BRIGHT

Erasmus+ strategic partnership for Higher Education

BOOSTING THE SCIENTIFIC EXCELLENCE AND INNOVATION CAPACITY OF 3D PRINTING METHODS IN PANDEMIC PERIOD

TOOLKIT 5

FUSED DEPOSITION MODELLING

Project Title	**Boosting the scientific excellence and innovation capacity of 3D printing methods in pandemic period 2020-1-RO01-KA226-HE-095517**
Output	**IO2 – BRIGHT e-toolkit manual for digital learning in producing medical parts by 3D printing methods in the context of the pandemic**
Toolkit	**Toolkit 5** **Production of medical parts with use of Fused Deposition Modelling and Reprap technologies**
Date of Delivery	**November 2021**
Authors	**Filip Górski** **Filip Sarbinowski**
Version	**Final variant**

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the author, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

Content

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the author, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

1. Introduction

This toolkit presents methods of production of medical products by use of additive manufacturing. A case of a customized product, which must be produced solely by 3D printing (based on 3D scanning of patient's anatomy) is presented in a step by step manner. Issues related to design and manufacturing are presented in more detail in the further chapters.

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

2. Case description

Hundreds of thousands of people every day experience injuries that require the stabilization of specific parts of the body to heal. Until recently, one of the most commonly used methods of stiffening were gypsum dressings (Fig 1), which are in fact bandages impregnated with an aqueous gypsum solution applied to the area of the body to be stabilized. This solution is characterized by a large number of disadvantages, including high weight, low durability, X ray impermeability and difficulty in maintaining the hygiene of the plastered area. Moreover, if it is inserted incorrectly, it can cause serious complications, such as necrosis, nerve paresis or weakening of muscles and tendons.

Fig 1. Gypsum dressing [www 01].

Fig 2. Universal orthosis [www 02].

Currently, one of the most popular alternatives to plaster are universal orthoses (Fig 2). There is no doubt that these types of stabilizers are much more user-friendly, if only because they can be removed without destroying them or because they are lighter, but due to their universal size, it is easy to make a mistake when fitting them, which in turn can lead to abrasions and a limited stabilization effect, and thus longer convalescence. One can also distinguish individualized orthoses, the shape of which is adapted to the body of a specific patient, which reduces the problems resulting from incorrect fit, but the need to carry out precise measurements around the stiffened area and the manual manufacturing process of each piece result in a high cost of the orthosis. This problem is particularly acute in the case

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

of orthoses for children, because - in the case of long-term use - it often turns out that the patient has already outgrown his orthosis and it is necessary to buy a new one.

Rapid Manufacturing technologies turn out to be a way to reduce the above drawbacks. Thanks to the use of 3D scanning and 3D printing with the FDM method, it is possible to quickly design and manufacture cheap and light orthoses for the upper limbs, lower limbs (Fig 3), neck or back braces (Fig 4) perfectly suited to the body of a particular patient. The growing popularity of such a solution is evidenced not only by the rapidly growing number of scientific studies on this subject [DOM14, GUI19, KUO19, TEL17], but also by the existence of commercial companies offering the production of personalized orthoses [www 03 – 06].

Fig 3. Individualized orthosis printed with FDM technology [www 07].

Fig 4. Individualized back brace printed with FDM technology [www 08].

Social awareness of these new opportunities is also growing. Patients realized the numerous drawbacks and limitations of standard stabilization techniques, thus they are looking for help in finding alternatives in additive manufacturing sector. This was also the case with nine-year-old boy named Jan, who suffered a double fracture of his left arm as a result of an accident on a playground. Doctors decided to insert Kirschner wires, which are an auxiliary and temporary element in fracture stabilization. As Jan is an extremely mobile boy, it was not decided to put on a plaster, but the hand had to be somehow immobilized. Looking for a good solution, the parents turned to the AutoMedPrint team operating

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

at the Department of Production Engineering of the Poznań University of Technology. The following paper describes the procedure which allowed Jan to enjoy his new orthosis two days after his arrival in the team's laboratory. The case, as well as the system itself, was presented at the website of the AutoMedPrint project [www 09]. The methodology of creating custom wrist hand orthoses and their manufacturing by 3D printing was presented in a scientific paper [GOR20].

3. Design

3.1. 3D Scanning

During consultations with a physiotherapist, it was determined that the patient needed an orthosis that would position his forearm at right angles to the arm. Moreover, details of the orthosis division planes and the method of connecting them were also specified. Then, geometric measurements of the patient's limb were carried out.

