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Research article

Structural analysis of generative design applied to ergonomic plantar orthoses

Análisis estructural del diseño generativo aplicado a órtesis plantares ergonómicas

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Abstract. - *Plantar orthoses are devices designed to provide support and correct the biomechanics of the foot. Generative design offers ample potential for personalization; however, the analysis of its structural behavior continues to be a significant challenge. This research aims to evaluate the structural optimization of orthoses designed by generative design compared to traditional models. An analysis of 33 middle-aged adult men classified as normal weight, with an average weight of 65.32 ± 6.79 kg, was performed using a baropodometric database. An optimized orthosis was designed by parametric modeling to evaluate its mechanical response in static standing conditions, using the finite element method with the TPU A95 material. The results indicated that the trabecular structures produced by generative design absorb more energy (0.3876 J) than a bilaminated orthosis made with EVA A40 and A15 materials (0.0362 J). The levels of deformation obtained (maximum principal strain = 1.34%, equivalent elastic strain = 2.14%) indicate that the composition of the generative model works well within the elastic regime, ensuring structural integrity. However, the low strain and strain energy values suggest relatively rigid behavior, which can limit the shock absorption capacity. The main contribution of this work is to demonstrate how generative design can be integrated into methodologies for designing plantar orthotics. It explores the potential benefits of this approach and examines how generative design parameters influence mechanical responses. This research provides a technical foundation for optimizing ergonomic orthoses through generative design and structural modeling. The findings emphasize the potential of generative design in creating optimized orthoses and highlight the significance of design parameters on the outcomes achieved. This insight is valuable for future applications of generative design in the field of ergonomics.*

Keywords: Finite element analysis; Generative design; Ergonomics; Elastomeric materials.

Resumen. - *Las órtesis plantares son dispositivos diseñados para proporcionar soporte y corregir la biomecánica del pie. El diseño generativo ofrece un gran potencial para la personalización; sin embargo, el análisis de su comportamiento estructural continúa siendo un desafío significativo. Este estudio tiene como objetivo evaluar la optimización estructural de órtesis diseñadas mediante diseño generativo en comparación con los modelos tradicionales. Se realizó un análisis de 33 hombres adultos de mediana edad clasificados como normopeso, con un peso promedio de 65.32 ± 6.79 kg a partir de una base de datos de baropodometría. Se diseñó mediante modelado paramétrico una órtesis optimizada para evaluar su respuesta mecánica en condiciones de bipedestación estática, utilizando el método de elementos finitos con el material TPU A95. Los resultados indicaron que las estructuras trabeculares producidas mediante diseño generativo absorben más energía (0.3876 J) que una órtesis bilaminada confeccionada con materiales EVA A40 y A15 (0.0362 J). Los niveles de deformación obtenidos (deformación principal máxima = 1.34%, deformación elástica equivalente = 2.14%) indican que la composición del modelo generativo funciona bien dentro del régimen elástico, asegurando la integridad estructural. Sin embargo, los bajos valores de deformación y energía de deformación sugieren un comportamiento relativamente rígido, lo que puede restringir la capacidad de absorción de impactos. La principal contribución de este estudio es demostrar cómo el diseño generativo puede integrarse en metodologías para diseñar órtesis plantares. Explora los posibles beneficios de este enfoque y examina cómo los parámetros generativos del diseño influyen en las respuestas mecánicas. Esta investigación proporciona una base técnica para optimizar las órtesis ergonómicas mediante modelado estructural y diseño generativo. Los hallazgos subrayan el potencial del diseño generativo para crear órtesis optimizadas y destacan la importancia de los parámetros de diseño en los resultados alcanzados. Esta información es valiosa para futuras aplicaciones del diseño generativo en el campo de la ergonomía.*

Palabras clave: Análisis de elementos finitos; Diseño generativo; Ergonomía; Materiales elastoméricos.

1. Introduction

The human foot is designed for load absorption and to provide stability to the body; however, increased body weight can lead to musculoskeletal alterations in the foot [1], [2], [3]. Several studies have associated body mass index (BMI) with increased plantar pressure, a larger contact area, and abnormal load redistribution in the plantar area, which directly influence the onset of pain and fatigue [4], [5], [6], [7].

To mitigate the adverse effects of these weight conditions, plantar orthoses are used to support, align, or redistribute the pressure of the foot, improving the function of the foot, treating pathologies with materials such as Ethyl-Vinyl-Acetate (EVA) in varying degrees of rigidity that can be prefabricated or customized to the needs of the patient [8], [9], [10]. However, the design of these orthoses is still based on solid geometries that have limitations in their mechanical capabilities [11], [12], [13]. Additive manufacturing has enabled the incorporation of advanced structures with adjustable mechanical properties, thereby improving plantar pressure distribution [14], [15], [16], [17].

Among the wide range of structural optimization techniques in human ergonomics, the application of generative design has great potential to meet patients' needs; however, it also faces certain challenges, including structural behavior, one of the most prominent [18], [19]. This research aims to investigate structural optimization through the application of generative design in plantar foot orthoses compared to traditional orthoses to design optimized orthoses from statistical data from a sample of baropodometric data and characterization of materials to analyze their structural behavior under static standing loads by finite element analysis

2. Background

The effect of optimized structures applied in plantar orthoses on load distribution has been investigated, demonstrating their potential to withstand areas of high pressure and energy absorption, including optimization methods and generative structures [20], [21], [22]. Generative design is an AI-assisted process where goals and constraints are defined to automatically explore and generate multiple optimized design solutions, producing biomimetic organic shapes [23], [24]. Generative design is based on four main algorithmic processes: shape synthesis to explore geometries and structures, surface optimization to determine optimal configurations, topological optimization to minimize weight while maintaining strength, and trabecular structures to generate complex geometries inspired by trabecular patterns [25], [26], [27]. In Hüseyin Özsoy's review [28], it is mentioned that ergonomics is one of the main approaches to generative design. Urquhart et al. [29] report that generative design focused on human factors, ergonomics, anatomy, and functionality is essential for applying discrete data and design intelligence in real case studies. Specifically, Schneider et al. [30] investigated the application of generative design in plantar orthoses; the study highlights the potential to optimize orthotic design that improves patient comfort and mobility and the impact of boundary conditions on structure generation.

