BRIGHT

Erasmus+ strategic partnership for Higher Education

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

O5 - BRIGHT e-case study 1

Project Title	**Boosting the scientific excellence and innovation capacity of 3D printing methods in pandemic period 2020-1-RO01-KA226-HE-095517**
Output	**O5 - BRIGHT e-case studies for project based learning method used in developing, testing and manufacturing of new medical products by 3D printing technologies in pandemic period** **BRIGHT e-case study 1 – wrist hand orthosis**
Date of Delivery	**February 2023**
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Version	**FINAL VERSION**

Co-funded by the Erasmus+ Programme of the European Union

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1 Introduction

This is a documentation regarding the e-case study #1 of the BRIGHT project, focused on 3D printable personalized wrist hand orthosis, based on own design that has been defined and created by team of Poznan University of Technology (PUT) in scope of another project (AutoMedPrint, automedprint.put.poznan.pl) with the main aim to be adjusted, realized and further on tested and used in the BRIGHT project. In this e-case study, all main four stages of work are presented – design using intelligent CAD models, simulations in CAE, manufacturing using FDM 3D printing technology and testing with patients (both adult and juvenile). The case was also extensively documented in BRIGHT webinar series (IO4) and used in both summer schools realized during the BRIGHT project.

2 BRIGHT e-case study #1 – main ideas

2.1 Main concepts of the product

The first case study is an orthosis used for wrist joint stabilization in time after an injury such as fracture or for patients with conditions that require stabilization (rheumatoid arthritis, muscle atrophy and many others). The orthosis is openwork (with several possible shapes), to enable skin access in both comfort and hygienic reasons (Figure 1). It is 3D printed using FDM technology, with one of the basic FDM technology materials: PLA, ABS, PET-G and PA-12 (nylon).

Figure 1. Wrist hand orthosis in various versions

The orthosis is customized on the basis of a 3D scan geometry of patient's hand and forearm. It is 3D printed using one of the basic FDM technology materials: PLA, ABS, PET-G and PA-12 (nylon), of which PLA and PA-12 are recommended due to proper combination of mechanical and processing properties, as well as no known issues with skin irritation. The 3D printing takes approx. 3-4 hours for one part of the orthosis, for an adult patient.

The orthosis design, solutions and application software for generating the points over patient scan are all a protected intellectual property of Poznan University of Technology. The orthosis and software has been developed as part of the AutoMedPrint system and is subjected to a patent and general intellectual property rights.

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It is not allowed to use the design for commercial purposes, the shared 3D model can be used solely for educational properties in the scope of the BRIGHT project, by authorized persons taking part in training performed with participation of instructors accepted by AutoMedPrint team.

2.2 Requirements and recipients

To realize a 3D printing and manufacture the prosthesis, the following is needed:

1) anthropometric data – 3D scan of a limb
2) customizable, parametric model of the orthosis
3) FDM printer (of any type – the cheapest ones are also able to perform) with PLA or other material,
4) cable ties for connecting of two halves
5) foam for internal lining (optional),
6) velcro straps for tightening,
7) basic tools for post processing (file, sandpaper, knife, driller etc.)

The orthosis can be used by both children and adults. It can be designed as a stabilizing one – after injuries, for short term continuous use – or as a therapeutic one, for long term, non-continuous use in rehabilitation, in conditions such as cerebral palsy, muscle atrophy and others.

2.3 Plan of work and task distribution

The orthosis model was first designed and created independently, in the AutoMedPrint project realized at Poznan University of Technology. Then, it was manufactured and tested, also with real patients. On that basis, educational materials were developed (lectures, instructions for the students, movies etc.). In the BRIGHT project it was then used as an educational tool during summer schools, the one held remotely in TUCN in 2021 and then the other in Pula, Croatia in 2022. Many groups have selected the orthosis for their work and it has been extensively used, analyzed and presented during the scope of the project, as the most substantial example of 3D printed medical part. The scope of work with the case is presented in the scheme presented in Figure 2.

