Influence Of Insoles In The Dynamic And Static Stability Of People With Transtibial Amputation: A Systematic Review

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Abstract: Although one of the main goals of the limb preservation team is to prevent amputations, they are sometimes unavoidable. Amputations, particularly major amputations above the ankle, are a major public health concern and represent a heavy health burden due to their impact on the physical and mental health and quality of life of those affected. With the loss of static and dynamic stability, people with major amputations may require orthopedic support such as foot orthoses. Current literature in the field is sparse and guidelines are lacking. *Objective:* To increase the level of evidence-based knowledge and consider professional recommendations, a systematic review was conducted to investigate the influence of foot orthoses in people with transtibial amputation. *Method:* A search strategy based on the PICO (Population, Interventions, Comparator, Outcomes) question was carried out in the public databases PubMed, Cochrane and PEDRO using keywords alone or combined such as 'leg amputation', 'rehabilitation', 'gait', 'balance' and 'insole'. *Results:* Of the 1856 potential manuscript identified, only two were included in this review. In people with unilateral transtibial amputation using prosthetics, data have demonstrated that rigid orthoses can improve stability. *Conclusion:* Rigid orthoses may play a role in the control of balance in people with transtibial amputations. Benefits of orthoses for this population is poorly investigated and the literature is too scarce to support recommendations.

Key words: *leg amputation, transtibial amputation rehabilitation, insoles, gait, balance, stability.*

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Introduction

Although one of the main goals of the limb preservation team is to prevent amputations, they are sometimes unavoidable.[1] Two types of lower extremity amputations (LEAs) are described: major amputations, which are above the ankle (e.g., below the knee and above the knee) and minor, which are below the ankle (e.g., toe, hallux, mid-tarsal, etc.).[2] Major LEAs, especially, have important individual-, organizational- and systemic- impact, and represent a heavy health burden due to their impact on physical and mental health, as well as on the quality of life of those affected.[3] There are several variations in terms of LEA epidemiology. In high-income countries, there seems to be a downward trend[4-6] due to better limb preservation programs.[7] However, this is a very fragile situation with the rise of chronic diseases such as diabetes, peripheral arterial disease and other multimorbidities, as well as the ageing of the population.[8] Moreover, males are more likely to have LEA. Some marginalized peoples and some ethnicities are also more at-risk.[9-11] Conversely, in developing countries, an increasing trend is indicated.[12] For example, in Brazil, both minor and major LEAs increased between 2019 and 2022, mostly due to vascular-, diabetes-related pathologies.[13]

With the loss of a significant part of the lower extremity, major LEAs often require a prosthesis to maintain as much function as possible. However, this has an inevitable impact on static and dynamic stability during the activities of daily living.[14]

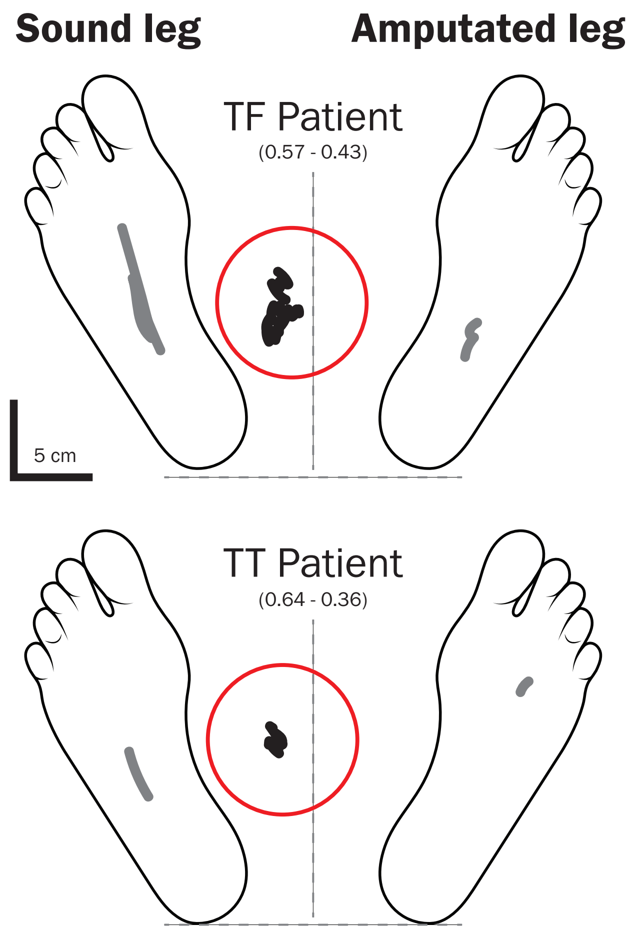

Figure 1: Centre of pressure in static analysis for individual with transfemoral and transtibial LEA. Adapted from: Rougier PR, Bergeau J. Biomechanical analysis of postural control of persons with transtibial or transfemoral amputation. Am J Phys Med Rehabil. 2009 Nov;88(11): 896-903. DOI: 10.1097/PHM.0b013e3181b331af

