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DEVELOPMENT OF POLYMER INSOLE IN ADDITIVE MANUFACTURING FOR PEOPLE WITH PLANTAR HYPERHIDROSIS[1]

DESENVOLVIMENTO DE PALMILHA POLIMÉRICA EM MANUFATURA ADITIVA PARA PESSOAS COM HIPERIDROSE PLANTAR

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ABSTRACT

The objective of this project is to develop a TPU (Thermoplastic Polyurethane) polymer insole using additive manufacturing technology, with the application of gyroid geometry. The insole is an essential component in footwear, providing comfort and support for the foot. The gyroid geometry has unique properties such as high porosity, lightness and flexibility, which makes it suitable for insole applications. Additive manufacturing allows for the precise and customized manufacturing of complex parts, which is advantageous for the production of insoles with specific geometries to meet the individual needs of each user. The project aims to explore the potential of combining these technologies to manufacture innovative and comfortable insoles, making walking easier and safer for people who suffer from plantar hyperhidrosis, a disease that characterizes excessive foot sweat. Consuming shoes that do not absorb excessive moisture limits these people to having the power of choice, therefore, a solution was proposed to adapt open shoes with a TPU insole developed through the software inventor fusion 360.

Keywords: thermoplastic polyurethane, gyroid, 3D printing.

RESUMO

O objetivo deste projeto é desenvolver uma palmilha em polímero TPU (Poliuretano Termoplástico) utilizando tecnologia de fabricação aditiva, com aplicação de geometria giroide. A palmilha é um componente essencial no calçado, proporcionando conforto e apoio ao pé. A geometria giroide possui propriedades únicas como alta porosidade, leveza e flexibilidade, o que a torna adequada para aplicações em palmilhas. A fabricação aditiva permite a fabricação precisa e customizada de peças complexas, o que é vantajoso para a produção de palmilhas com geometrias específicas para atender às necessidades individuais de cada usuário. O projeto visa explorar o potencial da combinação dessas tecnologias para a fabricação de palmilhas inovadoras e confortáveis, tornando a caminhada mais fácil e segura para pessoas que sofrem de hiperidrose plantar, doença que caracteriza o suor excessivo nos pés. Consumir calçados que não absorvem umidade excessiva limita o poder de escolha dessas pessoas, portanto, foi proposta uma solução para adaptar calçados abertos com palmilha em TPU desenvolvida através do software inventor fusion 360.

Palavras-chave: *poliuretano termoplástico, giroide, impressão 3D.*

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INTRODUCTION

In some people, the body's cooling mechanism is overactive, so overactive that they may sweat more than necessary. When sweating is so extreme, it can be embarrassing, uncomfortable and can generate anxiety, perceived threat and even incapacitation. It often disrupts every aspect of a person's life, from career choices and recreational activities, to relationships, emotional well-being and self-confidence. This type of excessive sweating is a serious medical condition (BERNHARD; KRAUSE; SYRBE, 2018).

Excess sweating can be worsened by anxiety and stress, and can range from moderate dampness to heavy dripping, which can, in turn, exacerbate associated anxiety and stress. The primary hyperhidrosis is related to hyperactivity of the sympathetic nervous system and can manifest differently in different affected areas, such as damaged clothing, wet paper and shoes, and obvious sweat marks on clothing or unpleasant cold, damp handshakes. Excessive sweating in the armpits, hands, feet or face can result in substantial harm to the individual, including limitations in work, social interaction, physical activities and leisure, as well as emotional and psychological distress (BERNHARD; KRAUSE; SYRBE, 2018; SHARGALL; SPRATT; ZELDIN, 2008; STRUTTON *et al*., 2004).

Hyperhidrosis affects millions of people around the world, approximately 3% of the world's population. Due to the lack of awareness among patients and the lack of awareness among healthcare professionals, the majority of people are never diagnosed or relieved of their symptoms. Therefore, it is extremely important to search for processes and products like insoles that can alleviate these symptoms, one of which focuses on additive manufacturing (BERNHARD; KRAUSE; SYRBE, 2018; COTOROS; STANCIU, 2020; NING *et al*., 2022).

