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Influence of insole material density in the stability of patients with prosthetic unilateral transtibial amputation

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People with lower limb amputation present greater displacements of their centre of gravity in a static situation than able-bodied individuals, as they depend on visual information to a greater extent, which implies an altered stability pattern. The efficacy of different hardness of plantar support to help maintain stability has not yet been determined. The aim of the present study is to assess stability in people with unilateral transtibial amputation with prosthesis in a static situation with insoles of different degrees of hardness and visual conditions with respect to the able-bodied population. For this purpose, 25 patients with amputation and 25 able-bodied individuals were included in both groups, postural stability was assessed by stabilometry. This assessment was carried out under normal conditions (on the floor of the dynamometric platform with eyes open), and under altered conditions (with the interposition of different materials such as plantar support: rigid and soft insoles and, eyes shut). Three variables were considered to assess stability: length of movement of the barycenter (mm), lateral velocity (mm/sg) and anterior velocity (mm/sg). All of them were analysed with the patient in static on the dynamometric platform. The results showed statistically significant differences between the two groups, (amputees and controls) with less stability in the amputee group ($p < 0.05$) when analysing the variables of length of movement of the barycenter, lateral velocity and anterior velocity. Amputee patients with open eyes exhibited greater stability than those with closed eyes. The hard insoles improved the stability data in amputees (length of movement of the barycenter and anterior velocity) with respect to the barefoot condition, and the soft insoles showed less stability than the patients with hard insoles, or than the barefoot patients. From the results obtained in this study, we can conclude that the PP-DWST 4 mm rigid insoles improve static stability in people with amputation. However, soft insoles impair stability and are therefore discouraged.

Postural stability is the ability to control the body position in space for the purpose of movement and balance¹. It is necessary for maintaining a static position and for assisting body coordination in dynamic position changes². Maintaining this posture entails a dynamic concept of posture where the control of neuromuscular activity is essential, as well as different variables that determine balance and stability³.

People with lower limb amputation show greater displacements of their centre of gravity in static situations than able-bodied individuals, depending to a greater extent on visual information⁴. In static balance, the ankle strategy is responsible for controlling displacements in the anterior–posterior axis by modulating the amount of torque developed by the plantar and dorsal ankle flexors. In people with lower limb (LL) amputation, the ability to use an ankle strategy is severely impaired, which would explain the instability in that direction⁴. As ambulation requires body movements primarily in the sagittal plane, it must be assumed that people with LL amputation will express greater difficulty in controlling and maintaining balance during gait. In fact, people with amputation have a higher risk of falling compared to age-matched able-bodied individuals (52% of individuals with transtibial

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amputation report at least one fall in a twelve-month period)^{5,6}. This leads to additional health care costs, and a setback in the social and occupational adaptation of the patient with amputation.

Different studies indicate that lower limb amputees suffer from postural and gait alterations^{7–9}. In this way Arya et al.¹⁰ studied three male patients with amputation aged between 43 and 47 years with dynamometric platforms, in order to assess the characteristics and evolution of gait in these patients. Jayakaran, Johnson, and Sullivan compared postural control of transtibial amputees of different amputation etiologies with healthy adults under altered sensory testing conditions^{11–13}.

Other studies focus on different ankle and foot prostheses to improve balance¹⁴; on the limits of stability in people with transtibial amputation with respect to alterations of prosthesis alignment¹⁵; on the stability of people with transtibial traumatic amputation during standing on different terrain, including flat terrain and on slopes, etc.^{16,17}.

However, no studies have been carried out on the influence of the use of insoles on the stability of amputee patients. It is known that a significant predictor of falls in the elderly population is attributed to postural instability. Shoe insoles have been identified as a mechanism to enhance postural control in older adults¹⁸. Insoles are considered cost-effective and easily adopted tools to improve balance. Numerous studies have verified their immediate effects on balance¹⁹. This leads us to hypothesize that the use of insoles can improve stability in amputee patients.

The aim of our study is to analyse and measure the influence of rigid and soft insoles on the instability of prosthetic transtibial amputees vs. able-bodied patients using a dynamometric platform in two situations: eyes open and shut; and to check whether the density of the insole material influences the maintenance of postural stability.

The static stability will be evaluated while barefoot rather than wearing shoes because footwear has been shown to affect sensory feedback, potentially acting as a sensory filter between the feet and the standing surface^{18,20,21}.

Our purpose is to investigate the effects on the static stability of different insole materials in unilateral transtibial amputation and to implement practical clinical interventions in terms of stabilizing postural sway, avoiding possible falls and therefore implying a benefit for these patients.

Methods

Design. A prospective pre-post longitudinal quasi-experimental study was carried out. The protocol was verified and approved by the Research Ethics Committee of the Community of Aragon (CEICA) (Registration no: PI18/403), and all subjects signed an informed consent form prior to participating in the study.

The ethical principles for medical research in human subjects of the Declaration of Helsinki adopted at the 18th Assembly of the World Medical Association (WMA) (Helsinki, Finland, June 1964) were followed, amended at the 52nd General Assembly (Edinburgh, Scotland, October 2000), with note of clarification of paragraph 29 (WMA General Assembly, Tokyo 2004) revised at the 59th WMA General Assembly (Seoul, Korea, October 2008) and last revised version at the 64th WMA General Assembly held in Fortaleza, (Brazil, October 2013)²².

