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DESIGN OF TRANSTIBIAL PROSTHESIS BASED ON MECHANICAL METAMATERIAL
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Guilherme Wolf Lebrao
Marcelo Otavio dos Santos
Fernando Malvezzi
Mechanical Engineering Depart., Mauá Institute of Technology
CEP: 09580-900, São Caetano do Sul – SP, Brazil
e-mails: guinet@maua.br, marcelo.santos@maua.br, fernando.malvezzi@maua.br

Abstract. *The use of 3D printing to create transtibial orthopedic prostheses has not been studied extensively, despite the increasing number of injuries in countries experiencing armed conflict. Mechanical metamaterials are being explored to simplify the manufacturing process and reduce costs. These metamaterials use artificial structures to create desired mechanical properties and can be designed to optimize strength and elasticity while minimizing weight. Additive manufacturing (AM) is a promising alternative to traditional prosthetic production methods, as it can create complex geometries necessary for mechanical metamaterials. This study proposes a design for a transtibial prosthesis that allows for autonomous movement without energy consumption. The prosthesis is made from a single material and constitutes a passive system. The design was created using 3D printing mechanical metamaterials and underwent static structural analysis by the Finite Element Method (FEM). A prototype was developed to evaluate the feasibility of employing 3D printing process for manufacturing a transtibial prosthesis based on mechanical metamaterials.*

Keywords: *mechanical metamaterials, additive manufacturing, prosthesis, finite element analysis*

1. INTRODUCTION

Research in orthopedic prostheses has gained importance due to the armed conflicts that continue to pose significant challenges in the 21st century, resulting in a several injured individuals, including both military personnel and civilians, often with severe mutilations. While transtibial prostheses have achieved significant advancements in terms of design and functionality, there is a lack of studies exploring the potential of mechanical metamaterials for this specific application.

Regarding 3D printing, there have been recent improvements in both printers and materials, contributing to increased applications in medical devices. According to Kermavnar et al. (2021), there were relatively few studies about the use of 3D printing for orthopedic devices before 2018. Lu et al. (2022), considered the term 'mechanical metamaterials' to represent a class of artificial materials that possess mechanical properties not typically observed in original materials. These properties can be obtained through the specific design and arrangement of constituent units' cells, rather than relying solely on the inherent properties of the materials themselves (Berger et al. 2017, Zheng et al., 2014, Hsieh et al., 2019, Christensen et al., 2015, Morris et al., 2019).

Nevertheless, the precise geometries required to attain such outcomes may not be obtained through conventional manufacturing processes used in prosthesis production.

Additive manufacturing, however, is a viable alternative to produce such complex geometries, offering significant potential for various biomedical applications, including the maxillofacial guides, medical components, endoluminal stents, and orthopedic implants (Guttridgea et al., 2022). This process utilizes printing technology to build components layer by layer, following a computer-aided design (CAD) model. Additive manufacturing is particularly suitable for producing precision complex pieces and enables the creation of personalized medical devices. (Lakkala et al., 2023).

The main materials commonly employed in additive manufacturing (AM) for medical applications include PLA (Polylactic Acid), ABS (Acrylonitrile Butadiene Styrene), PCL (Polycaprolactone), PA 2200 (Nylon Powder), and PETG (Polyethylene Terephthalate Glycol-Modified) (Guessasma et al, 2019; Roman et al, 2020).

This study introduces a design of a transtibial prosthesis constituted by only one piece built with single material without mechanical joints. The prosthesis is a passive system with 1-DoF (degree of freedom), without energy consumption. The prosthesis aims to provide the movement of human gait autonomously, contributing to the autonomous locomotion of a person who does not have lower limbs below the knee. Section 2 shows the methodology applied to achieve the goals of this study. Section 3 presents the results obtained, and some further discussions are addressed in Section 4. Finally, the conclusions are drawn in Section 5.

