Immediate repercussions on the spine posture from passive elevation of the heels in healthy subjects: a cross-sectional study

12-10-2022

ID: H&S01
Approved by IRB ManusSapiens on 03-31-2022
Protocol n° 2022/001
(translated version)
Introduction / background

Women who wear high-heeled shoes are considered more attractive, self-confident and elegant. Although commonly used in the female population, high-heeled shoes affect posture and gait and are generally thought to be associated with back pain (Lee et al. 2001; Bird et al. 2003; Russell 2010). The most popular etiopathogenetic hypothesis linked to this association is a compensation strategy with an increase in lumbar lordosis (Russell 2010). Investigations into the role of high-heeled shoes in altering the spinopelvic profile attempted to explore compensatory and adaptive structural changes as a cause of lower back pain. The conclusions of these studies, however, are controversial. Some studies (Snow et al. 1994; Cowley et al. 2009; de Oliveira Pezzan et al. 2011; Dai et al. 2015), in fact, have shown that high-heeled shoes significantly increase lumbar lordosis (LL), and consequently mechanical loading and degenerative changes in soft tissues (Snow et al. 1994). Other studies (de Lateur et al. 1991, Franklin et al. 1995), on the other hand, showed a reduction in LL and a compensatory increase in the activity of the erector spinal muscle (Pezzan de Oliveira et al. 2011). The results of other studies also indicated that heel elevation did not significantly change the LL in the subjects evaluated (Lee et al. 2001; Schroeder and Hollander 2018).

The results of Oliveira Pezzan et al. (2011) are indicative of an increase in pelvic anteversion and LL, but only in the group of subjects who frequently wore high heels, while the effect in the other group was a decrease in pelvic tilt and lordosis.

A precise, radiation-free and inexpensive method of detecting spinal posture, particularly for follow-up, is rasterstereography (Asamoah et al. 2000; Drerup et al. 2001; Hierholzer et al. 2002). The surface analysis is carried out by projecting a light grid modeled on the patient's back. Anatomical landmarks can be automatically detected by assigning concave and convex areas. Through the detection of predetermined anatomical points, the system is able to calculate a three-dimensional model of the human spine. From this model, relevant clinical parameters can be determined, such as: pelvic obliquity, trunk inclination and kyphosis and lordosis angles (Huysmans et al. 2005; Schulte et al. 2008; Betsch et al. 2010).

The reliability coefficients of the rasterstereographic assessment method for the study of the sagittal plane were reported as excellent (ICC > 0.95) for both intra-examiner (Schroeder et al. 2015) and inter-examiner (Mohokum et al. 2010). Another systematic review (Mohokum et al. 2015) concluded that rasterstereography can be considered valid for both screening and monitoring.
A recent study (Schroeder and Hollander 2018) used rasterstereography (spinometry) to evaluate the immediate effect in a group of young (less than 24 years old) and middle aged (24 to 56 years old) women who are habitual wearers of high-heeled shoes, after wearing their shoes without heels and with an average heel of 8.7 cm. The results are indicative of a reduction in pelvic tilt and not of lordosis when using the shoe with the heel.

**Objective of the study**

The aim of this study is, given the remarkable heterogeneity of the data in the literature, to investigate whether artificial heel lift affects spinal posture and pelvic position in the sagittal plane in a group of healthy men and women. A better understanding of the immediate reaction of the spinal column in search of equilibrium during heel lifting could increase the knowledge useful for understanding low back pain associated with the use of shoes with heels and help preventing and/or treating it.

**What is meant to prove**

The aim of this study is to investigate whether artificial heel lift immediately influences spinal posture and pelvic position in the sagittal plane in a group of healthy male and female subjects not used to wear high-heeled shoes. The recent study by Schroeder and Hollander (2018) used a sample of female subjects with habitual heels; moreover, compared to the previous work, this research also includes the investigation at the level of dorsal kyphosis.

**What is added to current knowledge**

Given the extreme variability of the data reported in the literature, a better understanding of the adjustments of the immediate reaction of the spine and pelvis to heel elevation. These data could increase knowledge of the pathogenesis of low back pain related to heel height and help prevent or treat it.

*Primary outcome*: investigate the immediate postural response of the pelvis, lumbar and dorsal spine in search of balance during the passive elevation of 3 cm and 7 cm of the heels with a non-invasive tool in non-users of high-heeled shoes.
Secondary outcome: investigate if there is a different response in the two sexes. Assuming that the reaction to heels can also be linked to the habit of wearing high-heeled shoes, use the response of a group of males, who are assumed to have never worn high-heeled shoes (7 cm) in their own life, can further clarify what type of response occurs in the search for immediate postural balance of the pelvis and the dorsal-lumbar spine after the raising of the heels.

Study design
Cross sectional study. Monocentric.

Duration of the study
Six months

Materials and methods
Setting: OSCE (Osteopathic Spine Center Education), osteopathic school based in Bologna.

