

Development of an Orthosis to Compensate Volumetric Dysmetria of Feet

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Abstract

The concept of symmetry applied to the two halves of the human body has been the subject of reflection by anatomists. One of the most common inequalities is dysmetria of the lower limbs (LL), especially the legs and/or feet. In the case of a height difference in the legs, if it is very pronounced, it is necessary to develop strategies capable of correcting or reducing its impact on the quality of life of people who live with it daily. A rare type of dysmetria is the volumetric difference of the feet, not accompanied by changes in the length of the legs. In these cases, filling with conventional orthopedic insoles to improve the fixation of the foot inside the shoe is completely inappropriate because it slightly increases the length of the respective lower limb, which is reflected in changes in the spine that can degenerate into severe scoliosis. To solve these problems, a volumetric compensation orthosis applicable to this type of situation was developed. Using modern three-dimensional scanning and 3D printing techniques, an orthosis was customized for placement inside the shoes of an individual with this volumetric anomaly. To ensure walking comfort, a common flexible material (TPU) was chosen, and the printing parameters were studied based on feedback given by the user. As a measure of the effectiveness of the developed product and to analyze the effect produced, tests were carried out to compare gait patterns before and after the correction was established. The results found showed an approximation to standard gait patterns, a considerable improvement in the fixation of the foot inside the shoe and an interchangeability that allows the use of the orthosis in any type of footwear, such as classic shoes, boots or sneakers.

1. Introduction

Lower limb dysmetria can be defined as a difference or discrepancy in the length of one or several segments of a limb in relation to the contralateral limb due to defects/shortening [1], which may affect the legs or feet. According to Pereira and Sacco [2], this anomaly, despite sometimes going unnoticed, is part of the reality of approximately 65% to 70% of the population and can be divided into two types, which are structural or acquired. Structural dysmetria can result from congenital malformations, changes in normal bone development and growth and bone diseases, while acquired dysmetria results from injuries external to the bone, osteoarticular infections or neurological or vascular diseases of mechanical or positional origin [2], [3], [4]. Knowing the value of the difference in limb length, which is the main factor responsible for the difference, can inform patients about the etiology of the problem and help them to decide which treatment is recommended and when to carry it out [5].

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The solutions available to compensate for dysmetria in the lower limbs fundamentally consist of the use of elevated shoes or lifting insoles. Elevated footwear is a classic but unsightly solution [6]. For small and medium dysmetria, orthopedic insoles [7], which are placed inside the footwear, are often used. It is important to note that the footwear chosen must be high enough to allow the placement of the insole inside as well as the accommodation of the individual's foot. The types of insoles can be divided into two groups: custom-made orthopedic insoles or generic/nonprescription insoles. Custom-made orthopedic insoles or plantar orthoses are orthopedic products designed to wrap the foot in its plantar region (lower part) for corrective or accommodation purposes. Its effect is enhanced when the insole is closely adapted to the foot, helping its positioning. As with any medical diagnosis, treatment using custom-made insoles, also known as postural or personalized insoles, begins with a complete assessment of the patient's physical condition, where important aspects such as the shape of the foot, range of movements are recorded, muscular strength, and even gait patterns [8], [9]. These elements act in the presence of a difference in the length of the lower limbs, thus placing an incompressible material under the shorter limb, whose height corresponds to the difference in length between the limbs. In the presence of significant differences between limbs, it is sometimes decided to gradually compensate for this difference to allow the body to gradually adapt to the compensated height [10]. Generic insoles, unlike the previous ones, are not custom-made and only provide support in the plantar arch, support in the toes or extra cushioning in the heel; therefore, they are not recommended for correcting problems. According to Nigg et al. [11], the use of insoles, as a means of prevention and treatment, presupposes a change in the input of sensory information into the foot, thus modifying the posture and balance of the body. Several authors argue that dysmetry of the lower limbs is one of the main factors responsible for affecting an individual's gait, mechanics, posture, and postural oscillation, as well as increasing the incidence of scoliosis, low back pain, hip and spine osteoarthritis and stress fractures in the lower limbs [12].

