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The application of additive manufacturing technology in designing and producing individualized lower limb orthoses

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ABSTRACT

The aim of this paper was to compare two different processes of rapid design and fabrication of personalized ankle orthoses using fused deposition modeling (FDM) technology. The intention was to assess the suitability of orthoses designed in a short time for practical use. The first tool used was the online platform Mecuris, while the second was an auto-generative model implemented into the Inventor software, developed within the AutoMedPrint project framework. Low-budget 3D scanners were employed to collect data for obtaining anthropometric measurements of patients, which were utilized for precise design of personalized orthoses. Several patients, volunteers, were selected for the conducted research. Orthoses for the patients were designed using both tools. The orthoses fabrication process was conducted using various printers and materials such as PET-G and PLA. As a result of the conducted work, three orthoses designed using the Mecuris platform and one utilizing the auto-generative model were obtained, and their fitting and functionality were positively verified. The analysis conducted on the advantages and disadvantages of both programs allowed for the conclusion that combining the capabilities of these tools would be an optimal solution. The automation of the design process significantly influenced the customization potential of orthoses to meet the needs of each patient.

Keywords: 3D printing, ankle-foot-orthosis, design automation, fused deposition modeling.

INTRODUCTION

Medical aids enhance mobility and recovery, with orthoses evolving from heavy plaster casts to lightweight, customizable solutions. Modern orthoses stabilize joints, improve healing, and reduce discomfort. Particularly in ankle injuries, they are preferred over traditional casts. Advances in additive manufacturing, especially Fused deposition modeling (FDM), enable personalized designs, making orthoses more accessible. The development of specialized software streamlines the customization process, balancing precision with efficiency for optimal patient care. An example of such an approach is the AutoMedPrint system, developed at Poznan University of Technology, which enables the rapid 3D printing of prostheses and orthoses, primarily for children. By utilizing a specialized 3D scanning station, it allows for the delivery of a functional device within a day at a fraction of traditional costs. This system addresses accessibility challenges, particularly for pediatric patients who often face long waiting times and high costs associated with conventional prosthetics [1–4].

3D printing is transforming medical device production, including prosthetics and orthoses, by enabling precise, patient-specific solutions. Techniques like fused filament fabrication (FFF), stereo lithography (SLA), and selective laser sintering (SLS) allow for customized designs can significantly improve comfort and function. For example, wrist-driven orthoses (WDOs) created with FFF and CAD significantly enhanced hand strength in spinal cord injury patients. Similarly, a 3D-printed leg orthosis provided better mobility and stiffness while reducing weight and bulk. Rapid prototyping also streamlines prosthetic design, making production faster and more affordable [5–7]. Automating these processes improves accessibility, especially for children needing common replacements[8]. Recent advancements in 3D printing have greatly improved ankle-foot orthoses (AFOs), addressing challenges in traditional manufacturing. Nowadays, a lot of accomplishments highlight the benefits of additive manufacturing (AM), particularly FDM, for creating customized, functional orthoses [9–12].

Recent advancements in 3D printing technology have significantly influenced the development AFOs, providing solutions to many of the challenges posed by traditional manufacturing techniques. A methodology for 3D-printed AFOs using digital modeling and AM to ensure precise anatomical fitting was developed. The transformation of digital foot scans into final products, demonstrating that CAD software and rapid prototyping offer faster, more customizable production than traditional plaster casts. This process reduces production time while enabling detailed, patient-specific customization, improving clinical outcomes [6, 13–15].

3D printing enhances AFO customization and functionality was explored. The role of 3D scanning and modeling in creating patient-specific orthoses, particularly beneficial for conditions like cerebral palsy. These designs improve comfort, adaptability, and biomechanical performance, reducing discomfort and poor fit often associated with traditional AFOs [16, 17].

Another study introduced a custom AFO for pediatric drop foot, designed with SolidWorks and analyzed using ANSYS. The structure was contoured for optimal foot-leg coordination, incorporating a linkage mechanism and an adjustable sliding pin for increased flexibility [18]. ANSYS software is increasingly used in the biomechanical design and optimization of ankle-foot orthoses, as evidenced by recent finite element analyses focusing on stress distribution, deformation behavior, and material evaluation in orthotic structures [19].

A lightweight, ergonomic AFO was also developed using Blender and 3D scans. A biomechanical analysis confirmed its effectiveness in promoting a natural gait by enabling controlled dorsiflexion. The study emphasized a user-centered, iterative design process, integrating patient feedback for better functionality [20].

This paper highlights the shift from traditional plaster bandages to modern, lightweight orthoses, which improve healing, joint stability, and skin protection. Studies confirm that 3D-printed AFOs significantly enhance mobility and quality of life, offering personalized, effective solutions. However, despite these developments, there is still a lack of research focusing on optimizing the design process of 3D printed AFOs to balance precision, personalization and manufacturing efficiency. This study aims to fill this gap by evaluating various design approaches and manufacturing techniques to improve both the functionality and availability of personalized AFOs. The results of the study contribute to the ongoing development of patient-specific orthotic solutions.

MATERIALS AND METHODS

Research concept and plan

The primary concept of this study was to compare the efficiency of designing AFO using two distinct design strategies. These methods were selected based on their potential to improve the flexibility, comfort, and overall performance of orthoses when compared to conventional plaster casts, offering improved patient-specific customization. The first design approach utilized the Mecuris virtual platform, a web-based solution for orthotic design. The second method relied on an auto-generating model developed within the AutoMedPrint system. The first method was to design manually but with significant simplifications, while the second assumes going for full automation of the design process. Both strategies utilized identical anthropometric data obtained from patients using non-contact measurement, allowing for a direct and meaningful comparison of the outcomes produced by each design path visible on Figure 1.