For the design of plantar foot orthoses, various anthropometric factors adjusted to the patient's needs are taken into account [31]. Among these factors, one of the most closely related to the distribution of plantar pressure is the areas of support of the foot [32]. This metric quantifies what percentage of the total load is distributed in certain areas. Generally, the plantar area is divided into three parts: forefoot,

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midfoot, and hindfoot. These areas are the ones that support the individual's body weight. It has been reported that weight is the main factor for the increase in plantar pressure in critical areas such as the forefoot and hindfoot [33], [34]. Ramos-Frutos et al. [35] reported that when people are in static standing, the hindfoot presents more pressure (55.64 ± 18.80%) than the forefoot (45.18 ± 19.50%) in the Mexican population.

For the manufacture of these orthoses, EVA material is usually used because it is a lightweight, flexible, durable material and offers good cushioning and support. Bilaminated orthoses of two degrees of EVA hardness are usually manufactured; high hardness grades serve as structural support and impact absorption, while lower hardness grades are used for plantar pressure redistribution [36]. However, these materials can only be applied to machinable solid geometries, which have limited capacity. With the incorporation of optimized structures, additive manufacturing has enabled the use of materials such as thermoplastic polyurethane (TPU) for structural support and shock absorption, owing to its high resistance to wear and abrasion. TPU offers high cushioning, ergonomic support, and durability [37], [38].

3. Methodology

As shown in Figure 1, a methodology was developed for the parametric modeling of an optimized orthosis with a generative design with anthropometric-based data from a representative sample of middle-aged adults classified as normal weight and the mechanical properties of characterized materials, finally analyzing their mechanical behavior through finite element analysis.

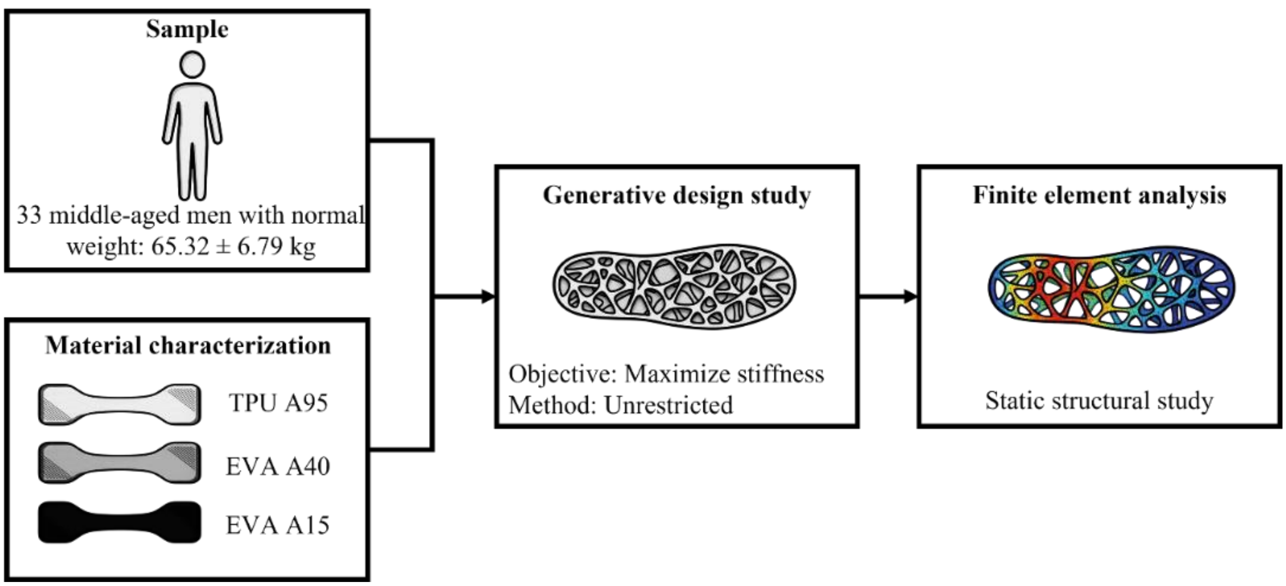

Figure 1. Workflow diagram of the study.

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3.1 Procedure

From a baropodometric database, an analysis of 33 middle-aged adult men classified as normal weight was carried out, with an average weight of 65.32 ± 6.79 kg and a BMI of 22.68 ± 1.82 kg/m^2. The data were taken directly from the FreeStep® software (version 1.6.009, Sensormedica®, Guidonia Montecelio, Rome, Italy). Once the data were obtained, an average body load of 640.78 N was calculated for the total sample. The right foot was selected for the orthosis design due to its functional predominance. According to the analysis carried out, it is determined that the right foot supports 46.70 ± 7.80% of the body weight of the sample, the forefoot supports 40.64 ± 17.85%, while the hindfoot supports 59.36 ± 17.85% of the load of the right foot.