Unlike leg dysmetry, volumetric foot dysmetry is a difficult problem to solve because it results in a conflict with the type of footwear used and there are no solutions available on the current market that can provide an individual response and at an affordable price. Figure 1 corresponds to an irrefutable example of volumetric dysmetria of the feet, showing the existence of a right foot that is smaller in length and width than the contralateral foot. In this specific case, the left foot had a length of 296 mm, 100 mm of with and 50 mm of thickness. On the right foot the corresponding measurements were 280×95×35 mm, respectively. Regarding the use of footwear, the appropriate size for one foot is not equally suitable for the other. If one of the feet is "tight" inside the shoe, the other is too "wide", causing discomfort and changes in the gait pattern, as well as an effort to attack the ground. Furthermore, several authors have reported that the perimeter at the level of the metatarsal is related to the region of discomfort [13], [14]. Therefore, the existing correction alternatives are reduced and not very viable. Buying pairs of shoes in different sizes or inserting insoles are the most realistic alternatives, but they do not solve the problem and may even make it worse. Using shoes of different sizes is unsightly and expensive because it requires the purchase of two pairs of shoes and the insertion of conventional orthopedic insoles to fill volume leads to an artificial increase in the length of the lower limb where there is a volumetric difference in the foot.

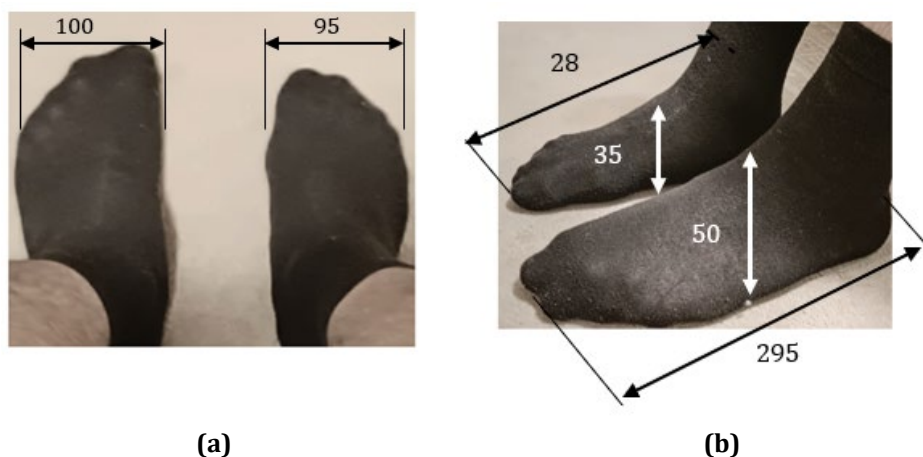


Fig. 1 Real example of volumetric dysmetria of the feet (a) top view; (b) side view. (dimensions in mm)

2. Materials and Methods

Based on a real case of a young individual with volumetric dysmetria of the feet, three-dimensional mapping of the right and left feet was used and, with the help of the commercial software Meshmixer and SolidWorks, their

volumes were obtained, which were subsequently subtracted to obtain the volumetric difference in the form of a dot file to be read by a 3D printer. With printing, the personalized orthosis allows it to be integrated into any type of footwear, maintaining stable comfort levels as well as a regular gait pattern for the individual.

2.1 Three-Dimensional Mapping and Model Acquisition

A portable 3D modelling scanner Sense Pro – TOMTOP, supporting OBJ/STL/PLY output was used to obtain a three-dimensional map of the individual's feet. The files were saved in STL format for later processing in the *Meshmixer* program. The contour surface was converted into a solid, and some corrections were made to the mesh using sculpting tools to smooth the final shape, as shown in Figure 2.

