DEVELOPMENT OF AN ORTHOPEDIC UNLOADING INSOLE FOR PATIENTS WITH DISABILITIES USING ADDITIVE TECHNOLOGIES

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Abstract

Since the war in Ukraine started, the number of people with lower limb amputations has increased significantly. After prosthetics in the case of unilateral amputation of the lower limb, during further walking, the load on the healthy leg is approximately twice as much as on the prosthesis. Therefore, it is advisable to use orthopedic unloading insoles for partial relief of a healthy leg.

This research looks at the advantages of manufacturing such insoles using additive manufacturing. Unlike traditional production, the production of printed insoles is automated and requires less human involvement in the processes. In traditional production, various orthopedic elements and layers of insoles use materials with different properties - EVA-pore, granitol, polymeric thermoplastic materials of different hardness.

This research addresses whether orthopedic insoles printed from one material (Flex filament) would meet the requirements, if the stiffness and elasticity of the insole zones were adjusted not by selecting another material, but by adjusting the filling of layers in the Ultimaker Cura slicer when slicing the model. FDM printing technology was used on an Anet Prusa i3 printer and Flex filament.

Keywords: *orthopedic insoles, FDM-printing, additive manufacturing, unilateral amputation*

1. INTRODUCTION

Today, a fairly large percentage of the population suffers from orthopedic foot problems of various origins. Previously, the vast majority of patients were elderly. However, since the beginning of the war in Ukraine, the number of people with gunshot wounds of various types has increased significantly. At the same time, according to statistical data, in 70% of cases, these are injuries to the limbs. Depending on the mechanism of gunshot wound formation (bullet, shrapnel, mine-explosive, etc.), such wounds can lead to bone fractures and significant soft tissue damage [1].

During clinical examination of the lower limbs in patients with unilateral lower limb amputation, the following observations were made: soft tissue injuries – in 82%, burns – in 64%, removed fragments in – 10%, and swelling – in 55%. As a result of single-leg loading during walking on the stumps of the examined individuals, the following were observed: calluses on the plantar surface – in 18%, calluses – in 36%, keratosis – in 10%, and consequences of foot abrasions – in 36% [2].

So when lower limb amputation occurs, even with prosthetic rehabilitation, a person's gait and weight distribution on certain areas of the foot change. Also there can be static foot deformities also occur as a result of unilateral amputation. These deformities disrupt a person's weight-bearing and kinematic function, leading to the emergence of pain and calluses, causing rapid fatigue, reducing work capacity, and depriving the ability to use standard footwear [2].

Unilateral amputations of the foot or lower limb (complete or partial) during treatment, rehabilitation, and daily life, require protection of the healthy foot from the destructive effects of overloading. This need arises in the first days of treatment when patients are allowed to assume a vertical position and move independently. Moving with the support of crutches does not compensate for the overall area of lost support and disrupts the normal biomechanics of all foot and limb support elements. Overloading of the front and rear sections of the foot is a consequence of this process, resulting in specific changes in the foot, including widening of the front section, lowered arches, splaying of the foot, varus deformity of the ankle-foot, the formation of painful calluses, and more designed to improve the physical condition of the foot with impairments in function and pressure distribution, resulting from injuries and unilateral limb amputation.

Prevention of these changes can involve the use of individual functional foot orthoses or orthopedic insoles. Ready-made orthopedic correction devices available on the market do not always meet the specific needs of the patient. Considering this, a current focus is on researching the conditions of the feet after injuries and developing specialized footwear and adaptations that contribute to enhancing the biomechanics of the human musculoskeletal system.

The aim of the work is to develop orthopedic insoles designed to improve the physical condition of the foot with impairments in function and pressure distribution resulting from injuries and unilateral limb amputation.

1.1 Methods for analyzing foot relief for insole production

Modern methods for analyzing foot relief for insole production were empirically investigated.

Modern diagnostic tools such as baropodometry or dynamic plantography allow the objective assessment of changes in the foot and a clear determination of overloaded zones (Fig. 1). They also enable the evaluation of the load vector on various sections of the foot, among other parameters.