3.2 Materials characterization

Material characterization was carried out on an Instron® 8872 universal testing machine (Instron®, Norwood, Massachusetts, USA) by tensile testing in accordance with ASTM D412-16 with type C specimens, applicable to thermoset rubbers and thermoplastic elastomers, commonly used to evaluate both EVA and TPU under tension [39], [40]. This choice is considering the trabecular nature of the generative design; the internal components of the geometry are subjected to complex stress states, including local stress and flexural forces. Therefore, it is crucial to evaluate the elongation capacity and strength of the base material under these conditions.

The tensile properties of two EVA hardness levels were evaluated: A40 (medium hardness) and A15 (soft hardness). EVA A15 exhibited low stiffness and reduced tensile strength, while EVA A40 demonstrated significantly higher rigidity, tensile strength, and elongation capacity, as shown in Figure 2. Both materials showed high flexibility and ductility, consistent with prior literature [41], [42].

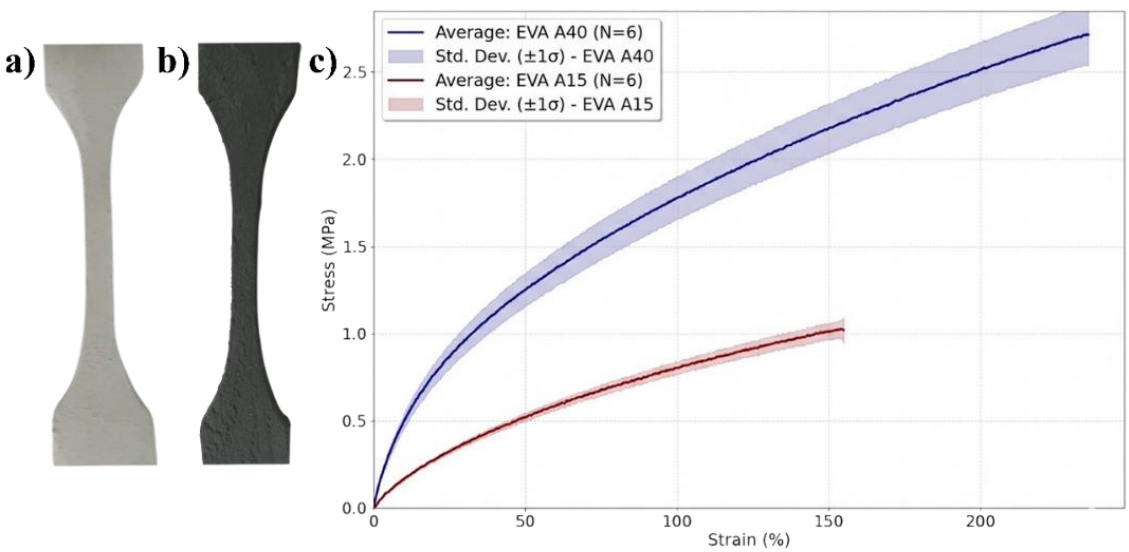

Figure 2. ASTM D412-16 Type C EVA specimens in different hardness grades. a) A40. b) A15. c) Stress-strain diagram.

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TPU A95 was characterized; its tensile properties exhibit ductile and elastomeric behavior, as shown in Figure 3. It demonstrates high deformation capacity prior to fracture and a stable load response, indicating good resistance to tension and impact, consistent with literature trends [43], [44].

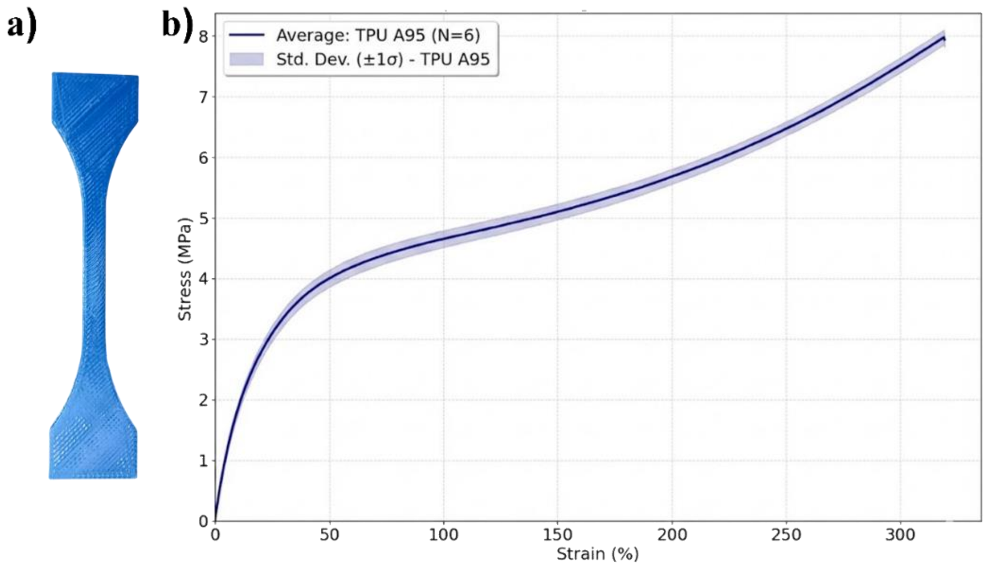

Figure 3. a) ASTM D412-16 Type C specimen of TPU A95. b) Stress-strain diagram.

The data obtained from the stress tests served as input data for the definition of materials and their properties for numerical simulation, simplified as a linear elastic material. The properties of the materials are shown in Table 1.