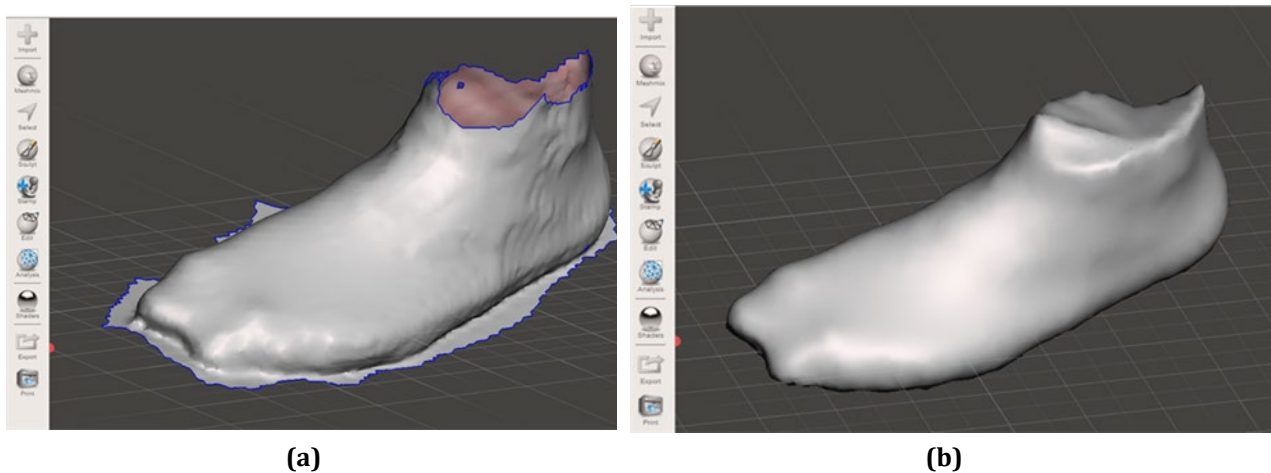


Fig. 2 3D mapping (a) selection of unnecessary areas; (b) Solid left foot

To enable overlapping, the larger foot was mirrored, and a common reference was defined, considering two cutting planes at the heel and ankle, as illustrated in Figure 3. After this step, 3D objects files exported by *Meshmixer* were created for each of the feet.

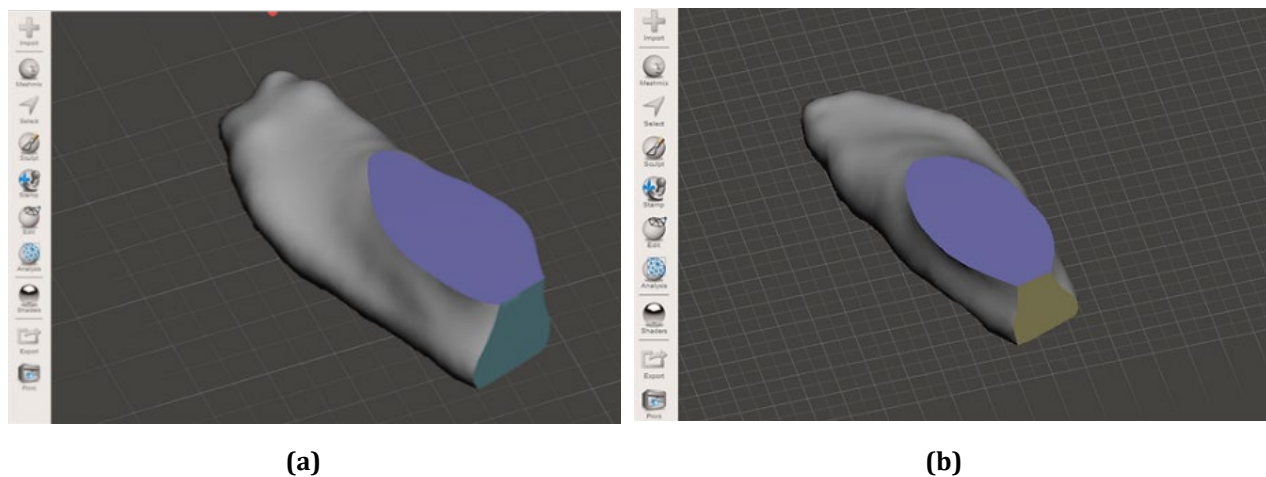


Fig. 3 Final foot (a) left; (b) right

2.2 Model Development in SolidWorks

Subtracting volumes in *SolidWorks* requires transforming the files into 3D parts produced in this software. For this purpose, the imported solid was transposed into an object as identical as possible to this one through successive lofts of the contour of the foot. First, we create planes coincident and parallel to the cutting face of the heel, and then, using the spline, we sketch the contour of the foot. The process is illustrated in Figure 4.