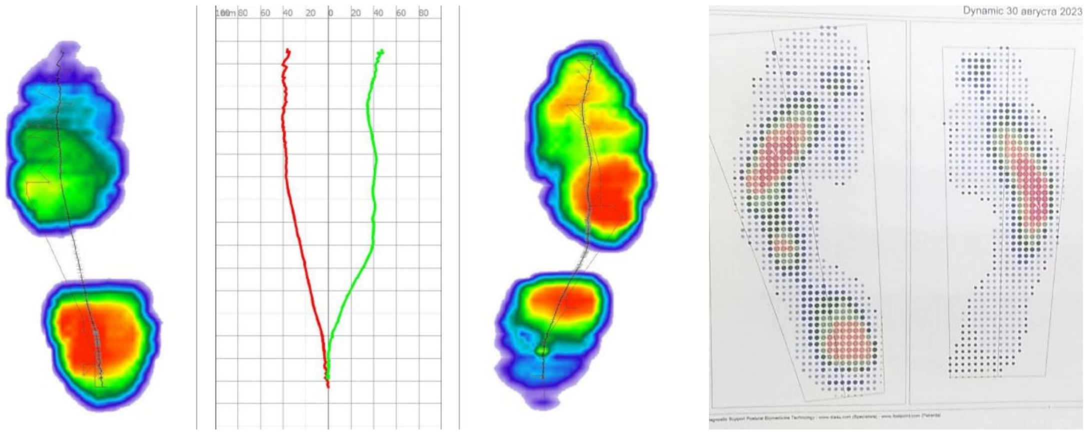

Figure 1: Results of foot diagnostics using baropodometry (a) and plantography (b)

Today the level of scientific and technological progress takes us the great opportunity to the use of 3D scanning to obtain initial information about the shape and dimensions of the foot.

Among the 3D scanners used to acquire anthropometric information about the foot, the InFoot 3D scanner has proven itself to be effective. However, the standard methodology for scanning the foot on a glass surface does not provide sufficiently comprehensive information about the relief of the plantar surface of the foot and the necessary adjustments that need to be considered in the development of orthopedic insole design [3].

So, one of the best and simplest ways to obtain information about the 3D shape of the plantar surface of the foot, including the affected foot, is to take an impression of the foot on a polymer foam.

A special polymer foam was used in the work for taking foot impressions, which accurately replicates the shape of the plantar surface of the foot, compressing soft tissues and visually highlighting the structural features of the foot.

The results of scanning the foot using the standard procedure on a 3D scanner and scanning the polymer foam with the foot impression demonstrated the necessity of using polymer foam. The standard foot scanning procedure on a 3D scanner does not provide as detailed information as the visualization on the polymer foam (see Fig. 2 and 3).

Figure 2: Obtaining information about the foot using the 3D scanner InFoot3D, creating a footprint on a polymer foam, and then scanning this polymer foam footprint

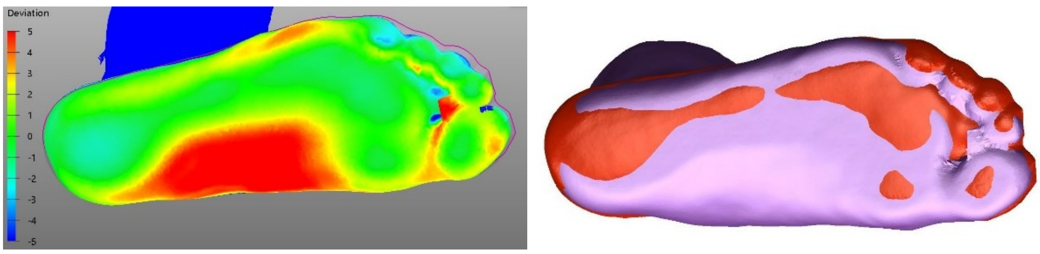

Figure 3: Comparison of a 3D scan of a foot under load and a footprint in polymer foam

1. 2 Analysis of traditional and additive methods for manufacturing custom insoles

3D printing of custom orthopedic insoles may offer advantages such as reduced time costs and automated production, potential long-term cost reduction through equipment use, and the ability to produce insoles that better match the contours of the foot [5, 6]. Additionally, there are preliminary studies indicating that orthopedic insoles manufactured using additive production are effective in reducing pain sensations in the heel area [7,8] and in altering the biomechanics of the lower limb [9,10].