Table 1. Tensile mechanical properties of the characterized materials.

Material	Poisson's ratio	Young's modulus (MPa)	Yield tensile strength (MPa)	Ultimate tensile strength (MPa)
EVA A15	0.48	0.60	0.002	0.648
EVA A40	0.48	2.20	0.020	2.768
TPU A95	0.40	9.70	3.694	8.002

3.3 Generative design of the orthosis

To establish a base geometry with which the generative design can be integrated, Autodesk® Fusion 360 software (version 2.0, Autodesk® Inc., San Rafael, California, USA) was utilized to model a bilaminated flat orthosis measuring 270 mm in length, 78 mm in width, and 10 mm in thickness. This design consists of 8 mm of EVA A40 for structural support and a 2 mm surface layer of EVA A15, intended for structural analysis purposes without considering the morphology of the foot, as shown in Figure 4.

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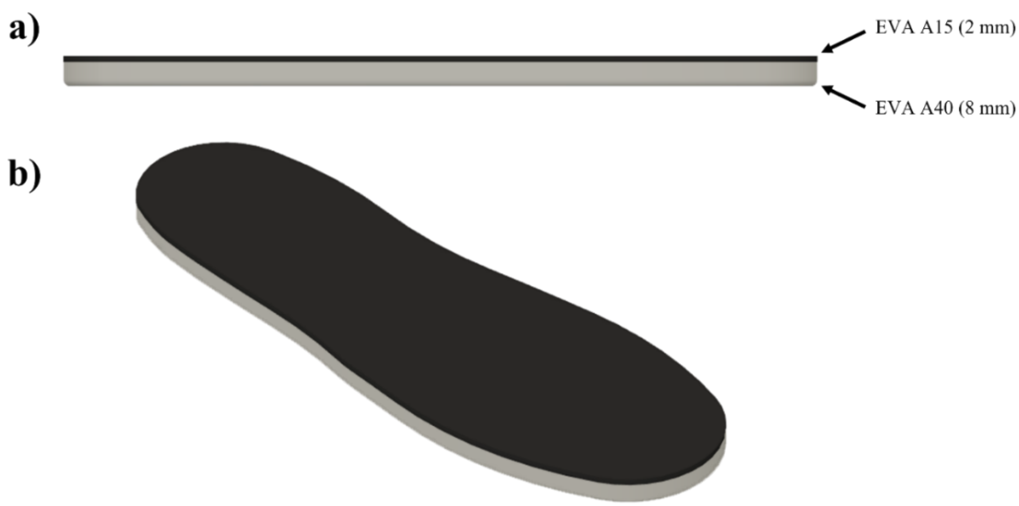

Figure 4. Bilaminated EVA orthosis. a) Lateral view. b) Isometric view.

A generative design study was carried out in which boundary conditions were established based on the inputs obtained from the database to define the loads distributed along the contact surface of the orthosis. According to Perry [45] in her Gait Analysis book and Schneider et al. [46], in their previous work on generative design applied to plantar orthoses, it is mentioned that shear forces should be considered within the parameters of the generative study. This is relevant, as the application of vertical loads on a single axis would lead to the creation of straight structures, designed exclusively to withstand vertical compression. Therefore, it was assigned a percentage of the total load to the forces on the horizontal axis; the assigned load values correspond to each area of the contact surface. These values were calculated according to the percentages of load distribution of the average right foot from the sample; the values are shown in Table 2.

Table 2. Loads corresponding to the boundary conditions of the analysis.

Zone	Component	Load (%)	Load (N)
Forefoot	X	23	-27.96
	Y	0	0
	Z	44.64	-121.59
Midfoot	X	0	0
	Y	0	0
	Z	7	-20.94
Hindfoot	X	13	23.09
	Y	0	0
	Z	59.36	-177.62

In addition, the movement of both rotation and translation of the lower contact surface of the orthosis was restricted. As can be seen in Figure 5, preserved volumes were defined in the direct contact areas

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that act as a solid interface to ensure a uniform load distribution towards the internal trabecular structure. Finally, a 6 mm-thick geometry core was established as the initial geometry for the generation of generative structures. The criterion of maximizing stiffness was chosen to guarantee structural support, a minimum safety factor of 2.0, and, as a manufacturing method, unrestricted was chosen. The material defined for the study was the previously characterized TPU A95.

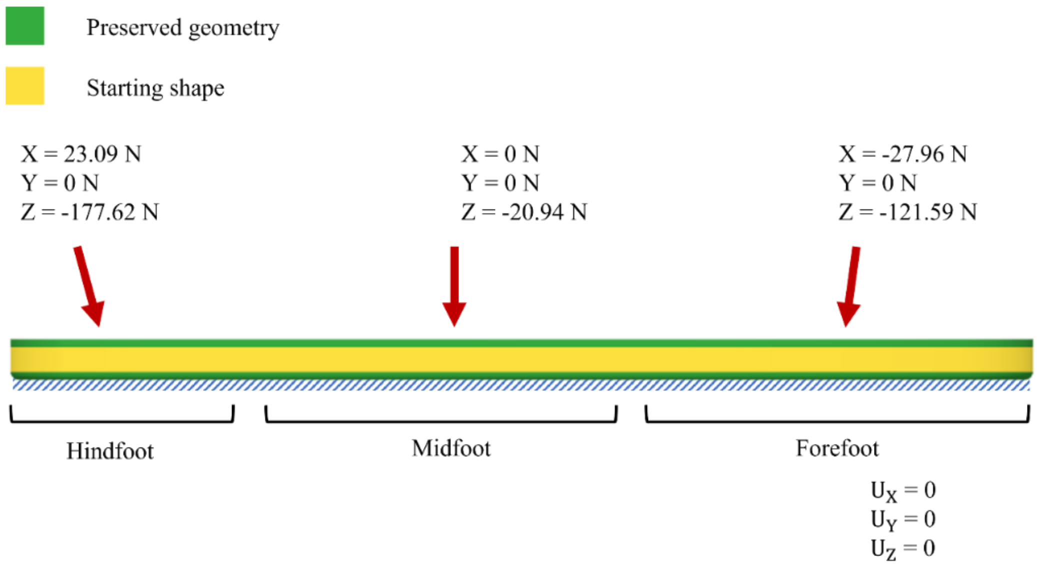

Figure 5. Boundary conditions for generative design study.