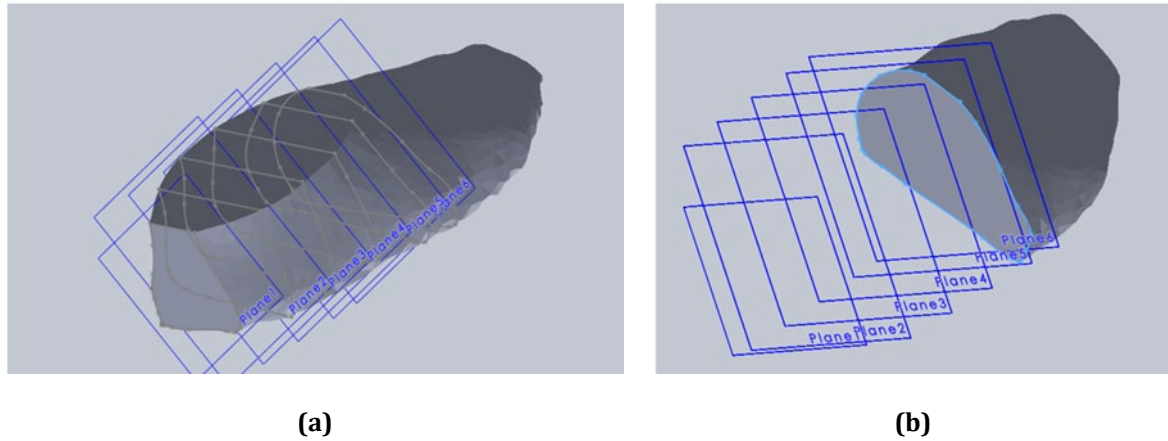


Fig. 4 Left foot mirror

2.3 Overlapping and Subtracting Models to Obtain the Desired Shape

To superimpose shapes, there must be correct alignment, and the most effective and quick way was to make a small insertion in the models in a plane perpendicular to the cutting face of the heel so that, when making the necessary mates, they would be aligned, as intended. With the shapes positioned in the appropriate location, the larger shape was subtracted from the smaller shape using the Combine command, resulting in the following shape in Figure 5a. As the objective is to insert the orthosis inside the shoe, only the front part of the foot is important for this study. Thus, cuts were made in the heel area to leave only the front and sole of the foot, as shown in Figure 5b. The decision to remain with the sole of the foot is made because it provides greater comfort for the individual when inserting and using it. Finally, for 3D printing purposes, it is necessary to save the *SolidWorks* file in an STL format.

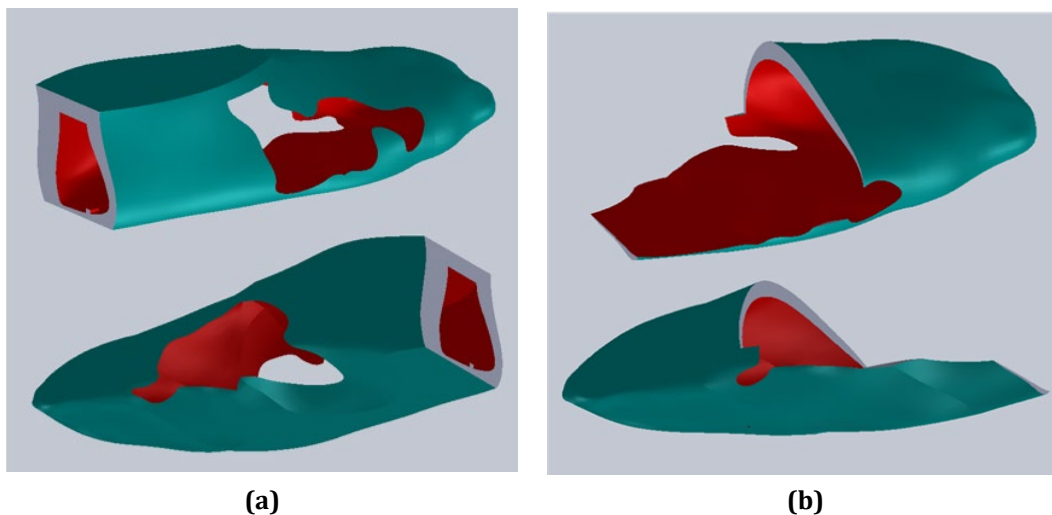


Fig. 5 Shape obtained (a) by subtracting the inverse of the left foot from the right foot; (b) Intended shape for 3D printing

2.4. Materials for 3D printing

To print in the desired way, a Prusa i3 MK3 printer was used. The part was imported into the STL format, and the printing and filament parameters were defined, as shown in Tables 1 and 2, respectively.

Table 1 *Printing parameters (Print Settings)*

Nozzle diameter	0.40 mm
Layer thickness	0.20 mm
Layer Width	0.45 mm
Number of perimeters	2
Infill Pattern	Gyroid
Infill density	15%
Infill angle	45°
<i>Brim</i> Width	3 mm
Distance between part and support	0.25 mm
Support	All over

Materials for orthopedic insoles must be, whenever possible, flexible, have good shock absorption, be soft and porous due to the natural perspiration/breathing of the skin, and have low density to allow the insole to adapt to the shape of the foot and not interfere with its correct movement [15], [16]. However, only a few materials are suitable for insoles and are recommended for 3D printing. In this specific study, two materials were used, namely, TPU (Thermoplastic polyurethane) and PLA (polylactic acid). TPU, due to its flexibility, conformity, nontoxicity, good chemical resistance to acids and bases and good resistance to wear and impact loads, is a material that can be easily processed by 3D printing because it has good resistance to low temperatures, excellent adhesion between layers and no curling or delamination during the printing process. Despite having low toxicity, good adhesion to the printing table, low shrinkage, and high versatility in the sense that PLA can be used in various applications, its use for insoles is not recommended because it is a rigid material with high surface hardness and is therefore not a suitable material for this purpose. However, it was used for creating a demonstrative form of the shape of the orthosis made and for visualizing and perceiving how the impression and geometry of the orthosis are made. Based on these conditions, the filament parameters defined in Table 2 were followed.