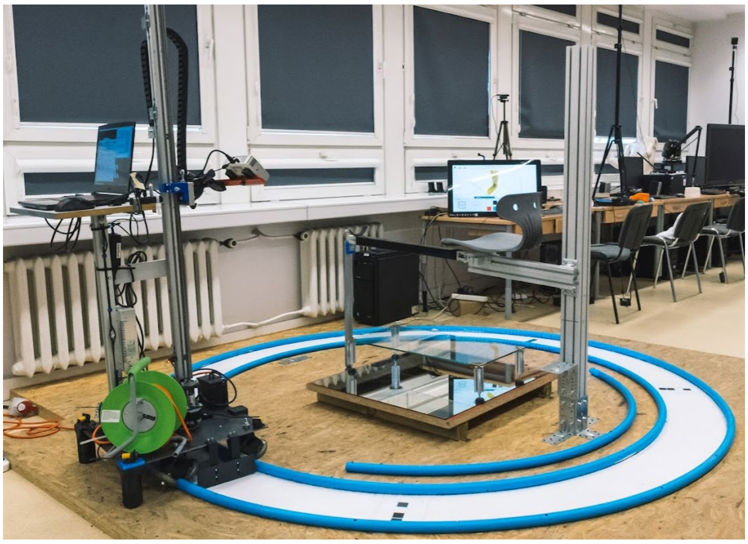


Fig 5. Measurement stand [www 09]

During this process, a series of images of the patient's limb in its various positions were taken, which were then combined on the basis of common points. For this purpose the custom automatic trolley with stationary structured light scanner David SLS-3 coupled with MeshLab software were used (Fig 5).

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

The data processing is shortly presented in (Fig 6) and illustrated in (Fig 7). In general, it focuses on obtaining a clean representation of a selected fragment of a given limb, of which data can be extracted for further design in a CAD system.

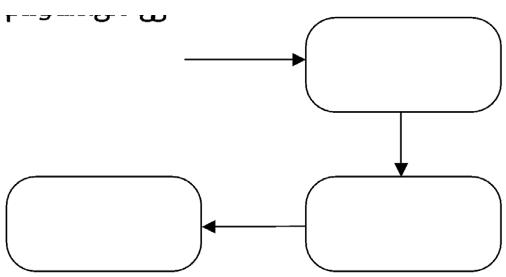


Fig 6. Scan data processing scheme.

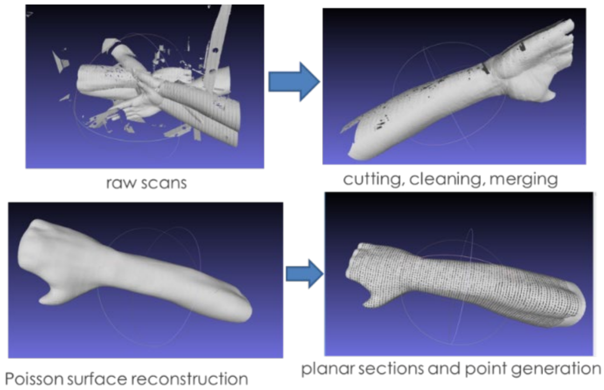


Fig 7. Mesh cleaning process.

The process consists of the following stages:

1. Combining scans
   - background cleaning,
   - geometric transformations (rotations, translations, mirror),
   - best fit.
2. Cleaning and processing the resulting scan
   - deleting unnecessary data,
   - closing holes,
   - smoothing,
   - removing artifacts, repairing,
   - triangle reduction, reconstruction (optional).
3. Data extraction
   - automated measurements,
   - creating sections,

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

- save to txt and workbooks (Excel).

The first two stages are done mostly automatically by scanners' software, however some manual adjustments (cleaning and closing holes etc.) were also required.

During the third stage, the point data has been extracted to create a parametric limb representation in CAD. External algorithms of MeshLab and Excel software (automation scripts) extracted points from a 3D scan of a limb by making a series of cross-sections, and then filtered and selected them on the basis of appropriate mathematical criteria.

3.2. CAD modeling

The basis for creating the outline of the orthosis is the so-called multi-section solid, i.e. the 3D solid spread over a group of spline curves (spline), placed on planes parallel to each other (Fig 8). These curves are made of points whose coordinates come directly from the measurement data, i.e. the 3D scan of the patient, processed with the MeshLab software and the automated Excel spreadsheet.

