 6, denotes by red color, represents a second level range of pressure range (220-295) kPa, and so on. The proposed analysis appeared to have an interpretation of plantar pressure distribution in terms of a number of pixels, while the color of that pixel represents the pressure range at that particular location over the insole area.

The data selection depends on the results of the test-retest reliability which measures test consistency, the reliability of a test measured over time. In other words, give the same test twice or more

to the same subject (person) at different times, but under the same conditions to see if the EMED measurements the same to select one of the data categories.

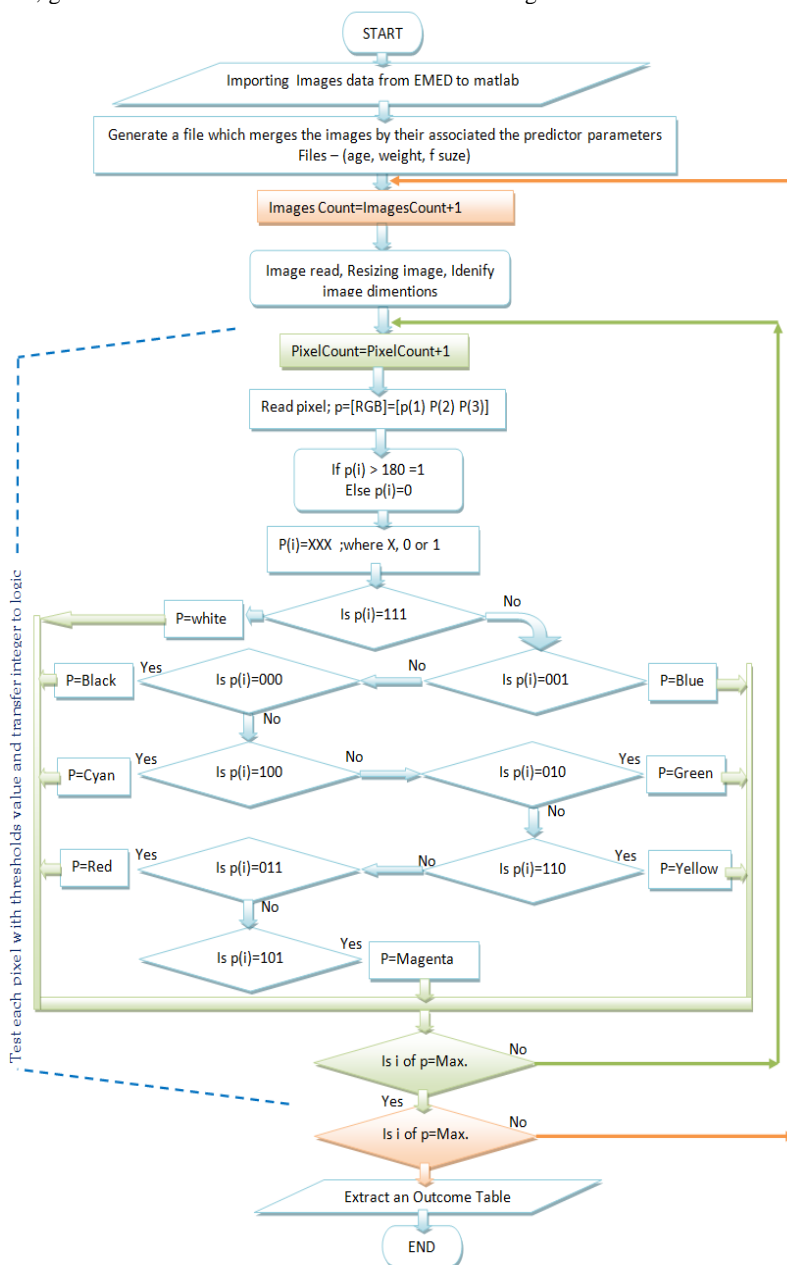


Fig. 3. Image processing algorithm.

Table 1. List of colors with associated range of pressure measurement.