Participants. Two population groups were recruited through voluntary participation.

The first group comprised 25 unilateral transtibial amputee participants between 18 and 70 years old with prosthesis. Study participants included 4 participants with vascular transtibial amputation, 3 participants with diabetes, 11 participants with traumatic transtibial amputation, 3 participants with agenesis, 2 participants with oncological amputation and 2 participants with infection.

The inclusion criteria were that all subjects were free from musculoskeletal disorders and leg pain; they were a competent walker, which means they could carry out a standing ambulation by themselves without the help of third parties or the help of walking devices such as walking sticks. Each patient used his/her own prosthesis and had at least two years' experience with the device to ensure that there was a correct adaptation (mean time since amputation was 15.1 ± 14.8 years).

A 7 cm transtibial amputation was assessed from the joint interline of the knee, being the optimal level of stump length 12 cm below the knee interarticular line.

The amputee participants did not have knee instability. The alignment of each prosthesis was checked by a technician before the test. All subjects used axial type prosthetic feet, and gave informed consent to the study. The prosthetic foot used for all amputees was the Vari-Flex® foot.

The second group comprised 25 control participants (control group) with no stability problems in standing position or mobility problems, and who gave their consent to the study. These were non-amputee participants between 18 and 70 years old, with similar height and weight to those of the amputee participants, and whose medical histories did not indicate any osteoarticular or neurological disorders. They went to the podiatric clinic for an occasional podiatric problem such as an incarnate toenail, hyperkeratosis or treatment of a plantar wart in foot.

The control participants were recruited from the Sarroca Podiatry Clinic, and the transtibial amputee individuals came from several entities: Asociación de Amputados Adampi, Ortopedia Axis, Ortopedia Alcalá, Ortopedia Zaraorto and different hospitals according to a random sampling method, after identifying the eligible population through a clinical examination by the principal investigator to determine inclusion.

Baropodometric study. The baropodometric study (Fig. 1) was performed by the same clinician who performed the outcome measurements before and after the interventions with a Footwork force platform (V-PLACA, Standard EN 46,003; Medicauteurs, Balma, France)²³. The Footwork force platform offers many parameters for assessing postural stability. For the present study, we have evaluated the most commonly used

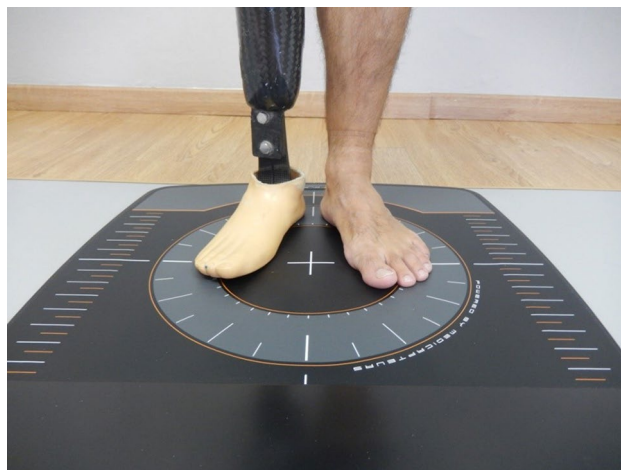


Figure 1. Baropodometry on a barefoot amputee patient in a comfortable bipedal position on the platform with both heels 2 cm apart with forefoot creating a 30° angle.

Size (length/width/height)	530 × 600 × 45 mm
Thickness	4 mm
Active surface	400 × 400 mm
Weight	6.8 kg
Sensors	Calibrated resistive
Sensor size	8 × 8 mm
Thickness sensor	0.15 mm
Number of sensors	2304 (48 × 48)
Permissible temperature	− 40 to 85 °C / − 40 to 185 °F
Pressure min/max sensor	0.4 N/m ² = 0.0004 kPa / 100 N/m ² = 0.1 kPa
Type PC interface/platform	USB
Supply	USB cable
Data acquisition frequency	200 images / second
Vertical force recording	60 Hz
Operating system required	Windows XP, Vista, 7

Table 1. Technical specifications of force platforms. Abbreviations: *mm* millimetres, *Kg* kilograms, °C degrees Celsius, °F degrees Fahrenheit, *N/m²* Newton/square metre, *kPa* kilopascals, *Hz* Hertzios.

in scientific literature and those that have shown the greatest reliability in different population groups^{24,25}. The characteristics of the Footwork dynamometric platform are specified in Table 1.

The system consists of a force platform placed on the floor. It was calibrated for the weight of each individual.

Data collection was performed with the subjects standing on the platform in a comfortable bipedal position according to standardised procedures: heels of the feet were 2 cm apart with the forefoot creating a 30° angle (Fig. 1). This ensured that the centre of gravity was positioned within a triangle formed by the foot support²⁶.

A reference point was located in front of the patients, based on their height, and they were asked to keep their gaze fixed on the reference point and hold their position for 30 s. If the participant moved during the test, then the data were discarded and the test was repeated²⁶.

Testing continued until data were obtained from 6 trials during which the participant was stationary. The participant did not know when he/she was actually being recorded. The average of 6 valid trials per foot was used for further analysis²⁶.

The following data were collected for each patient in both groups: length of movement of the barycenter (mm), lateral velocity (mm/sg), and anterior velocity (mm/sg).