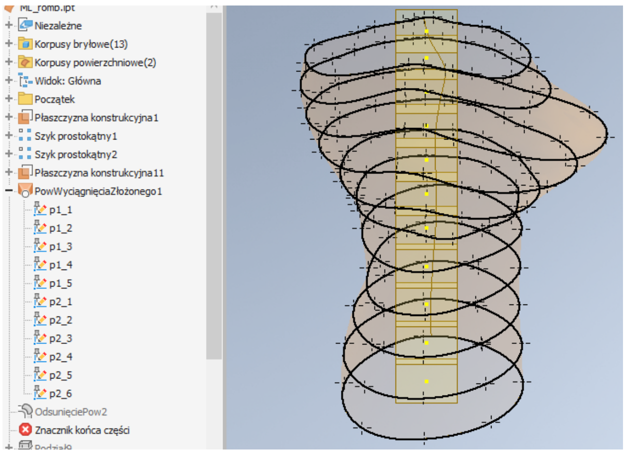


Fig 8. Wireframe curves.

Cross-sections made in the MeshLab software are created at a distance of 2 mm. From all the sections, 15 representative sections are then selected – 4 representing arm with elbow joint, 5 representing forearm and 6 - the wrist and hand. Sections are selected based on manual measurements entered into the software (Scan Assistant) during the 3D scan

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

or later to the patient data file or directly to the Excel spreadsheet. The measurements of forearm and hand are made in accordance with the diagram shown in Figure 9.

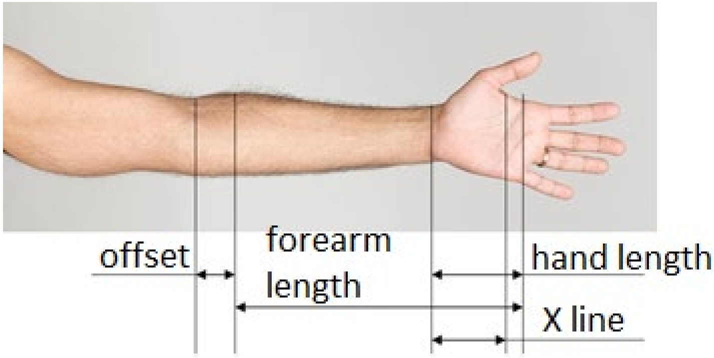
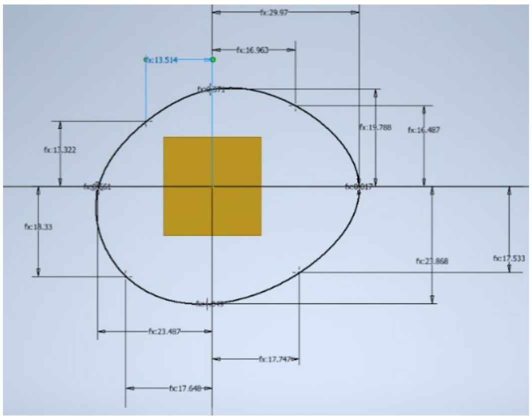


Fig 9. Forearm and hand measurements diagram.

For the 9 sections representing the forearm and arm, curves consisting of 8 points are created, and for the remaining 6 sections - curves consisting of 18 points, as shown in the examples in Figure 10.



This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

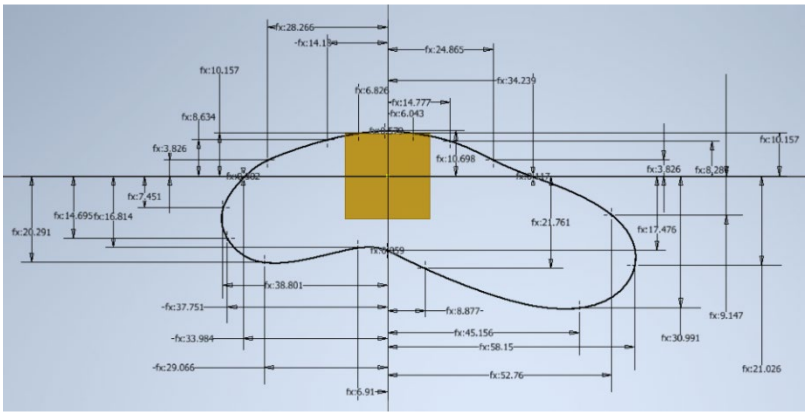


Fig 10. Wireframe sketches of a) wrist part and b) hand part.

On the basis of the base body, the orthosis shell was created - the contour moved away from the base body by the distance (clearance) of 3 mm. The shell is cut with planes to create a full contour of the orthosis (Fig 11). The standard thickness of the orthosis is 4 mm.

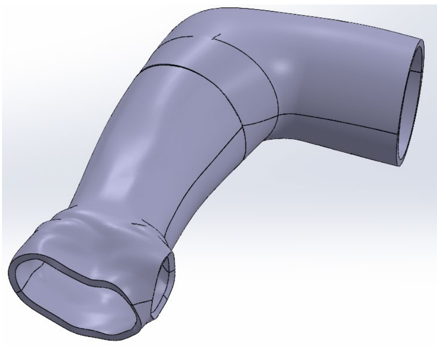


Fig 11. Orthosis shell.