In addition to the quality of life, LEAs affect the body particularly related to balance and gait.[15] Several modifications of gait pattern and stability were demonstrated in people with major LEA. As an example, in static analysis, the centre of pressure of both feet is shifted to the side of the residual limb, in both transfemoral and transtibial LEA.[16,17] When compared to the residual limb, the centre of pressure of the amputated limb is larger and shifted forward[17] (See Figure 1).

Gait is analyzed using two parameters: biomechanical and spatiotemporal. Several studies have shown modification in spatial parameters, such as an increased step length for the amputated limb particularly in people with transtibial LEA.[18-20] Other studies have demonstrated alterations in both people with transtibial and transfemoral LEA with an increased width and length step for the amputated limb.[21,22] These changes may be explained by the appearance of compensatory strategies. In terms of temporal parameters, gait velocity is decreased.[23] For the amputated limb, the stance phase is decreased and the swing phase is increased, leading to a decreasing gait velocity.[22,24-27] Biomechanics parameters are also altered. For example, it has been shown that the electromyographic signal is increased (i.e., larger amplitude) in people with LEA compared with control individuals since to stabilize the knee and to control the flexion, the body increases its muscle activity in the amputated limb.[28] Other biomechanical parameters are also modified, such as ground forces or power which are both decreased.[29,30]

With the loss of static and dynamic stability in people with major LEA, they may require additional orthopedic support, such as foot orthoses. These devices have demonstrated their benefits in terms of foot health, static balance, gait and support in different tasks.[31,32] However, knowledge about foot orthotics for people with major LEA is limited in terms of stability and balance, in addition to the type and characteristics of the orthotics. Guidelines are lacking to support the evidence-based practices of health-care professionals supporting the feet (or residual foot) of people with LEA, such as podiatrists, chiropodists, orthotists, prosthetists, physiatrists, orthopedists, etc.[33] Therefore, the aim of this study was to investigate the influence of foot orthoses, also identifying their type and characteristics, on static and dynamic balance in people with transtibial LEA.

Method

Study design: The aim of a systematic review is to identify, assess and summarize the literature about a specific PICO (Patient, Intervention, Comparison, Outcomes) question.[34] Our objective was to answer whether plantar orthoses have an influence (I) on static and dynamic stability (O) in people with transtibial LEA (P) compared with

Table 1: Keywords and MeSH based on a PICO-guided search strategy

	French Keywords	OR	English Keywords	OR	French MeSH	OR	English MeSH	
Population	• Amputation: transfémorale et transtibiale)		• Amputation		• Amputation chirurgical		• Amputations	
AND								
Intervention	• Semelles orthopédiques • Semelles texturées		• Orthopedic insoles • Textured insoles		• Orthèses plantaires		• Foot orthoses	
AND								
Comparison	• Pas de traitement • Patients sains • Contrôle		• Control					
AND								
Outcomes	• Locomotion • Marche • Équilibre • Dynamique • Statique		• Locomotion • Walking • Gait • Balance • Equilibrium		• Locomotion • Équilibre postural		• Locomotion	
								N total

the control group, i.e., people without LEA (C)? This study was guided by the PRISMA (Preferred Reporting Items for Systematic Review) methods.[35] This project was not registered in a systematic review database.

Search strategy: A search strategy was developed by combining keywords and MeSH (Medical Subject Heading) terms in the PubMed, Cochrane Library and Pedro databases, and this strategy was adapted to each database. This was guided by PICO (See Table 1).

Eligibility criteria for inclusion in study: The eligibility criteria targeted clinical trial studies that included people/patients with a major LEA, such as a unilateral transtibial or transfemoral amputation with impaired gait and the use of orthopedic support, such as a foot orthotics and/or insoles. There were no other limitations concerning the sociodemographic characteristics of the population or related to the comparison group. We were looking for results related to the effect of the intervention on the person's dynamic and static stability. Studies published in French or English between 2003 and 2023 were targeted.