In the research [11] participants were asked to walk along a corridor multiple times wearing textile sneakers without specialized insoles, in insoles made using traditional and additive methods. The survey revealed that both types of insoles significantly improved comfort compared to no insoles, with no significant differences noted between printed and traditional insoles. Measurements showed that the insoles produced via additive manufacturing were wider and had greater depth in the heel cup and higher longitudinal arch support. The difference in longitudinal arch support height was less than 2 mm, this difference did not affect insole comfort according to participant evaluations, but further investigation is needed to determine the clinical impact. One conclusion drawn from this study is the importance of further research comparing the biomechanical effects of insoles manufactured via additive and traditional methods.

In another study [12] for each participant, a plaster cast and a foot impression in a polymer foam box were made to gather initial information about the foot's relief. Based on this data, 4 pairs of individual orthopedic insoles were manufactured: a pair of supportive and regular insoles made traditionally from EVA, Poron, and XPE materials, and a pair of supportive and regular insoles made additively using the Object Connex 350 printer with a combination of TangoPlus and VeroClear materials.

The printed insole consisted of three layers:

- A base supportive layer made of three materials with varying stiffness in the heel, metatarsal, and arch areas.
- A load-distributing layer composed of small geometric cells.
- A thin top layer made of Plastazote material to give the insole a look similar to traditionally manufactured insoles.

Participants assessed forefoot and heel cushioning, arch support, overall insole condition, and overall shoe fit (size, width, etc.). No significant differences were noted between traditional and printed insoles at any stage of the study.

2. EXPERIMENTAL. DEVELOPMENT OF AN INSOLE PROTOTYPE BASED ON INDIVIDUAL FOOT PARAMETERS

2.1 Traditional methods of producing custom insoles and corrective orthoses

In this work we also analyzed recent researches about the production of orthopedic insoles using traditional subtractive and additive technologies. Their advantages and disadvantages were identified.

Classical methods of making orthoses/insoles will remain relevant for a long time. The layer-by-layer lamination of materials with different densities, followed by thermal and mechanical processing, requires relatively high material costs (a variety of materials and tools are needed) and proper technical equipment. The traditional process of making orthopedic insoles is on the Fig. 4.

Figure 4: Classical method of making individual insoles to prevent of deformities of the foot

We have crafted an orthopedic insole using the traditional method, incorporating layers of materials with varying elasticity and thickness. This will enable us to compare the comfort and effectiveness of the orthopedic insole produced through traditional methods with one created using modern innovative technologies.

Traditional manufacturing of custom-made orthopedic insoles is time-onsuming, labor-intensive process, and the quality and effectivness of the final product is largely dependent on the skill level of the manufacturing technician [4]. The production of a pair of insoles takes us approximately 2-3 hours, and apart from the duration of the process, we may face the challenge of finding specialists in this field. In the current conditions of war in Ukraine and the mobilization of the male population, this is a very important factor and a significant problem.

The designed insole can be manufactured using digital equipment through one of two primary methods:

1) Application of subtractive technologies (milling on a CNC machine with porous rubber);
2) Application of additive technologies (3D printing).

The use of CNC machines has long proven itself as a reliable method for manufacturing orthopedic insoles; however, it has several drawbacks (waste, noise, dust production etc.).

The idea of using 3D printing to create products with specific qualities from certain materials is not new but remains relevant.

In our work, we chose to focus on experiments with 3D printing to produce orthopedic insoles. By using a single material, our goal was to achieve different physical and mechanical properties in different areas of the product.

After analyzing previous information, tasks of the second part of the work, related to the manufacturing of orthopedic insoles through 3D printing were formulated. There are:

1. Development of a manufacturing technology for orthopedic products with specified properties using 3D design/modeling and 3D printing, employing thermoplastic materials based on domestic thermoplastic polyurethanes.
2. Development of technical recommendations and algorithms for the production of orthopedic products using accessible Fused Deposition Modeling (FDM) printing technology.
3. Optimization of production processes to reduce material, energy, and labor costs.

2.2 Designing the orthopedic insole using 3d modeling

By importing the scanned model of the impression surface into a 3D graphics program, we draw a horizontal plane through three points on the plantar surface: the point at the center of the heel, the point at the inner metatarsal arch, and the point at the outer metatarsal arch. The overall diagnosis of the foot, its alignment, and the position of anthropometrically significant points relative to the drawn horizontal plane indicate the necessary adjustments that should be considered in the design of the orthopedic insole: the parameters of the metatarsal bar (if needed), the shape of the bar to support the inner longitudinal arch, the need for pronators or supinators, and more (Fig. 5).