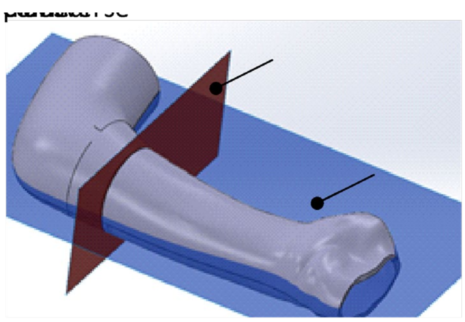


Fig 12. Planes of division.

The outline of the orthosis was divided into four parts – one of the dividing planes was oriented by the center of the thumb hole and the forearm axis, so that the orthosis can be easily put on (coronal division), while the other was defined in such a way that it was perpendicular to the fracture axis and offsetted from the top of the orthosis by 192 mm (Fig 12), which was dictated by anatomical reasons (transverse division).

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

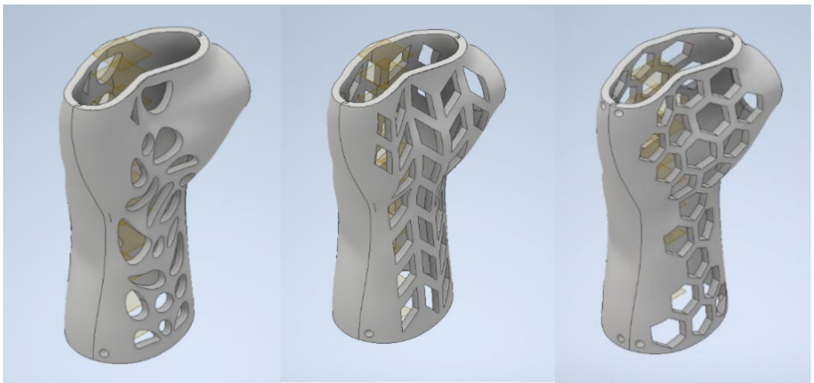


Fig 13. Orthosis with different types of openwork.

The openwork is parametric and can take one of three forms: standard curvilinear, rhomboid and hexagonal (Figure 13). In special situations, the openwork may be not implemented, and a monolithic orthosis is obtained (e.g. for therapeutic purposes, if it is made of a flexible material, such as TPU). In this case, to meet the patient's request, hexagonal openwork was used.

Segments resulting from the transverse division should be combined after manufacturing. For this purpose, connection manifolds has been manually added (Fig 14), that allow them to be connected with screws. The two halves ware joined by a form fit – a groove is generated in one of the halves, and a projection in the other with the same course as shown in Figure 15. In addition, the halves of the orthosis have holes that allow them to be attached to the patient's hands with disposable polymer clips.

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

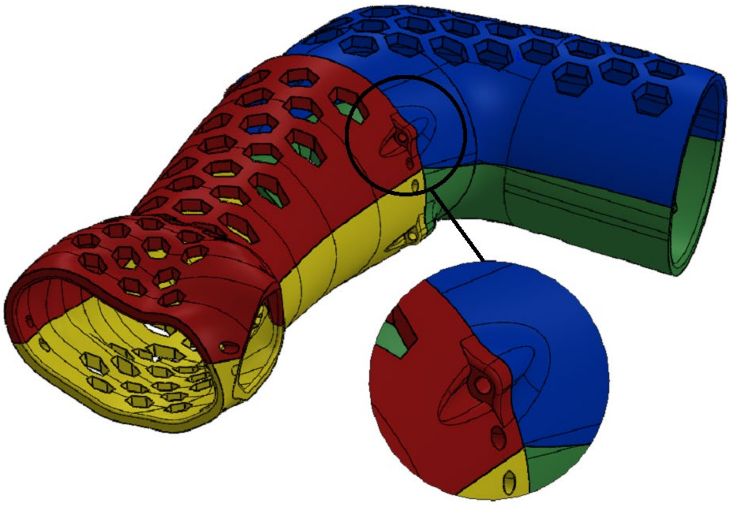


Fig 14. Connection manifolds.