Weight'slevel	Pressure indicator	Pressure Range (kPa)
7	Magenta	>300
6	Red	220~295
5	Yellow	150~215
4	Green	100~145
3	Cyan	60~95
2	Blue	30~55
1	Black	10~25

**Variance and standard deviation**

This study considered the variance and standard deviation to evaluate the acquired data from the proposed image processing algorithm to classify the 7 levels of the plantar pressure under 4 types of repeatability tests. The variance combines all the values in a data set to create a determine of spread. The variance, (which is denoted by var.) and a standard deviation which is the square root of the variance, and denoted by Svar, are the most usually used to measure of spread.

Thus, variance (var) = average squared deviation of values from the mean, and can be given by (1);

$$var^2 = \frac{\sum(X - \bar{X})^2}{n} \tag{1}$$

If we take the square root of the variance we'll get the standard deviation. Therefore;

Standard deviation (Svar) = square root of the variance, and can be given by (2);

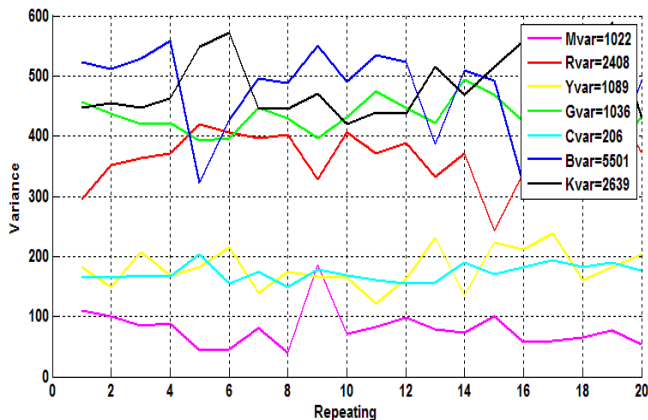
$$Svar = \sqrt{\frac{\sum(X - \bar{X})^2}{n}} \tag{2}$$

where  $\bar{X}$  = mean, Svar = standard deviation and X = a value in the data set.

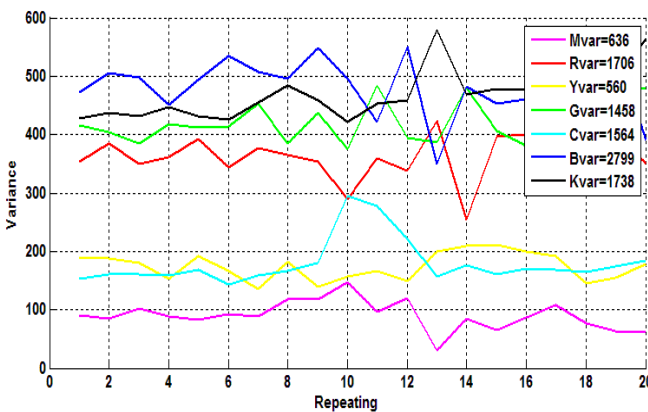
**RESULTS AND DISCUSSION**

Form the proposed algorithm that we've described above in Fig. 3, the 7 levels of plantar pressure values have been inserted as a legend in each classified results of test type. Same seven different colors equivalent to pressure level ranges have been selected and displayed in the four categories; dynamic (normal walking), dynamic with load, static (standing test), and static with load, respectively shown in figures (Fig. 4, Fig. 5, Fig. 6, and Fig. 7).

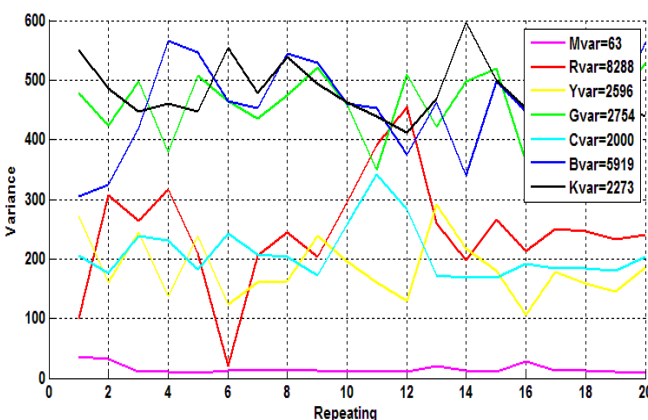
By comparing the variance coefficients of the mean pressures for the four considered categories, no significant differences were observed in the measurements in terms of values stability for the Fig. 4, Fig. 6, and Fig. 7. But there are relatively stable measurements of Fig. 5, which is the dynamic with load category, for all the mean pressure levels as can be signified in each legend of the above figures except the higher level (7) where the Static category compete with that of dynamic with load.