The research plan consisted of several key stages. Initially, anthropometric data from the participants were collected and used as input for both design approaches. Following the design phase, the orthoses were manufactured by FDM 3D printing method, enabling physical testing. The printed models were subjected to a three-stage evaluation process, which included fitting of the orthosis to the limb, performing stability tests

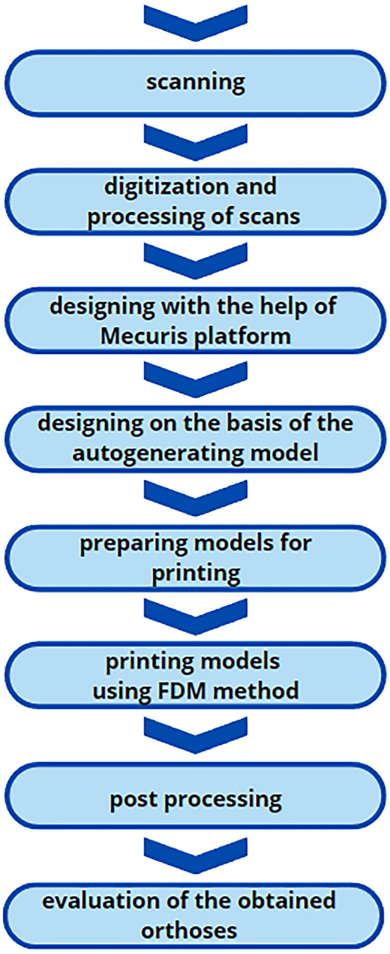


Figure 1. Diagram of work steps

during standing, and evaluating the efficiency of the orthosis during walking. Three patients were selected for the study, all of whom were physically healthy and participated as volunteers. The first participant was a 25-year-old (patient No. 1) male, the second a 27-year-old female (patient No. 2), and the third participant was a 22-year-old female (patient No. 3). Each participant has been subjected to the same testing procedures.

The evaluation was to provide valuable information on the effectiveness of both design strategies. Testing of the orthoses was intended to evaluate user comfort and functional performance. These assessments were necessary to determine which method offered better results in terms of ease of use and suitability for future use in orthotic device design. It is expected that the results of this comparative analysis will make a significant contribution to the development of advanced, patient-specific design methods in the field of orthopedics and medical device customization.

Programs

Several software tools were used throughout this study to design, prepare, and analyze 3D models for AFO. Each program played a crucial role in different stages of the research, from model creation to data analysis.

To obtain and process 3D scans, free tools were used – Meshmixer and MeshLab. Meshmixer was used to improve the 3D scans by smoothing surfaces, filling gaps, and making precise cuts. MeshLab helped clean, align, and process the scan data to create accurate models. Both tools worked together to make the scans more precise and ready for further design. Two separate methods were used to design the orthoses. One assumed the use of the methodology known from AutoMedPrint, which required the use of Inventor, MeshLab and MS Excel software. The other assumed the use of the Mecuris platform.

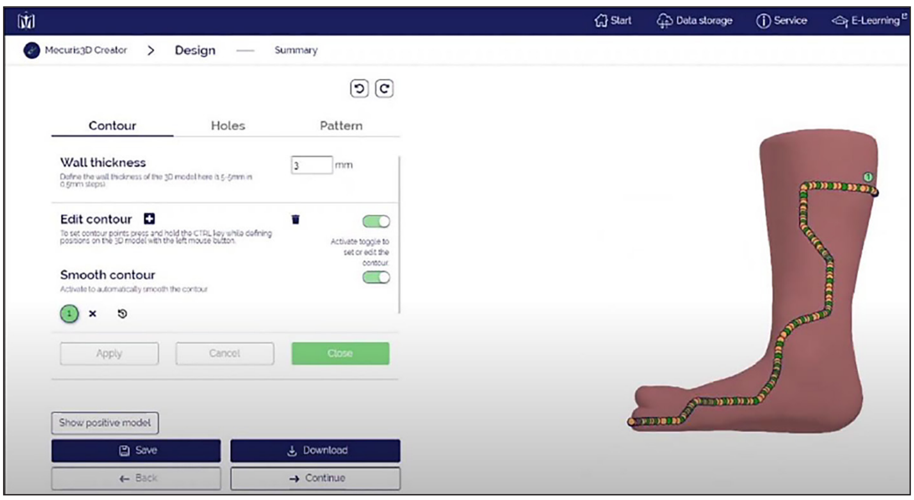


Figure 2. Representation of an orthosis contour consisting of a chain of single points

The first method used the AutoMedPrint approach with Inventor, MeshLab, and Microsoft Excel. MeshLab was used to clean and improve the 3D scans, making them ready for design. Microsoft Excel helped organize data and make necessary calculations to adjust the model. Inventor helped create detailed 3D models and test their strength, ensuring a good fit.

The second method used the Mecuris platform, an online tool for designing prosthetics and orthoses. Interface is clearly visible as is shown in the Figure 2. Mecuris made it easy to adjust limb position, change thickness, and add custom features like cut lines or holes. Its simple interface allowed for quick and efficient customization of patient-specific orthoses.

Scan methodology

Scanning method, which was chosen for this study being the use of an automated scanning station developed by the AutoMedPrint team at Poznan University of Technology [1]. This setup featured the David SLS-3 scanner (David Vision Systems GmbH, Koblenz, Germany), specifically designed to capture precise measurements of lower limbs. The scanning station was constructed to ensure both the repeatability of measurements and the stability of the patient's position throughout the scanning process.

The limb being scanned was positioned on a glass platform, which played a critical role in ensuring the accuracy of the measurements, as can be seen in Figure 3. One of the key factors influencing the precision of the scans was maintaining a 90-degree angle at the knee joint, a crucial parameter for precisely representing the anatomical structure. At the same time, the other limb was extended on a specially designed support, allowing both limbs to be measured simultaneously. The primary goal of employing this automated scanning station was to obtain precise and repeatable data on the shape and dimensions of the lower limbs [2, 3]. After obtaining results from this scanner, the quality of these meshes was judged by experts to be insufficient. Therefore, the EinScan Pro Shining 3D was used on the same workplace and scanned manually. Final meshes are shown in the Figure 4.