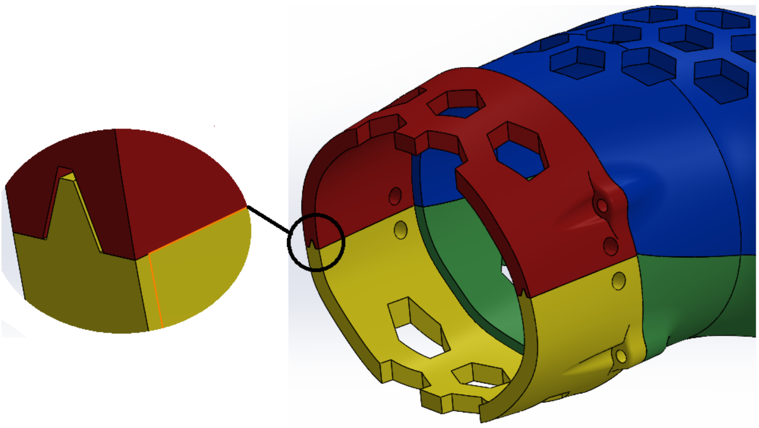


Fig 15. positioning groove.

The edges of the model have been rounded to eliminate uncomfortable sharp edges in use (especially in the area of the thumb).

All parameters of the auto-generating model are saved in a dedicated Excel sheet (Fig 16). In addition to the coordinates of the points of individual curves, it also contains parameters such as offset (clearance), orthosis thickness or openwork parameters. The sheet is linked to the orthosis model saved in a single file in .ipt (Inventor Part) format.

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

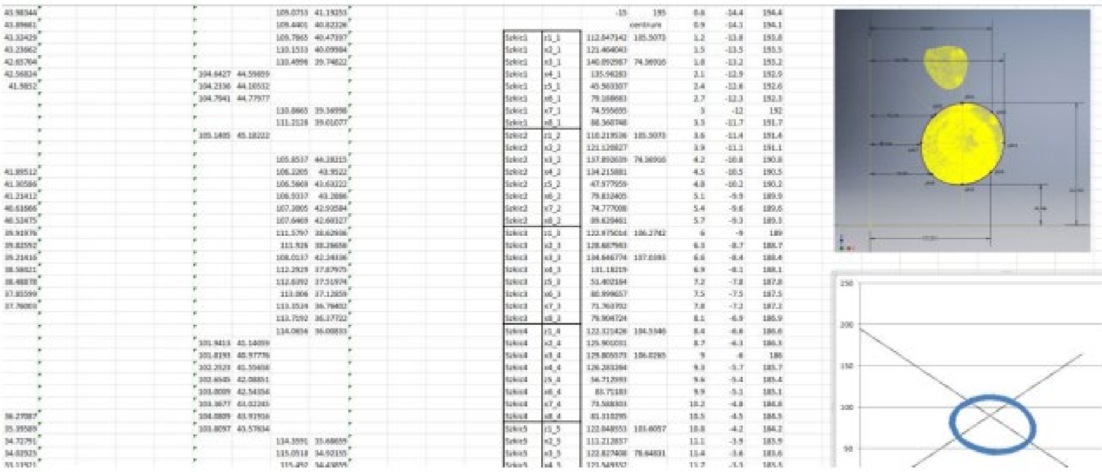


Fig 16. Sheet with model parameters.

After a successful update, files with the parts of the orthosis were generated in the triangle mesh (STL) format to be printed on an additive manufacturing device. After generating the files for printing, the information is transferred to the software controlling the operation of the additive manufacturing device. The end result is shown in the Figure 17. The orthosis consists of 4 parts – two halves of the wrist-forearm part and two halves of the elbow part.

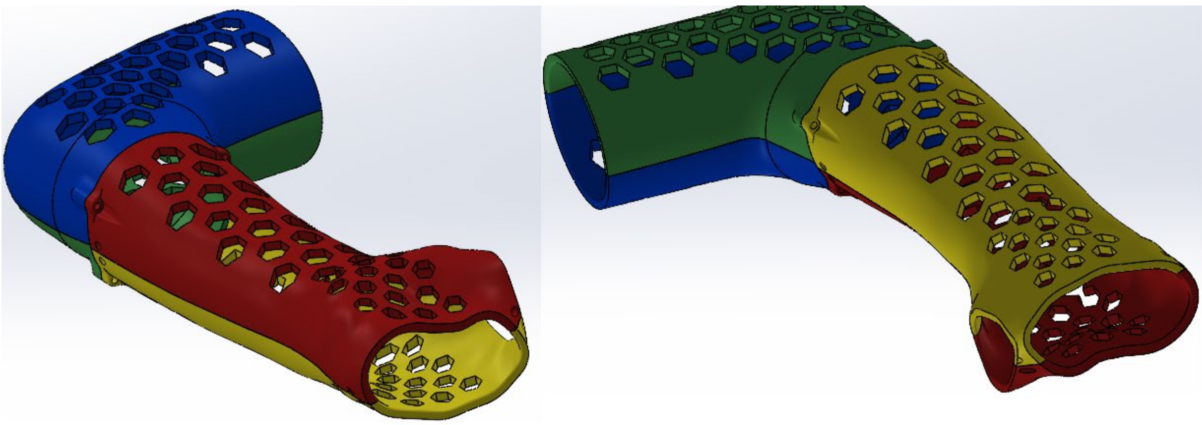


Fig 17. Model of the orthosis.