2. METHODOLOGY

The methodology applied in this study consists of the choice of the material and the appropriate geometry based on metamaterials, the static structural analysis by the finite element method (FEM), and the building of a prototype for proof of concept of the proposed design. This prosthesis prototype was made of metamaterial by additive manufacturing. Each step of this methodology is described below.

2.1   Transtibial prosthesis design

The premise of this study is to design a transtibial prosthesis consisting of a single body constructed with a single material type without mechanical joints. The objective is to apply the findings of this research to human prostheses made from metamaterials. According to Brockett and Chapman (2016), the normal range of motion for ankle dorsiflexion is between 10 and 20 degrees. In this study, dorsiflexion is defined with a target of 10 degrees.

The architectural design proposed in this study is based on the triangular cells topology, as presented by Lu et al. (2022). This particular unit cell was chosen due to the excellent mechanical resistance offered by triangular structures and their capacity to facilitate the rotational movement of the foot. The prosthesis width is 70 mm, which was defined based on the 95th percentile of heel width of an adult man (DIN 33402). Figure 1 shows a CAD model of the proposed transtibial prosthesis.
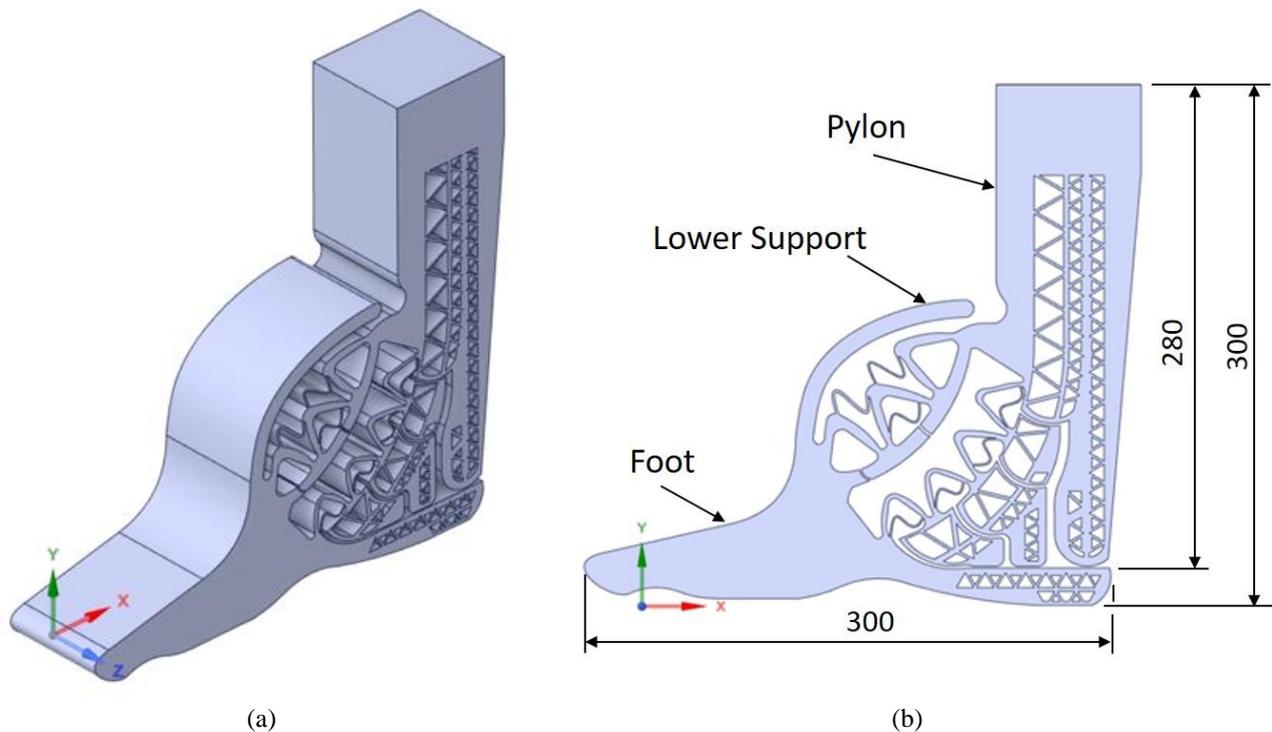

| (a) | (b) |

Figure 1. The CAD model of the proposed transtibial prosthesis: (a) Isometric view; (b) Front view.

