INFLUENCE OF AGE, GENDER AND OBESITY ON PRESSURE DISCOMFORT THRESHOLD OF THE FOOT: A CROSS-SECTIONAL STUDY.

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ABSTRACT

Background: Foot pain is a highly prevalent health problem for which measures such as a pattern of Pressure Discomfort Threshold of the foot plantar surface can provide valuable information for orthosis design. This study aimed to describe such pattern as a tool for **the assessment of painful conditions** of the feet and to analyse how it modifies according to age, gender and obesity.

Methods: A cross-sectional study was performed with participants allocated in: Group 1 people aged 20 to 35 years, Group 2 aged 50 to 65 years and Group 3 aged over 65. Pressure Discomfort Threshold on twelve points of the foot plantar surface was measured with an adapted manual dynamometer. Inferential analyses of the data were performed using one-way analysis of variance (ANOVA) considering foot areas, age group, gender and obesity.

Findings: 36 participants were analysed. The pattern of Pressure Discomfort Threshold for all individuals showed a significantly higher threshold on the heel and external foot (***P*<0.001,** η^2=0.124) and was statistical significantly influenced by age (***P*<0.001**, η^2=0.17), especially in participants aged over 65; by gender, with women having higher values **(*P*<0.001**, η^2=0.13), and by obesity (***P*<0.001**, η^2=0.19).

Interpretation: A Pressure Discomfort Threshold pattern exists in the foot plantar surface. The characteristics of the discomfort pattern of the foot and its association with aging, gender **and obesity may** have considerable implications for orthosis and footwear design.

Keywords: Foot, Discomfort, Gender, Aging, Body Mass Index.

1. INTRODUCTION

Foot pain is a highly prevalent health problem, 29% of women and 19% of men suffer from it.[3] **The existence of high plantar pressures in certain areas of the foot has been associated to pain and discomfort[25] even leading to hyperkeratosis[7] and, subsequently, metatarsal and heel pain, especially in older people.[1,19]** In addition, alteration of foot function in one area can instigate unfavourable outcomes such as high pressure onto a new area, imbalance and/or injury when walking.[25]

Foot pressure has different effects, thus depending on its magnitude the resulting sensation can vary from superficial touch to pain previously passing through discomfort.[18] Whereas superficial touch provides the sensory feed-back necessary for balance and locomotion, discomfort and pain are mechanisms that warn of potentially harmful situations.[38]

The most frequent treatment options are advice acquiring appropriate fit shoes, plantar orthosis or footwear modifications.[33] Therefore, minimising foot pain and discomfort due to pressure generated during human locomotion is an important user requirement for plantar orthosis or shoes.

Pressure pain threshold (PPT), understood as the minimum pressure that induces pain, has been evaluated at selected locations or through a full plantar surface map.[36] It is generally accepted that discomfort is a precursor of pain. Thus, pressure discomfort threshold (PDT) understood as the minimum pressure that produces discomfort[21] is presented as a more suitable standard in product design.[14] A foot plantar PDT pattern can provide valuable information for footwear and orthosis design, aid in preventing pain and identify individuals who may be at risk of developing or worsening an injury due to high pressure. It could also be useful in order to detect patients with loss of hypersensitivity and to evaluate the effects of treatments on various pathological conditions. But before studying the different conditions, the existence of normal patterns in healthy subjects are needed. However, few studies have focused on it.[13, 21, 36, 38]

In addition, there are several potential risk factors for foot pain and discomfort that have been identified from cross-sectional studies, and should be taken in consideration: increased age with a prevalence between 14.9 and 41.9% of **adults aged over 50 years**,[15] gender, with women having higher prevalence of foot pathologies[11] and obesity, with obese people possibly being more sensitive to pain.[28] Unfortunately, there is limited knowledge on how foot discomfort relates to age, gender or body mass index (BMI).

In the present study it was hypothesized that there are different PDT depending on different areas of the foot plantar surface and that it modifies with age, gender and increase of BMI. Therefore, the main purpose of this study is to describe a pattern of PDT as **a tool for the assessment of painful conditions** of the foot.