The center of gravity (COG) is considered to be the point where the entire weight of the body is concentrated. Stabilometry therefore measures the stability of individuals by reducing them to a point, being able to objectively define the average position of the COG, as well as the small movements that it may undergo around this position.

- Length of movement of the barycenter is the length traveled by the center of gravity; the length of the trajectory covered by the centre thrust, and is measured in millimeters (mm).

- Lateral velocity is the velocity of the displacement of the COG projection in the X axis in postural oscillations and is measured in mm/sg.
- Anterior velocity is the velocity of the displacement of the COG projection in the Y axis in the postural oscillations and is measured in mm/sg.

To examine the influence of altered somatosensory information on postural stability, the participants performed standing balance tests under three surface conditions:

1. Subject with bare feet.
2. Subject with hard textured surface insole. 4 mm rigid material: Polypropylene PP-DWST. Manufactured by SIMONA (D-55606 Kirn, Germany) and distributed in Spain by Al-Mar Técnicas Ortopédicas S.L. (Arganda del Rey, Madrid).
3. Subject with soft silicone comfort surface insole. Soft silicone material (Varisan® hydrogel insoles, Farmavari S.A.U., Meres, Spain).

For each of the surface conditions, participants were tested in two vision conditions (eyes open, eyes shut) on three permanent surfaces (barefoot without insole, barefoot on hard insole and barefoot on soft insole). This was done barefoot because if we shoe the patient the Center of Gravity could be displaced depending on the drop of the sole or the height of the heel^{10,24,27,28}.

According to previous research^{24,25,27,28}, our study used measurements derived from centre of pressure (COP) displacement, and included the anterior and lateral velocity range.

The platform pressure sensor measurements were close to 0.001 kg/cm². Before each use, automatic calibration was performed according to the manufacturer's instructions²⁹.

For each situation, three measurements were performed, and the mean subsequently calculated in order to assess reliability. After a few days, the same variables were measured again to check repeatability³⁰.

Data recording was performed with a personal computer linked to the pressure sensor platform. The commercially available S-plate software program version 7.0 (interactive rehabilitation software) for Windows (Medi-capteurs, Balma, France) was used for all data collection and management.

Statistical analysis. Continuous variables were expressed as mean with standard deviation (SD) whereas qualitative variables were expressed as frequencies and percentages. The Kolmogorov–Smirnov test was used to assess the normality of the quantitative variables under study.

To assess the reliability of the parameters within the same test day in each patient, the intraclass correlation coefficients (ICC) were used^{31,32}. Using the classification proposed by Landis and Koch³¹, ICCs between 0.20 and 0.40 are considered to demonstrate reasonable reliability. Scores between 0.40 and 0.60 have moderate reliability, scores between 0.60 and 0.80 have considerable reliability, and in the highest category, scores ranging from 0.80 to 1.00 are considered near perfect. Other authors³³ indicate that to obtain reliability, an ICC value of at least 0.75 must be obtained.

To assess the relationship between the study group (patients vs. controls) and the sociodemographic, clinical and stability variables, the Mann–Whitney test or Student's t-test was used for quantitative variables, according to normality criteria. In the case of qualitative variables, the Chi-square test or Fisher's test was used.

To compare the results of stability in the different situations evaluated (support, vision), methods of comparison of means for related samples were applied. Wilcoxon test for two situations and Friedman test for three or more when the variable does not follow a normal distribution, and Student's t-test or repeated measures ANOVA if the variable follows a normal distribution.

The significance level was set at $p < 0.05$. However, in order to address the issue of conducting multiple comparison, the Bonferroni correction was applied ($P\text{-value} < 0.05/3 = P\text{-value} < 0.017$).

Statistical analyses were performed using the statistical software IBM SPSS Statistics, version 26 (SPSS Ibérica, Madrid, Spain).

Informed consent statement. Informed consent was obtained from all subjects involved in the study.

Results

Sociodemographic characteristics attending to the division by treatment groups. We had 50 participants in the study, 25 controls and 25 participants with amputation. In each of the groups, 80.0% of the subjects were men (20/25) and 20.0% women (5/25). The average age of the patients with amputation was 44.0 ± 12.9 years and that of controls was 38.4 ± 12.4 years. This difference between the groups was not statistically significant ($p = 0.124$). The average body mass index (BMI) of individuals with amputation was 26.4 ± 4.8 kg/m² and that of controls 25.0 ± 3.1 kg/m². This difference between the groups was not statistically significant ($p = 0.220$) (Table 2).

Length of movement of the barycenter. Table 3 shows the descriptive parameters of the variable “Length of movement of the barycenter” for the six situations evaluated, showing statistically significant differences ($p < 0.05$) between the two groups, with patients with amputation obtaining higher average levels than controls.

Annex 1 shows the p values of the two-to-two comparisons. The differences were statistically significant when comparing open eyes vs closed eyes for the three supports (barefoot, soft footbed, hard footbed) in both groups.

Variable	Total n = 50	Control Group n = 25	Amputee Group n = 25	p value*
Male	20 (80.0%)	20 (80.0%)	20 (80.0%)	1.000
Average age (years) ± SD	41.2 ± 12.9	38.4 ± 12.4	44.0 ± 12.9	0.124
Average BMI (kg/m ²) ± SD	25.7 ± 4.0	25.0 ± 3.1	26.4 ± 4.8	0.220

Table 2. Sociodemographic characteristics of participants by study group. *BMI* Body Mass Index, *SD* standard deviation. *Mann–Whitney Test.