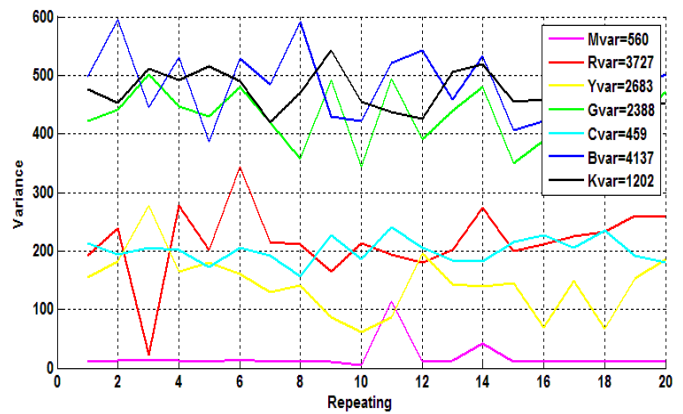
**Fig. 4.** Dynamic (normal walking).



**Fig. 5.** Dynamic with load (normal walking, carrying 1.5 kg).



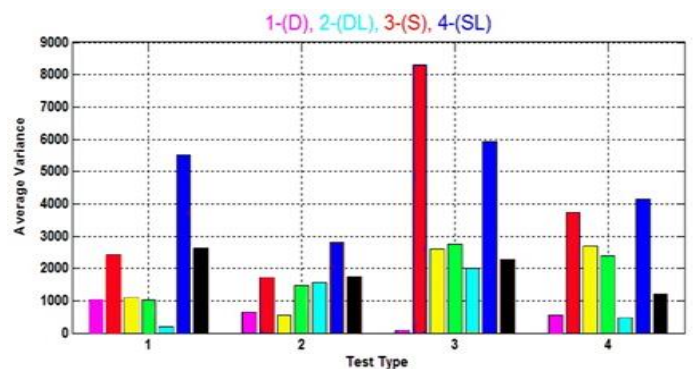
**Fig. 6.** Static (standing test).



**Fig. 7.** Static with load (standing, carrying 1.5kg).

The repeatability reported a good result on plantar pressure applications in (Ahroni, Boyko, and Forsberg 1998), where the repeatability of a Pedar system was considered according to variation coefficient, various results were obtained among the insole areas. EMED plantar pressure has been addressed in another study in which the between day repeatability was assessed in ten regions over the foot (Gurney, Kersting, and Rosenbaum 2008). Healy et al. (Healy et al. 2012), addressed 3 subjects during walking using F-scan and WalkinSense systems in two different days, and the WalkinSense was showing a similar level of repeatability with respect to other plantar pressure measurement systems. However, our conclusions were mainly based on one subject analyses, but with four categories of measurement types, therefore, it is difficult to compare our results with some previous work in this field like (Gurney et al. 2008) and (Healy et al. 2012) but there is an agreement with them in the concept. We've selected two related research articles that may very benefit the achievement of this work (Ghazali et al. 2015) and (O. Hussein, W.Z. Wan Hasan 2011), because they investigated the plantar pressure distribution and compared their results with EMED system.

Acceptable overall within and among-trial repeatability has found for all dependent parameters (pressure levels 1-7) in this investigation. However, the average mean pressure (AMP) for each individual level variations among the regions over the insole touch areas and for the four different categories can be explained in the barchart shown in Fig.8.



**Fig. 8.** Barchart for the four measurement categories

Based on the comparison for the variance coefficients of the mean pressures for the considered 7 levels and four categories, there are relatively best and stable measurements for Dynamic with load category with respect to other categories.

The data selection depends on the results of the test-retest reliability which measures test consistency, i.e. the reliability of a test measured over time. In other words, the same test is performed twice or more on the same subject (person) at different times, but under the same conditions to see if the EMED measurements can be repeated.

This research adopts data from the second category, dynamic with load, for further analysis. This decision was made according to the repeatability tests for the four measurement categories that are shown in Fig. 9.