2. METHODS

2.1 Study design

A cross-sectional study was performed at the Biomechanics Institute of Valencia (Instituto de Biomecánica de Valencia) from January to March 2019. Participants were allocated to three different groups according to their age: Group 1 (G1) people aged 20 to 35, Group 2 (G2) aged 50 to 65 and Group 3 (G3) aged over 65. **The gender distribution was done for the full sample in a balanced way to avoid possible biases, although it was not possible to balance all groups.**

Each participant was assessed once by an experienced physiotherapist trained in the method. Participants provided informed consent following an explanation of the study aims and procedures. The study was approved by the Institutional Review Board of the University of Valencia (H1378729223575) and procedures agreed with the Helsinki Declaration. The manuscript was written in accordance to the Strengthening the reporting of Observational Studies in Epidemiology (STROBE) protocol.[35]

2.2 Participants

Participants were recruited through an advertisement on the University Campus. Students and administration staff attended. The sample included individuals who met the following inclusion criteria: aged 20-35 or over 50, living independently in community and able to walk without any assistance. **Excluded from the study were those with: diabetes, peripheral vascular disease or other conditions that affect gait pattern or significantly influence pain sensitivity and discomfort as well as any person with pain in the foot plant. We also excluded severe flat and cavus feet (3rd degree)[31] and severe foot deformities, pathologies or previous injuries that could distort the results. Therefore, participants had normal feet (including common**

non-severe problems and deformities: i.e. non-painful hallux valgus or non-pathological cavus or flat feet). Also people with neurological diseases, cognitive disorders and/or depression, sensory impairment of the lower extremities, history of serious injury or previous surgical intervention in the foot or ankle, presence of pain at the time of the study, taking any analgesic or sedative medication in the last 48 hours, pregnant, and with hearing or speech problems were excluded.

2.3 Outcome measures

PDT on foot plantar surface was measured with a commercial manual dynamometer (EFG 1-2, Salter). An aluminium cylindrical cap with a contact flat surface of 1.3 cm^2 and round edges had been adapted to the dynamometer. The participant had a switch to press when discomfort was felt due to pressure application. Both systems were connected to a computer by means of a data acquisition card.[13] Pressure was applied at a rate of 1000kPa/s, much faster than in other studies since it was intended to simulate **the actual load that occurs when walking**[4,6,10,34] and not the one of a static test. **This method has been proved capable of discriminating between the sensitivity of different zones on the foot plantar surface and between different subjects, showing a moderate value (ICC for men: 0.55; ICC for women: 0.47)**.[13] Twelve anatomical points in the plantar surface of the foot were selected **(Figure 1)** based on biomechanical criteria, physiological or functional significance and for being anatomically identifiable.[23]

2.4 Experimental protocol

Participants were advised to come rested and without having been 30 minutes standing or 40 minutes walking in the two hours prior to the tests. Before taking the data an example was carried out with a single test performed on one point of the left foot to get used to the perception of discomfort distinguishing it from pain.

Measurements were done with participants resting in a reclining position, bare right foot and dynamometer perpendicular to each tested point's skin **(Figure 1).** Participants were instructed to indicate when the sensation changed from pressure to the first onset of discomfort (emphasizing not feeling pain), moment when they had to say the word "Stop" and also had to press the switch on their hand. Pressure was applied 5 times for each of the twelve anatomical points, leaving a six-second interval between consecutive applications. The sequence of application was assigned in a randomized way and dismissing consecutive neighbouring areas. Neither the examiner nor the subject saw the dynamometer screen during the load application, thus eliminating possible bias.

The three studied variables were: pressure when the subject said the word "Stop" (kPa), pressure when the subject pressed the switch (kPa) and pressure gradient (kPa/s).

2.5 Statistical analysis

Descriptive results of continuous data were expressed as mean and standard deviation. Normality was checked by the Shapiro-Wilk test. Pearson's correlation coefficient (p <0.05) was used to determine interrelationships between the three studied variables. Coefficient of variation (CV) was calculated to know which of the three variables was more robust.

In order to study the PDT pattern, the intraclass correlation index (ICC) was used.[32] A high index (between 0,5 and 0,75) indicates variability between zones is greater than in the intrazone, and the existence of a reliable pattern.

