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DEVELOPMENT OF ACTIVE MANUFACTURING INSOLES FOR THE PREVENTION OF FOOT ULCERS IN INDIVIDUALS WITH DIABETES

DESENVOLVIMENTO DE PALMILHAS EM MANUFATURA ATIVA PARA A PREVENÇÃO DE ÚLCERAS NOS PÉS DE INDIVÍDUOS COM DIABETES

Sofia Maria Mecenas Areias Lima[1*], Vitória Souza de Oliveira[2], Pedro Henrique Gonçalves[3]

[1* 2 3] Universidade Federal de Goiás (UFG), Goiânia, GO, Brazil.
[1*]sofia.areias@discente.ufg.br [2] oliveira_oliveira@discente.ufg.br [3]pedrogoncalves@ufg.br
***Autor Correspondente**: **Lima, S.M.M.A.**

ABSTRACT: Diabetes mellitus is characterized by insulin resistance and/or insufficient production of this hormone, and one of its complications is peripheral neuropathy, which alters plantar sensitivity and can cause foot ulcers due to high pressure or traumatic agents. Custom insoles are a therapeutic approach often recommended for these individuals, as they contribute to the redistribution of plantar pressures and the reduction of shear forces, acting to prevent these injuries and assisting in treatment. This study evaluated the production of custom insoles by rapid prototyping for the prevention of plantar ulcers in diabetic individuals, with the aim of establishing a technically viable protocol. This method was divided into stages, which involved scanning, software modeling, 3D printing, and post-processing, which includes cutting the coating materials and attaching them to the insole. The manufacture of insoles by additive manufacturing has proven to be efficient and sustainable, as it reduces costs, optimizes time and materials, and generates less waste. Thus, this method enables accurate and customizable production, allowing for better adaptation to the specificities of each individual.

KEYWORDS: Diabetes; Insoles; Plantar Ulcers; Active Manufacturing

RESUMO: A diabetes mellitus é caracterizada pela resistência à insulina e/ou produção insuficiente desse hormônio, e tem como uma de suas complicações a neuropatia periférica, que altera a sensibilidade plantar e pode ocasionar aparecimento de úlceras nos pés devido à altas pressões ou agentes traumáticos. As palmilhas personalizadas são um abordagem terapêutica frequentemente indicada para esses indivíduos, visto que contribuem para a redistribuição das pressões plantares e para a redução das forças de cisalhamento, atuando na prevenção dessas lesões e auxiliando no tratamento. Este estudo avaliou a produção de palmilhas personalizadas por prototipagem rápida para a prevenção de úlceras plantares em pessoas diabéticas, com o objetivo de estabelecer um protocolo viável tecnicamente. Esse método foi dividido em etapas, que envolveram processo de escaneamento, modelagem em softwares, impressão 3D e pós-

processamento, que inclui o recorte dos materiais de revestimento e a fixação dos mesmos na palmilha. A fabricação de palmilhas por manufatura aditiva demonstrou eficiência e sustentabilidade, visto que há redução de custos, otimização de tempo e materiais, com menor geração de resíduos. Dessa forma, esse método viabiliza uma produção precisa e personalizável, permitindo melhor adaptação às especificidades de cada indivíduo.

PALAVRAS CHAVE: Diabetes; Palmilhas; Úlceras plantares; Manufatura Ativa..

1. INTRODUCTION

Diabetes Mellitus (DM) is characterized by insulin resistance and/or insufficient production of this hormone by the pancreas, resulting in a state of hyperglycemia (American Diabetes Association, 2011). Chronic hyperglycemia (CH) can lead to macro- and microvascular damage, preventing blood vessels from maintaining healthy tissue (Cameron *et al.,* 2001), notably resulting in conditions such as peripheral diabetic neuropathy (PDN), a dysfunction of one or more nerves in the body's extremities (Feldman *et al.*, 2019). PDN is a significant concern due to the complications that may arise in this population, as it leads to the loss of protective sensation in the feet (Van Netten *et al.,* 2024), which is closely related to the poor distribution of plantar pressures (Stoicescu, 2020), increasing the risk of developing plantar ulcers (PU). Without proper treatment, PUs become the main risk factor for lower limb amputations, considered the most severe outcome of PUs (Assumpção *et al.,* 2009; Hingorani *et al.,* 2016; Veves *et al.*, 1992).