Screening process: Potential study references were imported into the Rayyan® online tool[36] and we excluded duplicates before titles and abstract selection. Two independent reviewers read the title and abstract and decided whether or not to include the studies based on the inclusion criteria. After this initial selection, a consensus was reached on which studies should potentially be included for full-text review. A third reviewer was available to resolve any discrepancies between the two reviewers to facilitate the full-text-review. After the selection process, the reviewers checked the reference list of potential studies and also contacted the authors to support the identification of relevant ongoing studies on this topic.

Data extraction and management: Data from included studies were extracted via a Microsoft Word PICO-based form by the lead reviewer. No bias analysis was performed considering the scarce literature on this domain, as well as no meta-analysis. The data were reported in a descriptive manner, given that the objective was to determine the state of knowledge that could form the basis of clinical recommendations for the population targeted by this study.

Results

Included studies: A total of 1856 potential studies were included in Rayyan's databases, including 1843 studies from PubMed, 7 from Pedro and 6 from the Cochrane Library. After removing duplicates, 1833 articles were reviewed based on titles and abstract. At the end of the selection process, only two studies remained which were included in the present analysis (See Figure 2) and reported in a narrative synthesis.

Both included studies assessed the influence of orthoses on the static stability[37] and on the gait.[38] Both are recent studies (2022 and 2021), from the same group of authors from Spain and were conducted on the same population of individuals with transtibial LEA.

Characteristics of included studies are listed in the Table 2. In both studies, hard surface insoles were made with polypropylene PP-DWST with a height of 4 mm and soft comfort surface insoles were made with silicone material (Varisan© hydrogel insoles).

Influence of plantar orthoses on gait: Gait was analyzed through the intensity of muscle activity using electromyography signals for two muscle groups (i.e., hamstrings and quadriceps) under four conditions:

1. Controlled conditions (barefoot)
2. Running shoes
3. Soft insoles and running shoes
4. Rigid orthoses and running shoes) at four different speeds (i.e., V1 (0.7 m/s), V2 (1.0 m/s), V3 (1.3 m/s) and V4 (1.6 m/s) on a treadmill.

In intragroup analysis, i.e., results between the limb with the LEA and the contralateral limb, they found statistically significant differences related to a higher quadriceps activity on the contralateral side compared to the LEA side with bare feet at V4, with soft insoles at V2, V3, V4 and with rigid orthoses at V4.

In the intergroup analysis, i.e., results between the limb with the LEA and compared to the contralateral limb of the control group, decreasing electromyographic activity was found for the quadriceps, no matter the condition at V3 and V4. Moreover, at V4 with rigid orthoses, significative diminution was found for hamstring groups in people with LEA, compared to the control group and in the condition of bare feet in people with LEA. Finally, a trend is observed in this study; with rigid orthoses which seems to have an influence on hamstring activity. Indeed, in bare feet or without insoles, results showed