2.2   Structural static analysis of transtibial prosthesis

The goal of the structural static analysis is to know the values of stress and displacement that arise in the prosthesis when subjected to loading conditions compatible with walking gait. For this purpose, the finite element method (FEM) was used.

This method has been employed not only for typical mechanical structures (Dua et al., 2023; Colatto et al., 2017), but also in various medical applications (Al-Tam et al., 2023; Knop et al., 2015).

The mesh was generated using 20-node Hexahedral elements with the multizone method and element size of 4 mm, resulting in a total of 623,751 nodes (Figure 2). The average aspect ratio mesh quality parameter was 1.64.

(a)   (b)

Figure 2. Transtibial prosthesis: (a) FEM mesh; (b) FEM mesh details.

The chosen material to build the prosthesis is the PETG (Polyethylene Terephthalate Glycol-Modified), which properties are listed in Table 1. This material has good mechanical resistance and an excellent proper adhesion of the layer. In addition, it is more flexible and less fragile than PLA (Polylactic Acid), material often used in 3D printing (Roman et al. 2020).

Table 1. Properties of PETG (Roman et al., 2020).

Properties	Values
Young's Modulus, GPa	2.1
Ultimate Strength, MPa	45.8
Elongation, %	14.0

To evaluate the mechanical resistance of the prosthesis, two loading conditions were considered in FEM simulations.
The first involved a vertical force applied to the upper region of the prosthesis, highlighted in red in Figure 3. This condition simulates the weight of an 80 kg person exerting pressure on one leg.

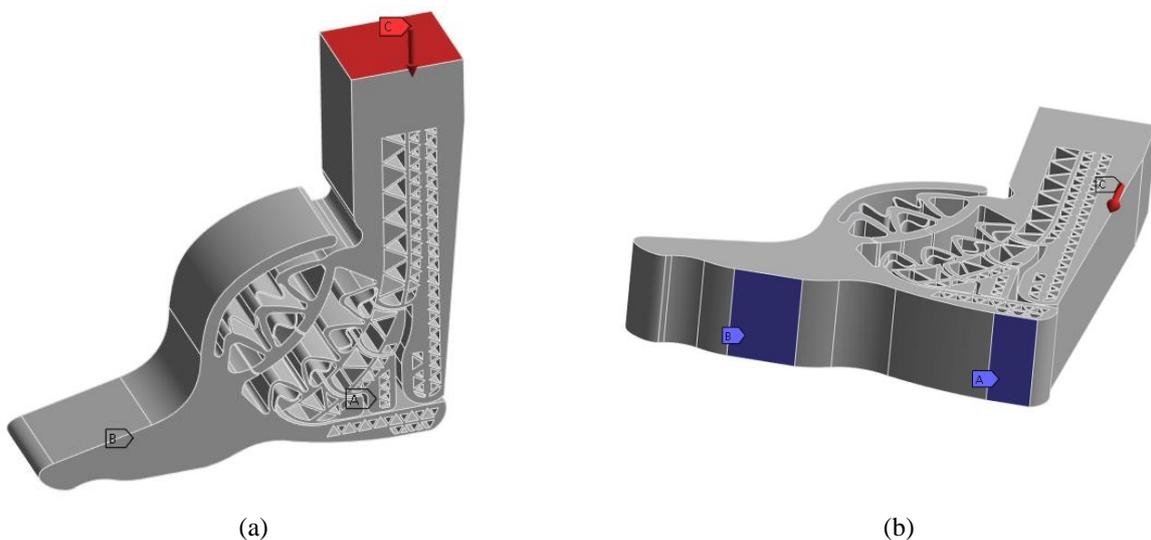(a)   (b)

Figure 3. Loading type 1: (a) Vertical force applied on upper region of the prosthesis; (b) Constraint type fixed support (A) and Frictionless support (B).