With the progression of PDN, structural changes involving the musculoskeletal system emerge, characterized by deformities such as claw toes, bony prominences, and joint stiffness (Pham *et al.,* 2000). These changes promote biomechanical imbalances (Andreozzi *et al.,* 2020), resulting in the anomalous redistribution of plantar pressures, which predisposes to the development of ulcers (Caselli *et al.,* 2002; Kim, 2013). Furthermore, ulcerative lesions are commonly complicated by bacterial infections, which can progress to severe conditions such as cellulitis, osteomyelitis, and gangrene (Stoicescu, 2020). Thus, when not adequately addressed, these complications potentiate the risk of amputations, constituting a severe and significantly impactful outcome for the patient (Assumpção *et al.,* 2009; Hunt, 2011; Pham *et al.*, 2000).

Access to preventive measures to reduce the risk of foot ulceration in cases of Diabetes Mellitus (DM), such as podiatric care and the use of appropriate footwear and custom insoles, is essential to prevent complications in this population (Bus *et al.,* 2023). However, many patients arrive at the healthcare system in advanced stages of the disease, consistently presenting with glycemic dyscontrol and complications that are incapacitating for their daily living activities (Jorge *et al.,* 1999; Nunes *et al.*, 2006; Wan *et al.,* 2020). Although plantar orthoses and associated off-loading devices, such as insoles, have shown efficacy in reducing PUs, the acquisition of these technologies remains limited, and the adherence to and usability of insoles by the diabetic population are challenging.

Insoles can be classified by their manufacturing process, molding type, length, corrective element, and therapeutic objective (Mendes, 2020). In the literature and the market, both prefabricated and customized insoles are found. However, the fabrication of orthopedic insoles is still predominantly manual and requires a high level of customization and finishing, which increases costs and prolongs production time (Ribeiro *et al.,* 2024). The traditional production method generates waste throughout all its stages, which, being difficult to reuse and recycle, impacts the environment and can lead to soil and water contamination, as is the case with plaster-derived materials (Pinheiro, 2011).

From this perspective, production via Additive Manufacturing (AM) has shown promise in the fields of clinical practice, being applied in the most diverse areas of health, including orthotics (Barani *et al*., 2005; Giannopoulos *et al.*, 2016; Ren *et al.*, 2024; Singh, 2024). Thus, the combination of 3D scanning with 3D printing enables larger-scale production of plantar orthoses and insoles, incorporating a high degree of automation and refinement in the finishing.

Therefore, the objective of this study is to test and develop a protocol and to investigate the technical possibilities for the production of insoles via rapid prototyping for the prevention of plantar ulcers in people with diabetes.

2. LITERATURE REVIEW

The association of insoles with therapeutic footwear reduces the recurrence rate of PUs in diabetic patients, acting to prevent new lesions (Elraiyah *et al.,* 2016). This effect can be attributed to the personalization of the insoles, which, by significantly reducing forefoot pressure time compared to prefabricated models, potentially reduces the risk of ulceration in neuropathic patients (Paton *et al.*, 2012; Ahmed *et al.*, 2020). Finite Element Modeling (FEM) studies have allowed for the design of insoles that selectively relieve stress in high-risk areas, such as the heel and metatarsal heads (Barani; Haghpanahi; Katoozian, 2005; Chen *et al.,* 2015).

AM, or 3D printing, stands out as a technology with increasing potential. The combination of 3D modeling and CAD/CAM software allows for the creation of customized designs that precisely adapt to the patient's individual anatomical features (Yick *et al.,* 2019; D'Amico *et al.,* 2021; Singh, 2024). In addition to geometric personalization, it also allows for the exploration of new materials and internal structures. Recent research investigates the use of polymers such as TPU (Park; Fu, 2021), as well as the incorporation of lattice or auxetic structures (Kumar; Sarangi, 2023; Leung *et al.*, 2022; Nickerson *et al.*, 2023), which enable stiffness gradients and superior impact absorption, combining comfort, durability, and clinical efficacy (Tang *et al.,* 2019; Shaulian *et al.,* 2023). Furthermore, coating can be performed with a combination of materials to ensure better absorption and softness; these materials include silicone, EVA, Plastazote®, and PORON® (Ghassemi *et al.,* 2015; Shi *et al.*, 2022; Telfer, *et al.,* 2017). The number of studies that clearly and thoroughly detail the step-by-step process for replicating the modeling and printing of insoles is still scarce.