A plantar orthosis optimized under the parameters of the generative design of a single iteration was obtained, as observed in Figure 6.

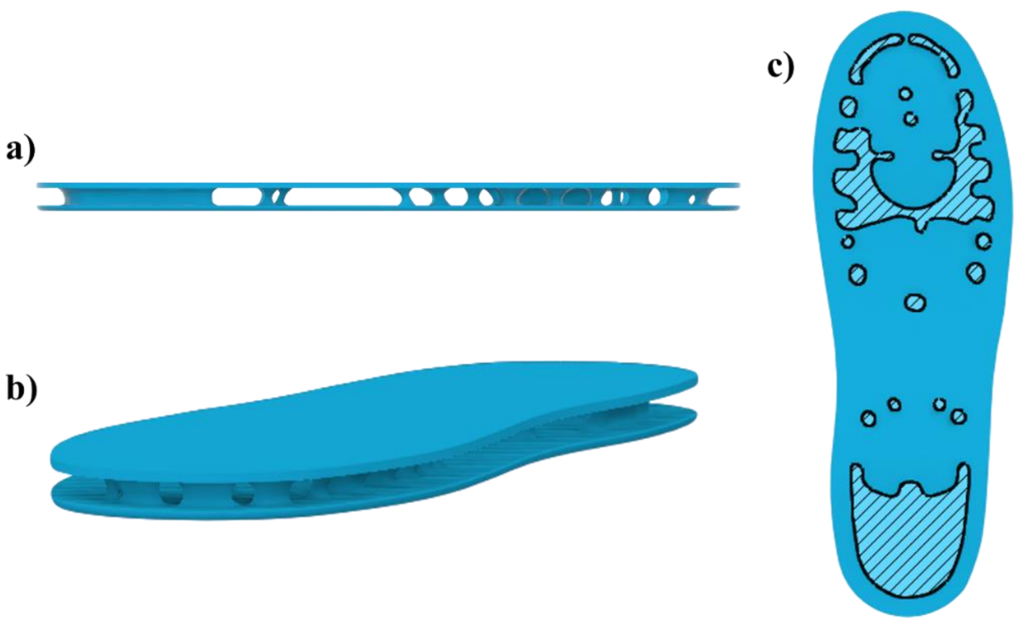

Figure 6. Orthosis (generative design). a) Lateral view. b) Isometric view. c) Top view (plane cut).

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3.4 Numerical simulation

Finally, a static structural analysis was performed using the finite element method, both for the bilaminated EVA orthosis and for the generative design orthosis for comparison. The same boundary conditions used in the generative design study were defined, with the difference that only the compressive forces exerted on the Z axis were considered, simulating standing loads, as shown in Figure 7. These conditions were applied to both models. Additionally, a mesh sensitivity analysis was performed, from which a second-order tetrahedral element mesh with an element size of 2 mm was chosen for both models, with an error of less than 2%.

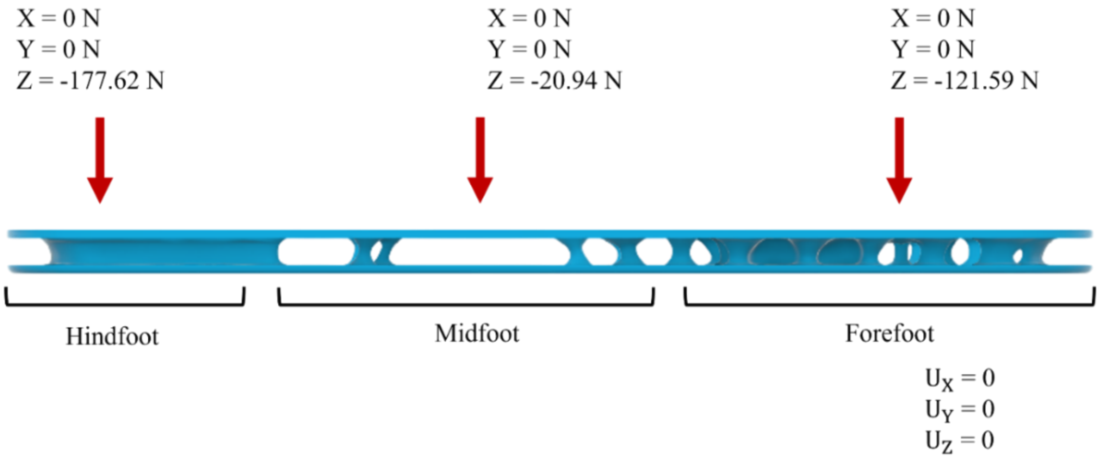

Figure 7. Boundary conditions for static structural study**.**

The mechanical behavior was interpreted using criteria based on deformation, displacement, and energy, which allow the evaluation of effective stiffness, absorption capacity, and load distribution, avoiding the use of classical failure criteria that are not representative of linear and nonlinear elastic materials. The selection of the four variables analyzed is based on the need to evaluate the structural performance of both EVA and TPU materials, which were considered as plastic materials. Maximum principal strain and equivalent elastic strain were examined to observe the structural capacity of these materials and their behavior within their yield strength. Likewise, total deformation was used to study the overall geometric change of the device under load. Finally, energy absorption was chosen as a parameter to quantify the efficiency of orthoses in load management.