	Control group	Amputee group	Difference	Sig. ¹ (p)
Barefoot				
Eyes open	64.8 (20.4)	120.1 (46.3)	55.3 (10.1)	< 0.001
Eyes shut	84.9 (31.1)	274.7 (181.1)	189.8 (36.8)	< 0.001
Soft insole				
Eyes open	80.6 (28.2)	126.8 (66.0)	46.2 (14.4)	0.001
Eyes shut	116.7 (61.3)	292.2 (171.7)	175.5 (36.5)	< 0.001
Hard insole				
Eyes open	58.2 (25.3)	116.2 (74.6)	58.0 (15.8)	< 0.001
Eyes shut	80.9 (38.1)	228.9 (136.3)	148.0 (28.3)	< 0.001
Sig. ² (p)	< 0.001	< 0.001		

Table 3. Comparison of Length of movement of the barycenter between experimental groups. Significant values are in [bold]. Mean (standard deviation). ¹Mann–Whitney Test. ²Friedman Test. Length of movement of the barycenter (mm).

	Control group	Amputee group	Difference	Sig. ² (p)
Barefoot				
	74.8 (24.8)	197.4 (103.6)	122.5 (21.3)	< 0.001
Soft insole				
	98.6 (43.4)	209.5 (111.7)	110.9 (24.0)	< 0.001
Hard insole				
	69.5 (30.6)	172.5 (95.2)	103.0 (20.0)	< 0.001
Sig. ¹ (p)	< 0.001	0.006		

Table 4. Comparison of length of movement of the barycenter between the different insoles in each experimental group. Significant values are in [bold]. Mean (standard deviation) [IC. For the mean (at 95%)]. ¹Friedman Test. ²Mann-Whitney Test. Length of movement of the barycenter (mm).

In addition, in the control group, significant differences ($p < 0.05$) were observed between soft insole and barefoot or soft insole and hard insole (at the same vision condition), also between hard and barefoot for open eyes. In amputee patients, there were differences between the supports in relation to the average length of movement of the barycenter only for closed eyes.

Length of movement of the barycenter according to support. Table 4 shows the descriptive parameters of the variable “Length of movement of the barycenter” for the three supports: barefoot, soft insole and hard insole. The data are grouped into eyes open and eyes shut.

Statistically significant differences were observed between the three supports in the two groups ($p < 0.05$), with greater stability (shorter length of movement of the barycenter) with the hard insole.

Hard insole, barefoot and soft insole would be the order of the three supports from most to least stable, both for people with amputation and controls.

In the group of amputees, the hard insole obtained significantly lower length of movement of the barycenter values than barefoot ($p = 0.010$), but no differences were observed between barefoot and soft insole ($p = 0.925$). In the control group this was different, the hard insole did not show values significantly lower than barefoot ($p = 0.061$), but there were differences between barefoot and soft insole ($p < 0.001$). Annex 2 shows the p values of the two-to-two comparisons.

Lateral velocity. Table 5 shows the descriptive parameters of the variable “Lateral velocity” for the six situations evaluated, showing statistically significant differences ($p < 0.05$) between the two groups for all of them, with people with amputation obtaining higher levels on average than controls.

	Control group	Amputee group	Difference	Sig. ¹ (p)
Barefoot				
Eyes open	1.4 (0.5)	2.7 (0.9)	1.3 (0.2)	< 0.001
Eyes shut	1.7 (0.5)	5.6 (3.3)	3.9 (0.7)	< 0.001
Soft insole				
Eyes open	1.7 (0.5)	2.8 (1.4)	1.1 (0.3)	< 0.001
Eyes shut	2.4 (1.3)	6.1 (3.5)	3.7 (0.7)	< 0.001
Hard insole				
Eyes open	1.2 (0.6)	2.6 (1.7)	1.4 (0.4)	< 0.001
Eyes shut	1.6 (0.7)	4.9 (2.8)	3.3 (0.6)	< 0.001
Sig. ² (p)	< 0.001	< 0.001		

Table 5. Comparison of lateral velocity between experimental groups. Significant values are in [bold]. Mean (standard deviation). ¹Mann–Whitney Test. ²Friedman Test. Lateral velocity (mm/sg).

	Control group	Amputee group	Difference	Sig. ² (p)
Barefoot				
	1.6 (0.5)	4.2 (1.9)	2.6 (0.4)	< 0.001
Soft insole				
	2.1 (0.9)	4.4 (2.3)	2.3 (0.5)	< 0.001
Hard insole				
	1.4 (0.6)	3.8 (2.1)	2.4 (0.4)	< 0.001
Sig. ¹ (p)	< 0.001	0.125		

Table 6. Comparison of lateral velocity between the different insoles in each experimental group. Significant values are in [bold]. Mean (standard deviation). ¹Friedman Test. ²Mann–Whitney Test. Lateral velocity (mm/sec).

Annex 3 shows the p values for each of the two-to-two comparisons. The differences are statistically significant when comparing open eyes vs closed eyes for the three supports (barefoot, soft insole, hard insole) in amputee patients and in controls.