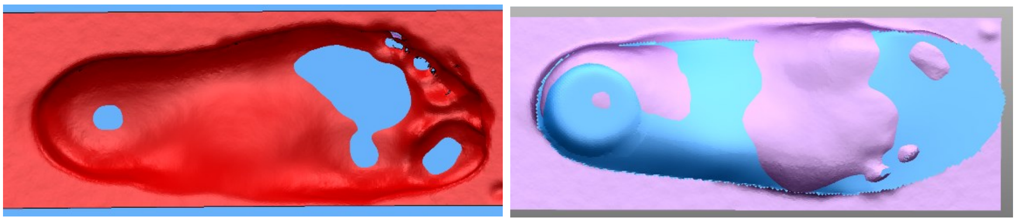

Figure 5: Preparing 3D data for the design of orthopedic insoles, comparing the patient's foot relief with the basic shape of an anatomical insole

The chosen design environment for the project is Rhinoceros 7 by McNeel with the Grasshopper plugin, which allows for algorithmization of specific actions and takes advantage of parametric modeling while automating the sequence of calculations.

The insole shape modeling was done in Rhinoceros according to the following algorithm:

1. Designing the upper surface of the insole based on the 3D scan of the foot impression on the polymer foam.
2. Fitting the constructed 3D surface into the contour of the inner sole of the footwear for which the insole is intended.
3. Aligning the resulting model with the foot pressure map to determine areas of extreme pressure.
4. Creating contours that delimit high-pressure zones.

5. Constructing surfaces to slice the 3D insole model into individual zones.
6. Saving the obtained separate zones of the insole.
7. Converting and importing them into the Cura slicer environment.
8. Setting printing modes in the Cura program for each zone.

The shape of the relieving insole has been adapted to the specific structural characteristics and needs of the patient, including the height and shape of the metatarsal arch, the height of support for the longitudinal arch, the depth and area of the heel bed, and so on (fig. 6).

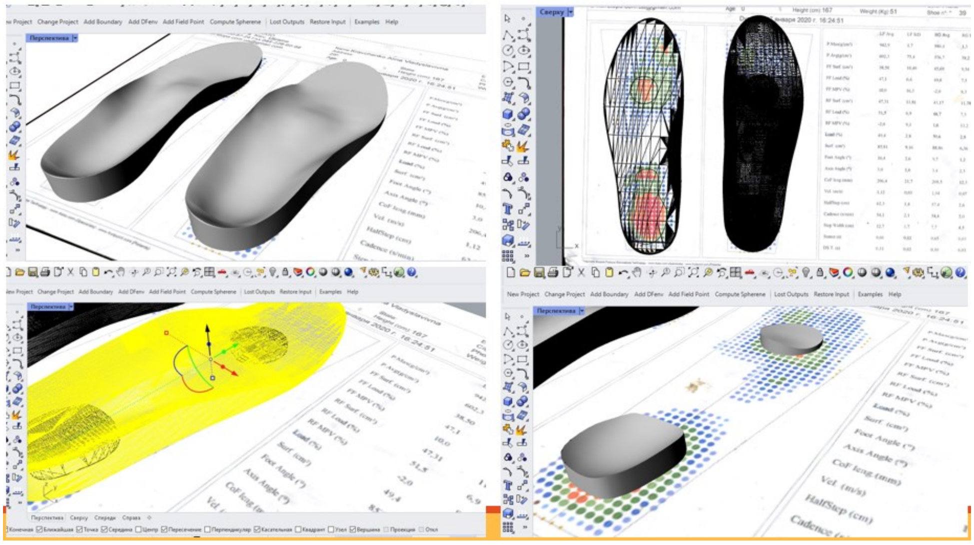

Figure 6: Designing insole in Rhinoceros 7

2.3 Insole manufacturing

We analyzed information from open sources regarding the results of experiments with different types of infill offered by the CURA slicer. In the initial stages of the experiments, a gyroid-based lattice structure was selected as the infill structure for the products. This is a natural structure found in biological objects, having the largest surface area and the lightest weight. Additionally, it offers high shear strength and other favorable properties. Although this structure can be challenging to model in CAD systems, it is present and easily implemented in most slicers, including CURA.

For CAM design, we use the CURA slicer version 4.6 and 5.4.0 by Ultimaker, which is the most accessible and free slicer available on the market (fig.7).