The processing of anthropometric data was limited to the use of Meshmixer software. The data obtained from the 3D scanner were exported in the widely used STL format, which was then imported into Meshmixer. The first step involved positioning the scanned limb in space using the "Transform" function. Noise reduction followed, where unnecessary parts of the mesh were removed using a designated plane. Any cracks and holes in the mesh were addressed with the "Close Cracks" function, which automatically sealed gaps in the model.

The primary focus during this process was on maintaining the accurate geometry of the calf, ankle joint, and foot, while the toes were considered less significant for orthotic design and often posed challenges during scanning. The toes were not a priority in the processing. The prepared model, with an emphasis on the key anatomical areas, was then ready for further processing and design within the subsequent platforms, providing a clean and usable mesh suitable for orthotic development. The models differed slightly from each other, for example, by the choice of mesh density.

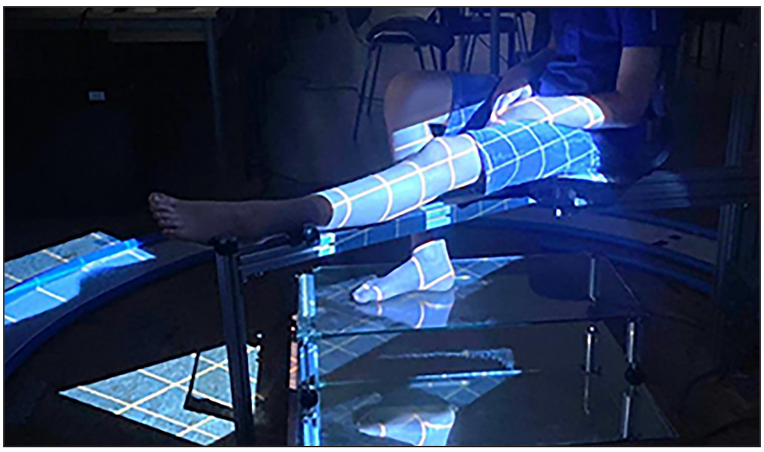


Figure 3. The scanning process on the AutoMedPrint workstation; orthoses for this patient was not included in this research

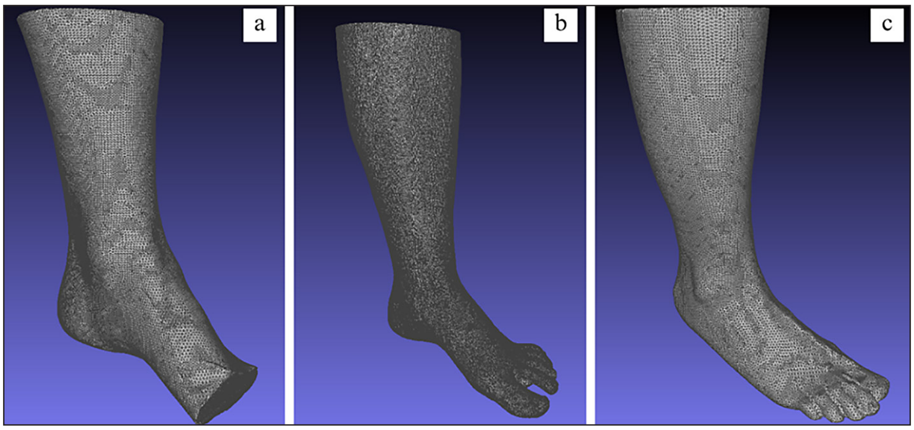


Figure 4. Prepared meshes for three different patients

Designing an orthosis using Mecuris platform

The design process using the Mecuris platform began with importing the processed STL or OBJ file and selecting the appropriate module from the available options. The steps of the design procedure is shown in Figure 5. For the design of an AFO, the Mecuris3D Correction Module was chosen, which, as the name suggests, allows for the correction of limb positioning. The imported scan was then processed by identifying and marking anthropometric reference points on the limb, which corresponded to specific anatomical landmarks.

The key feature of this tool was the ability to correct pathological limb alignment, allowing adjustments in inversion, eversion, abduction, adduction, as well as plantarflexion and dorsiflexion within the ankle and forefoot region. The foot was positioned in a neutral alignment, enabling precise adjustments tailored to the patient's individual needs.

Next, the Mecuris3D Modeling tool was used, particularly the "Offset" function, to create space between the limb and the orthosis. This process ensured there was sufficient clearance between the orthosis and the limb. The problematic area around the toes required additional attention, so an extension piece was added to the model. This extension, universally applicable and customizable size, was designed to ease the creation of a smooth, elongated surface, particularly challenging around the toes due to their complex geometry. The extension was merged with the scan into a single object using the "Merge" function, and surface irregularities were smoothed.

Finally, the Mecuris3D Creator Tool was employed to define the orthosis' thickness and create the cutting line. The user manually selected points on the model to outline the shape of the orthosis. These cutting lines could be further edited to ensure the contour of the orthosis was precisely defined, with modifications allowing for the movement of individual or grouped points. The model was then split into two independent parts, enabling more flexibility in the final design adjustments.

The final model could be further customized by adding holes, adjusting colors, or incorporating patterns for enhanced visualization of the final product. The orthoses were either prepared for 3D printing in their current form or shortened by removing

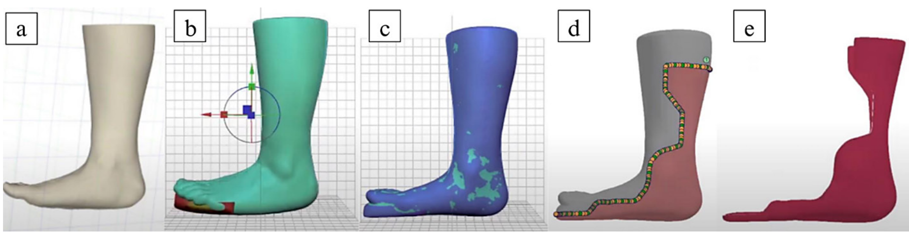


Figure 5. Steps of the design procedure using Mecuris: (a) setting the foot in the normal position; (b) adding an offset and an extension; (c) merging into one solid; (d) determining the cutting line; (e) separating the model along the cutting line

the toe area, depending on the specific requirements of the design.