Table 2 *Filament parameters defined for printing*

	TPU Filaflex 82A	PLA Filament PM
Print bed temperature	40°C	60°C
First layer temperature	232°C	215°C
Extrusion temperature	232°C	210°C
Speed in the first layer	20 mm/s	20 mm/s
Infill printing speed	40 mm/s	80 mm/s
Retraction	0 mm	with retraction

With these parameters established, the slice command was executed so that it was possible to obtain a printing preview of how the printing would be performed. It should be noted that to improve printing, time and material consumption, the piece was tilted to reduce these factors, resulting in a final printing time estimated at 10 h 19 min. Having defined all the parameters, the model was printed as shown in Figure 6.

Although the results obtained were satisfactory, some improvements were made, namely, in the upper area and sole of the foot, to reduce printing time and the amount of material. The perimeters were reduced from 2 to 1, and a second model was obtained with a printing time of 5 h and 59 min. Finally, to corroborate the applicability of the foot dysmetria compensating orthosis, an experimental evaluation of the load profile was carried out during gait with and without the orthosis.

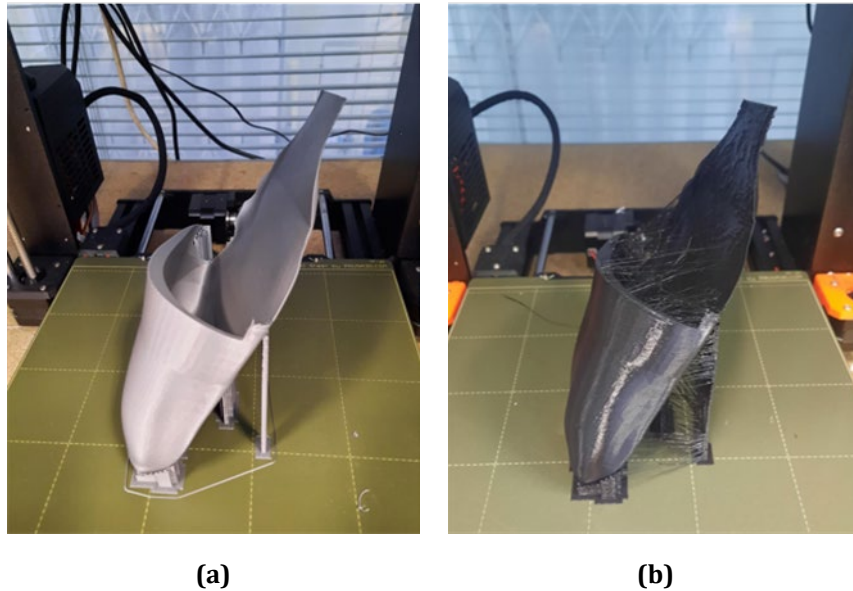


Fig. 6 Printing the model (a) PLA Filament PM; (b) Filaflex 82nd TPU

3. Results and Discussion

To evaluate the influence of the developed orthosis on the individual's walking, we used a set of six aligned platforms that allow the analysis of forces and moments in three directions, as well as the center of pressure (CoP), according to Figure 7. It should be noted that only one of the platforms was used for the study.

3.1 Force Platform

Force platforms, as shown in Figure 8, lead the biomechanics sector regarding the study of the center of pressure and precision measurement of force in the three directions of ground reaction that act on the body during walking and running. The data collected by the force plate are subsequently analyzed in specific software and converted into force-time graphs. For the study, Bertec fixed force plates measuring 400x600x150 mm and 600x900x150 mm were used.