Population: 100 students (50 females and 50 males) to be enrolled in OSCE school by making announcements during the lessons. The number of subjects to be evaluated was decided on the basis of the most recent work which used the same methodology, which evaluated a sample of 36 women (Schroeder and Hollander 2018). A similar number between males and females was set to improve the statistical comparison.

Following the ethical principles of the Declaration of Helsinki, a paper information will be provided where there will be an explanation of the intent and purpose of the study to all subjects prior to their participation; in addition, a paper consent will be provided, together with the information, on which to obtain the voluntary written informed consent.

Inclusion criteria: asymptomatic young subjects.

Exclusion criteria:
- structural or neurological anomalies that may prevent from maintaining an upright position for 5 sec. with their heels elevated on a 7 cm high basement;
- habitual users of shoes with 7 cm high heels, with a frequency of at least twice a week and / or less than 3 hours / week as proposed by a previous study (de Oliveira Pezzan et al. 2011);
- low back pain in the past 30 days.

**Measurement method**
A three-dimensional posterior surface analysis is performed with the Formetric 4D® rasterstereographic device (Diers International GmbH, Schlangenbad, Germany). The device, already supplied at the Spine Center rehabilitation center in Bologna and made available free of charge for the study, is non-invasive and non-dangerous. The analysis of the spine curve with rasterstereography is performed with a purely optical modality.

*fig. 1 - Scheme of the spinometric parameters to be recorded: pelvic inclination, lordotic angle, kyphotic angle.*
fig. 2 - Scheme of the spinometric parameters to be recorded: cervical and dorsal arrow, anterior flexion of the trunk.

Investigated parameters

The data collected by the Formetric evaluation will be:

1) pelvic tilt angle (PI), the angle determined by the vertical and the tangent to lumbosacral junction (ILS);
2) ITL-ILS lordotic angle, measured between the tangents of the thoracolumbar junction (ITL) and the lumbosacral junction (ILS);
3) ICT-ITL kyphotic angle, measured between the tangents of the cervicothoracic junction (ICT) and the thoracolumbar junction (ITL); see fig. 1;
4) lumbar arrow (FL) horizontal distance in millimeters from the vertical line that passes through the kyphotic apex in the lumbar spine;
5) cervical arrow (FC) (horizontal distance in millimeters from the virtual vertical plumb line that passes through the kyphotic apex in the cervical spine);
6) antero-posterior flexion of the trunk (Trunk Inclination-TI) measured as the angle between the vertical line and the line passing through the prominent cervical vertebra (VP) to the line connecting the two dimples (DM); see fig. 2.

Participants will provide information on age, height and weight. A questionnaire will be administered to standardize the types of high-heeled shoes used and to verify their frequency of use.
**Evaluation Protocol**

1) sample 1: barefoot neutral position;

2) sample 2: barefoot neutral position;

3) sample 3: 3 cm rise under both heels;

4) sample 4: 7 cm rise under both heels.

The positioning with respect to the measurement system will be carried out according to the indications provided by the supplier.

To standardize the position subjects will be prepared for analysis as follows:

1. standing, back to the detection system, in a relaxed posture with the knees fully extended with bare feet on the floor (neutral position);
2. bare trunk with pants and briefs lowered to half of the glutei
3. in the case of long hair, it will be required to tie it with suitable means (cap, hair clips, hair bands, etc.) so that the neck is visible up to the hairline;
4. rings, watches and necklaces will be removed to avoid any interference with light lines (necklaces in particular increase this probability).

In the third survey, the heel will be raised by inserting a plastic bar symmetrically under both heels, as proposed in previous studies in which wood was used (Bendix et 1984; Franklin et al. 1995), by 3 cm; for the fourth evaluation it will be 7 cm.

After the first evaluation in the neutral position, before the evaluation with the heel lift, a second evaluation will be performed under the same conditions to evaluate the reproducibility of the data. The time between the two assessments will be less than 1 minute and the subject will not change position.

The spinometric analysis will be performed by specialized operators; the data will be entered after anonymization with an identification code on an Excel spreadsheet; the statistical analysis will be performed with the Prisma statistical program.
Statistic analysis

Descriptive analysis will be performed to determine mean values and standard deviations (SD).

It will be used:
- Kolmogorov-Smirnov test to verify the normal distribution;
- intra-class correlation coefficient test (ICC) and the t-test for paired data to evaluate the repeatability of the data between the first and second detection in neutral conditions;
- One-way ANOVA and paired t-test for data for comparison between neutral position, heels raised by 3 cm and 7 cm in both males and females;
- Cohen's d will be calculated for the difference between neutral conditions (NEU) and those with the rise (3-7cm) (d = 0.20 indicates a small effect size, d = 0.50 an effect size mean and d = 0.80 a large effect).
- t-test for independent data to evaluate if there are significant differences between the different positions (0-3 cm-7cm) between males and females.

Statistical significance will be accepted for p values <0.05.

Data analysis will be performed using Prism 8 software (Graphpad Software, S. Diego).
Bibliography