Designing an orthosis using intelligent model

The design process using the parametric auto-generating model followed a systematic workflow. It began with importing the STL file into MeshLab and positioning it within the appropriate coordinate system. The next step involved creating seven cross-sections along the Y and Z planes using the Compute Planar Section function in MeshLab. Each section was placed at specific distances from the origin, based on a predefined algorithm, ensuring a total of 14 cross-sections per limb, which can be seen in Figure 6. These cross-sections were then saved individually in.xyz format, with each plane recorded separately to ensure clarity and consistency in the dataset. Each patient's cross-section distances varied slightly, depending on the size and shape of the limb. The accurate positioning of these cross-sections was essential for the integrity of the model. Once the cross-sections were created, the next step was to export them into Microsoft Excel. The data was imported as a space-delimited file, and the format was set to general. Decimal points were used as text qualifiers. The files, now structured in Excel, were saved as workbooks, which was a crucial step in preparing the data for further analysis and modeling.

The next stage involved utilizing a spreadsheet tool called the "Coordinate Calculator". Cross-sections from both the Y and Z planes were imported in ascending order, ensuring proper data processing. Macros within the spreadsheet helped fill in tables, as can be seen in Figure 7, generating charts that organized and visualized the data effectively.

After generating the charts, the processed data from the final tab of the spreadsheet was copied and saved as values (without formulas) in a new file. The key final step was to replace the data source in the auto-generating model within Inventor with the newly processed data

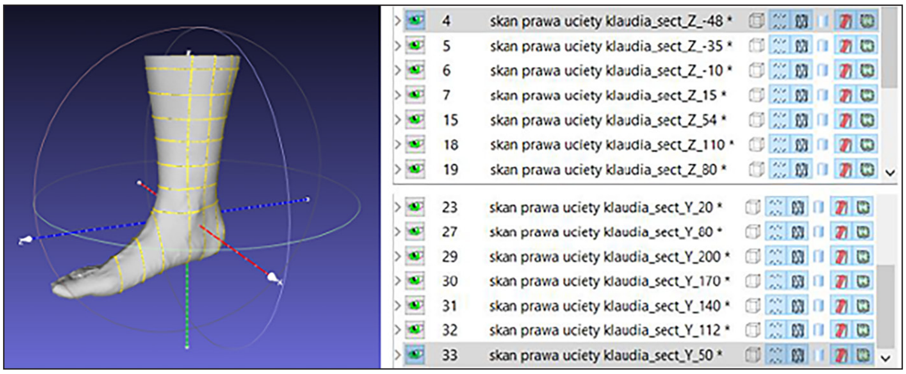
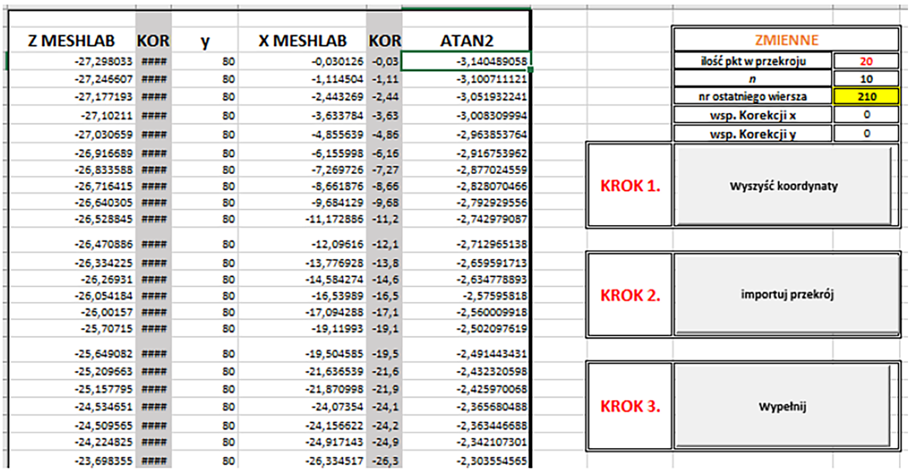


Figure 6. Determination of planes in Meshlab software



Z MESHLAB	KOR	y	X MESHLAB	KOR	ATAN2
-27,298033	####	80	-0,030126	-0,03	-3,140489058
-27,246607	####	80	-1,114504	-1,11	-3,100711121
-27,177193	####	80	-2,443269	-2,44	-3,051932241
-27,10211	####	80	-3,633784	-3,63	-3,008309994
-27,030659	####	80	-4,855639	-4,86	-2,963853764
-26,916689	####	80	-6,155998	-6,16	-2,916753962
-26,833588	####	80	-7,269726	-7,27	-2,877024559
-26,716415	####	80	-8,661876	-8,66	-2,828070466
-26,640305	####	80	-9,684129	-9,68	-2,792929556
-26,528845	####	80	-11,172886	-11,2	-2,742979087
-26,470886	####	80	-12,09616	-12,1	-2,712965138
-26,334225	####	80	-13,776928	-13,8	-2,659591713
-26,26931	####	80	-14,584274	-14,6	-2,634778893
-26,054184	####	80	-16,53989	-16,5	-2,57595818
-26,00157	####	80	-17,094288	-17,1	-2,560009918
-25,70715	####	80	-19,11993	-19,1	-2,502097619
-25,649082	####	80	-19,504585	-19,5	-2,491443431
-25,209663	####	80	-21,636539	-21,6	-2,432320598
-25,157795	####	80	-21,870998	-21,9	-2,425970068
-24,534651	####	80	-24,07354	-24,1	-2,365680488
-24,509565	####	80	-24,156622	-24,2	-2,363446688
-24,224825	####	80	-24,917143	-24,9	-2,342107301
-23,698355	####	80	-26,334517	-26,3	-2,303554565

ZMIENNE	
ilość pkt w przekroju	20
n	10
nr ostatniego wiersza	210
wsp. Korekcji x	0
wsp. Korekcji y	0

KROK 1.	Wyszyść koordynaty
KROK 2.	importuj przekrój
KROK 3.	Wypełnij

Figure 7. Example of correctly exported and sorted data

and update it accordingly. After the data source was updated in Inventor, the parametric model regenerated, resulting in a customized, precise model ready for further use. In case there were some defects, there were a couple of options to correct them. One was to correct the points in Excel, creating Inventor planes, or by changing the modifications only in Inventor itself. In more difficult cases, it was necessary to go back to the Meshlab itself and correct the planes.