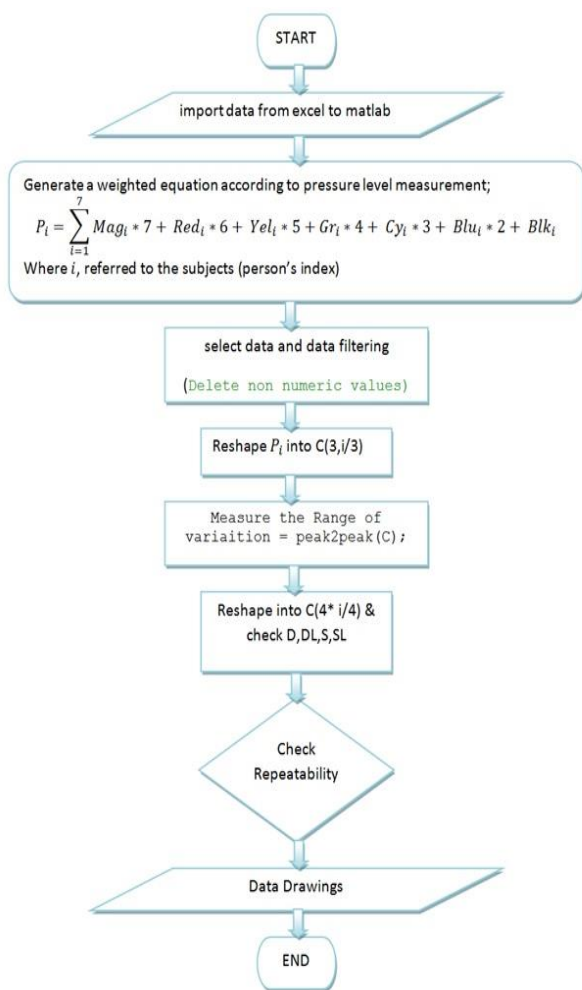


Fig. 9. Data selection and repeatability test diagram.

The results of this process were applied under four repeatability detailed experiments in the categories (dynamic (walking), dynamic with load, static (standing), and static with load) according to (Franco et al. 2015). This experiment is important to check the lower variance one for more accurate formulation results, the selection can be shown in Fig. 10.

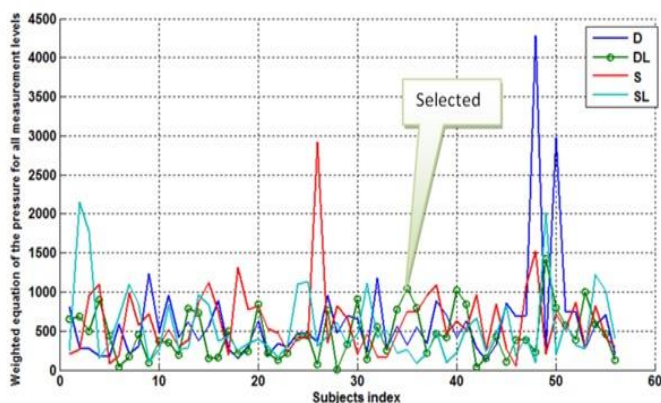


Fig.10. Selecting a category (DL) from the results of the weighted equation of the pressure for all measurable levels.

Therefore the selection of DL was based on the lower fluctuating data that results from the following equation:

$$P_i = \sum_{i=1}^k Mag_i * 7 + Red_i * 6 + Yel_i * 5 + Gr_i * 4 + Cy_i * 3 + Blu_i * 2 + Blk_i \quad (1)$$

where i, (1-k) represents the number of subjects,  $Mag_i$ ,  $Red_i$ ,  $Yel_i$ ,  $Gr_i$ ,  $Cy_i$ ,  $Blu_i$ ,  $Blk_i$ , represents the pressure levels starting from the maximum respectively.

**Limitations**

This study presents some limitations, such as (i) the standardized position of the EMED sensors for the two pairs of Pedar insoles that did not necessarily correspond to the point of maximal pressure for all subjects; (ii) the description of values provided in this study that can only be considered for the proposed arrangement of the sensors, and (iii) the differences between the EMED and the Pedar (i.e., layout, sensor area, and kind). It need also periodical calibration according to the device data sheet (Anon n.d.).

