STUDY PROTOCOL

Baropodometric parameters variation with body weight loss: a prospective cohort study

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Scientific Background

Obesity is in one of the major public health problems of the 21st century and its prevalence has tripled in many European countries in the last decades (1). It is a strongly problem associated with a lower quality of life, as well as with the development of serious chronic metabolic, cardiac and circulatory pathologies and musculoskeletal disorders (2,3). Quantitative data showed that excessive body weight negatively effects on standing and walking (4,5).

Plantar pressure measurement is commonly used to determine specific loads on the plantar surface of the foot. There are many case studies that assess pressures of the normal foot and try to establish patterns of pathological pressures (6). The CoP represents the average of all the weight that is in contact with the surface of the floor and is expressed as the point where the vector of the vertical reaction forces of the soil is located (6,7).

In the literature it can be found how body weight influences on plantar pressure data and on the position of the CoP (8-10). Excesses of body weight has shown to have negative structural consequences in the feet and lower limbs (11-14). Obesity is also related with an anterior displacement of the CoP (15), since the instability in obese people, associated to weight increasing, seems to be determinant with CoP in an anterior position (16).

Computerized baropodometry is helpful for foot diseases diagnosis, foot function evaluation and to follow-up the treatment. It has been practiced to determine specific weight parameters in obese adults, among others (10,14). Nonetheless, there are not in the literature specific studies that have analyzed by computerized baropodometry how plantar pressures and CoP improve by decreasing body weight in obese adults.

Objective

The present research wanted to evaluate plantar pressures and antero – posterior CoP improvement by decreasing body weight in static and dynamic baropodometry data collection in obese adults.

Design

The design of the present research was based on and executed according to the STROBE reporting guideline. The study was approved by the Ethics Committee of Clinical Research of Aragón (CEICA) with number C.P.-C.I. PI17/0203. Participants voluntarily signed an informed consent. The study has been conducted in accordance with the Helsinki Principles.

Participants

The study would include overweight subjects between 18 and 65 years old, medical weight loss indicated, no lower limb or spine pathology that might affect normal gait, nor structural or functional deformities in the feet. Candidates who not comply inclusion criteria, or reported pain in their feet within the previous 6 months, or had any previous foot surgery would be excluded. Them would be recruited at one Endocrinology and Nutrition private clinic in Huesca, Spain.

Procedure

Participants would be rigorously evaluated by the same endocrine doctor and podiatrist at baseline (Session 1) and at the end of the study after weight loss intervention (Session 2), when each participant lost between 11-12% of its corporal weight. Therefore, we will obtain 2 weight related with the two sessions: Session 1 – Weight 1; Session 2 – Weight 2.

In order to achieve the propose weight loss, lifestyle modification would be applied (17): A specific very low-calorie diet (<800kcal/day), and 2 daily sessions of 15 minutes of anaerobic physical exercise depending on the capacity of the participants (18,19).

At Session 1 and Session 2, before and after weight loss intervention, participants would be subjected to a baropodometric examination (static and dynamic). It allows to quantitatively mapping pressures in each segment of the plantar surface (20,21). For the static, participants would be asked to stand in the center of the platform for 5 seconds, with their arms on either side of the body in a natural position looking straight ahead (22). To minimize individual´s corporal fluctuations in static (as body weight oscillation and imbalance) the procedure would be applied 3 times per session (22). For the dynamic, participants would be asked to walk barefoot on the platform at their normal pace following the 3-step protocol, which requires landing on the platform on the third step of gait (23). To minimize corporal individual fluctuations in dynamic (as body weight oscillation, imbalance and changes in gait speed) the procedure would be applied 3 times per session (22). Both feet would be subdivided into 9 areas: heel, midfoot, 5 MTHs, the Hallux, 2-5 toes. Selection of the areas of the present study are based in the research of Hills et al. (11), who performed a complete study of the differences of pressures between obese and non-obese subjects.

Peak pressures of these areas in kg/cm2 and the position of the CoP, were obtained using the Footwork® software (20). Peak pressure data were graphically exposed and related with the two weights for each patient.

Equipment

Participant´s weight and height were measured during each session with an Año-Sayol scale and stadiometer, respectively (Año-Sayol SL, Barcelona, Spain).

Footwork® platform (AM3-IST®, France), was used for the baropodometric analysis (22, 24).

Statistical Analysis

An initial exploratory analysis of all clinical variables would be carried out. Continuous variables would be expressed as mean ± standard deviation (SD), whereas qualitative variables would be expressed as frequencies and percentages. Continuous data would be checked for normality by Kolmogorov-Smirnov Test. Chi-Square Test would be applied to show the relationship between qualitative variables. To compare mean weights between two independent groups according to normality, Student's-T Test and ANOVA Test to “m” groups would be used. Differences between Session 1 and Session 2, would be performed using mean comparison methods, Wilcoxon when the variable does not follow normal distribution, and Student's T for related samples when there is normality. To quantify the difference between weight and plantar pressures and the CoP at Session 1 and Session 2 the "change percentage" would be calculated, which would be defined as the relative variation in percentage points between both sessions: Weight-Change % (WC%)= [(Weight at Session 2 – Weight at Session 1)/ Weight Session 1] x 100; Plantar-Pressure-Change % (PPC%) = [(Pressure at Session 2 – Pressure at Session 1)/ Pressure at Session 1] x 100; CoP-Change % = [(time CoP X+1 – time CoP X)/ time CoP X] x 100. The “change percentage” would be analyzed through Spearman correlation coefficient, according to normality.

The "improve" variable would be established in order to analyze the possible relationship between weight loss and the 9 pressure foot areas considered at Session 1

and Session 2 for both: static and dynamic baropodometry. Statistical significance level would be set at $p < 0.05$, confidence level set in the comparisons was 95%. The statistical analyses would be performed using the SPSS software 22.0 for Windows (SPSS Ibérica, Madrid, Spain).

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