3. METHODOLOGY

This work is part of a broader research project from the Laboratório de Estudos Inventivos em Tecnologia Assistiva (LAB.E.I.T.A.), focused on the development of new assistive technologies, approved by the Research Ethics Committee under number 7.828.871. The study's production process via rapid (3D) prototyping was carried out at the Laboratório de Ideias, Prototipagem e Empreendedorismo (IPElab) of the Federal University of Goiás - GO, located in Goiânia. The test was conducted on a non-diabetic female individual, aged 21, with no foot deformities. For this reason, a simulation of calluses was performed at forefoot points (Figure 1 (a)), a region with a high potential for the development of PUs in individuals with severe diabetic neuropathy (BUS *et al.*, 2023; Caselli *et al*., 2002).

4. RESULTS AND DISCUSSION

4.1 FEET SCANNING

Although there are various methods for feet scanning, such as computed tomography (CT) (Jafarzadeh *et al*., 2021) and even photogrammetry (Kumar; Sarangi, 2023), the scanning process for developing the custom insole enables the obtainment of the exact specificities and dimensions of the feet (Ribeiro *et al.*, 2024), in addition to allowing for future additional changes, if necessary (Jonnala U.K.; Sankineni R.; Kumar Y. R, 2023). In this study, a portable 3D scanner was used for digitalization, the model being the EinScan PRO 2X Plus, with an accuracy ranging between 0.05 and 0.01 mm. This equipment is defined as a non-contact, non-destructive digital device that employs light or laser to accurately capture the geometry of a physical object and convert it into CAD (Computer-Aided Design) data. During the scanning process, the foot was positioned on a static platform, allowing for an approximate representation of its support on the ground or inside the shoe (Figure 1 (a), Figure 1 (b) and Figure 1 (c)). After digitalization, the data undergo point cloud processing and are converted into an STL (stereolithography) file format, which structures the geometric image and is widely used in 3D printing.

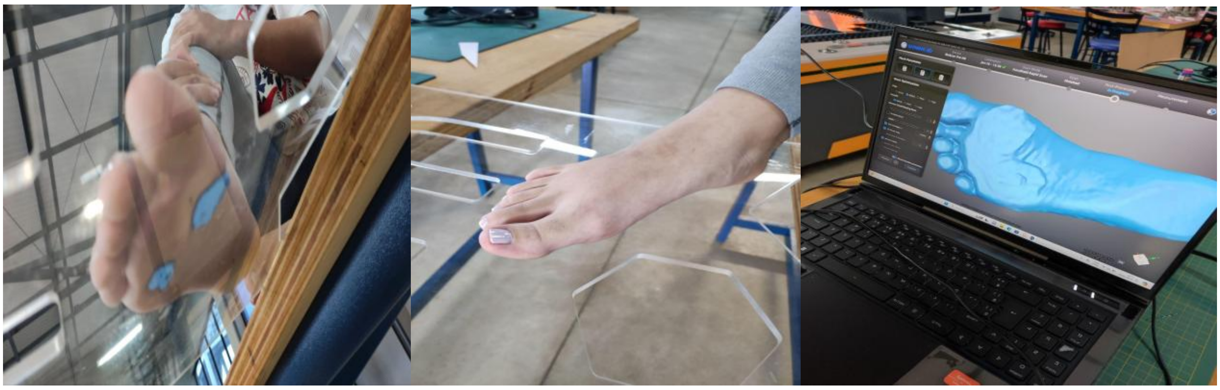

Figure 1: Scanning Process: (a) Callus simulation on the forefoot, (b) foot supported on a surface, and (c) Foot scanned in the EinScan PRO 2X Plus software. Source: Developed by the authors.