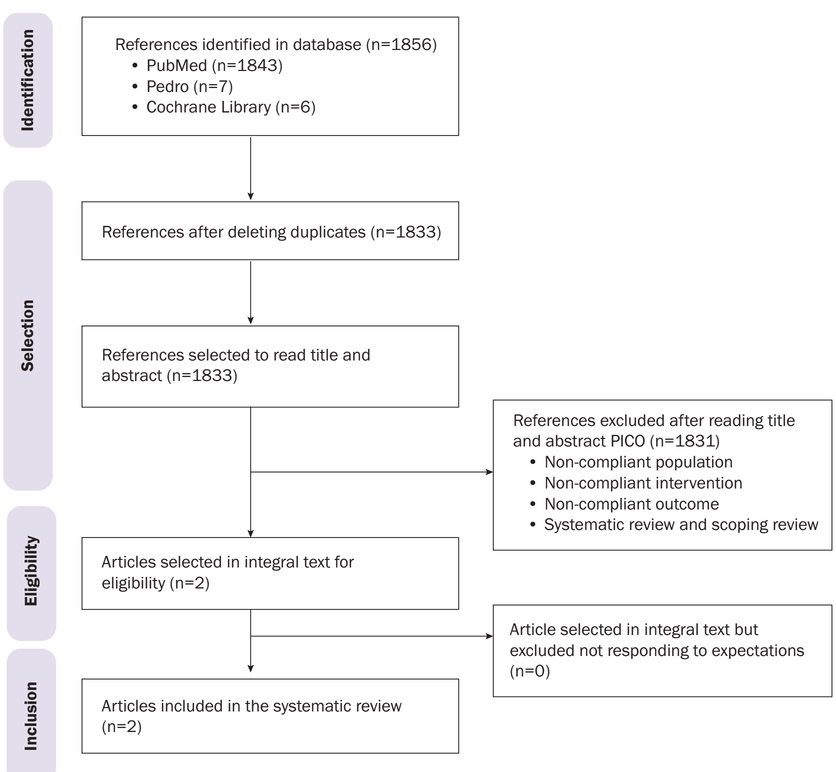

Figure 2: PRISMA Chart flow for identification, selection, eligibility and inclusion.

Table 2: Characteristics on included studies

Authors, Year, Country	Population				Intervention		Results	
	Total	*Mean age*	*Time passed since amputation*	*Type of prosthesis*	*Types of orthoses/ insoles*	*Comparison*	*Outcome*	*Result*
(Sarroca et al., 2021), Spain	N (amputees) = 25 N (control) = 25	44 ± 12.9 yo	At least 2 years	Vari-Flex® prosthetic foot with rigid fitting carbon fibre TSB	Hard orthoses Soft silicone insoles	Bare feet Running shoes	Muscular activity during gait on a treadmill	Significantly decreasing of hamstring activity with hard insole at the highest speed
(Sarroca et al., 2022), Spain	N (amputees) = 25 N (control) = 25 orthopédiques Semelles texturées	44 ± 12.9 yo	At least 2 years	Vari-Flex® prosthetic foot	Hard orthoses Soft silicone insoles	Bare feet	Centre of pressure in static measured with force platform	Better stability with hard insoles

higher hamstring activity for the side with LEA compared to the contralateral limb.

Influence of plantar orthoses on static balance: Static balance was analyzed through displacement and velocity (lateral and anterior) of the centre of pressure with a force platform, in three conditions: controlled condition bare feet, with hard orthoses and with soft insoles. Each of these conditions was assessed with eyes opened and closed. In terms of static stability, a reduction in the length of the displacement of the centre of pressure was observed with hard orthotics. However, in barefoot conditions, the displacement was greater with hard orthotics, but smaller with soft insoles. Regarding the centre of pressure with lateral velocity, significant differences were demonstrated for the control group, with a significant decrease in this velocity with the wearing of rigid orthoses. In barefoot condition, the values were reduced compared with soft insoles, but not higher with rigid orthoses. In the group of people with LEA, significant differences were observed between both soft insoles and rigid orthoses. The latter led to a reduction in lateral velocity compared with soft insoles. Analysis of the anterior velocity of the centre of pressure revealed the same trend as the other parameters studied, with an increase in stability when rigid orthoses were worn (i.e., decrease in the anterior velocity of the centre of pressure). Finally, in ascending order of stability, the different conditions are classified as follows: soft silicone insoles, barefoot and rigid orthoses. Summary of these findings are displayed in Table 3.

Discussion

This study has investigated the influence of foot orthoses on static and dynamic balance in people with transtibial LEA. Our review showed that there is very little literature on this topic. However, the studies included support our hypothesis that foot orthoses lead to improved gait and static balance.[37,38] However, there are many gaps in knowledge about optimal types and characteristics of orthoses for peoples with LEA.

Table 3: Influence of plantar orthoses/insoles on muscle activity and the displacement and velocity of the centre of pressure

Group	**Individual as control**	**Individual with amputation**	
Limb	Paired with amputated side	Contralateral side	Amputated Side
Muscle activity			
Hamstring	• Rigid orthoses (1.6 m/s) ↑*		• Rigid orthoses (1.6 m/s) ↓*
	• Soft insoles • Rigid orthoses ↓		• Barefoot • Without insoles/orthoses ↑
	• Soft insoles • Rigid orthoses ↑		• Barefoot • Without insoles/orthoses ↓
Quadriceps		• Barefoot ((1.6 m/s) • Insoles (1.0; 1.3 and 1.6 m/s) Rigid orthoses (1.6 m/s) ↑	
			• All condition (1.3 and 1.6 m/s) ↓
Displacement and velocity of CoP†			
Length of displacement of CoP (mm)	• Rigid orthoses ↓* • Soft silicon insoles ↑*		• Rigid orthoses ↓* • Soft silicon insoles ↑*
Lateral velocity of CoP (mm /sec)	• Rigid orthoses ↓* • Soft silicon insoles ↑*		• Rigid orthoses ↓ • Soft silicon insoles ↑
Anterior velocity of CoP (mm /sec)	• Rigid orthoses = • Soft silicon insoles ↑*		• Rigid orthoses ↓* • Soft silicon insoles ↑*