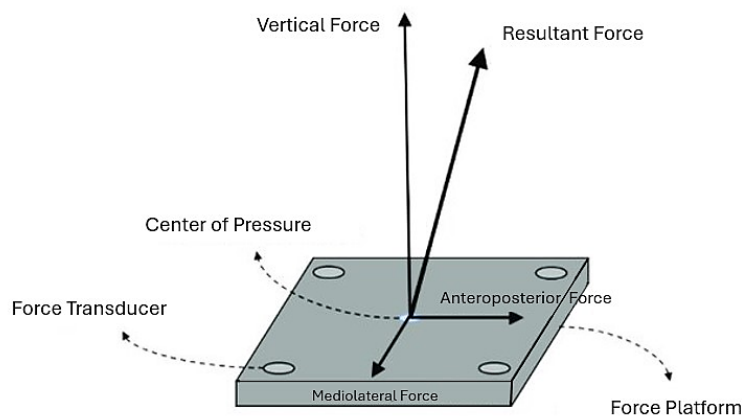
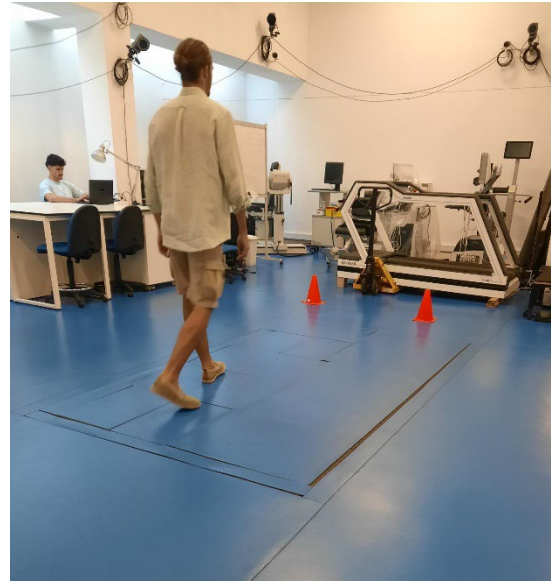
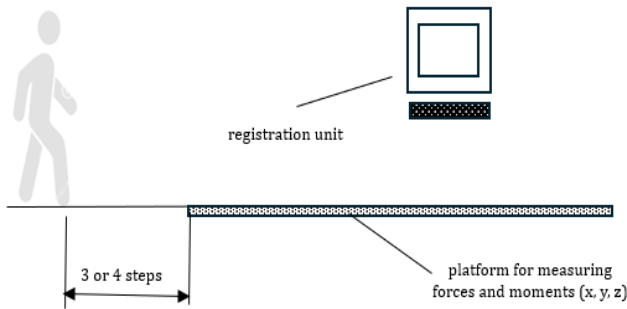


Fig. 7 Platform of reaction forces and their direction [17]

It should be noted that before starting the test, there are several factors to consider, namely, the amount of footwear used during the test and the distance between the start of the walk and the first signs. Footwear should be as simple as possible, without insoles or cushioning components, to effectively evaluate the behaviour of the foot throughout the walk, and the distance between the beginning of the walk and the plates should be equivalent to five steps for the individual. This distance is justified because the aim is to eliminate the acceleration phase of the stride, allowing the data collected to be as close as possible to a normal walk at a constant speed, thus avoiding any interference with the study track. In this way, the individual's walk will correspond to approximately ten

meters. Once the factors conditioning the study were established, it was carried out. Several attempts were made both in walking without the orthosis and with the orthosis. However, the study was based only on one of the attempts, in which a uniform stride and a constant walking speed were guaranteed. Figure 8 illustrates the setup used.



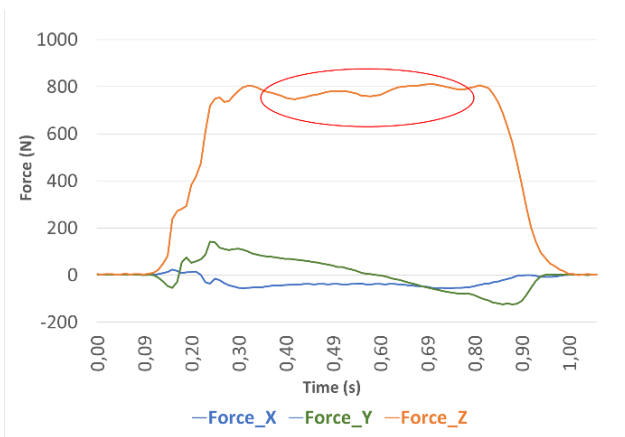
(a)

(b)

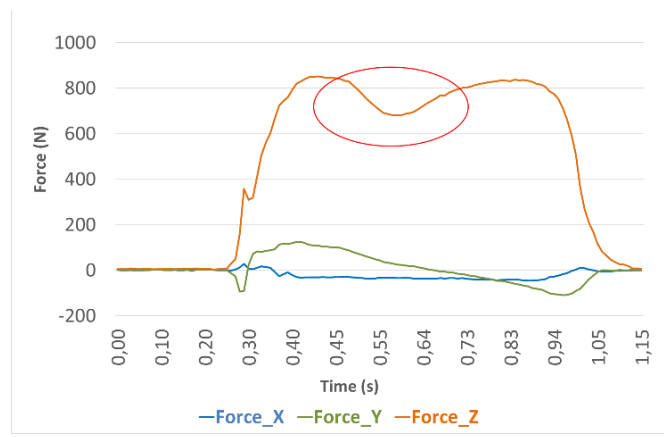
Fig. 8 Individual walking under the force platforms (a) schematic representation (b) real test

3.2 Results

For the analysis, the platform was chosen where the foot to be compensated touches first. Figures 9 and 10 show the force–time and moment–time graphs obtained without and with orthosis, respectively.