4. Results

The finite element analysis allowed for the comparison of the mechanical behavior of the bilaminated EVA orthosis and the TPU orthosis with generative design under the same load conditions. The mechanical variables obtained by simulation were compared, evaluating absolute and relative differences, as well as the performance ratios between materials, consistent with linear and nonlinear elastic models.

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4.1. Strain distribution

In the equivalent elastic strain, the orthosis with a generative design presented an average value of 2.14%, higher than that observed in the EVA orthosis with a value of 1.54%. This increase suggests that TPU experiences greater total strain, reflecting more flexible material behavior and lower effective structural stiffness. As shown in Figure 8a, a more homogeneous pattern, with moderate deformations mainly in the forefoot and hindfoot regions, is observed, while in Figure 8b, the deformation is heterogeneously distributed with concentrations located on the trabecular structures.
Regarding the maximum principal strain, the EVA orthosis exhibited an average principal strain of 3.75%, significantly exceeding the 1.34% observed in the generative design orthosis. These results suggest more pronounced local strain concentrations, especially in the hindfoot, as shown in Figure 8c. Conversely, the trabecular structures in Figure 8d facilitate deformation redistribution, thereby lowering the maximum strain between the deformed areas. These specific strain values suggest that the trabecular structures operate strictly within the elastic regime of the TPU material, significantly below its yield point. Consequently, this prevents any permanent plastic deformation. However, analytically, these low strain levels also suggest a relatively rigid structural response.

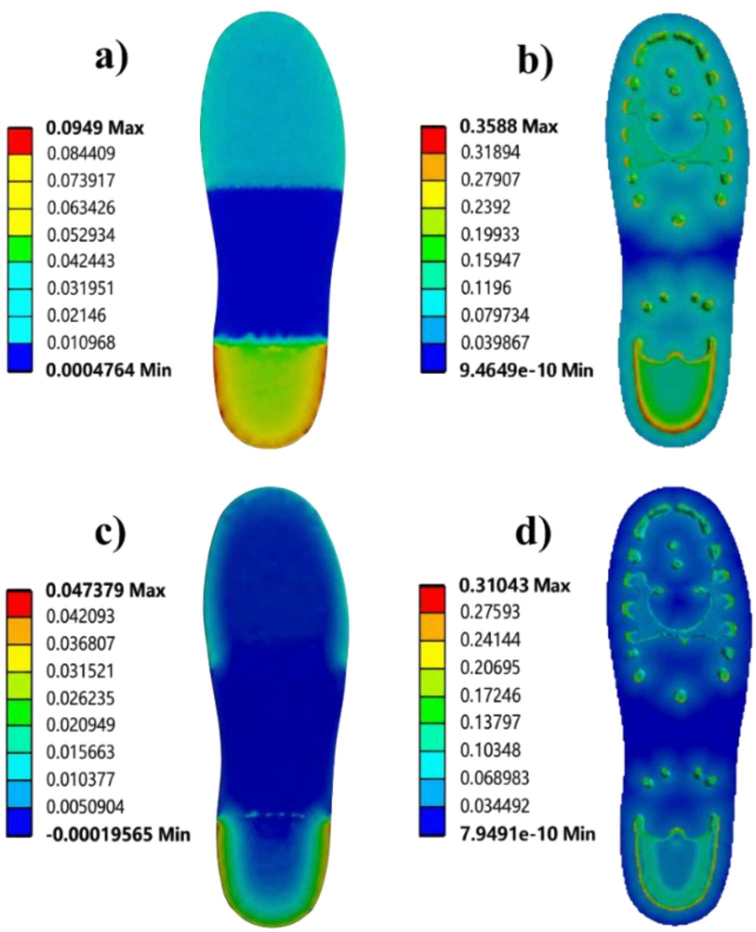

Figure 8. Elastic strain. a) Equivalent strain in EVA orthosis. b) Equivalent strain in generative design orthosis. c) Maximum principal strain in EVA orthosis. d) Maximum principal strain in generative design orthosis.

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4.2. Structural deformation

The total deformation showed marked differences between both configurations; the EVA orthosis, shown in Figure 9a, presented an average displacement of 0.0783 mm, suggesting a limited structural response. The greatest displacements are concentrated in the hindfoot. This distribution suggests that EVA acts as a more rigid structure, concentrating deformation in specific areas of support, consistent with the use of EVA A40 as a structural support.

In contrast, the generative design orthosis showed in Figure 9b, an average total displacement of 1.1137 mm was observed, higher than that observed in EVA. This suggests a deformable behavior, mainly associated with the intrinsic properties of TPU A95 and the structures generated in relation to the properties of the material. A distributed deformation is observed, particularly in the hindfoot and forefoot, where the trabecular structures allow greater displacements without abrupt concentrations. The controlled magnitude of this deformation indicates that the orthosis preserves its geometry under static loading without structural collapse. Unlike a solid volume where deformation concentrates at the point of impact, the trabecular structure efficiently redistributes the load across its entire geometry, maintaining functional stability while preventing localized stress areas.