Furthermore, in the control group, it is worth noting the significant differences ($p < 0.05$) between hard insole and soft insole, regardless of the vision condition.

Lateral velocity according to support. Table 6 shows the descriptive parameters of the variable "Lateral velocity" for the three supports: barefoot, soft insole and hard insole, grouping the data into eyes open and eyes shut.

Statistically significant differences between the three supports are observed in the control group, with greater stability (lower lateral velocity) with the hard insole. However, in the amputee group there are no significant differences in the lateral velocity of the patients in the different types of support ($p = 0.125$).

Hard insole, barefoot and soft insole would be the order of the three supports from the highest to the lowest stability for both groups (Table 6).

Statistically significant differences were observed between the three supports in the control group, presenting greater stability (lower lateral velocity) with a hard insole. Hard insole, barefoot and soft insole would be the order of the three supports from highest to lowest stability for controls; the three situations show statistically significant differences in comparisons two to two (Annex 4). In the group of amputees, the hard template obtained significantly lower lateral velocity values than the soft template ($p = 0.005$). Although the mean value of lateral velocity shows the same trend in amputees, there are no significant differences between the three types of support in this group.

Anterior velocity. Table 7 shows the descriptive parameters of the variable "Anterior velocity" for the six situations evaluated, showing statistically significant differences ($p < 0.05$) between the two groups for all of them, with people with amputation obtaining higher average levels than controls.

Annex 5 shows the p values for each of the two-to-two comparisons. The differences are statistically significant when comparing open eyes vs closed eyes for the three supports (barefoot, soft insole, hard insole) in both groups.

Furthermore, in the control group, it is worth noting the significant differences ($p < 0.05$) between hard insole and soft insole, regardless of the vision condition. In the group of patients, hard insole shows significant differences with barefoot and soft insole with eyes open.

	Control group	Amputee group	Difference	Sig. ¹ (p)
Barefoot				
Eyes open	1.4 (0.5)	2.5 (1.1)	1.1 (0.2)	< 0.001
Eyes shut	1.9 (0.8)	6.1 (4.5)	4.2 (0.9)	< 0.001
Soft insole				
Eyes open	1.7 (0.7)	2.6 (1.4)	0.9 (0.3)	0.003
Eyes shut	2.5 (1.4)	6.3 (3.9)	3.8 (0.8)	< 0.001
Hard insole				
Eyes open	1.3 (0.5)	2.4 (1.5)	1.1 (0.3)	< 0.001
Eyes shut	1.9 (1.0)	4.9 (3.1)	3.0 (0.7)	< 0.001
Sig. ² (p)	< 0.001	< 0.001		

Table 7. Comparison of anterior velocity between experimental groups. Significant values are in [bold]. Mean (standard deviation). ¹Mann–Whitney Test. ²Friedman Test. Anterior velocity (mm/sec).

	Control Group	Amputee Group	Difference	Sig. ² (p)
Barefoot				
	1.6 (0.7)	4.3 (2.6)	2.7 (0.5)	< 0.001
Soft insole				
	2.1 (1.0)	4.5 (2.4)	2.4 (0.5)	< 0.001
Hard insole				
	1.6 (0.7)	3.6 (2.1)	2.0 (0.4)	< 0.001
Sig. ¹ (p)	< 0.001	0.013		

Table 8. Comparison of anterior velocity between the different insoles in each experimental group. Significant values are in [bold]. Mean (standard deviation) [IC. For the mean (at 95%)]. ¹Friedman Test. ²Mann-Whitney Test. Anterior velocity (mm/sec).

Anterior velocity according to support. Table 8 shows the descriptive parameters of the variable "Anterior velocity" for the three supports: barefoot, soft insole and hard insole, grouping the data into eyes open and eyes shut.

Statistically significant differences were observed between the three supports in both study groups ($p < 0.05$), with greater stability (lower anterior velocity) with the hard insole. Hard insole, barefoot and soft insole would be the order of the three supports from greater to lesser stability.

Annex 6 shows the p values of the two-to-two comparisons. In the group of amputees, the hard insole obtained significantly lower anterior velocity values than barefoot ($p = 0.012$) and soft insole ($p = 0.001$), but no differences were observed between barefoot and soft insole ($p = 0.914$). In the control group, however, the hard insole did not show significantly lower values than barefoot ($p = 0.158$), but there were differences between barefoot and soft insole ($p < 0.001$) and between hard insole and soft insole ($p < 0.001$).

Reliability analysis. The measurements showed good/acceptable reliability with CI levels of above 0.79 for all stability variables considered, thus justifying the use of the mean value for the data analysis. The specific CI values are provided in Annex A.

Discussion

Taking into account the "length of movement of the barycenter" parameter, which projects the amplitude of the centre of gravity in millimetres, patients with amputation show less stability (higher mean levels) than controls. There are differences between the proposed situations (support and vision), obtaining greater stability (shorter length of movement of the barycenter) with eyes open compared to eyes shut, and with hard insole compared to barefoot or soft insole (less stable situation), both in people with amputation and controls.

In our study, people with lower limb amputation present greater displacements of their centre of gravity in a static situation than able-bodied individuals, depending to a greater extent on visual information. These data are similar to those of other studies carried out on 6 people with amputation and 6 controls in 2002⁴. Considering the "lateral velocity" parameter, people with amputation show less stability (higher mean levels) than controls. In people with amputation, there are differences between the two proposed vision conditions, obtaining greater stability (lower lateral velocity) with eyes open compared to eyes shut. However, the differences according to support are not significant in this group in terms of lateral velocity.