(a)



(b)

Fig. 9 Force vs Time for test (a) without orthosis; (b) with orthosis

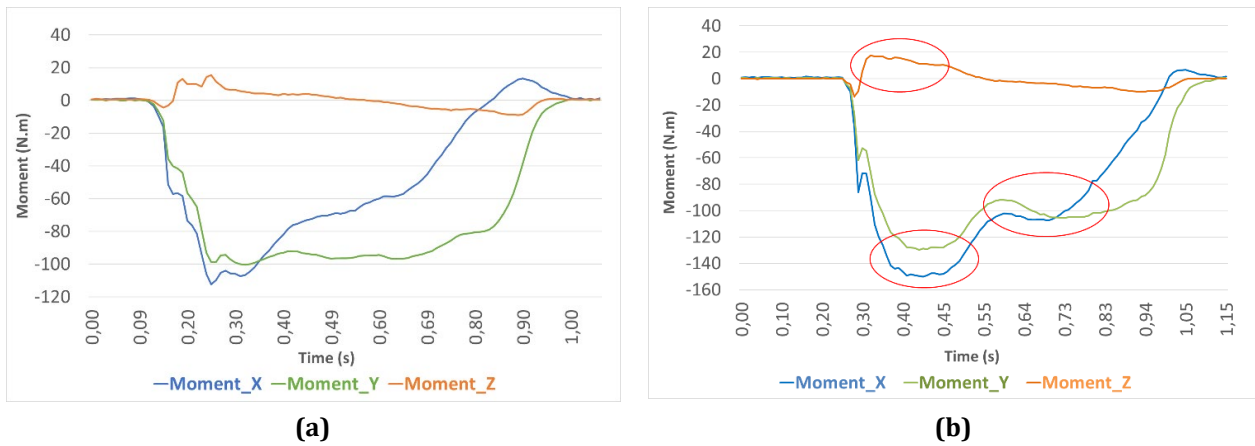


Fig. 10 Moment vs Time for test (a) without orthosis; (b) with orthosis

The comparison shows a notable difference between the force-time plots in the ZZ direction and great similarities in the other directions. As evident in the areas surrounded in red, the force in the ZZ direction presents a continuous level between the moment the heel strikes the ground and the moment the foot takes off to articulate the next step. With the introduction of the orthosis, there is an evolution of the profile to present two peaks corresponding, each one, to these two moments. There is also a notable difference between the moment-time curves of the two graphs, highlighted in the areas surrounded in red. It is interesting to note that the moments that coincide with the beginning of the attack on the ground made by the heel and its exit to formulate the next step, are moments that present some signal fluctuation, which are attenuated when the orthosis is placed. Using the models proposed by Gilchrist et al. [18] and Lanferdini et al. [19], which are briefly represented in Figure 11, a comparison was established with a normal gait pattern.

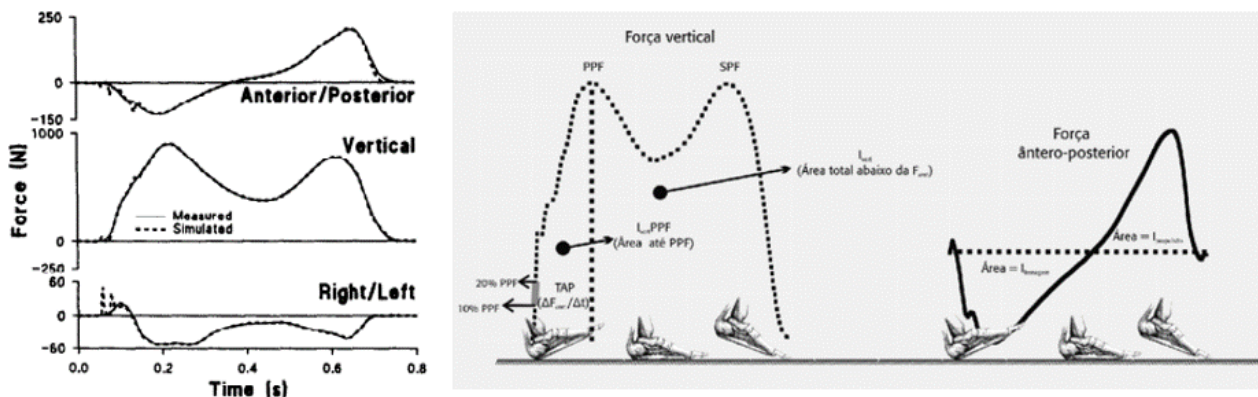


Fig. 11 Graph of reaction reference forces obtained from a pressure platform [18], [19]

The curves of the graph corresponding to the non-insertion of the orthosis are irregular, and the negative values are greater when compared to the graph corresponding to the presence of the orthosis. On the other hand, the graph corresponding to the insertion of the orthosis resembles the graph of a normal gait, thus highlighting the advantageous behavior of the orthosis during gait.