**CONCLUSION**

This research adopts the second category, which is the dynamic with load as a repeatable measured pressure according to the variance values of the classified seven levels of plantar pressure that conducted via the repeatability test for the four measurement categories.

We had also proposed a procedure for capturing plantar pressure levels over the insole touch area in a sample method based on image processing algorithm to classify the pressure into seven levels.

This study had demonstrated that the collection of reliable plantar pressure data for a single subject and among four types of test categories is possible to assess the selection of measurements. The results can serve a further statistical analysis of more reliability for analyzing the plantar pressure variables such as; peak pressure, pressure-time integrals, peak force, and force time integrals.

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## Appendix A

Table 1. A summary of noteworthy contributions of Plantar Pressure Repeatability Test for healthy persons.

Ref.	No. of healthy participants	A measurement device	Test condition	Results
(Putti et al. 2008)	17 females 36 males	EMED ST4	Walking	The percentage CT was in the range 75-85% under the metatarsal heads, and 70% under the hallux.
(Ramanathan et al. 2010)	27 Male (range 20–44 years)	Pedar-X® in-shoe pressure measurement system.	Walking	Repeatability was analysed using the coefficient of variation. Of the 160 parameters considered, 93.1% revealed a coefficient of variation value of less than 25. Heel and the metatarsal head areas were the most repeatable.
(Maetzler et al. 2010)	14 females 9 males	the EMED® ST4 system.	Walking	The coefficient of repeatability (CR) was less than 16.0% for all 63 parameters considered. In 87.3% of the parameters investigated (55 of 63) the CR (expressed as a percentage of the mean) was less than 10%.
(Healy et al. 2012)	3 Male Average age of 36.3 (±8.1 years)	F-Scan System	Walking	In the present study a new portable system capable of continuous monitoring of plantar pressure is assessed for its repeatability when compared to other commercially available and widely used system.
(Castro et al. 2014)	20 males 20 females Age of 21.6 ± 3.4	Prototype of eight force-sensing piezoresistors	Walking	The WalkinSense showed good-to-excellent levels of accuracy and repeatability for plantar pressure variables during static bench and dynamic gait analysis.
(Franco et al. 2015)	5 men 5 women	Shapiro–Wilk	Walking	Mean and peak plantar pressure values were similar between the different days of evaluation. Asymmetry indexes were similar between the different days evaluated.
(Putti et al. 2007)	17 females 36 males	Pedar® system	Walking	Pedar® system was repeatable. The normal pressure values identified can therefore be used to provide a reference range in clinical practice using this specific type of footwear.
(Hafer et al. 2013)	22 healthy	Novel emed-x® and two Tekscan MatScan1	Walking	Inter-emed-x1 reliability was greater than 0.70 for all parameters. Inter-MatScan1 reliability was greater than 0.70 for parameters. Inter-manufacturer reliability was greater than 0.70 for 52 of 56 parameters. Trial average Inter-emed-x1 reliability was greater than 0.70 for all parameters. Inter-MatScan1 reliability was greater than or equal to 0.70 for 52 of 56 parameters. Inter-manufacturer reliability, including all four platforms was greater than 0.70 for all parameters.
(Tong and Kong 2013)	21 children (Age = 9.9 _ 1.8 years)	Emed®	Walking Static and dynamic	Dynamic footprint and plantar loading parameters of children using a two-step approach displayed good to excellent reliability (0.61 _ ICC _ 0.98) for all geometric and most loading measurements. Static measurements were invalid on children due to incomplete footprint acquisition with the Emed® M system.
(Jonely et al. 2011)	92 healthy	Tekscan	Standing and walking.	In healthy participants, lower arch foot postures are associated with greater pressures under the hallux and medial mid-foot and lower pressures under the medial forefoot, but the strength of these relationships may be only poor to fair.
Proposed	71 subjects	EMED system	Standing and walking. (carrying load and not)	Dynamic with Load is the best selection according to the repeatability results among 4 measurement categories. This proposed procedure is useful for the capture of plantar pressure levels based on image processing and pressure level's classification.