Additive manufacturing has been gradually gaining ground due to its flexibility, low maintenance and minimum level of operation. Consequently, it can replicate a variety of processes that manufacture models directly from CAD (computer-aided design) software using a sequence of joined and integrated layers. This system does not have the same restrictions as subtractive manufacturing, allowing the generation of complex offering the possibility of mass reduction shapes with increased product functionality. With this tool it is possible to use different materials for this purpose, such as PU (polyurethane) (VOLPATO, 2021; ZHANG *et al*., 2019)

PU was patented by Otto Bayer and collaborators in 1937, which is obtained through the polyaddition reaction of an isocyanate (di or polyfunctional), with a polyol and other reagents such as curing agent or chain extenders, containing two or more groups reactants, catalysts; blowing agents; surfactants; loads; anti-aging agents; dyes and pigments; flame retardants, release agents, etc. This material can be found in the form of foams, which finds application in the area of thermal and acoustic insulation, in addition to civil construction and furniture and when combined with rare earth elements, they present a significant improvement in their thermal stability (ALVES *et al*., 2021; ALVES *et al*., 2022; ALVES *et al*., 2024; DA SILVA; ALVES, 2023; PEGORARO *et al*., 2023; VILAR, 1998).

Among the various types of polyurethanes are thermoplastic PU (TPU), which are soldered in granules and processed using the usual thermoplastic techniques, such as injection, extrusion or blowing. TPUs are block copolymers containing rigid segments (hard segments, HS) and flexible segments (soft segments, SS), separated into microphases or domains. SS are composed of amorphous domains generally made up of long-chain polyols, while HS are mainly composed of the diisocyanate/chain extender group. TPU is an excellent material option for various biomedical applications, mainly polyether) urethane, which present greater resistance to hydrolytic manipulation, and exhibits several properties, such as biocompatibility, biostability, flexibility and electrical insulation (VILAR, 1998; VOGELS *et al*., 2017)

Thermoplastic polyurethane (TPU) is a multifaceted material popular in additive manufacturing, also known as 3D printing. It is a type of PU that can be melted and molded several times without losing its mechanical properties, making it the ideal choice for additive manufacturing (VILAR, 1998; WANG *et al*., 2020).

It is worth mentioning that TPU, in relation to other raw materials commonly used for 3D printing, such as polyethylene terephthalate (PETG), acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA), stands out in terms of properties relevant to the application of insoles. Among them, softness stands out, making it a less hard, flexible material with good elasticity and resistance to humidity. This last characteristic is essential for the application of insoles in cases of plantar hyperhidrosis, as it prevents the absorption of sweat (BRANCEWICZ-STEINMETZ *et al*., 2022; ELMRABET; SIEGKAS, 2020; GNATOWSKI *et al*., 2019; ÖZSOY; ERÇETIN; ÇEVIK, 2021; SOLTANMOHAMMADI *et al*., 2024).

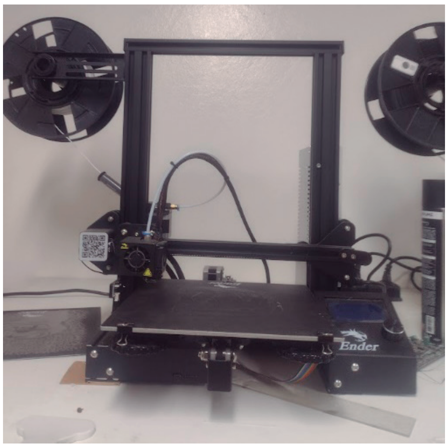
When researching solutions for plantar hyperhidrosis, immediate relief options are not widely explored and most are invasive solutions (surgeries) or drug treatments that can generate side effects such as the use of antiperspirants containing aluminum salts which can cause irritation. Furthermore, the surgical or chemical lumbar sympathectomy, is not highly recommended for plantar hyperhidrosis, as surgery is associated with significant adverse effects (HORNBERGER *et al*., 2004; HOLZLE; KLIGMAN, 1979). Thus, the objective was to develop something for immediate relief, adaptable and using few resources, being something personalized for greater comfort and adaptability for the user. Therefore, it was necessary to create an insole, using 3D CAD technology (Fusion 360), manufactured through additive manufacturing with flexible filament (TPU).