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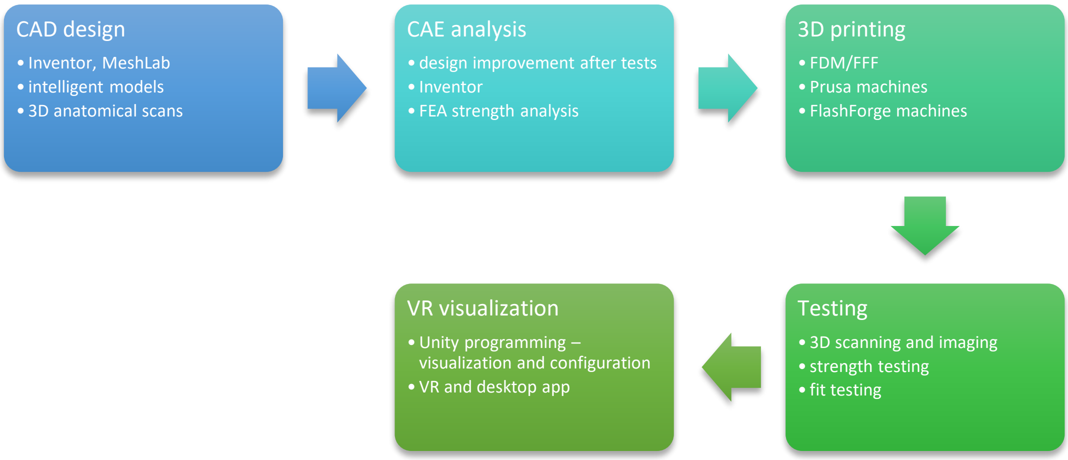

Figure 2. Scope of the work and stages defined in relation with realized case study 1

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3 BRIGHT e-case study #1 – realized work

3.1 Design of the orthosis

The orthosis is customized on the basis of a non-contact measurement of geometry of patient's hand and forearm (or mirror image of the other limb, when the actual limb is damaged and e.g. wrapped in plaster cast). The measurement is done by optical 3D scanning, usually at the workplace developed as a part of the AutoMedPrint system, developed at Poznan University of Technology. After measurement, data is processed from raw scans to reconstructed, smooth limb model (Figure 3). Out of this model, sets of points are extracted to feed the intelligent CAD model.

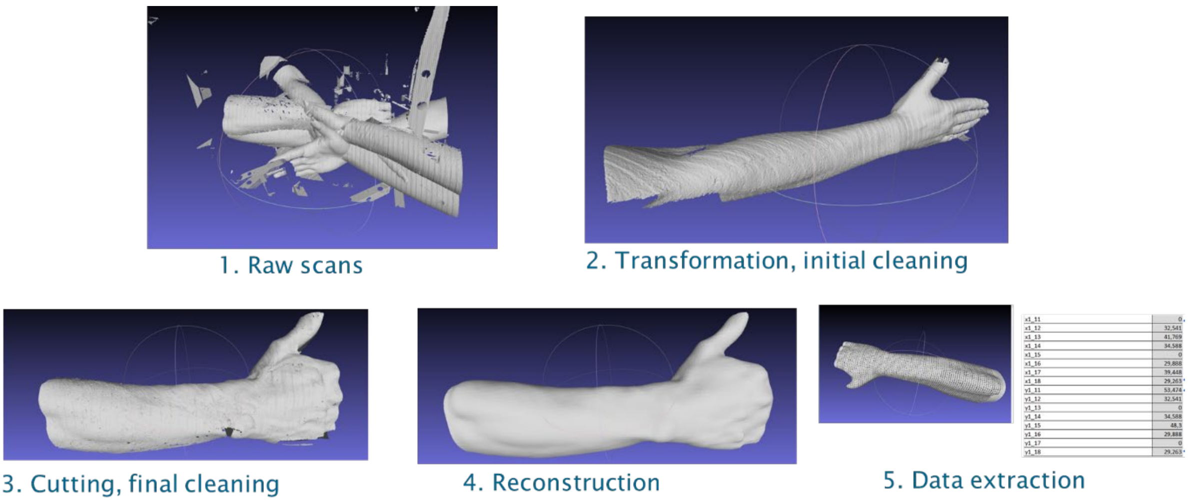

Figure 3. Data processing of 3D scans for the wrist hand orthosis model (AutoMedPrint system materials)

The product was originally designed in the Autodesk Inventor CAD system (Figure 4), as an intelligent model – its design can be changed freely by supplying it with various data from 3D scanning, leading to automated re-design. The model and its know-how is a part of AutoMedPrint system developed at Poznan University of Technology (automedprint.put.poznan.pl), which was awarded as the Polish Product of the Future of year 2022.