After scanning and processing the foot model, the insole modeling was performed using the free software Gensole (Figure 2), which enables the modeling of insoles with customized stiffness regions that allow for a more efficient load distribution in the plantar region, according to the user's biomechanics and anatomy. This contributes to the reduction of high plantar pressures, which is fundamental for the prevention of plantar ulcers. It also offers other functions, such as molding the top surface of the foot according to its structure through the "Solemorph" process and configured contour curves to provide better accommodation of the insoles inside the footwear (Ribeiro *et al.,* 2024).

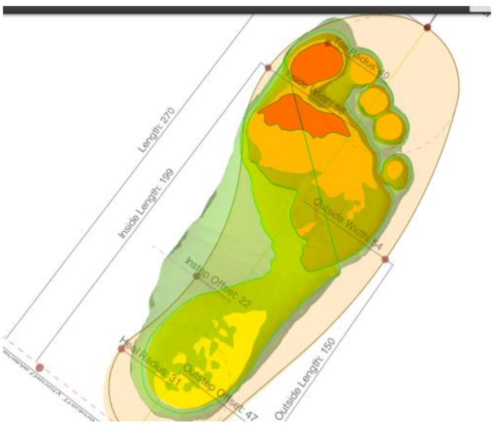

Figure 2: Insole modeling in the Gensole software. Source: The authors

4.2 3D PRINTING

Subsequent to the insole design in the Gensole software, the file is exported in AMF format to the free Slic3r program. This step is important because this format allows for the combination of multiple files into a single 3D model, enabling the configuration of materials with different densities during printing. For the insole fabrication, the model was adjusted in the OrcaSlicer software, where the file slicing occurred (Figure 3 (a)), resulting in the G-code which was then sent to the Creality K1 MAX printer (Figure 4 (b) and Figure 4 (c)). A 0.4 mm nozzle was used for printing, and the infill density was variable according to the pressure zones. The material employed in the printing was UltraFlex TPU 40 SHORE D, a thermoplastic based on polylactic acid derived from corn starch (Kumar & Sarangi, 2023). This material is used in AM due to its elastic properties and abrasion resistance, being common in the production of orthopedic insoles, sandal soles, prostheses, and other personalized devices. Subsequently, the total printing time was 3 hours and 20 minutes, and the insole's weight was 46g.

Figure 3: (a) Insole slicing in the OrcaSlicer software. (b) Creality K1 MAX printer, and (c) Insole printing in progress. Source: Developed by the authors.

4.3 POST-PROCESSING

The materials for the coating were cut on a laser cutting machine (Figure 4 (a), Figure 4 (b), and Figure 4 (c)), and subsequently, tests were conducted with two adhesives, one being instant adhesive and the other a spray adhesive (Figure 5 (a) and Figure 5 (b)), to analyze which would have greater adhesion potential with the printed insole material. People with insensitive feet, such as diabetics, require insoles with soft materials and good impact absorption. Thus, one insole model was coated with PORON® 4701-40-20 (Maximum thickness 3.18mm) (Figure 6 (a)), a polyurethane in the form of a soft foam already used in insole coating (Mendes, 2022), which exhibits physical characteristics such as compression force, tensile strength, and elongation over long periods, and maintains integrity under long temperature fluctuations (Shi *et* *al.*, 2022). The other model was coated with two layers (Figure 6 (b)), one of PORON® 4701-40-20 and another of Vinyl Acetate (EVA), 0.4 mm thick, which is a flexible, pressure-resistant polymer with shock-absorbing capacity, also providing greater comfort during gait.