Inferential analyses of data were performed using one-way analysis of variance (ANOVA) considering foot areas, age group, gender and obesity as fixed independent factors and adjusted by the Bonferroni correction. Interaction between age group, gender and BMI with foot areas were included in the model. Statistical analysis was performed using SPSS v. 26.0 (SPSS Inc., Chicago, IL, USA). An external assistant not involved in the study performed the statistical analysis.

3. RESULTS

From the eligible 45 possible participants 36 were finally included (Figure 2), aged between 20 to 81 (mean age 34.91, SD 17.60) and 50% women. A 30.56% of the sample had a BMI of 30 or more and were, therefore, considered obese. Demographic and clinical characteristics of the participants by age groups are depicted in Table 1. Variable distribution showed to be normal by the Shapiro-Wilk test.

Pearson's correlation between the pressure registered when the subject pronounced "Stop" was high both with the pressure when the switch was pressed (0.99; *P* <0.01) and the pressure gradient (0.77; *P* <0.01). The CV showed that pressure registered when the subject pronounced "Stop" was lower, thus more robust, plus this parameter had less invalid data. Therefore, for further analysis the pressure when the word "Stop" was pronounced was chosen as the PDT.

A general PDT pattern was observed on the foot plantar surface for all subjects (Figure 3). The ICC for subjects was between 0.45 and 0.95 (mean of 0.81, SD 0.1). The highest PDT was found on the heel (1700 kPa), followed by external midfoot area (1500 kPa), central midfoot area and arch (between 1200 kPa and 1300 kPa). The lowest PDT was found on the first toe (close to 1200kPa).

With the numbers available, there were significant differences between foot areas in relation to PDT (F_{11}=27.31, ***P*<0.001,** η^2=0.124). The heel zones tolerated significantly greater pressures than the rest of the areas, and the external midfoot tolerated higher pressures than the internal midfoot, 1st, 4th and 5th metatarsals heads or the first toe.

Age showed to be a factor that significantly influences PDT on foot plantar surface (F_{33}=12.78, ***P*<0.001**, η^2=0.17) (Table 2). Significant differences were found between the three age groups, with G3 having a higher tolerance compared to participants of both other groups. In fact, G3 had higher PDT for all foot areas compared with G1 and G2, except for the fifth metatarsal head. Significant differences occur between G3 and G1 and G2 in all midfoot and heel areas, with G3 having a higher PDT (Figure 4). There are also differences between G3 and G1 in the first toe, and between G3 and G2 in the fourth metatarsal head area, with G3 having higher PDT in both areas. No significant differences were found between G1 and G2 in any area, except areas of the fourth and fifth metatarsal head with G1 having higher PDT.

The differences between gender considering all age groups were also analysed. The ANOVA was performed with the foot plantar surface area and gender as factors. Significant differences in PDT by gender in the different zones were found (F_{22}=14.36, ***P*<0.001,** η^2=0.13). Women had higher PDT than men in all the foot, particularly in some areas: significant differences **(Bonferroni corrected P value <0.017)** were found in the three heel areas (internal, central and external), in the arch, in fourth metatarsal head and first toe (Figure 4).

Regarding BMI, as the number of people with obesity was insignificant in G1 (n=2, 11.11%), only G2 and G3 were taken into consideration (Table 2). There was a positive significance between BMI and PDT in the different areas of the foot surface (F_{22}=11.40, ***P*<0.001**, η^2=0.19). The obese participants had higher PDT than the non-obese in the foot plantar surface generally. Significant differences **(Bonferroni corrected P value**

<0.017) were found in the central heel area, the three midfoot areas and the head of the first metatarsal (Figure 4).

4. DISCUSSION

The results of the present study confirm the hypothesis that there is a PDT pattern for the foot surface and that it depends on age, gender and obesity. The three points of the heel area are the ones that have higher PDT with significant differences with the rest of the areas.