The planes that we obtained from the excel worksheet are clearly visible in Figure 8 a and No. 8 b. It is on the basis of these that the whole model comes together. Firstly the calf part is rebuilt and then the foot. Then the two parts are joined together and at the very end the heel is glued, as shown in Figure 8. The next steps are shown in Figure 9. After the whole leg model is formed, an offset is added, from which the shape of the orthosis is cut out.

MANUFACTURING

Selection of printer materials and parameters

Once the design was completed, the orthoses was manufactured using FDM on a Flsun SR delta-type 3D printer. For each orthosis, the process began by importing the STL model into the Ulti Maker Cura - printer's dedicated software, where the model was sliced into layers of 0.3 mm thickness and supports were added as necessary. The placement of the model was adjusted to fit the printer table, which can be seen in Figure 10. The software also allowed customization of the infill density, which ranged from 30% to 40% depending on the specific model.

In the FDM process, the printer's nozzle was heated to the melting point of the material. As the filament became liquid, it was carefully deposited layer by layer onto the print bed,

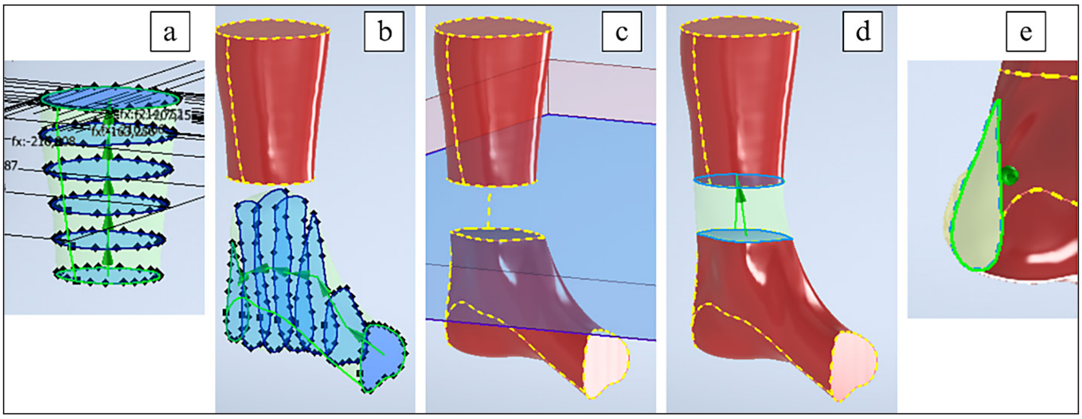


Figure 8. Steps to create a model in inventor: (a) view of the planes forming the calf; (b) view of the planes forming the foot; (c) calf and foot with overlapping parts cut out; (d) view of the direction of joining solids; (e) view of attaching the heel

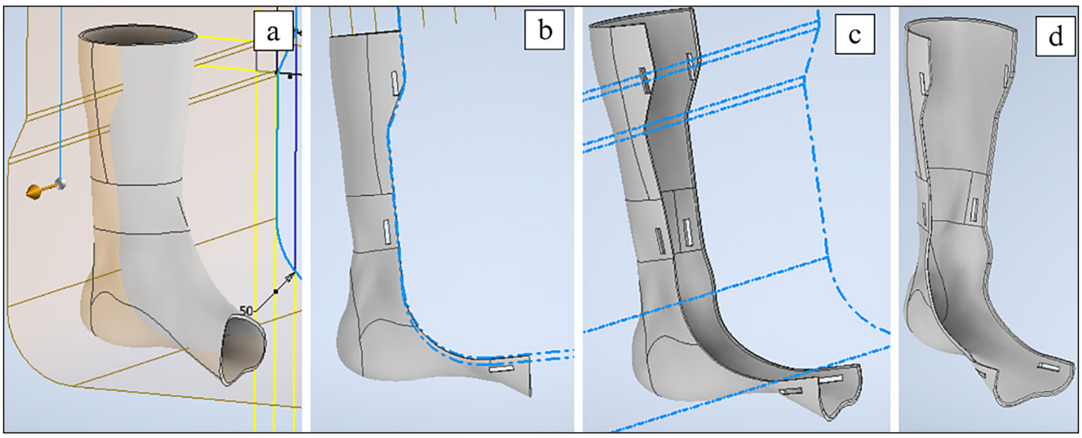


Figure 9. Diagram of cutting out the orthosis from the leg model: (a) model shell; (b, c) cutting line of the model from two different perspectives; (d) orthosis model