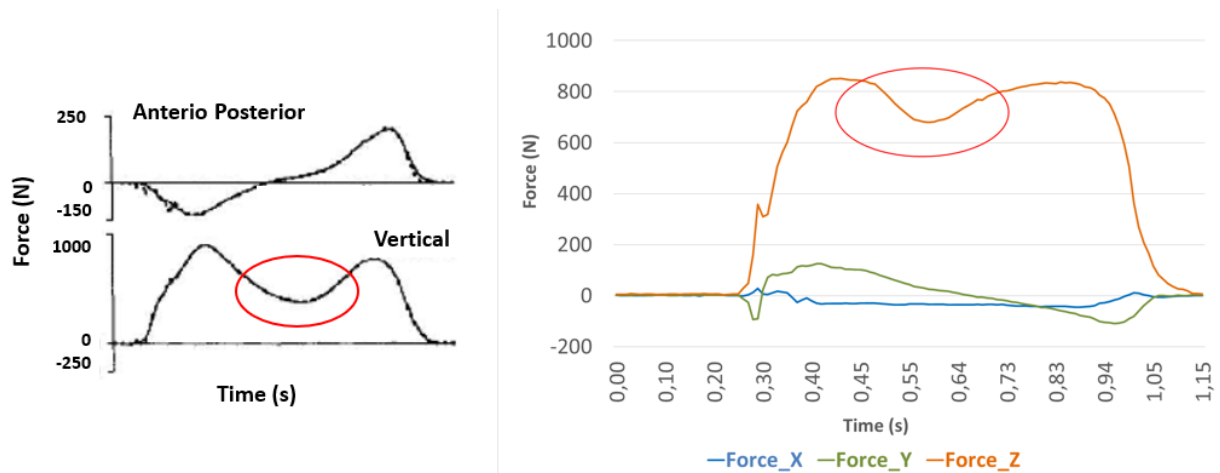


Fig. 12 Comparison between the reaction reference force graph and the orthosis test force graph

As shown in Figure 12, the anteroposterior force corresponds to the force in XX, the mediolateral force corresponds to the force in YY, and the vertical force corresponds to the force in ZZ. The experimentally measured results and the results published in the specialty bibliography appear to be comparable. This approach to the normal walking profile is understandable and explainable. The smaller volume of the foot does not allow the shoe to be filled and tends to take the individual off their feet, creating a situation of discomfort. To compensate for this effect, there is a tendency to prolong the contact of the foot on the ground. When the orthosis is introduced, the entire volume is filled, there is greater fixation of the foot inside the shoe and allows the degree of confidence in walking to be increased, making the existence of the moments of starting and removing the foot from the ground visible, according to the model described by Lanferdini et al. [19]. The comparison of the standard walking profiles (without any volumetric dysmetry) and those presented with an orthosis in the case studied clearly highlights the advantage of including the orthosis proposed.

Conclusion

Using a three-dimensional mapping technique, a volumetric scanner was used on the feet of a young individual with hemihypertrophy to develop an orthosis via 3D printing. The use of software such as *Meshmixer* and *SolidWorks* allowed the development of compensation using a volumetric subtraction technique. The orthosis was manufactured in thermoplastic polyurethane (TPU) on a Prusa i3 MK3 printer, and its contribution to the comfort and gait pattern profile was studied. According to the study, the comparison of the gait profile after placing the orthosis shows an approximation to the standards typified in the literature for normal cases. Filling the space inside the shoe makes it possible to walk regularly, even when there is a significant difference in the structural volume of one of the feet. This solution allows the use of normal and identical footwear on each foot, ensuring aesthetic compromise, comfort, and interchangeability for any type of footwear. This aspect is extremely relevant because it is a product that, although personalized, has a very low execution and development cost.

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Conflict of Interest

Authors declare that there is no conflict of interests regarding the publication of the paper.

Author Contribution

The authors confirm contribution to the paper as follows: **study conception and design:** Carla Peixoto, António Magalhães; **data collection:** Carla Peixoto; **analysis and interpretation of results:** Carla Peixoto, António

Magalhães; **draft manuscript preparation:** Carla Peixoto. All authors reviewed the results and approved the final version of the manuscript.

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