In general, heel and external midfoot areas showed more tolerance to higher pressures than the rest. These are the areas bearing most of the foot contact when walking, so they bear higher loads, are adapted to such an important function and tend to be less sensitive than areas bearing lower loads.[17]. Messing and Kilbom[24] studied foot plantar PPT of workers in standing position and found that areas mostly in contact with the floor had higher PPT than those with less contact, thus being explained by the mechanical characteristics of the different structures in each area. It could also be due to greater thickness of the epidermis.[27] However, since the epidermis measures approximately 1.4mm in the plantar surface and 0.1mm in the dorsum of the foot, it would be expected that all the plantar areas had higher thresholds than dorsum. Although this is the trend, the central area of the foot and the arch have lower thresholds than the heel area.[37]

So the difference in discomfort thresholds is due to several factors, in addition to the thickness of the epidermis it may also be influenced by the existence of different concentrations of mechanoreceptors depending on each area and the adaptation of the different areas of the plantar surface to their function and load bearing when standing and walking.

According to our results, it would be possible to establish a turning point at the age of 65 for the PDT pattern, with the heel, midfoot and forefoot areas having higher thresholds. This could be explained by age-related changes of the mechanical properties of plantar surface. With age, skin gets harder, dryer and loses elastic recoil, thereby predisposing the older person to xerosis, fissuring and development of its possible consequences: hyperkeratosis, metatarsalgia or talalgia among others.[29]

In addition, changes in nervous system must be taken into account since aging is related to reduction in response to normally painful stimuli which may be due to both progressive degenerations of the central nervous system and impaired conduction of peripheral nerves.[2] Moreover, with advancing age, soft tissues pads of the foot demonstrate greater stiffness, dissipate more energy when compressed and are slower to recover after the load is removed.[22] Therefore, higher peak plantar pressures when walking have been found in older adults (775.7kPa - 699.1kPa) compared to young ones (165.04 kPa) and have been associated with foot pain and falls.[25] So, the existence of prior warning mechanisms such as discomfort becomes very important. Noticing pressure discomfort can be interpreted as an "alert mechanism" that would allow to make changes in gait biomechanics in order to reduce or avoid overpressures.

In relation to gender, women showed higher PDT than men. In previous studies, a high prevalence of women in many clinical entities related to pain have been shown and there is growing evidence of gender differences in sensitivity and the effect of analgesics[5] but there is no consensus. Some studies regarding PPT quantification suggest that there are robust differences between genders, with women exhibiting lower thresholds.[12] As for foot PDT a previous study showed that men had higher threshold than women, however it was assessed on young people.[35] Another study concludes that results cannot be generalized because gender differences depend on many factors: stimulus zone, type of pain and population characteristics.[16] Hence, for each condition and population specific research is required.

In accordance to our results PDT pattern of obese people had higher tolerance pressures than non-obese, being significantly different in central heel, midfoot and head of first metatarsal. These are the areas that have been previously identified in people with obesity to present greater soft tissue thickness than non-obese[26] which could be explained because bone areas of obese people have a greater coverage of soft tissue. Moreover, adaptation plays an important role, an increase in body weight will result in higher forces on the foot that a person may adapt to over time.[37] In fact, when walking significantly higher peak pressures have been found in people with obesity with the greatest effect of body weight found under the longitudinal arch of the foot and under the metatarsal heads.[20] Excessive weight bearing due to obesity is believed to cause structural foot dysfunction, such as collapse of the longitudinal arch, which leads to increased middle foot contact area.

To the best of our knowledge this is the first study to analyse PDT in relation to age, gender and BMI. This analysis has allowed to establish objective data of pressure without causing pain. The PDT map is essential in order to establish design criteria for shoe or accessory since it should be below the discomfort threshold.[37] Recently, customized plantar orthosis has been used since it adapts to each person's anatomical characteristics, reducing high pressure and being more comfortable, thus, potentially improving the treatment effect.[39] **In this sense, several studies have focused on orthosis effectiveness for objective outcome measures through pressure relief and load redistribution across plantar regions[8,9,30]. This has proven to be an important issue when there are foot conditions, and redistribution of the pressure can alleviate and improve the condition of the patient.[39]** When designing footwear or orthosis, the criteria is usually based on plantar pressures when walking. So, PDT appear to be a highly valuable information for intervention in plantar pressure management. However, it seems that there is some adaptation to plantar pressures when walking. In this sense, for future research it could be interesting to know if there is a relation between PDT and dynamic surface plantar pressures.