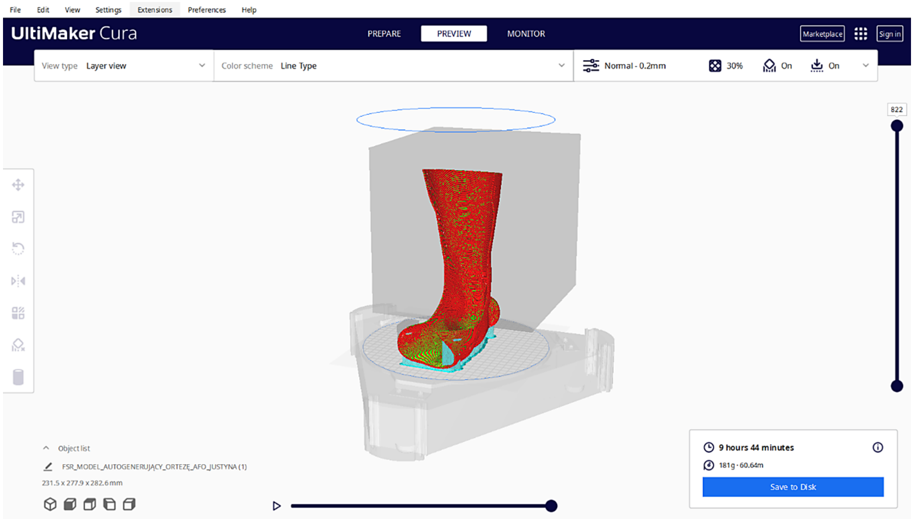


Figure 10. Prepared orthotic design for printer

gradually building the final shape. The main materials used were PLA and PET-G. For PLA, the nozzle temperature was set at 230 °C and the print bed at 60 °C, while PET-G required higher temperatures, with the nozzle at 250 °C and the bed at 80 °C. The larger size of the orthoses meant that each printing process took over 10 hours to complete.

The manufacturing process utilized the Flsun SR 3D printer, a delta-type system known for its speed and precision. Although it lacks an enclosed chamber, this does not affect FDM process. The printer features a heated round build plate and a touchscreen interface for easy operation. With a build volume of 260 × 330 mm and an automatic leveling system, it ensures proper alignment before printing.

The Table 1 shows the manufacturing parameters for 4 different prints. They difference depending on the used material: PLA (Spectrum premium filaments, Spectrum Group, Sosnowiec, Poland) or PET-G (ROSA 3D Filaments, Hipolitów, Poland). The layer thickness was consistently maintained at 0.3 mm across all prints. All samples were in form of 1,75 mm filament and they were printed at a velocity of 50 mm/s, with five closing layers at both the top and bottom to enhance structural integrity. Additionally, each sample was designed with three contour lines to provide stability and improve surface quality.

Evaluation methodology

The orthoses were evaluated based on three key criteria, which can be seen in Figure 11 that determined their effectiveness and user comfort: fit, stability, and durability during movement.

The first critical aspect of the evaluation was the fit of the orthosis to the patient's limb. A detailed analysis was conducted to ensure that the orthosis was appropriately sized, with no protruding elements that could cause discomfort or irritation to the patient. Special attention was given to how well the orthosis conformed to the contours of the limb, and in some cases, the fit could be further improved by the application of foam padding to enhance comfort.

Table 1. Characteristics of the printing parameters of the materials used

Parameter	No. 1	No. 2	No. 3	No. 4
Material	PLA	PET-G	PLA	PLA
Filling [%]	40	30	30	30
Layer thickness [mm]	0.3	0.3	0.3	0.3
Nozzle temp. [°C]	230	250	230	230
Table temp. [°C]	60	80	60	80
Velocity [mm/s]	50	50	50	50
Number of closing layers (from the top, from the bottom)	5	5	5	5
Number of contours	3	3	3	3

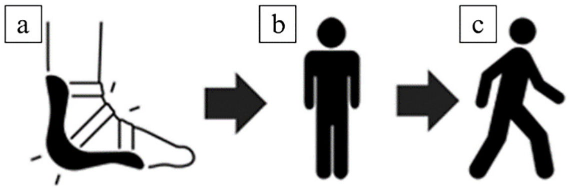


Figure 11. Diagram of the stages of evaluation of the obtained orthoses: (a) fit; (b) stand; (c) walk

If the orthosis failed to meet the fit criteria, further testing was not conducted. However, if the orthosis was properly fitted, the evaluation proceeded to the second criterion: stability. In this phase, the patient was asked to bear their full body weight on the orthosis, and the structural integrity of the device was assessed. The focus of this test was to ensure that the orthosis could withstand pressure without cracking, deforming, or showing any signs of material fatigue.

The third and final stage of evaluation was the assessment of the orthosis during walking. The patient was instructed to perform a short walk while wearing the orthosis to determine whether the device maintained its structural integrity and functionality under dynamic conditions. This test was crucial in determining whether the orthosis would be effective and comfortable during daily activities.

RESULTS

In the case of Project No. 2, at the Figure 10a a more neutral limb alignment was achieved after scan pre-processing. After correction of the alignment angles, the orthosis was generated with a flat sole and holes for fixing the bindings. The grouping of designs and printouts is listed in Table 2.

Project No. 3 was characterised by the use of a shortened model, with the removal of the part covering the toes, which was a conscious effort to improve wearing comfort (Figure 12b). The orthosis was accurately fitted to a scan of the limb.

Project No. 1a (Figure 12c) was generated automatically, but analysis indicated severe deformities in the heel section and incorrect alignment of the ankle joint. Such shortcomings could have significantly affected the functionality of the orthosis and patient comfort.

Printout No. 2,which can be seen on Figure 13a, using design in Mecuris (PET-G) showed numerous supports that were difficult to remove. On the surface, projected strips of material were visible, which affected the aesthetics.

Printout No. 3 (Figure 13b) from PLA had a smooth surface and no sharp edges. Despite minor problems with the removal of the support, this was one of the better quality models.