The second loading condition consisted of a longitudinal horizontal force applied to the upper part of the prosthesis, as illustrated in Figure 4. This simulation was employed to evaluate the displacement and stress in the prosthesis during dorsiflexion plantar flexion.
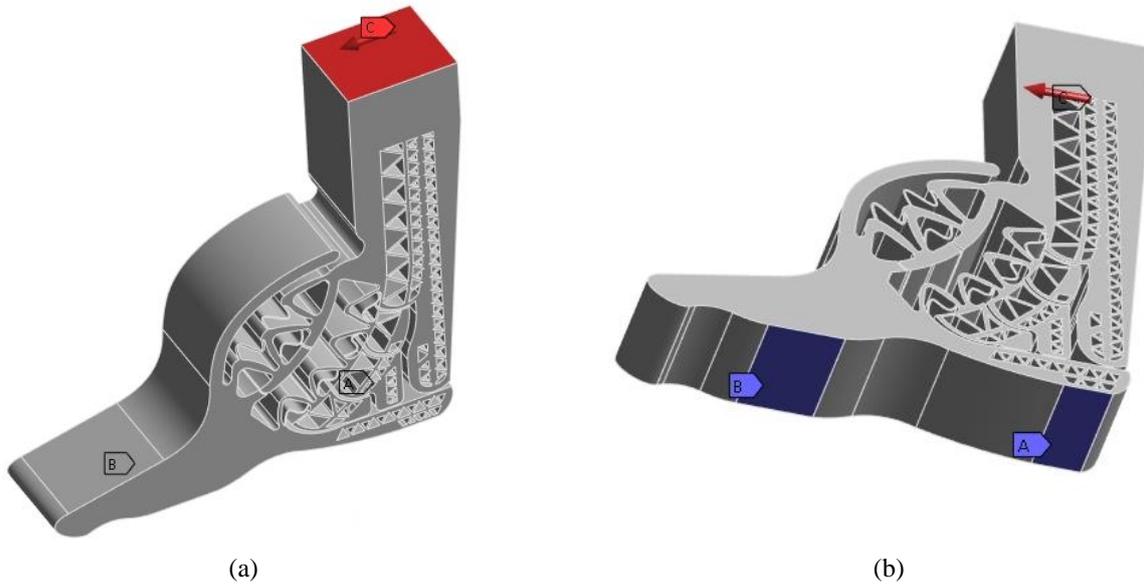

(a)   (b)

Figure 4. Loading condition 2: (a) Horizontal force applied on upper region of the prosthesis; (b) Constraint type fixed support (A) and Frictionless support (B).

3. RESULTS

Section 3.1 presents the results of static structural analysis obtained from the finite element method, while Section 3.2 shows the built prosthesis prototype.

3.1 Static structural analysis

Figures 5 and 6 show the stress and displacement results obtained from the finite element method for the first set of load conditions, respectively.