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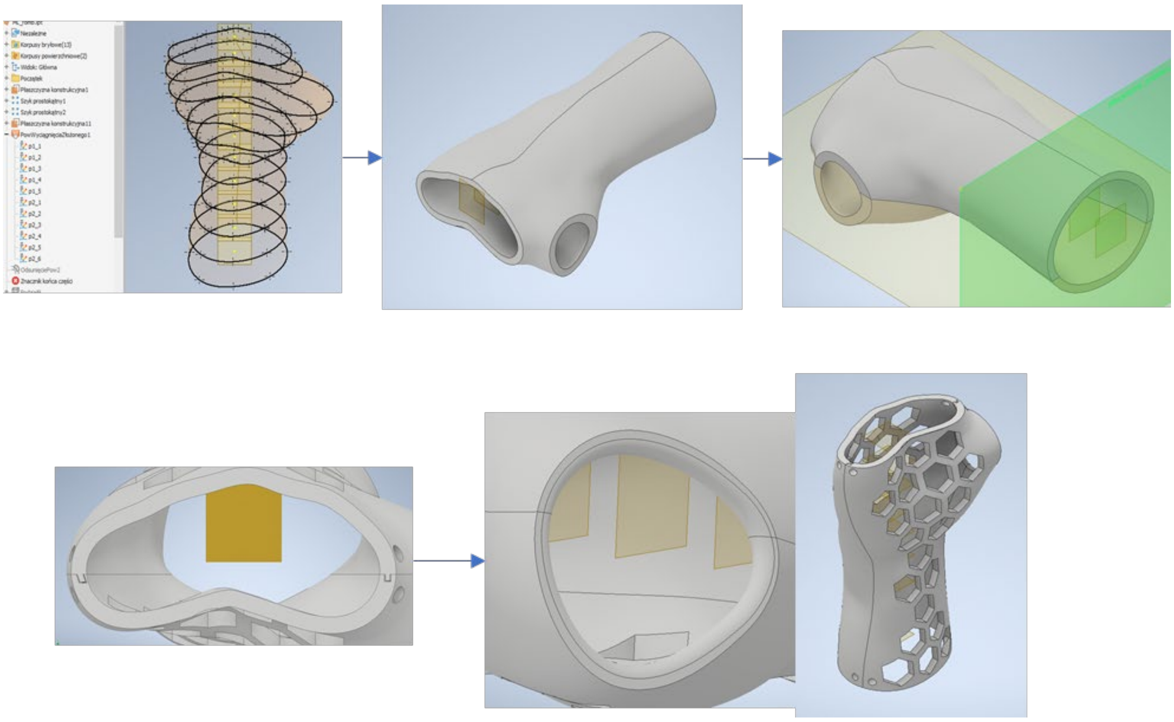

Figure 4. Design of orthosis in Inventor (AutoMedPrint system materials)