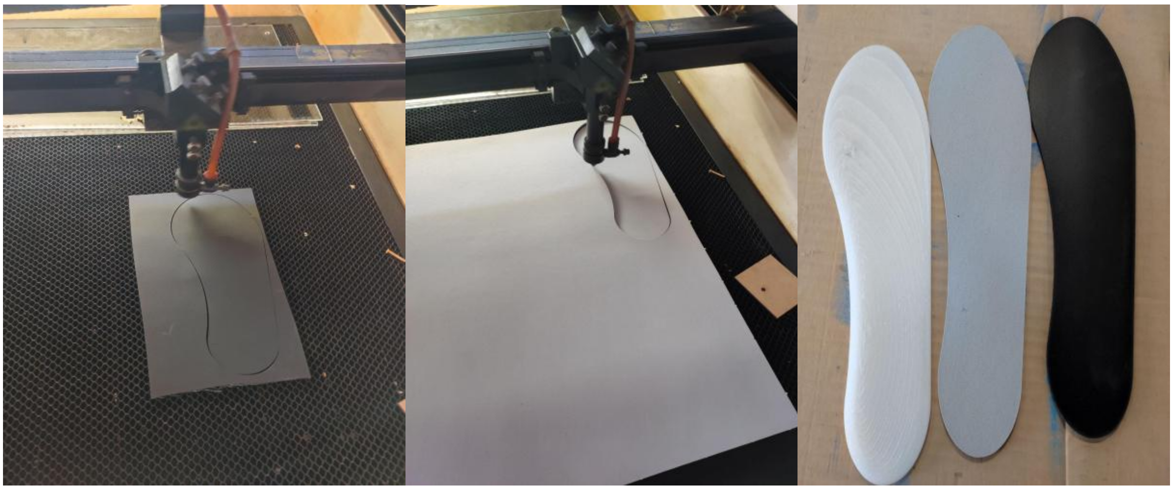

Figure 4: Post-processing: (a) PORON® 4701-40 laser cut, (b) EVA laser cut, and (c) 3D printed insole and cut coatings. Source: Developed by the authors.

Figure 5: Adhesion test: (a) Tested adhesive glues, and (b) Insoles with the test performed. Source: Developed by the authors.

Figure 6: Coated Insoles: (a) Insole coated with a single layer of PORON® 4701-40, and (b) Insole coated with two layers: EVA and PORON® 4701-40. Source: Developed by the authors.

O The rapid prototyping process enabled the production of personalized insoles in 5 steps: foot scanning, modeling through the scanned images, 3D printing, cutting the coating materials, and insole finalization. In both insole models fabricated in this study, the density was modified at the points where callosity simulation occurred, in order to result in pressure relief in these regions. This approach aimed to provide pressure relief in these specific regions, highlighting the importance of personalization to meet the individual needs of users and, consequently, minimize the occurrence of plantar ulcers, given the uniqueness of each individual's specificities.

Furthermore, the coating materials are important for achieving a better outcome regarding pressure relief and the occurrence of plantar ulcers. From the obtained results, it was found that the spray adhesive demonstrated greater adherence between the coating layers and the insole; however, more tests need to be performed to assess durability.

Corroborating the literature, Shi (2022) and Ren *et al*. (2024) emphasized that soft surfaces can contribute to impact cushioning, causing a significant reduction in plantar pressure off-loading. Given this, by coating the 3D printed insoles fabricated for this study, the objective was to bring greater comfort to the user and better quality to the developed product, selecting PORON® and EVA, materials with soft textures. It is worth noting that the final mass between the insoles varied by around 5g, with the insole coated with a single layer of PORON® 4701-40-20 having a final mass of 62g (Figure 7(a)), while the double-layer insole had 67g (Figure 7 (b)).

Figure 7: Insole weighing: (a) weight of the single-layer insole, and (b) weight of the double-layer insole. Source: Developed by the authors.

Customized insoles are prescribed in clinical practice as they are among the main mechanisms described in the literature for reducing the occurrence of PUs (Muir *et al.*, 2022). The fabrication of these devices can be done by the conventional method, but also by AM, which has been gaining increasing notoriety due to its benefits.

AM is a sustainable mode of production that provides material and energy savings, in addition to minimizing environmental impacts (Park; Fu, 2021). In this sense, it is observed that processes utilizing AM present advantages over conventional methods, notably the significant reduction in time and waste generation, as illustrated in the flowchart in Figure 8.

From this perspective, another important aspect that should be highlighted is the advantage that 3D printing possesses in relation to the precision of applying different density levels to various points of the insole, requiring changes to be made through the scanned images of the foot. This contrasts with the conventional method, which requires manual sanding or the addition of EVA layers to make the adjustments.