The study is not without limitations. **A larger sample size could allow studying the interaction of age groups with gender and BMI, as well as balancing groups adequately regarding gender. Therefore, further studies in relation to gender and BMI should be carried out with a suitable sample size calculation to confirm the findings of the present study.** It might also have been interesting to recruit people between 35 and 50 years old but as one of the objectives was to observe aging it seemed adequate to compare young and aged participants. Even though the chosen locations are somewhat justifiable, more data are needed to map the discomfort thresholds on the complete surface of the foot. Even though the experimenter was experienced, the landmark locations may not be consistent across different experimenters or across different days. This should be taken in consideration for future research. **Moreover, further studies with larger sample size could focus on different feet structures or specific pathologies to understand better how these factors affect foot plant PDT.**

5. CONCLUSIONS

This study has shown a pattern for PDT in the foot plantar surface, with significant higher thresholds on the heel and the midfoot which are related to first contact and adaptation when walking. Moreover, this research has provided an overview of the changes in the discomfort pattern of the foot associated with aging, gender and BMI, and that have considerable implications. There is a turning point around 65 years old when PDT is increased significantly on the heel, midfoot, and forefoot compared to younger adults. In relation to women, PDT is higher than men in all areas and significantly on heel, arch and forefoot. People with obesity have a higher PDT pattern than non-obese for all areas, with the midfoot showing significant differences. Unlike many other studies that have investigated foot sensations, this study investigated discomfort thresholds of healthy young and aged adults. The findings can have important implications on orthosis and footwear design and **in the evaluation of painful conditions.**

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TABLES AND FIGURES

Table 1. Distribution and anthropometric characteristics of the participants.

Group*	Gender	n	Age			BMI			Obesity (n)
			Mean (SD)	**Min.**	**Max**	**Mean (SD)**	**Min.**	**Max.**	
G1	Men	9	22.78 (1.92)	20	25	23.54 (3.52)	19.69	31.44	1
	Women	9	21.78 (3.99)	20	28	22.33 (2.32)	19.95	27.59	1
G2	Men	3	61.33 (3.21)	59	65	28.67 (2.80)	26.03	31.62	2
	Women	6	54.33 (3.67)	51	61	28.93 (4.77)	24.77	36.12	3
G3	Men	6	73.83 (4.37)	68	81	26.10 (4.80)	23.05	35.11	2
	Women	3	69 (3.61)	66	73	29.31 (5.70)	23.50	34.90	2

**Group: G1 (20-35 years old); G2:(50-65 years old); G3: > 65 years old.*
Data are shown with mean (standard deviation), as well as the minimum and maximum values. The variables are expressed in years in the case of age, and points in the case of body mass index (BMI) ***. Subjects with a BMI of 30 or more were considered obese.***

Table 2. Pressure discomfort threshold according to age group, gender and Body Mass Index.

Group	N	PDT Mean (SD)	Min.	Max.	CV	ANOVA		
						F_{33}	*P**	η^2
Age								
G1	1,070	1,337.89 (506.28)	261.60	3,594.40	0.38	12.78	<0.001	0.17
G2	580	1,289.65 (510.78)	352.00	3,181.64	0.40			
G3	569	1,628.87 (729.37)	430.46	3,783.73	0.45			
Gender						F_{22}	*P**	η^2
Men	1,099.00	1,321.46 (634.13)	261.60	3,783.73	0.48	14.36	<0.001	0.13
Women	1,120.00	1,476.85 (529.13)	352.00	3,399.96	0.36			
Body Mass Index						F_{22}	*P**	η^2
Obese	716	1,528.43 (640,06)	435.58	3,783.73	0.42	11.40	<0.001	0.19
Non-obese	1,418	1,359.09 (552.83)	261.60	3,594.40	0.41			

Group: G1 (20-35 years old); G2:(50-65 years old); G3: > 65 years old; ***N: number of total measurements per participant's feet, for all the sample.***
PDT: Pressure discomfort threshold, measured in kPa. Data are shown with mean (standard deviation), as well as the minimum and maximum values and the CV (coefficient of variation: SD/mean). ***Subjects with a BMI greater than 30 were considered obese****. η^2: effect size.* ****Bonferroni corrected P value < 0.017.***

Figure 1. Illustration of the anatomical points of the foot plantar surface where the measures were applied and the Pressure Discomfort Threshold procedure, (A): participant position, (B): examiners contact.