Figure 13c shows a Printout No 2.a based on an automatically generated model. Although deformation is visible in the heel area, it was

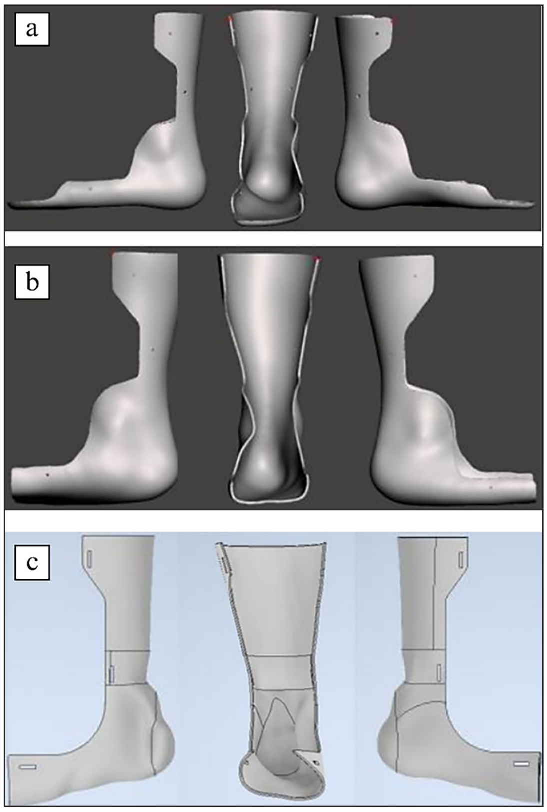


Figure 12. Orthosis projects: (a) Project No. 2 from Mecuris; (b) Project No. 3 from Mecuris; (c) Project No. 1a from Inventor

Table 2. Listing of designs and prints

Parameter	Patients		
	No. 1	No. 2	No. 3
Mecuris	Project No. 1	Project No. 2	Project No. 3
Mecuris	Printout No. 1	Printout No. 2	Printout No. 3
Inventor	-	Project No. 1a	Project No. 2a
Inventor	-	Printout No. 2a	-

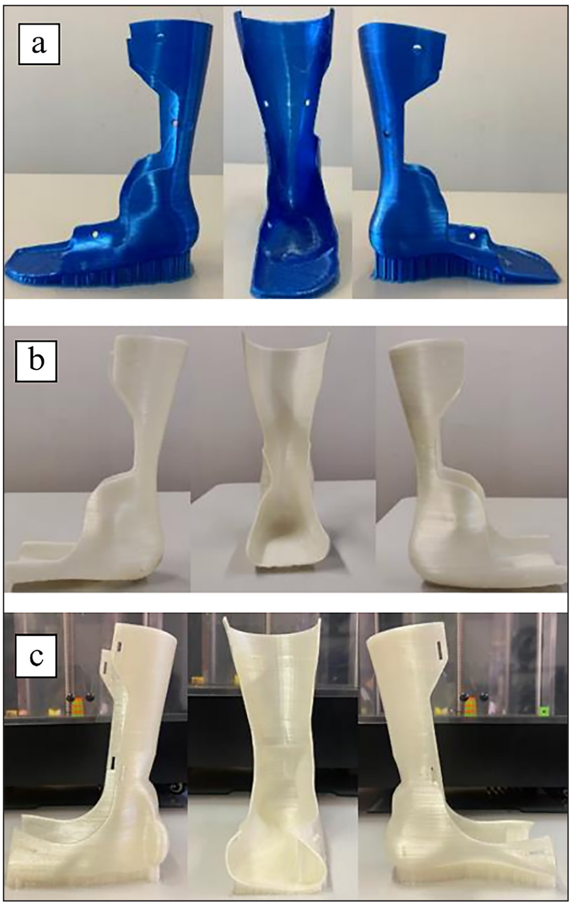


Figure 13. Orthosis Printout: (a) No. 2 from Mecuris; (b) No. 3 from Mecuris; (c) No. 2a from Inventor

characterized by a fitted surface and comfortable wear. The PET-G material used, although more flexible than PLA, did not protect the model from cracking during finishing.

The orthoses were evaluated based on several tests, including fit, standing, and walking assessments. The orthoses designed using the Mecuris platform were generally well-sized for the patients and did not crack when subjected to the full body weight during standing. In the Figure 14a, there was one case with an issue with the alignment of the orthosis, where the angle between the foot and the calf was not perpendicular as expected, leading to improper positioning.

Printout No 2a, created using the auto-generative model, exhibited a deformation near the heel, which can be seen on Figure 14b but was otherwise perfectly fitted to the patient's limb. The patient was able to put it on without any difficulty, and the overall fit was satisfactory.

Printout No. 2, designed with a space for the toes, cracked along the layers during the walking test, as clearly shown in the Figure 15, despite being made from PET-G, a more flexible material than PLA. The crack may not have been caused by poor design or material choice. Instead, it could have resulted from a microfracture that occurred during the finishing process, which would

Figure 14. Printed orthoses: (a) Mecuris; (b) Inventor

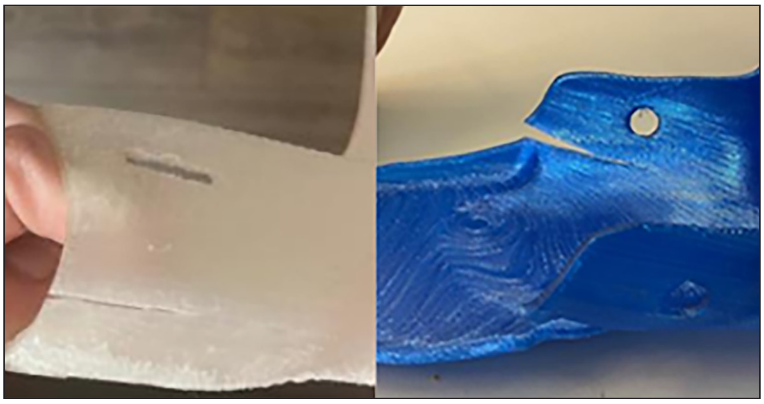


Figure 15. Defects in printouts

not have been visible without the use of a microscope. However, printout No 2a experienced a structural failure along the layers during the finishing process.

The supports were tightly adhered to the surface of the orthosis, leading to cracking when they were removed. This fracture is clearly visible in the accompanying figure. Despite the damage, the patient reported that the orthosis was comfortable and well-fitted.