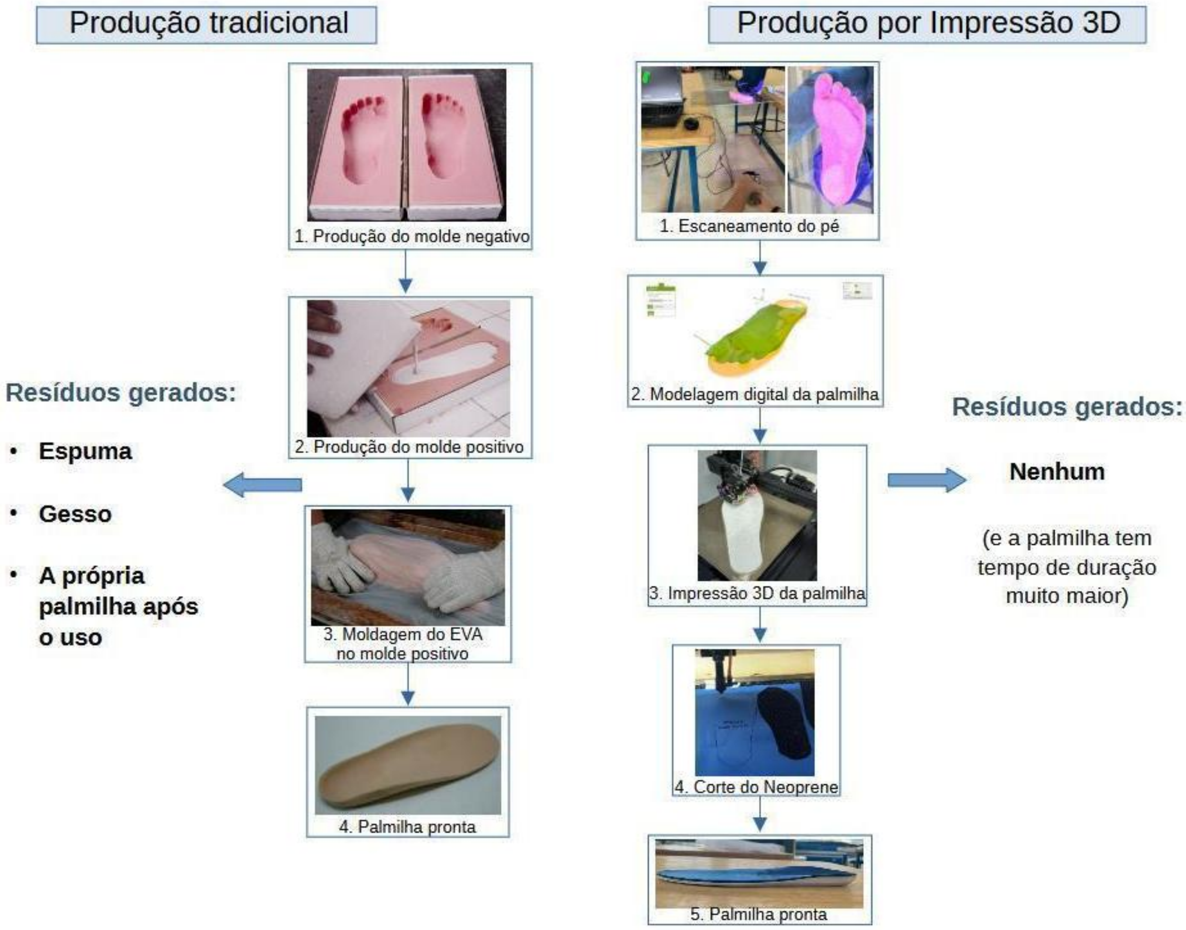

Figure 8: Flowchart of traditional production and rapid prototyping printing. Source: Ribeiro *et al.*, 2024

Regarding costs, in Brazil, besides private initiatives and prefabricated models on the market, insoles are devices linked to the public health system, the Sistema Único de Saúde (SUS). The pricing of traditional manufacturing is based on the values established by the SUS Table of Procedures, Medications, and Orthotics, Prosthetics, and Assistive Devices Management System (SIGTAP), as illustrated in Figure 9. Thus, the individual costs of each material were not described. The total outpatient value for the production of an insole is R$170,30 (Figure 9). The production time varies according to the production and targets of orthopedic workshops and Specialized Rehabilitation Centers (CER), potentially exceeding one month for the final product delivery to the user (Ribeiro *et al.,* 2024).