1.External heel area (EHA)
2. Central heel area (CHA)
3. Internal heel area (IHA)
4. External midfoot area (EMFA)
5. Central midfoot area (CMFA)
6. Arch (ARCH)
7. Fifth metatarsal head (5MTH)
8. Fourth metatarsal head (4MTH)
9.Third metatarsal head (3MTH)
10. Second metatarsal head (2MTH)
11.First metatarsal head (1MTH)
12. First toe (FT)

Figure 2. Flow diagram of study participation.

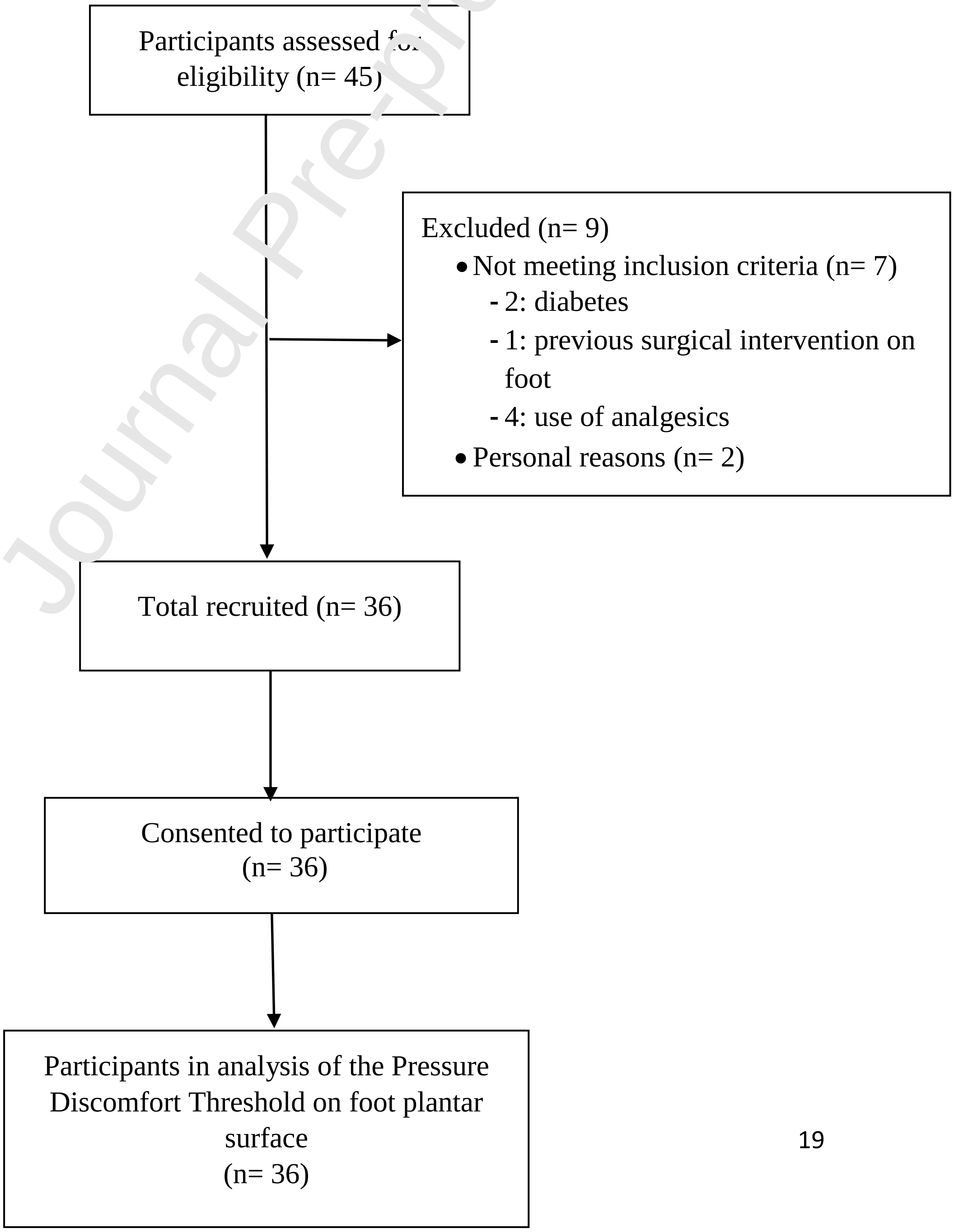
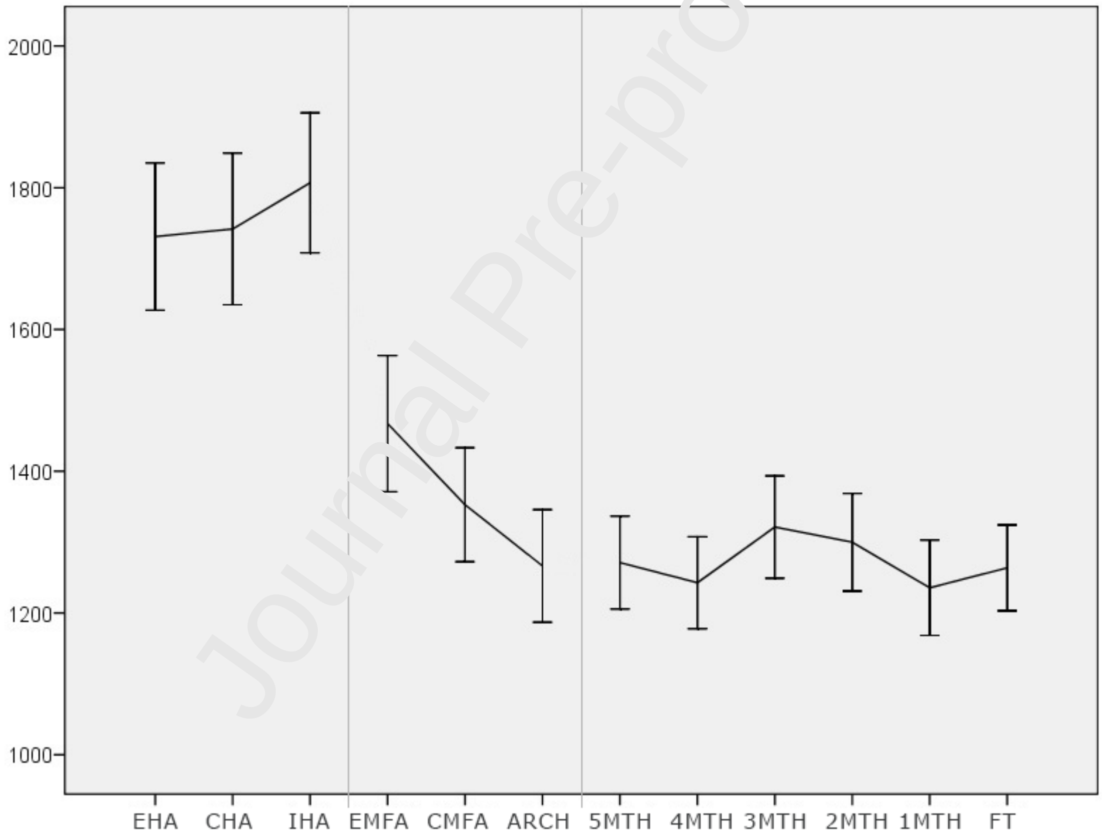
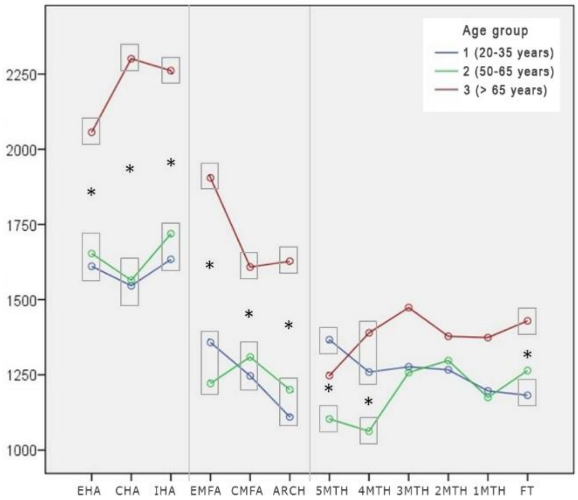


Figure 3. Pressure Discomfort Threshold on foot plantar surface for all participants.