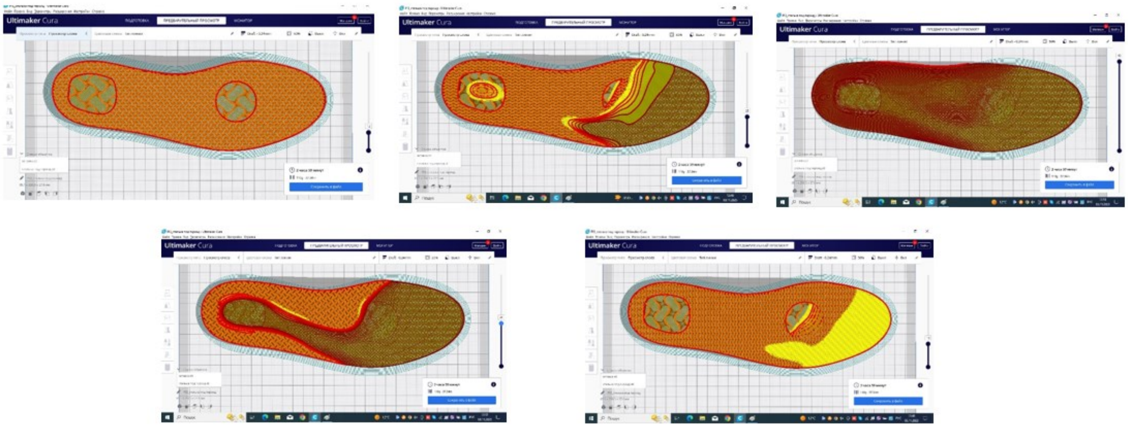

Figure 7: Configuring printing modes in the Cura software for each zone of the insole

To manufacture the products, we focused on using FLEX material from the domestic company Plexiwire.

3. DISCUSSION

During the study, samples of insoles were produced using traditional methods and 3D printing technologies.

A comparison of patients' subjective feelings from using both types of insoles led to the conclusion about the feasibility of applying additive technologies for the production of insoles to support arches, improve shock absorption during walking, reduce the load on the arches, heel, and, if necessary, other areas of the foot with calluses.

At the same time, the cost of manufacturing insoles using a 3D printer turned out to be lower compared to the traditional method of layer-wise addition of thermoplastic materials of varying stiffness. Due to the reduced time spent by the specialist on insole production and the lower quantity of materials used, additive manufacturing is economically more advantageous (the initial cost of equipment, such as the 3D-printer, was not taken into account).

The potential of this method for manufacturing insoles requires further research to determine the degree of therapeutic effectiveness and the possibility of using additive technology to produce insoles for patients with different types and levels of foot disorders and musculoskeletal pathologies. Further investigation is also needed into the methods and technology of insole production using 3D printing to identify the optimal approach, materials, and patterns of filling for achieving a satisfactory stabilizing, supporting, or therapeutic effect of customized insoles.

The creation of products with lattice structures and specified properties is a highly relevant issue today. FDM printing with rigid, flexible, and superelastic filaments is the most accessible method for experiments and obtaining guaranteed desired results.

Modeling lattice structures in CAD systems requires a lot of time, complex algorithms, and significant computing power. Our proposed method for preparing a model for 3D printing is quite simple, does not require extensive computing power, and can be easily implemented on basic CAD systems and freely available slicers (such as Ultimaker Cura).

We have proposed the following algorithm for the development process of a relieving insole by using types of input information such as a 3D scan of the foot, a 3D scan of the foot impression on polymer foam and a plantar pressure map. The process of collecting input data and designing insole is shown on the Fig. 8.