On the other hand, the values related to the insole manufactured via 3D printing were calculated based on the total production time, estimated at 3 hours and 20 minutes, and the materials used during the process, resulting in a total cost of R$120,7, as detailed in Table 1.

	Quantity	Cost
TPU	46g	R$ 8,59
PORON®	2 sheets	R$ 102,06
3D Printing	1.184 Kw/h	R$ 0,79
EVA 3mm	½ sheet	R$ 1,80
Glue	20g	R$ 2,46
Laser Cutting	≈ 2 minutes	R$ 5,00
Total cost		R$ 120,7

Table 1 - Production costs of the 3D-printed orthosis per insole. Reference value of 0.671 kw for the calculation of energy consumption. Source: The authors


Procedimento

Procedimento: 07.01.01.015-0 - PALMILHAS PARA PÉS NEUROPÁTICOS CONFECCIONADAS SOB MEDIDA PARA ADULTOS OU CRIANÇAS (PAR)

Grupo: 07 - Órteses, próteses e materiais especiais
Sub-Grupo: 01 - Órteses, próteses e materiais especiais não relacionados ao ato cirúrgico
Forma de Organização: 01 - OPM auxiliares da locomoção

Competência: 10/2025 Histórico de alterações

Modalidade de Atendimento: Ambulatorial
Complexidade: Não se Aplica
Financiamento: Média e Alta Complexidade (MAC)
Sub-Tipo de Financiamento:
Instrumento de Registro: BPA (Individualizado)
Sexo: N/A
Média de Permanência:
Tempo de Permanência:
Quantidade Máxima: 1
Idade Mínima: Não se aplica
Idade Máxima: Não se aplica
Pontos:
Atributos Complementares: Exige CPF/CNS

Valores
Serviço Ambulatorial: R$ 170,30 Serviço Hospitalar: R$ 0,00
Total Ambulatorial: R$ 170,30 Serviço Profissional: R$ 0,00
Total Hospitalar: R$ 0,00

Descrição | CID | CBO | Leito | Serviço Classificação | Habilitação | Redes | Origem | Regra Condicionada | Renases | TUSS

Descrição
PALMILHAS ESPECIAIS PARA PES NEUROPATICOS, CONFECCIONADOS SOB MEDIDA. (PAR).

Figure 9: Cost of custom-made special insoles for neuropathic feet. Source: Brazil, 2025

Overall, the 3D insole fabrication process has several benefits when compared to manual production, given the optimization of time and materials, cost reduction, and the feasibility of subsequent changes in the modeling without additional costs. Moreover, the 3D-printed insole can contribute to the reduction of environmental impact, as the material used in printing is recyclable, and there is minimal waste generation from both the printing support and the coatings.

5. FINAL CONSIDERATIONS

AM presents itself as a viable and advantageous alternative for the production of orthopedic insoles intended for the diabetic population. The capacity to offer personalization with agility, cost reduction, and waste minimization positions this technology as a promising path to make treatment more accessible and efficient. The application of this approach demonstrates potential not only to prevent plantar ulcerations and reduce the risk of amputations, improving the quality of life, but also to underpin the creation of increasingly complex and adapted devices that can expand patients' mobility and autonomy. Therefore, 3D printing is consolidated as a fertile field for innovation in health, with a direct impact on the standardization of protocols and the continuous improvement of products oriented toward specific needs.

Nonetheless, the limitations of this research are recognized, particularly regarding the need for clinical trials in individuals with insensitive feet and PDN, as well as tests for durability and therapeutic efficacy. Thus, future studies are essential to consolidate the practical applications of this technology, evaluating the effectiveness, safety, and acceptance of insoles produced by rapid prototyping.

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