Legend and abbreviations
Black blocks: No significant results or observations
†: compared to the condition: bare feet
*: statistically significant
↓ : decreasing
↑ : increasing
=: equal
CoP: Centre of pressure

In barefoot conditions, with soft insoles and rigid orthoses, the quadriceps of the LEA side had decreased activity compared with the control group. When compared to the non-LEA side, the quadriceps activity of the LEA side was smaller with insoles, regardless of the hardness of insoles and under highest speeds. As for the hamstrings of the LEA side, wearing rigid orthoses while walking (at high speed) significantly reduces their muscular activity compared to the control limb.[38] Wearing soft or rigid insoles/orthoses reduces hamstring muscular activity regardless of walking speed. This is a new finding given that in people with major LEA, hamstring muscle activity is generally increased.[39] Orthopedic insoles/orthoses, therefore, have the potential to bring this muscular activity closer to normal physiology (without LEA). Therefore, more investigation is needed to understand why such effects were found. We can hypothesize that during gait with foot orthoses, the body being more stable, the muscles are less solicited, thus leading to a decrease in muscle activity in people with major LEA.

Some studies have analyzed insole/orthoses wearing and electromyography signals in other populations. For example, it has been proposed that insoles made in a particular way (i.e., according to joint kinematics), reduced muscle activity in the lower limb.[40] A study in ten individuals among 30 females (mean age: 22.8 years) with idiopathic pes cavus foot showed that wearing orthoses significantly reduced muscle activity during gait.[41] This is explained by a better distribution of loads under the feet and, consequently, reduced muscle activity in the participants. Rigid orthoses have been shown to improve stability in older adults.[42,43]

In terms of static balance, wearing rigid orthoses provided greater stability for both people with LEA and the control group, compared with soft silicone insoles and barefoot condition.[37] Thus, rigid orthoses have provided greater stability than bare feet, the latter providing greater stability than soft insoles. These results are coherent with those related to the influence of orthopedic orthoses on stability in other populations, whether it be adults, elderly adults or people with Parkinson's disease.[44-46] This trend between rigid insoles, which provide greater stability, and silicone insoles which, on the contrary, reduce this stability and may even lead to instability were also found in another study with older adults.[43]

Strengths and limitations: This systematic review brings together evidence from the scientific literature on a common and important clinical question concerning the type of and effects on orthoses in this population. It provides clinicians with a quick overview of the current situation. However, our review has limitations. Although it was carried out using a rigorous method, the search strategy could have been validated by a librarian. The small number of studies included limited understanding of the results, which probably explains the lack of guidelines to support evidence-based practices by health-care professionals who support the foot (or residual foot) in people with transtibial LEA. Although the two studies do not assess the same parameters, the total number of patients in this review is limited to 25 individuals with major LEA, with 80% of male individuals in each group, with an average age of 44 years in controls and 38 years in individual with LEA. Furthermore, an error was found in the study regarding the influence of orthoses on the static stability.[37] This study has examined the movements of the centre of mass, which would be equivalent to the displacement of the centre of gravity. However, the analyses were conducted using a force platform, which provides the displacements of the centre of pressure of both feet, not the centre of gravity. Indeed, to analyze the centre of gravity, 3D cameras and other software would be required, which was not stated in this study. This confusion reduces the internal validity of the results. These studies from the same group of authors were heterogeneous in terms of the parameters studied and results reporting.

Nevertheless, our study shows that it is essential to intensify research in this sector, particularly to improve the quality of life of people with major LEA, with a perspective toward limb preservation and rehabilitation. Best practice in foot orthotics for this population has yet to be demonstrated, but patient-centred approaches that also consider the expertise of health-care professionals should be considered. More studies are needed to improve clinical application so that patients with LEA have better care in the orthopedic domain, including rehabilitation and prevention of reamputation.

Conclusion

Benefits of foot orthoses/insoles in people with major LEA are poorly described in the literature but there seems to be a beneficial trend towards stability and bringing muscle activity back close to normal physiology before LEA. Clinicians need to assess each patient's needs and situation individually. ■

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