(a)   (b)
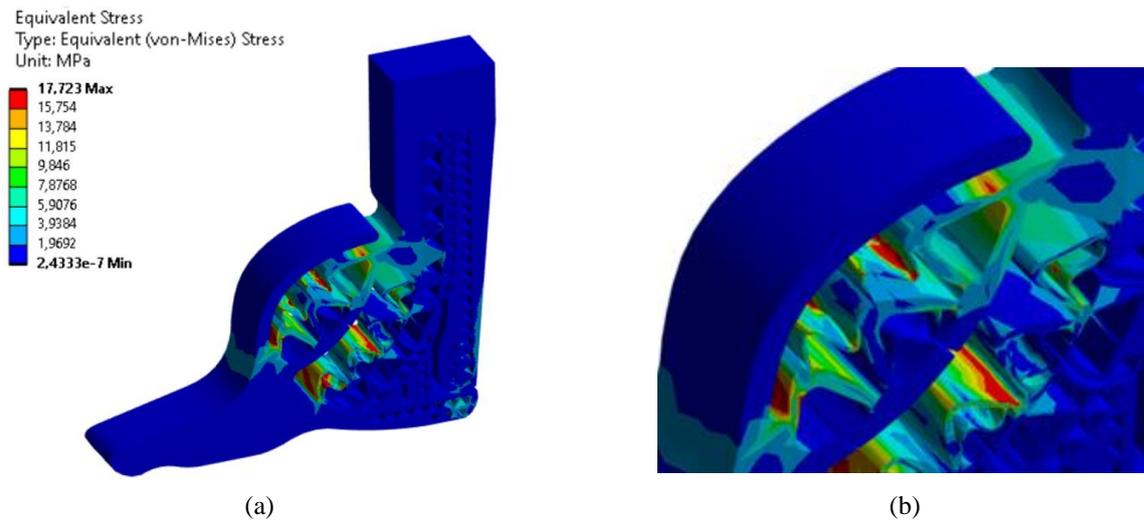
Figure 5. FEM analysis of loading condition 1: (a) Stress distribution, (b) Maximum stress region.

The maximum applied vertical force was 784.8 N (or a distributed load of 0.1354 N/mm^2 on the red region shown in Fig. 3a). The maximum equivalent von Mises stress was 17.7 MPa, resulting in a yield safety factor of 1.58. The maximum displacement observed was 1.8 mm until contacting the lower support. Under this loading condition, the prosthesis is able to support a person weighing 80 kg during walking.

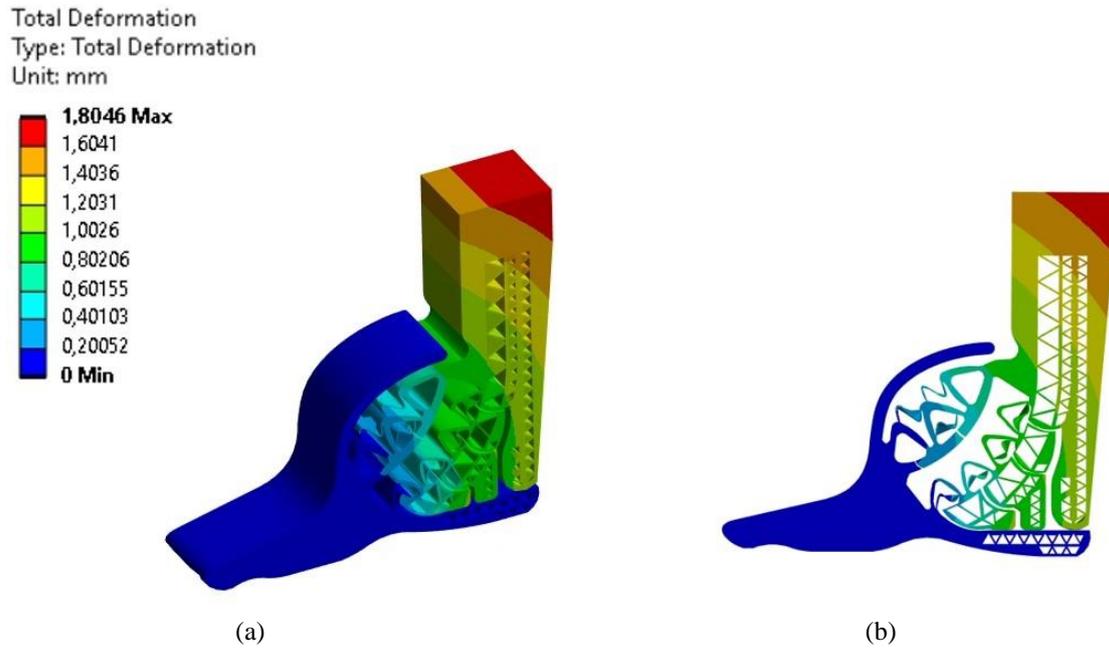(a)   (b)

Figure 6. FEM analysis of Load condition 1: (a) Displacement-3D view; (b) Displacement-Front view.