The process of designing and manufacturing AFOs in this study provided valuable insights into the strengths and limitations of different digital tools and methods used for orthosis creation. One of the key technologies employed in this research was 3D scanning, which played a crucial role in capturing the geometry of the patient's limb. The Mecuris platform proved effective in addressing alignment issues in the initial phase by allowing corrections to the limb position. However, in the subsequent stages where angle corrections were not possible, the final shape of the orthosis did not meet the desired expectations, highlighting the need for improved control over positional adjustments throughout the process.

The Mecuris platform offered several advantages, such as the ability to adjust the foot and ankle angles without requiring the scanning process to be repeated, saving time and effort. The platform also provided a user-friendly interface, allowing for manual adjustments of the orthosis design, though this process was time-consuming and lacked automation. A notable limitation of the software was the absence of a dimensioning tool, which made it difficult to ensure symmetry and

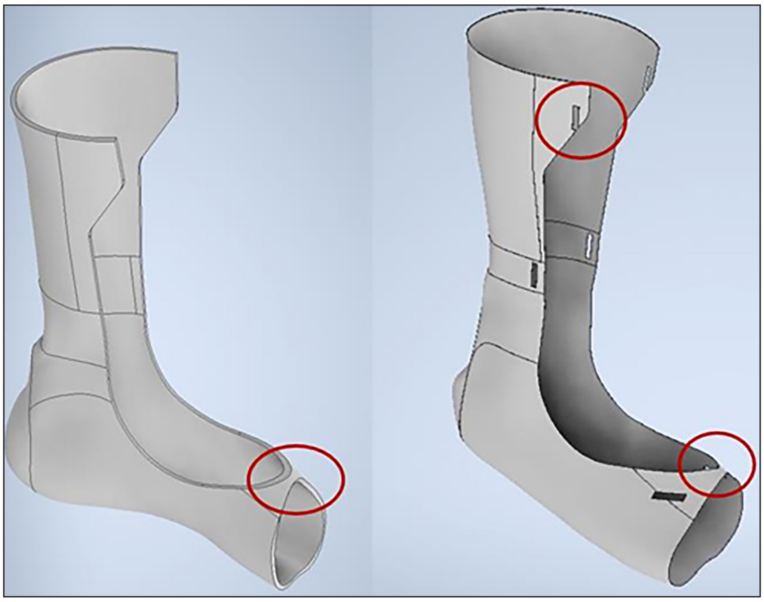


Figure 16. Disadvantages of the autogenerated model without making adjustments

Table 3. Qualitative evaluation indicators of both methods - summarizing the observations and opinions of the authors' expert team

Parameter	Mecuris	Intelligent model	Standarized modeling in CAD
Repeatability	Low	High	Medium
Qualifications required	Medium	Low	High
Designing time	1–1.5 h	1–1.5 h	8–16 h
Potential for automation of the process	None	High	Time-consuming
Software capabilities	The software environment is specifically dedicated to the design of orthoses, the interface does not offer the possibility of creating products from other fields	The software environment is very versatile and allows the design of models from different fields, but allows the design of orthoses	The software environment is very versatile and allows the design of models from different fields, but allows the design of orthoses

precise placement of design elements like holes and edges.

While the Mecuris platform offered flexibility and ease of use, the process of working with the autogenerating AFO model had its own challenges. The need to repeatedly switch between MeshLab and Inventor software to make adjustments increased the overall design time. Furthermore, the lack of full parameterization in the model led to inaccurate design elements, such as the orthosis cutouts and holes, which impacted the final product's functionality. The results of not completely parameterizing the model can be seen in Figure 16.

Nonetheless, it took the same amount of time to generate orthoses using the smart model or Mecuris – 1 h to 1.5 h. However, the autogenerating model, in concept, is dedicated to the lower-skilled user, and its automation in the future would allow for a repeatable and fast process.

Table 2 presents the main factors highlighting the differences between both approaches. In the case of Mecuris, the process cannot be shortened any further, whereas the auto-generating model aims for full automation. The process is intended to be limited to simply uploading a patient scan and receiving the final product in the form of a designed orthopedic aid. This approach allows for high repeatability, which cannot be said about Mecuris, as it has lower repeatability and requires higher qualifications to obtain the final product. Despite these difficulties, the process demonstrated the feasibility of using both digital platforms for AFO design, although with some limitations that could be improved in future iterations (Table 3).

Figure 17. Orthosis made for a boy with a broken metatarsal

CONCLUSIONS

The study evaluated the design of AFOs using the Mecuris online platform and compared it to an automatically generated model. The main objective was to determine whether the rapidly designed orthoses were suitable for use, rather than to improve the manufacturing process or test durability.

Using FDM additive manufacturing technology, three orthoses were successfully printed using the Mecuris platform, and one with an automatically generated model. However, further designs could not be created due to the platform's closure, highlighting the potential risks of relying on online tools. In contrast, no such problems occurred with MeshLab or Inventor Professional software.

The study showed that the orthoses without the toe part performed better when walking. In addition, the scanning process was crucial to the accuracy of the orthosis design. The Mecuris platform proved to be advantageous, allowing limb alignment corrections without the need to create new scans. Automating the export of files in the automatically generated model could reduce errors, while further parameterization could improve its functionality, and be more functional to use in the future than Mecuris because of less required qualification.

Future improvements could include a combination of both design approaches – using Mecuris for limb alignment and integrating physiotherapy consultations with the automatically generated model to improve rapid AFO production. Also, long-term durability of the designed and manufactured orthoses will be studies, as well as their impact on the rehabilitation process. The project ultimately contributed to the development of a lightweight orthosis for a boy with a metatarsal fracture.

The authors are aware of the study limitations – it involved only three healthy volunteers and four orthosis models were designed and manufactured. Such a number could be insufficient to draw more universal conclusions, however – it is noteworthy that design and manufacturing of a functional orthosis is a time-consuming process. The presented studies are an introduction to a broader research – after selecting an appropriate, efficient method of design, a larger number of orthoses for real patients will be designed and manufactured, to fully assess the impact of 3D printed automatically designed orthoses on the healing and rehabilitation processes.

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