Taking into account the "anterior velocity" parameter, people with amputation show less stability (higher mean levels) than controls. There are differences between the proposed situations (support and vision) in both people with amputation and controls, obtaining greater stability (lower anterior velocity) with eyes open compared to eyes shut, and with hard insole compared to barefoot or soft insole. In this case, in static balance,

the ankle strategy is in charge of controlling the displacements in the anterior–posterior axis, modulating the amount of “torque” developed by the plantar and dorsal ankle flexors. In people with LL, the ability to use an ankle strategy is severely impaired, which would explain the greater instability in this direction compared to the lateral direction⁴.

There are studies that indicate that individuals with unilateral transtibial amputation would have serious difficulties in bearing the load on the lower limb as a consequence of the joint instability that seems to exist in the sagittal and frontal planes, essentially at the level of the knee joint³⁴.

Despite improved prosthetic components, the most recent studies still show asymmetries in the load between the two lower limbs of the individuals with amputation^{35–37}. As a result of this asymmetry, the healthy lower limb is continuously subjected to high mechanical stresses, which can lead to pain or degeneration of the articular cartilage^{38,39}.

The visual system shows great importance in the control of balance in all the subjects studied, both those with amputations and those belonging to the control group, as in all the variables and situations studied, better stabilometric results are obtained with eyes open as opposed to eyes shut.

There are studies that state that it is sufficient for the subject to close their eyes for their oscillations to increase by 250%⁴⁰.

In 2000, Fransson et al.⁴¹ concluded that all individuals change tactics when they close their eyes, with the control of postural oscillations being much less precise. Similarly, in our study, an increase in postural oscillations can be observed when vision with eyes shut is eliminated.

Consistent with our results, Buckley et al.⁴ state that people with lower limb amputation show greater displacements of their centre of gravity in a static situation than controls, depending to a greater extent on visual information. People with amputation had a greater problem controlling dynamic balance in the anterior–posterior direction than in the mediolateral direction.

Therefore, like Arifin et al.⁴², the results obtained recognise proprioception as an important quality for maintaining stability and postural strategy depending on the different support surfaces. They also point out that distorted somatosensory inputs are among the problems leading to impaired balance control in people with amputation. They further mention that reduced proprioception is associated with asymmetry in load bearing and decreased confidence in people with amputation. In the present study, this is reflected in the difference between eyes open and shut on the pressure platform to assess stability. Arifin et al.⁴² state that flexible or unstable surfaces reduce the ability to accurately detect body orientation, which is fully consistent with the findings presented in our study.

However, other studies show controversial results in relation to visual inflow and postural stability in people with amputations.

Nevertheless, Vittas et al. tested 20 people with transtibial amputation and concluded that their vertical axis stability was as good as the group of able-bodied individuals⁴³.

These contradictory results between researchers could be due to the different methods used to assess stability.

To our knowledge, no previous investigations have described the effects of insole density on the stability of amputee patients, but the use of different devices to increase stability has been addressed in other vulnerable populations such as older adults. Finlay et al. reported that foot function and stability is enhanced when subjects wear a prescribed shoe (orthopaedic) compared with values obtained when subjects wear their own footwear in this population^{18,44}. In fact, shoe insoles have also been identified as a mechanism to enhance postural control because they improved somatosensory function and may be useful in balance control⁴⁵. Changes in muscle activity as a consequence of various insole densities suggest an enhancement of plantar surface sensory input^{18,19}, which is important since the maintenance of postural stability is dependent on a range of somatosensory inputs. Shoe insoles can increase plantar foot surface contact and potentially increase somatosensory input. Regarding the influence of insole material in amputee patients, Sarroca et al. described an increase in thigh muscle activity recorded by electromyography studies in this vulnerable population⁴⁶.

Losa et al. reported significant improvements in postural sway when older adults stood on both soft and hard insoles compared to standing barefoot¹⁸. However, our results exhibit that the soft insole shows the most unstable situation in the amputee group and in the group of able-bodied patients, followed by barefoot patients. The most stable situation in both groups in our study (healthy and amputees) is on the rigid PP-DWST insole which is consistent with the results provided by Losa et al. in which they also found more pronounced improvements when a hard insole was used in older adults¹⁸.

It is worth highlighting the importance of the sample size in our study (25 patients with amputation, 25 controls) compared to others, which demonstrates the reliability of the results and the incorporation of new lines of research with plantar support rigidity in stabilometry.

Conclusion

After evaluating postural stability by means of stabilometry under normal conditions (on the floor of the dynamic platform with eyes open), and under altered conditions (with the interposition of different materials such as plantar support and shut eyes) in two groups (25 patients with amputation and 25 able-bodied individuals), we can conclude that subjects with unilateral transtibial amputation present less stability in terms of length of movement of the barycenter, lateral velocity and anterior velocity than the able-bodied population. Greater stability is obtained in both groups with eyes open compared to eyes shut, and the length of movement of the barycenter and anterior velocity in both groups is significant (more stability) with hard insole compared to barefoot or soft insole. However, in the group of people with amputation there are no significant differences in the lateral velocity of the patients in the different types of support. Providing increased sensory inputs with hard insoles may be an effective way to reduce the rate of falls, which are related to decreased quality of life in amputee individuals.