Figures 7 and 8 display the stress and displacement results obtained through the finite element method (FEM) for the second loading scenario. In this simulation, the longitudinal force was gradually increased until the pylon and lower support made contact, as shown in Fig. 8-b. The required longitudinal force to achieve this condition was 68.7 N, resulting in a maximum displacement of 21.7 mm and a maximum equivalent von Mises stress of 22.5 MPa. The corresponding yield safety factor for this stress was 1.24.

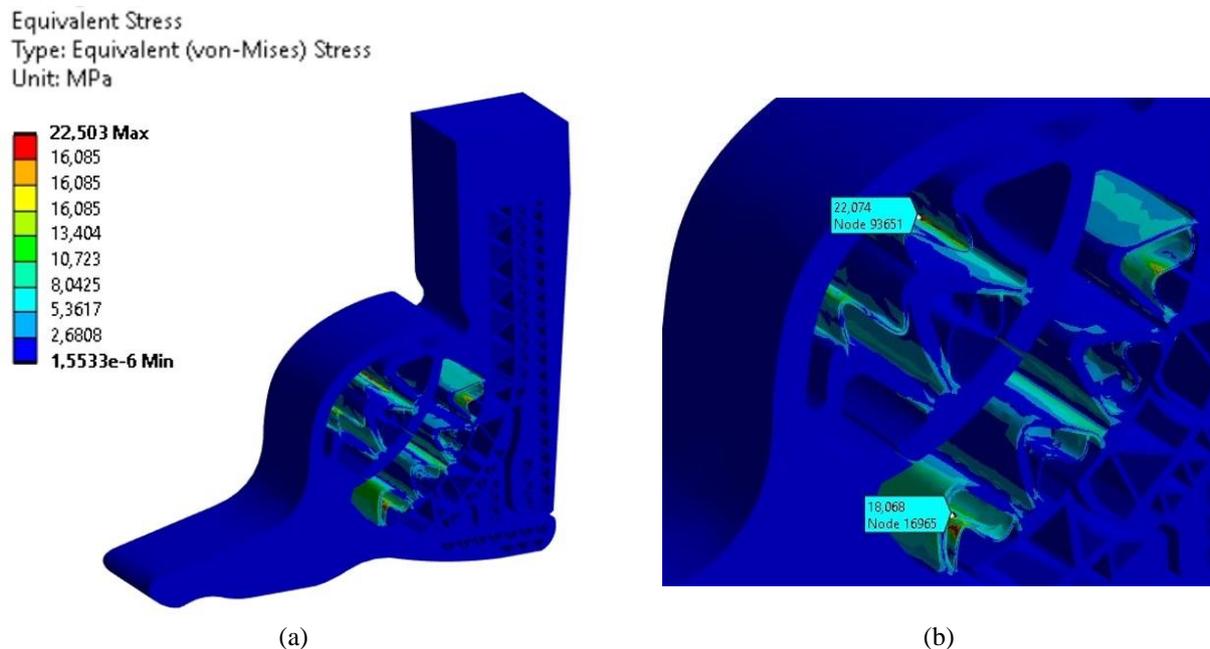(a)   (b)