MATERIALS AND METHODS

To carry out 3D printing of the insole, the Ender 3D Printer was used, as shown in figure 1. The insole was modeled in 3D CAD using the Fusion 360º and STL software used for printing.

To manufacture the TPU insoles, called 3D insole. the process was carried out using 3D FDM printing (fusion deposition modeling), which basically consists of the deposition of filaments layer upon layer, the material is extruded onto a head at a certain temperature, the parameters used in the process of printing are described in table 1 (RODRÍGUES-REYNA, 2022; DAVIA-ARACIL, 2018).

Figure 1 - Ender 3D Printer.



Source: Authors.

Table 1 - Parameters used in the 3D printer.

Room temperature	25 °C
Nozzle temperature	230 °C
Print speed	30 mm/s

Source: Authors.

For comparison purposes, a commercial insole composed of EVA was used as a control and, in addition to the 3D printed TPU insole, the same insole printed with cotton fabric was also used to make the insole more comfortable. Still in the 3D printing process, as seen in figure 2, a gyroid-type geometry was used for the insole structure. Something notable about the gyroid-type structure is its biological structure, which consists of the similarity in the morphological structure of butterfly wings, for the required application, its high permeability characteristics, will help the flow of sweat and the passage of air, bringing a high lightness of the final product, and good compression resistance, being a required property for an insole. The geometric structure guarantees isotropic properties in the insole, that is, its compression properties remain the same regardless of the direction of force, in addition to facilitating the printing of the insole (DECKER, 2022; TRIPATHI, 2021).

Figure 2 - Separate and assembled prototype.

Source: Authors.

MOISTURE TEST

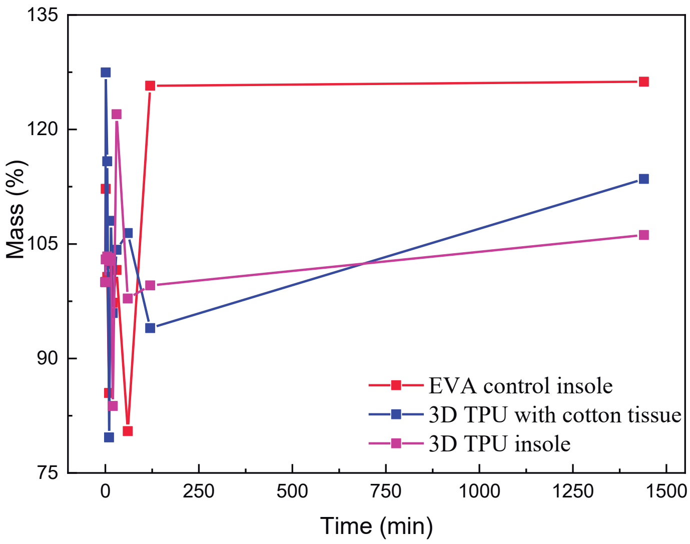
In the tests carried out there are the following results, as shown in figure 3, it was carried out humidity tests using phosphate buffer solution (PBS) pH 7. It was carried out immersion analysis and weighing the masses in the respective times (min): 1; 5; 10; 15; 60; 120; 1140. The process was repeated for all weighings. The control sample is a commercial insole composed of EVA and the 3D sample is the printed TPU insole.

Figure 3 - Control samples on the left insole and the right 3D insole.

Source: Authors.