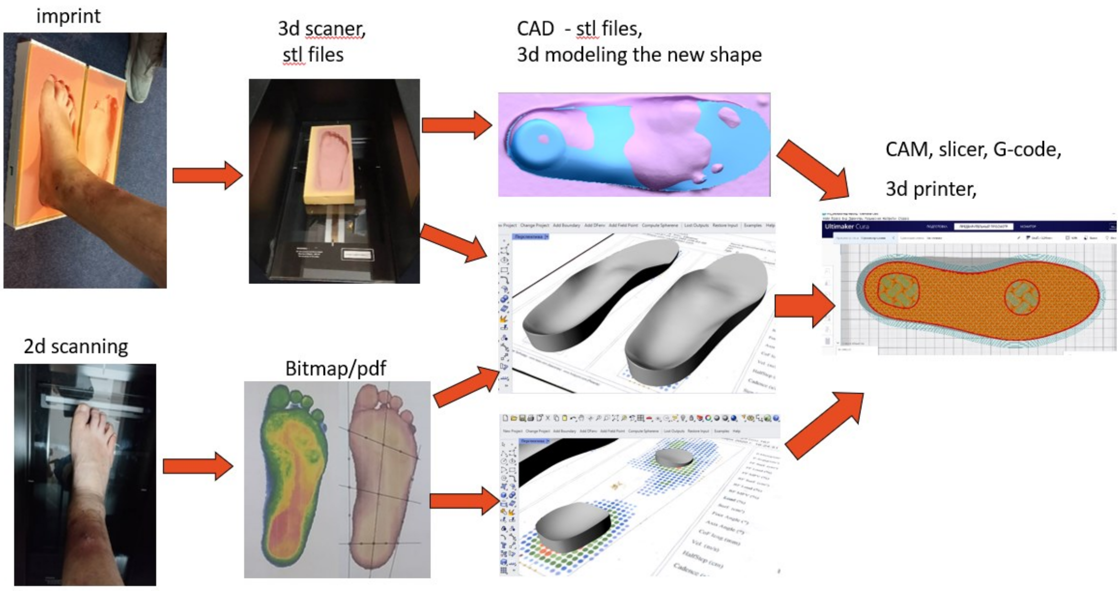

Figure 8: An algorithm of collecting input data and designing insole

1) Obtaining the initial information about foot (2D/3D scanning, imprinting orthopedic foam and 3D scanning, dynamic baropodometry)
2) Importing the primary data into the CAD environment, processing
3) Modeling the new shape of the orthotic using the insoles library files
4) Uploading orthotic model files to the CAM environment (Cura/Prusa slicer)
5) Obtaining g-code, starting 3D printing

During experiments, we had to adjust temperature settings, the printing speed of the insole model's casing and its infill, print height, various extruder nozzle diameters (Fig. 9).

Figure 9: Aditive made insole using FLEX material

High-quality FDM printing with elastomers is achievable on inexpensive printers with the simplest kinematics, even on open-type systems. A crucial rule is the use of direct extruders in 3D printers. Elastomeric materials may require some adjustments to the geometry of direct extruders, specifically reducing it to 0.3 mm and minimizing gaps between the feeder mechanism and the hotend of the extruder, reducing friction forces and resistance in the hotend, and using small heating blocks.

The manufactured insole shows printing defects such as filament residues due to retraction and color variations of the material. Therefore, it is necessary to establish optimal print parameters by reducing printing speed and temperature settings during model slicing. After some adjustments to the process parameters, we have achieved satisfactory results (fig.10).

Figure 10: Aditive made insole using FLEX material, second attempt

The insole turned out to be flexible and exhibits noticeably different levels of hardness in various areas. However, through experimental wear, we need to determine the operational and comfort characteristics of these insoles.

The total duration of the design and manufacturing process using this method was just over 6 hours (3D printing took 3 hours and 15 minutes). A significant advantage is the ability to produce several insoles simultaneously during this time without engaging the master's working hours (printing according to specified parameters occurs fully automatically). Further research is required to assess the comfort of wearing the insole and to determine the significance of its biomechanical effects.

4. CONCLUSIONS

Today, in Ukraine, the war continues, and unfortunately, the number of people with injuries is constantly increasing. This requires increased attention to improving the quality of life for people with injuries and limb amputations. Proper footwear is an element that can significantly improve the physical condition of patients with lower limb injuries. For the design of a specialized orthopedic insole designed to relieve pressure on the foot due to biomechanical disturbances resulting from severe injuries and unilateral limb amputations, a series of studies were conducted.

In this work, we initiated a series of experiments related to the production of orthopedic components with specified properties using digital technologies and 3D printing. To obtain the initial data, we used the InFoot 3D scanner and polyurethane foam to create foot impressions. Rhinoceros 7 and Cura slicer were used for modeling and slicing, and FDM 3D printing technology with a Prusa i3 printer was used for the insole production.

The technology is promising and economically advantageous, however, it requires further research into the extent of its therapeutic efficacy.

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