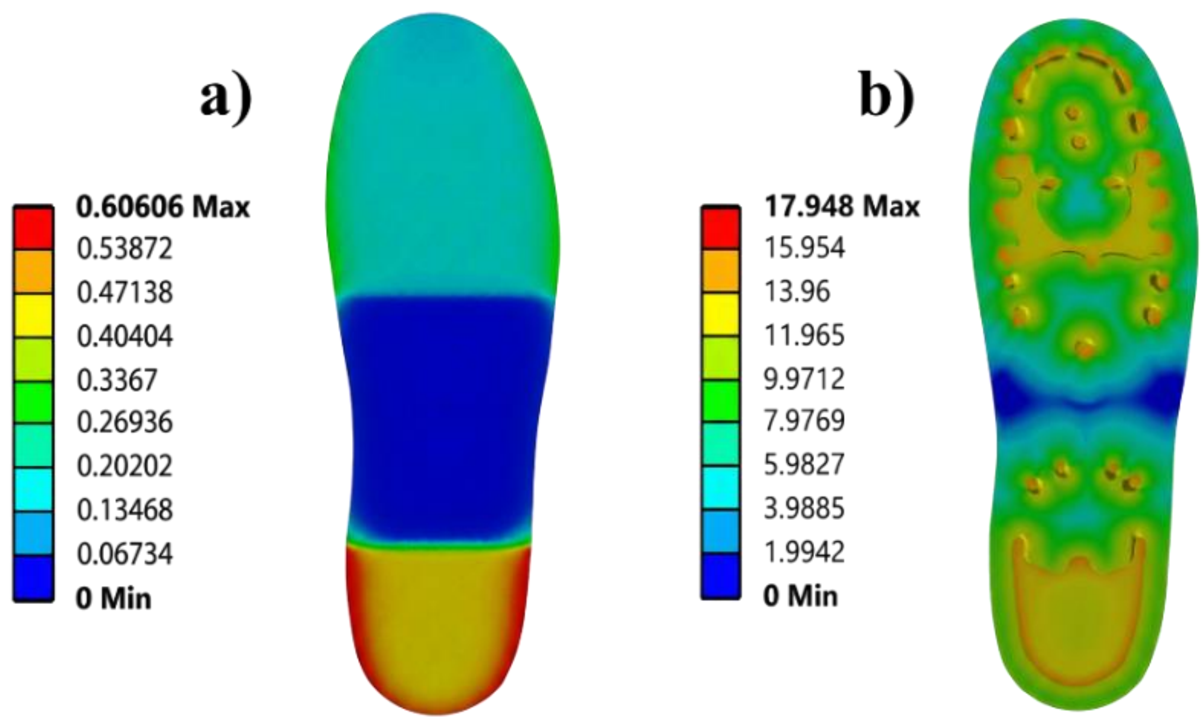

Figure 9. Total deformation. a) EVA orthosis. b) Generative design orthosis.

4.3. Energy absorption

Finally, the EVA orthosis presented a total value of 0.0362 J, a value that suggests a limited elastic energy storage capacity. Figure 10a shows a contained distribution with moderate values concentrated

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mainly in the hindfoot region and, to a lesser extent in the forefoot. On the contrary, the orthosis with a generative design presented a deformation energy of 0.3876 J, a value higher than that of EVA, suggesting a high capacity to absorb and store mechanical energy without concentrating it at critical points, if compared to its EVA counterpart. Figure 10b shows a distribution of strain energy along the entire plantar surface, with elevated values in the forefoot and hindfoot over the trabecular structures, showing a dissipation and redistribution of the load. This difference suggests that the generative design surpasses the energy dissipation capabilities of solid EVA structures. While the traditional system relies on limited material hysteresis, the optimized TPU network functions as a complex system of interconnected beams that distribute stresses three-dimensionally.