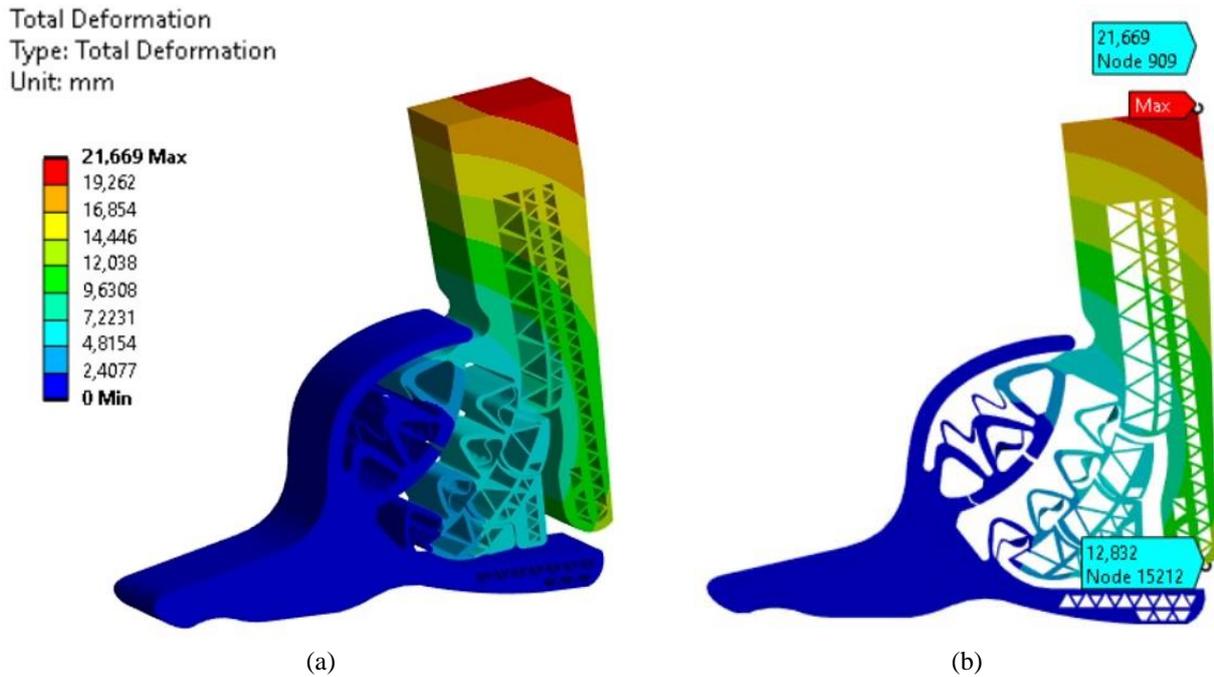Figure 7. FEM analysis of Load condition 2: (a) Stress distribution, (b) Maximum stress region.

Figure 8. FEM analysis of Load condition 2: (a) Strain-3D view; (b) Strain-Front view.

3.2 Transtibial prosthesis prototype

The prototype was built to evaluate the feasibility of employing 3D printing process with PETG material for manufacturing a transtibial prosthesis based on mechanical metamaterials.

Table 2. Parameters of 3D printing process

Parameters	Value
Printing speed, mm/s	40
Nozzle diameter, mm	0.4
Extrusion temperature, ºC	230
Primary layer height, mm	0.2
Top solid layers	9
Bottom solid layers	3
Outline/Perimeter shells	2
Interior fill, %	80
Internal fill pattern	*Full honeycomb*

The 3D printer used was the Ender-5 Plus, and the parameters applied in the 3D printing process are listed in Table 2. Figure 9 shows the prototype of the transtibial prosthesis made by 3D printing process with the parameters provided in Table 2.

This prototype aligns the dimensions shown in Fig. 1-b, with the exception of its thickness, that is 20 mm. Even with this adjustment, the 20 mm-thick prosthesis remains suitable for assessing the feasibility of 3D printing production.