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

4. Manufacturing

4.1. Additive manufacturing by Fused Deposition Modeling technology

The FDM technology uses thermoplastics in the manufacturing process, i.e. plastics used to form geometry at high temperatures. Models printed in this technology are created by applying successive layers of semi-liquid material, which is extruded from a heated nozzle. The material, called filament has the form of a line with a constant diameter (1.75 mm or 2.85 mm) wound on the spool.

It is important to deliver the filament to the extruder and the print head of the device in the continuous and uninterrupted way. To facilitate this, the filament is usually guided through the tube. The print head is heated to the temperature needed to only plasticize the given material - filament shouldn't be melted. Plastic that is extruded to the worktable solidifies almost immediately and thus, forms a desired structure. The diagram of an exemplary FDM printer is presented in the figure 18.

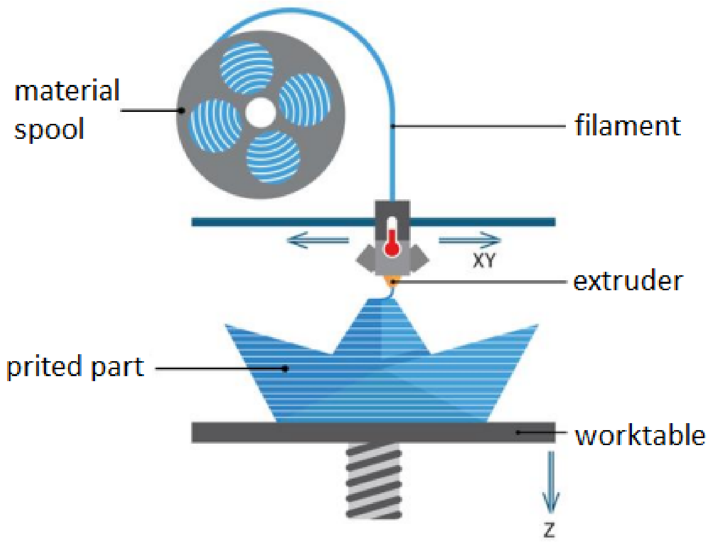


Fig 18. FDM printer [www 09].

The first stage of the process of additive manufacturing of the orthosis in the FDM technology was the import of 3D models of its parts in the form of STL files to the 3D printer

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

software in order to create instructions for the device in the form of a G-code file. Each of the models was oriented in the virtual workspace of the Simplify3D software in such way that the largest dimension was perpendicular to the table. It was also decided that the orthosis would be produced of two different materials: PLA and PA12 (nylon). The PLA orthosis was produced in two colors (blue and red), while the nylon orthosis was completely white.

Various machines were used for printing of different parts and materials. The list is presented below:

- PLA, elbow parts – FlashForge Creator Pro
- PLA, forearm orthosis – Creality CR-10V
- PA12, elbow parts – Zortrax M200+
- PA12, forearm orthosis – Zortrax M300 Dual

The machines were selected for material and build size. The parameters were selected by the authors' best knowledge, some of them were impossible to change (Zortrax machines – speeds and some other parameters can't be changed in the machine software).

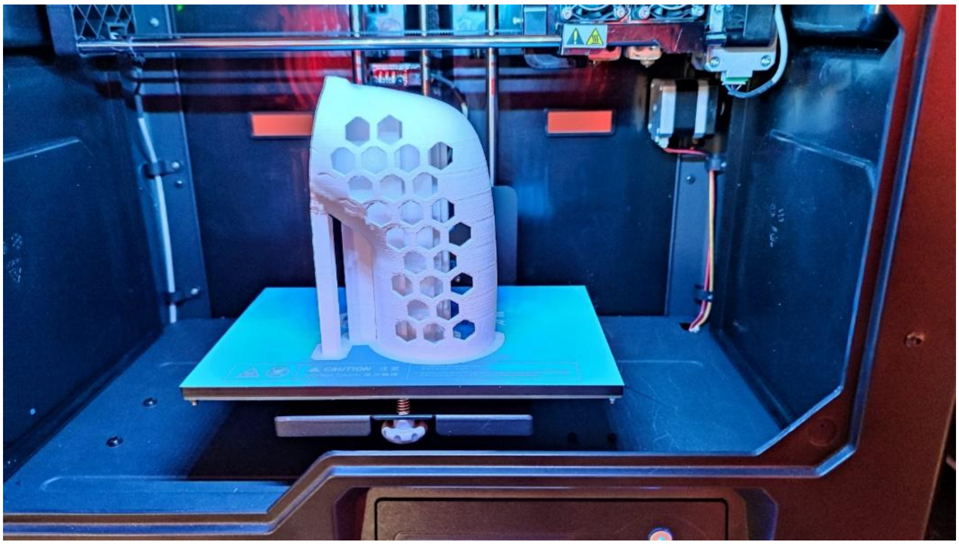


Fig 19. Manufactured orthosis part in the printer.