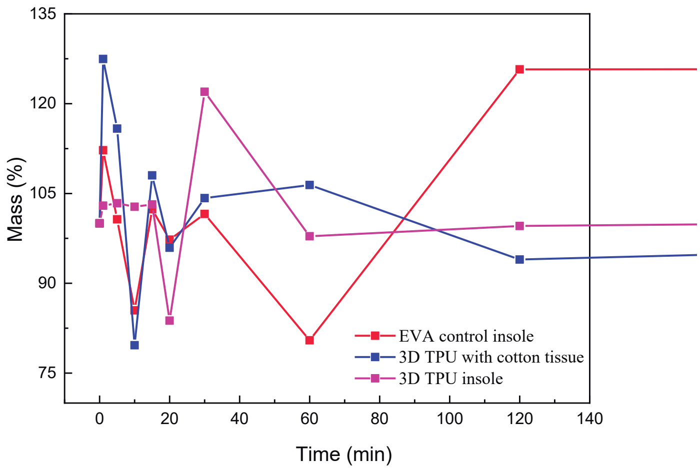
Figure 4 illustrates the graph with the results obtained in the general overview of the control insole (commercial), the TPU printed insole and the TPU insole with 100% cotton fabric. The figure 5 illustrates the graph enlarged in the first minutes for a better understanding of the data obtained. It is important to analyze the moisture absorption capacity of the insoles, given that in certain conditions some insoles can absorb between 85 and 90% of sweat. (SERWETA; OLEJNICZAK; WOŹNIAK, 2018).

Figure 4 - Moisture analysis result graph overview.



Source: Authors.

Figure 5 - Graphs of the first minutes in an enlarged form.



Source: Authors.

It is possible to notice through these tests that the result was satisfactory, where the 3D TPU insole was the one that absorbed the least moisture and the 3D TPU insole with cotton fabric was the one that absorbed the most water with the EVA insole, given that cotton fabrics are quite hydrophilic, interacting easily with water. (ATWAH *et al*., 2020; FENG *et al*., 2020; HARYŃSKA *et al*., 2018; KASAR *et al*., 2022; LIANG *et al*., 2013). Since the 3D TPU insole presented less moisture absorption compared to the control insole made by EVA, this indicates that the insole can provide greater comfort to the user, in addition to having several pores in its structure, as shown in figure 2, which can reduce discomfort caused by heat. It is worth noting that most insoles sold in shoes, such as EVA, are hygroscopic materials, which end up absorbing high amounts of water, and which consequently, in the presence of certain temperatures, can promote the unwanted growth of fungi and bacteria on the insoles. (IRZMAŃSKA; BROCHOCKA, 2014; MANAIA; CEREJO; DUARTE, 2023; NING *et al*., 2022).

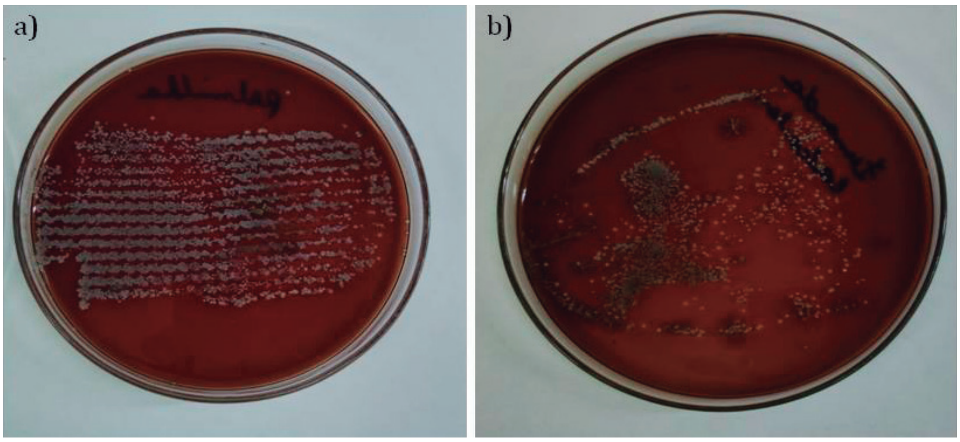
MICROBIOLOGICAL TEST

In microbiological analysis it was used blood agar culture media for the development of bacteria and Saboraud agar for the development of fungi.