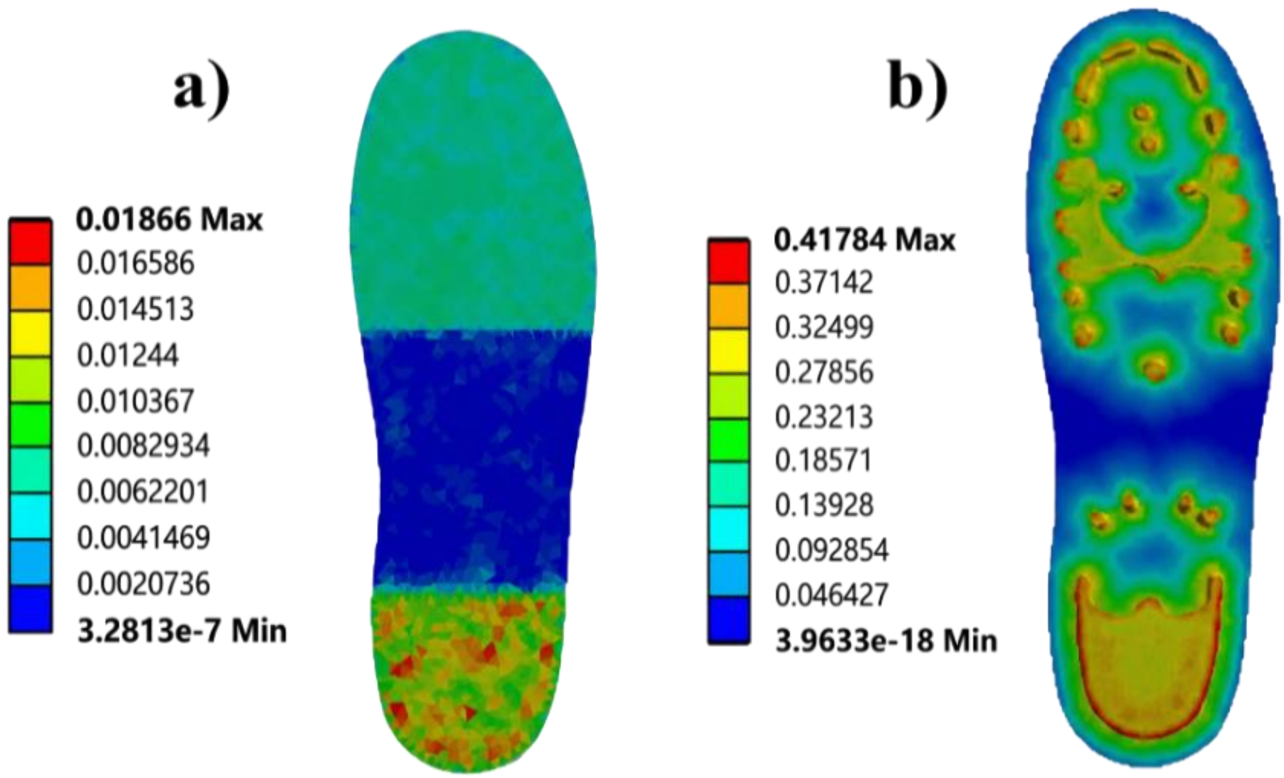

Figure 10. Energy strain. a) EVA orthosis. b) Generative design orthosis.

5. Discussions

This study aimed to investigate structural optimization by applying generative design to plantar orthoses and comparing them to traditional designs from a finite element analysis focus. The main contribution of this work is to demonstrate how generative design can be incorporated into the processes for designing plantar orthotics; the results suggest that generative design has significant potential in the field of ergonomics. The implementation of generative design leads to more optimal performance due to the inherent properties of the materials used and the topology of the structures.

In this study, areas of deformation were concentrated in the trabecular regions, which enhances the distribution and redistribution of these deformations throughout the overall structure. In contrast, the

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mechanical behavior of the bilaminated EVA orthosis demonstrates a limited structural response, primarily serving as a stiffness support structure. This stiffness is beneficial for supporting musculoskeletal structures and favoring alignment. Nevertheless, the mechanical behavior of the orthosis designed with generative principles indicates a more deformable and flexible character. This flexibility is advantageous for the anatomical adaptation of the foot and helps achieve a more uniform load distribution. This characteristic is inherent to TPU, which has shown such behavior in various studies, reflecting a more stable load distribution [38], [47], [48], [49].

A remarkable density of the trabecular structures was observed in the hindfoot, where just over 50% of the load of the foot is concentrated. However, it is the combination of the structure with the appropriate material that determines the global mechanical behavior of the orthosis. The generated topology allows for greater design freedom and flexibility compared to other advanced structures, such as lattices, auxetic, or triply periodic minimal surfaces (TPMS) structures. However, a comparative analysis between different topologies is necessary to establish a benchmark of efficiency.

In comparison, the work of Schneider et al. [30], where the density of material generated was in the forefoot; In this work, it was the area of the hindfoot where there was a greater concentration of material generated. To consider where there are more materials, where greater loads are applied, making the structure denser in that area. In this design, there are more dispersed structures in the forefoot than in the rearfoot, a structure that is responsible for the absorption of energy from the load. Finally, the results must be interpreted within the limitations of the numerical model, since both materials were treated as linear elastic under the specific load conditions. Given the hyperelastic behavior of EVA and TPU, in future work, they could opt for non-linear constitutive models, in addition to incorporating dynamic analyses to more realistically evaluate the absorption and dissipation of energy during walking and the interaction between orthoses and the foot. The results presented should be considered preliminary. While these simulations offer detailed predictions of mechanical behavior based on the properties of previously characterized materials, it is important to note that they represent theoretical models. Therefore, these findings need to undergo future experimental validation and subsequent experimental testing to confirm the correlation between computational predictions and the actual performance of the orthosis under real-use conditions; additionally, the possibility of manufacture prototypes to validate experimentally with test subjects to evaluate their functionality in redistributing plantar pressure and their interaction with the foot, considering the morphology of the foot in orthosis design, other materials, boundary conditions and data from particular conditions such as overweight or obesity.

6. Conclusions

In conclusion, applying generative design to plantar orthoses shows significant potential for optimizing mechanical response and stress distribution compared to traditional designs. However, the importance of these findings lies in their role as a preliminary design framework based solely on computer simulations. The main limitation of this study is the absence of physical evidence; therefore, the clinical applicability of these results depends on future research that involves the creation of prototypes and their experimental validation with real test subjects. This is necessary to confirm the structural integrity and ergonomic effectiveness predicted by the numerical models.

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8. Authorship acknowledgment

Christian Enrique Nava-Alcantar: Conceptualization, formal analysis, methodology, investigation, and writing—original draft; *Israel Miguel-Andrés:* Supervision, visualization, and writing—review & editing; Agustín *Vidal-Lesso*: Writing—review & editing, and technical consistency review; *Marco Antonio Martínez-Bocanegra:* Writing—review & editing, visualization; *Luis Ángel Ortiz-Lango: V*isualization, and writing—review & editing; *Juan Carlos García-Valadez*: Technical consistency review*; Sergio Alonso-Romero: Supervision*, and writing—review & editing.

9. Conflict of interest

The authors have no competing interests to declare that are relevant to the content of this article.

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