After setting the parameters, the solids were divided into layers, automatic supports and raft were added (Fig 20), and then the control program was generated. The FlashForge Creator Pro device does not allow to import G code directly from a PC, so it was first saved on

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

an SD card, and then placed in the device's reader. In case of other machines, they were linked by USB. The next step was to print the part.

Before starting the printing process, it was necessary to check the condition of the build plate and remove any dirt and filament residues. The printing process was monitored in the event of possible errors. If an error occurred, printing was interrupted. During this step, the printing time of each part was measured. After printing was finished and the heatbed had cooled down, the model was torn off the platform and removed from the device (Fig 21).

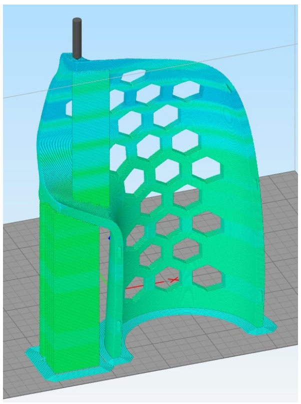


Fig 20. Part with supports. Fig 21. Manufactured orthosis parts – nylon

Table 1 presents summary of all prints – used machines, materials, manufacturing parameters and results (time and mass).

Table 1. Summary of printed parts of the orthosis

No.	Part ID	Materia l	Machine	Parameters	Outcome
1.	Elbow 1	PLA	FlashForge Creator Pro	nozzle=0,4 mm l. thickness=0,2 mm top bottom 3/3 perimeters 3 infill=15% support on temp 200° / 60° C	time = 5 h material = 66 g
2.	Elbow 2				time = 7,5 h material = 114 g

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

				speed 50 mm/s	
3.	Forearm 1		Creality CR-10 V3	nozzle=0,6 mm l. thickness=0,2 mm top bottom 3/3 perimeters 3 infill=15% support on temp 210^o / 60^o C speed 52 mm/s	time = 3,5 h material = 54 g
4.	Forearm 2				time = 3,5 h material = 55 g
5.	Elbow 1	PA12 (nylon)	Zortrax M200+	nozzle=0,4 mm l. thick=0,19 mm top bottom 5/5 perimeters 3 infill=30% support on temp 260^o / 85^o C speed 40 mm/s	time = 12 h material = 57 g
6.	Elbow 2				time = 13,5 h material = 41 g
7.	Forearm 1		Zortrax M300 Dual	nozzle=0,4 mm l. thickness=0,2 mm top bottom 5/4 perimeters 3 infill=20% support on temp 260^o / 95^o C speed 30 mm/s	time = 9,5 h material = 90 g
8.	Forearm 2				time = 9,5 h material = 92 g

4.2. Post processing, assembly and fitting

The parts of the orthosis are not ready for use right after manufacturing – it is necessary to subject them to finishing. The first step was to carefully remove the supports and the raft so as not to damage the printed element. It was also necessary to sand the parts by hand with sandpaper - there were imperfections on their outer surfaces that negatively affected the aesthetics of the orthosis. In order to reduce the risk of abrasions and increase the overall

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

comfort of use, the inner surface of the orthosis has been padded with soft EVA (Ethylene-vinyl acetate) foam (Fig 22), certified for skin contact. The final stage of the work was to join the parts by nuts and bolts. The final effect of the work, already in use, is shown in Figure 23.

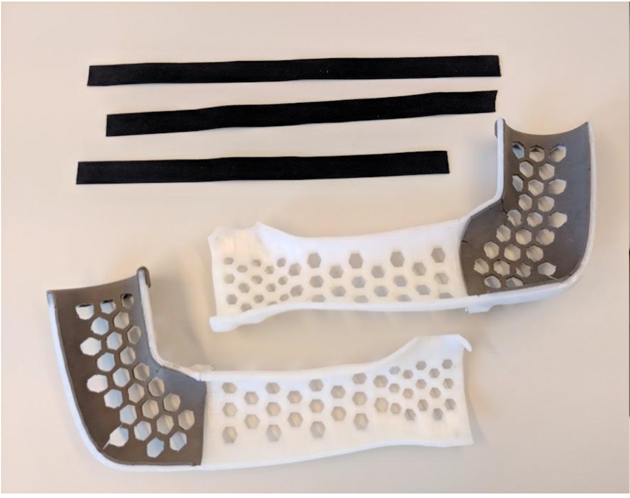


Fig 22. Ready-to-use parts of the orthosis (nylon).