In figure 6 and 7 item a; b; c and d, with the culture medium previously prepared using techniques from the microbiology laboratory at PUC Sorocaba, was imprinted the 3D insole on the left side and on the right side carried out the same procedure with the control insole. It was incubated in the incubator with a temperature approximately between 36 ºC and 37 ºC for 24 hours. After this period, observation analysis was carried out.

It is proposed that the bacteria present in the cultural media are from the environment itself, since the skin is indeed a complex organ that plays a crucial role in protecting the body against pathogens. The coexistence of commensal microbiota on the skin is a fascinating example of symbiosis, where beneficial microorganisms can compete with invading pathogens. Dryness and acidity of the skin are also factors that hinder colonization by pathogens, which highlights the importance of these physical conditions in host defense. However, it is important to highlight that microorganisms on the skin are recurrent, due to this factor, the culture medium obtained only natural microorganisms from the skin, therefore the result did not obtain any results unchanged from the usual (USMAN *et al*., 2023).

Figure 6 - Microbiology test with blood agar culture medium to highlight all types of bacteria - 3D insole.

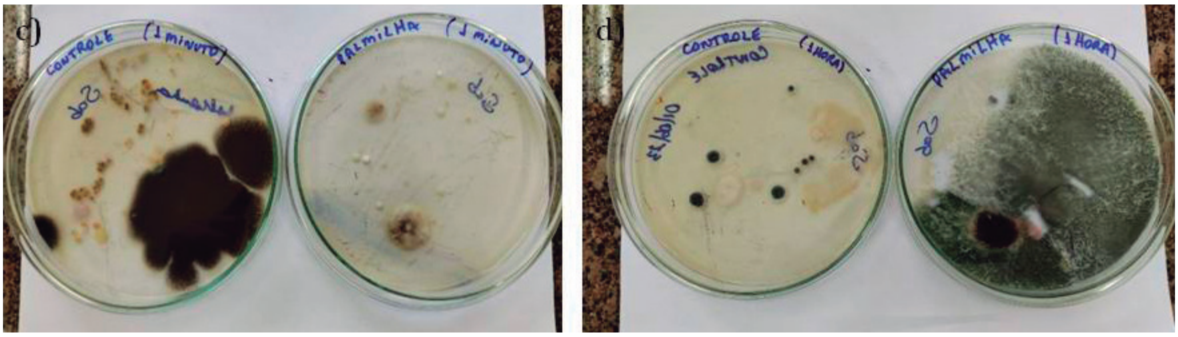


Source: Authors.

In figure 7 with the Saboraud culture medium, prepared previously, we performed the imprint method with a 3D insole on the right side, which was used in contact with the skin for approximately one hour and on the left side the control insole, after which they were incubated for 7 days for the development of possible microorganisms. In figure 7 item d is the duplicate of item c.

It was observed that fungi proliferated in both insoles, it is suggested that the result did not favor the material developed, since no inhibition agent was inserted to prevent the growth of fungi and bacteria on the material. Therefore, there may be a restriction on its use in certain environments where there is a high exposure of microorganisms, such as hospitals. Although the 3D printed insole showed the lowest moisture absorption among the insoles investigated, it did show fungal growth. Thus, it is also necessary to carry out additional tests in order to investigate this property in greater depth. (DAVIA-ARACIL *et al*., 2020; KOHAN *et al*., 2019).

Figure 7 - Duplicate of the microbiological test with Saborund culture medium, for fungi.



Source: Authors.

CONCLUSION

Through this research, it was possible to successfully obtain a 3D polymeric insole from TPU through additive manufacturing. Using gyroid geometry, it was possible to reduce moisture, as demonstrated by the tests, in which the 3D insole was the one that absorbed less than the control insole. In the microbiological tests it was noticed, especially the test with bacteria, it was possible to notice that the bacteria that developed came from the human body itself, while for the fungicide test, it was noticed that the 3D insole showed a greater growth of fungi in comparison to the control insole.

For future work, an additive that inhibits the growth of microorganisms can be incorporated into the polymeric material, more in-depth microbiology tests and testing with recycled materials to involve the circular economy, to integrate industry 4.0.

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