This study can aid in better understanding the insole design features associated with improved postural stability in amputee individuals.

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References

1. Woollacott, M. & Shumway-Cook, A. Attention and the control of posture and gait: a review of an emerging area of research. *Gait Posture*. **16**, 1–14 (2002).
2. Nusseck, M. & Spahn, C. Comparison of Postural Stability and Balance Between Musicians and Non-musicians. *Front. Psychol.* **11**, 1253. <https://doi.org/10.3389/fpsyg.2020.01253> (2020).
3. Miralles, R.C., Miralles, I.; Puig, M. *Biomecánica clínica de los tejidos y las articulaciones del aparato locomotor*. 2d ed. (Masson, Barcelona, Spain, 2005).
4. Buckley, J. G., O'Driscoll, D. & Bennett, S. J. Postural sway and active balance performance in highly active lower-limb amputees. *Am. J. Phys. Med. Rehabil.* **81**(1), 13–20 (2002).
5. Vanicek, N., Strike, S., McNaughton, L. & Polman, R. Postural responses to dynamic perturbations in amputee fallers versus nonfallers: a comparative study with able-bodied subjects. *Arch. Phys. Med. Rehabil.* **90**, 1018–1025 (2009).
6. Miller, W. C., Speechley, M. & Deathe, B. The prevalence and risk factors of falling and fear of falling among lower extremity amputees. *Arch. Phys. Med. Rehabil.* **82**(8), 1031–1037 (2001).
7. Merriman, L. M. & Tollafield, D. R. *Assessment of the Lower Limb* (Churchill, 1995).
8. Collado Vázquez, S., Pérez García, C. & Carrillo Esteban, J.M. *Métodos de estudio de la marcha. Motricidad. Fundamentos y Aplicaciones*. (Dykinson, Madrid, 2004).
9. Sánchez-Lacuesta, J. *Biomecánica de la marcha humana normal y patológica*. Instituto de Biomecánica de Valencia. (Martín Impr SL, Valencia, 1993).
10. Arya, A. P., Lees, A., Nirula, H. C. & Klenerman, L. Biomechanical comparison of the SACH, Seattle and Jaipur feb using ground reaction forces. *Prosthet. Orthot. Int.* **19**(1), 37–45 (1995).
11. Jayakaran, P., Johnson, G. M. & Sullivan, S. J. Test-retest reliability of the sensory organization test in older persons with a transtibial amputation. *PM R.* **3**(8), 723–729 (2011).
12. Jayakaran, P., Johnson, G. M. & Sullivan, S. J. Turning performance in persons with a dysvascular transtibial amputation. *Prosthet. Orthot. Int.* **38**(1), 75–78 (2014).
13. Jayakaran, P., Johnson, G. M. & Sullivan, S. J. Postural control in response to altered sensory conditions in persons with dysvascular and traumatic transtibial amputation. *Arch. Phys. Med. Rehabil.* **96**(2), 331–339 (2015).
14. Koehler-McNicholas, S. R. *et al.* Bimodal ankle-foot prosthesis for enhanced standing stability. *PLoS ONE* **13**(9), e0204512 (2018).
15. Kolarova, B., Janura, M., Svoboda, Z. & Elfmark, M. Limits of stability in persons with transtibial amputation with respect to prosthetic alignment alterations. *Arch. Phys. Med. Rehabil.* **94**(11), 2234–2240 (2013).
16. Thomas-Pohl, M. *et al.* Microprocessor prosthetic ankles: comparative biomechanical evaluation of people with transtibial traumatic amputation during standing on level ground and slope. *Disabil. Rehabil. Assist. Technol.* **16**(1), 17–26 (2021).
17. Davot, J. *et al.* Experimental characterization of the moment-angle curve during level and slope locomotion of transtibial amputee: Which parameters can be extracted to quantify the adaptations of microprocessor prosthetic ankle?. *Proc. Inst. Mech. Eng. H.* **235**(7), 762–769 (2021).
18. Losa, M. E., de Bengoa, R. B. & Palacios, D. Impact of soft and hard insole density on postural stability in older adults. *Geriatr. Nurs.* **33**(4), 264–271 (2012).
19. Park, J. H. *et al.* Immediate effect of insoles on balance in older adults. *Foot (Edinb)*. **47**, 101768 (2021).
20. Arndottir, S. A. & Mercer, V. S. Effects of footwear on measurements of balance and gait in women between the ages of 65 and 93 years. *Phys. Ther.* **80**, 17–27 (2000).
21. Mundermann, A., Stefanyshyn, D. J. & Nigg, B. M. Relationship between footwear comfort of shoe inserts and anthropometric and sensory factors. *Med. Sci. Sports Exerc.* **33**, 1939–1945 (2001).
22. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. *JAMA* **310**(20), 2191–2194 (2013).
23. Giacomozzi, C., Keijsers, N., Pataky, T. & Rosenbaum, D. International scientific consensus on medical plantar pressure measurement devices: technical requirements and performance. *Ann. Ist. Super Sanita.* **48**(3), 259–271 (2012).
24. Kitabayashi, T., Demura, S. & Noda, M. Examination of the factor structure of center of foot pressure movement and cross-validity. *J. Physiol. Anthropol. Appl. Human Sci.* **22**(6), 265–272 (2003).
25. Sobera, M., Siedlecka, B. & Syczewska, M. Posture control development in children aged 2–7 years old, based on the changes of repeatability of the stability indices. *Neurosci. Lett.* **491**(1), 13–17 (2011).
26. Salom-Moreno, J. *et al.* Changes in spasticity, widespread pressure pain sensitivity, and baropodometry after the application of dry needling in patients who have had a stroke: a randomized controlled trial. *J. Manip. Physiol. Ther.* **37**(8), 569–579 (2014).
27. Geurts, A. C., Nienhuis, B. & Mulder, T. W. Intrasubject variability of selected force-platform parameters in the quantification of postural control. *Arch. Phys. Med. Rehabil.* **74**(11), 1144–1150 (1993).
28. Mesure, S. & Lamendin, H. *Posture, Pratique Sportive et Rééducation* (Masson, 2001).
29. Becerro-de-Bengoa-Vallejo, R., Losa-Iglesias, M. E. & Rodríguez-Sanz, D. Static and dynamic plantar pressures in children with and without sever disease: a case-control study. *Phys. Ther.* **94**(6), 818–826 (2014).
30. Becerro-de-Bengoa-Vallejo, R., Losa-Iglesias, M. E., Zeni, J. & Thomas, S. Reliability and repeatability of the portable EPS-platform digital pressure-plate system. *J. Am. Podiatr. Med. Assoc.* **103**(3), 197–203 (2013).
31. Landis, J. R. & Koch, G. G. The measurement of observer agreement for categorical data. *Biometrics* **33**(1), 159–174 (1977).
32. - Portney, L.G. & Watkins, M.P. *Foundations of clinical research: applications to practice*. 3rd ed. (Pearson Prentice Hall, Nueva jersey, USA, 2009).
33. Burdock, E. I., Fleiss, J. L. & Hardesty, A. S. A new view of inter-observer agreement. *Pers. Psychol.* **16**, 373–384 (1963).
34. Francisco Molina Rueda. *Estrategias de control motor en sujetos protetizados con amputación transtibial unilateral: análisis instrumental* (Rey Juan Carlos University, Madrid, 2012).
35. Prinsen, E. C., Nederhand, M. J. & Rietman, J. S. Adaptation strategies of the lower extremities of patients with a transtibial or transfemoral amputation during level walking: a systematic review. *Arch. Phys. Med. Rehabil.* **92**(8), 1311–1324 (2011).
36. Soares, A. S., Yamaguti, E. Y., Mochizuki, L., Amadio, A. C. & Serrão, J. C. Biomechanical parameters of gait among transtibial amputees: a review. *Sao Paulo Med. J.* **127**(5), 302–309 (2009).
37. Sagawa, Y. Jr. *et al.* Biomechanics and physiological parameters during gait in lower-limb amputees: a systematic review. *Gait Posture*. **33**(4), 511–526 (2011).
38. Nolan, L. *et al.* Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees. *Gait Posture*. **17**(2), 142–151 (2003).