The time production of this prototype was 47 hours. In order to avoid quality problems due to the excessive long production time, we suggest to build the prosthesis from the assembly of modules of 10 mm or less. Regarding interior fill, the percentage of 80% was chosen to obtain a rigid prosthesis but without a prohibitive time production.
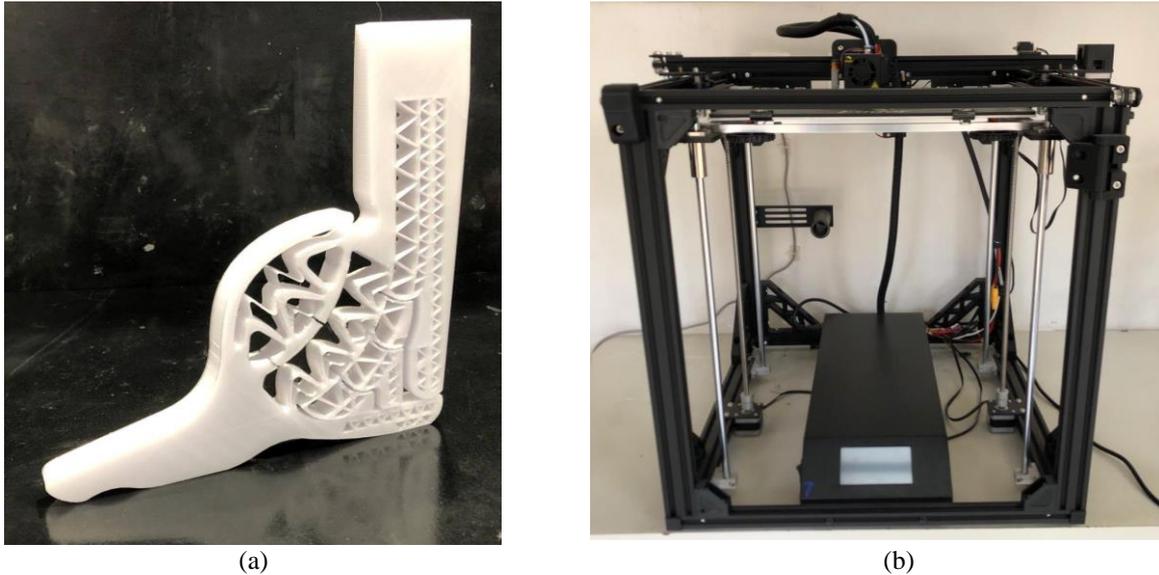
Figure 9. (a) Transtibial prosthesis prototype; (b) Ender-5 Plus printer used to make the prototype.

4. DISCUSSION

- The results of the static structural analysis confirm its efficacy. When a vertical load of 784.8 N is applied on the upper region of the prosthesis, the maximum equivalent von Mises stress was 17.7 MPa, resulting in a yield safety factor of 1.58. When a longitudinal force was applied, causing contact between the pylon and lower support, the maximum displacement was 21.7 mm, and the maximum equivalent von Mises stress was 22.5 MPa. The corresponding yield safety factor for this stress was 1.24.

- The range of motion achieved by the proposed prosthesis for dorsiflexion was close to 5 degrees, which permits walking. However, a normal person achieves dorsiflexion within a range of 10 to 20 degrees. In the continuation of this study, we will analyze a prosthesis with a heel thickness different from the rest of the foot, mirroring the natural human foot. This adjustment will provide increased width in regions experiencing higher stress, potentially allowing for greater dorsiflexion amplitude.

- The potential to produce prostheses with a 10 mm thickness using the modular concept should be explored. Further research is needed to evaluate the durability and flexibility of adhesive prostheses constructed from 10 mm thick modules. This approach facilitates the prosthesis production on smaller printers, enabling the final prosthesis to be assembled from modules of 10mm or less, tailored to the individual foot size.

5. CONCLUSIONS

In this study, we present a design for a passive transtibial prosthesis composed of a single body consisting of PETG material, based on mechanical metamaterials. The static structural analysis, conducted through the finite element method, demonstrates the promising potential of the proposed design to enable autonomous human gait movement. Furthermore, the built prototype confirms the feasibility of 3D printing process for producing such a transtibial prosthesis.

The next steps of this study include the FEM model validation, and a fatigue behavior analysis and life prediction of this transtibial prosthesis. In addition, alternative designs could be proposed, based on the metamaterials triangular structures employed in this work.

6. ACKNOWLEDGEMENTS

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8. RESPONSIBILITY NOTICE

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