Fig 23. Manufactured orthosis (PLA) during use.

5. Conclusions

The module describes the process of creating an individualized, incrementally manufactured upper limb orthosis for a fractured patient. As part of this procedure, anthropometric measurements of the patient's limb were carried out using a 3D scanner. The data obtained during the scanning was loaded into the proprietary software, which, in a way that did not require the user's participation, processed them into geometric information describing the appropriate dimensions of the parametric model of the orthosis. The automatically generated model was manufactured additively from PLA material using the FDM technology.

The orthosis produced in this way is equal to, and in many respects even surpassed, classical solutions. The key aspect here is individualization - in contrast to universal orthoses, the one described in this paper is precisely adapted to the human body, which increases its rehabilitation effectiveness. Another important feature is the very short production

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

time - only two days passed from the start of measurements to the handover of the device to the user, which means not only a short waiting time but also a significant costs reduction - their sum, including the cost of machine operation and the cost of the material, is about EUR 70. The ease of assembly and disassembly will also be a great comfort for the user, which translates into easy hygiene. It is also worth noting that further development of the described technology may make it possible to implement it in medical clinics.

Acknowledgements

The realization of the studies on individualized product design was possible thanks to the financing of the Polish National Center of Science and Development, programme "LIDER VIII".

References

DOM14	Dombroski C.E., Balsdon M.E., Froats A., The use of a low cost 3D scanning and printing tool in the manufacture of custom-made foot orthoses: a preliminary study, BMC Res Notes, Vol 60 (2014), 443. https://doi.org/10.1186/1756-0500-7-443
GUI19	Guida P., Casaburi A., Busiello T., et al. An alternative to plaster cast treatment in a pediatric trauma center using the CAD/CAM technology to manufacture customized three-dimensional-printed orthoses in a totally hospital context: a feasibility study. J Pediatr Orthop B., Vol 28 (2019), pp. 248-255. https://doi.org/10.1097/BPB.0000000000000589
GOR20	Górski F., Wichniarek R., Kuczko W., Żukowska M., Lulkiewicz M. (2020), Experimental Studies on 3D Printing of Automatically Designed Customized Wrist-Hand Orthoses, Materials, 13(18), 4091.
KUO19	Kuo Y.R., Fang J.J., Wu C.T., et al. Analysis of a customized cervical collar to improve neck posture during smartphone usage: a comparative study in healthy subjects. Eur Spine J, Vol 29 (2019), pp. 1793-1803. https://doi.org/10.1007/s00586-019-06022-0;
TEL17	Telfer S., Woodburn J., Collier A., et al. Virtually optimized insoles for offloading the diabetic foot: A randomized crossover study, J Biomech, Vol 60 (2017), pp. 157-161. https://doi.org/10.1016/j.jbiomech.2017.06.028;
www 01	Ten materiał zastąpi w przyszłości gips - https://geekweek.interia.pl/raporty/raport-medycyna-przyszlosci/medycyna/news-ten-material-zastapi-w-przyszlosci-gips,nId,940794; accessing date: 14.11.2021
www 02	https://www.orteo.pl/ortezy-kostki-i-stopy/orteza-na-stope-i-golen-but-marszowy-krotki-walker-fixed-walk?gclid=CjwKCAiAm7OMBhAQEiwArvGi3AeUOjtYjW9RQawhHEe3GFV0Fp7-w0jQtEaBwXYatM6V5btEbxMmfRoCY4gQAvD_BwE; accessing date: 14.11.2021
www 03	iSun 3D – https://www.isun3d.com/en/; accessing date: 14.11.2021
www 04	EOS – https://www.eos.info; accessing date: 14.11.2021
www 05	Korthotics – https://www.korthotics.com.au/; accessing date: 14.11.2021
www 06	Ortheo 3D – https://ortheo3d.com/; accessing date: 14.11.2021
www 07	3D Print Innovations – https://www.biotechnc.com/posts/3d-print-innovations/383; accessing date: 14.11.2021
www 08	https://massportal.com/back-brace/; accessing date: 14.11.2021
www 09	Scopri la stampa 3D – https://www.superficilab.com/scopri-la-stampa-3d/; accessing date: 14.11.2021

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

This project has been funded with support from the European Commission. This publication [communication] reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.