39. Hurwitz, D. E., Sumner, D. R., Andriacchi, T. P. & Sugar, D. A. Dynamic knee loads during gait predict proximal tibial bone distribution. *J. Biomech.* **31**(5), 423–430 (1998).
40. - Gagey, P.M. & Weber, B. Posturología. Regulación y Alteraciones de la Bipedestación. 2d ed. (Masson, Barcelona, Spain, 2001).
41. Fransson, P., Johansson, R., Hafström, A. & Magnusson, M. Methods for evaluation of postural control adaptation. *Gait Posture*. **12**(1), 14–24 (2000).
42. Arifin, N., Osman, N. A. A., Ali, S., Gholizadeh, H. & Abas, W. A. Postural stability characteristics of transtibial amputees wearing different prosthetic foot types when standing on various support surfaces. *Sci. World J.* **2014**, 856279. <https://doi.org/10.1155/2014/856279> (2014).
43. Vittas, D., Larsen, T. K. & Jansen, E. C. Body sway in below-knee amputees. *Prosthet. Orthot. Int.* **10**, 139–141 (1986).
44. Finlay, O., van de Meer, D. & Beringer, T. Use of gait analysis to demonstrate benefits of footwear assessment in elderly people. *Physiotherapy* **85**, 451–456 (1999).
45. Priplata, A. A., Niemi, J. B., Harry, J. D., Lipsitz, L. A. & Collins, J. J. Vibrating insoles and balance control in elderly people. *Lancet* **362**, 1123–1124 (2003).
46. Sarroca, N. *et al.* Muscle activation during gait in unilateral transtibial amputee patients with prosthesis: the influence of the insole material density. *J. Clin. Med.* **10**(14), 3119. <https://doi.org/10.3390/jcm10143119> (2021).

Author contributions

All authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript, as follows: Conceptualization, N.S. and M.L.; data curation, N.S., J.C. and T.L.; formal analysis, M.J.L., J.V., M.P.C., J.B., C.A. and J.C.; writing—original draft, N.S., M.J.L., J.V., J.B. and M.L.; writing—review and editing, N.S., M.J.L. and M.L. All authors have read and agreed to the published version of the manuscript.

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Competing interests

The authors declare no competing interests.

Additional information

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