Error bars represent confidence intervals (95%). The zones correspond to the plantar areas of: External heel area (EHA); Central heel area (CHA); Internal heel area (IHA); External midfoot area (EMFA); Central midfoot area (CMFA); Arch (ARCH); Fifth metatarsal head (5MTH); Fourth metatarsal head (4MTH); Third metatarsal head (3MTH); Second metatarsal head (2MTH); First metatarsal head (1MTH); First toe (FT).



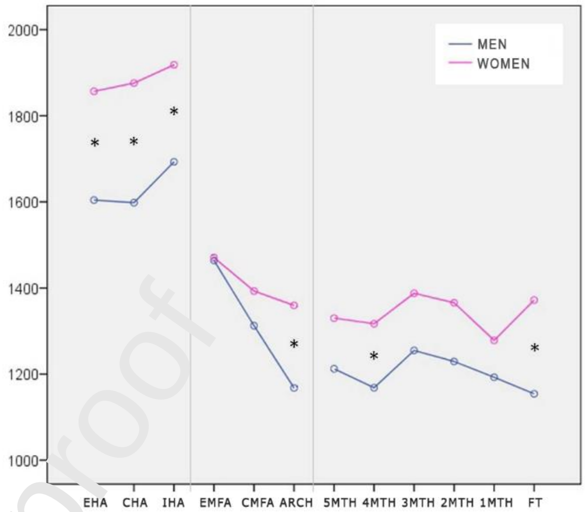


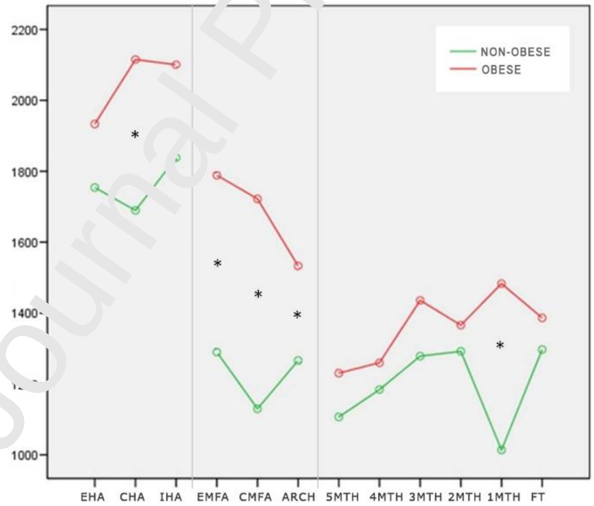
Figure 4. Estimated marginal average pressure discomfort thresholds by foot plantar surface area, for the different age groups (A), gender (B) and obesity (C).

A

B

C

Asterisks (*) represent areas where significant differences were found ***(Bonferroni corrected P value <0.017).*** *The zones correspond to the plantar areas of: External heel area (EHA); Central heel area (CHA); Internal heel area (IHA); External midfoot area (EMFA); Central midfoot area (CMFA); Arch (ARCH); Fifth metatarsal head (5MTH); Fourth metatarsal head (4MTH); Third metatarsal head (3MTH); Second metatarsal head (2MTH); First metatarsal head (1MTH); First toe (FT).*
(A): The boxes include the age groups among which there are such differences. For example, in the EHA there are differences between G3 with the other two groups, whereas in 5MTH these differences occur only between G1 and G2.



TITLE: INFLUENCE OF AGE, GENDER AND OBESITY ON PRESSURE DISCOMFORT THRESHOLD OF THE FOOT: A CROSS-SECTIONAL STUDY.

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TITLE: INFLUENCE OF AGE, GENDER AND OBESITY ON PRESSURE DISCOMFORT THRESHOLD OF THE FOOT: A CROSS-SECTIONAL STUDY.

Highlights of this study:

- It shows a pattern for Pressure Discomfort Threshold in the foot plantar surface.
- This discomfort pattern changes due to aging, gender and body mass index.
- The findings can have important implications on orthosis and footwear design.