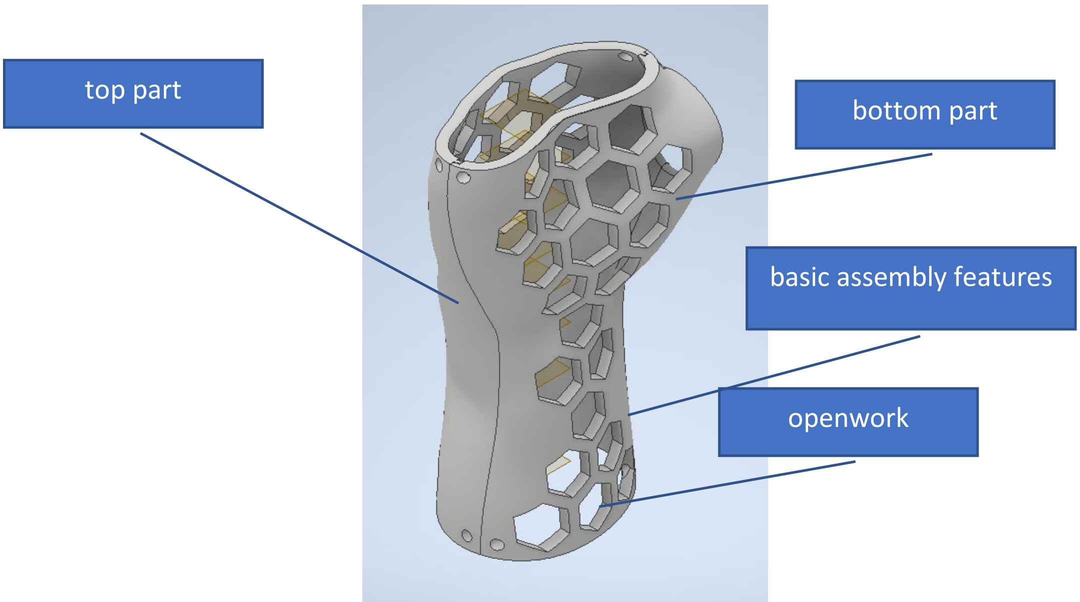

Figure 5. Wrist hand orthosis - parts

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The orthosis consists of basic parts (as visible in the Figure 5):

- bottom part (in contact with palm),
- top part (in contact with back of the hand),
- optionally – the bottom and top part could be transversally divided if orthosis

The orthosis design table contains points extracted from the limb reconstruction. It is an Excel spreadsheet and it looks as in Figure 6.

	A	B
1	P1	178
2	P2	197.25
3	P3	216.5
4	P4	235.75
5	P5	255
6	P6	268.6
7	P7	282.2
8	P8	295.8
9	P9	309.4
10	P10	323
11	P11	340
12	offset	2
13	thickness	4
14	length	162
15	printer_max_leng	170
16	openwork_1	0
17	openwork_2	0
18	openwork_3	0
19	holes_diam	4
20	side	1
21	aux1	100
22	aux2	0
23	aux3	0
24	aux4	0
25	X1_1	-26.8281
26	Y1_1	-10.8234
27	X2_1	-33.5156
28	Y2_1	-0.17997

Figure 6. Wrist hand orthosis – design table (fragment)

The point extraction is realized by AutoMedPrint system algorithms, using Excel and MeshLab software. Integral element is a custom application (made in Unity) for selection of characteristic planes along the image of patient's limb (Figure 7).

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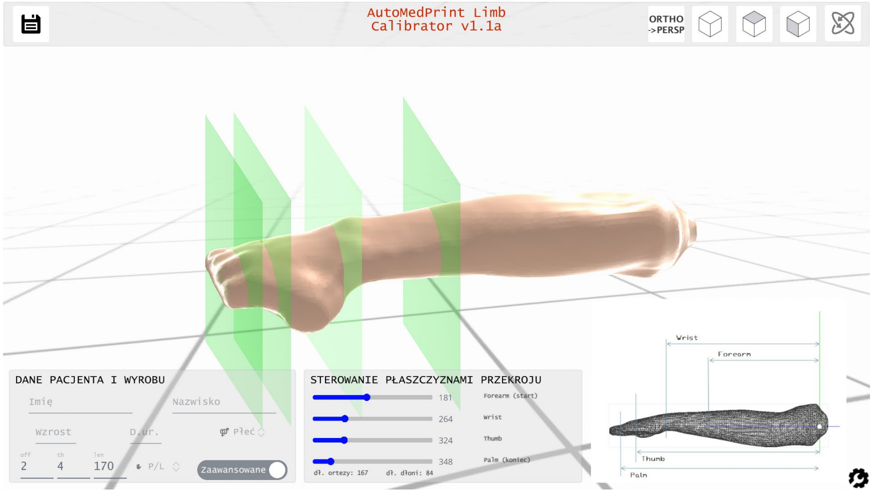

Figure 7. WHO plane selector application (developed at PUT)

The process of data extraction is automatic. As a result, new Excel spreadsheed is generated. Then the user (e.g. a student) opens the Inventor model and updates the design table. After updating, check for errors and possible improvements, the model must be saved to external file for further use. It is usually done in two ways:

- whole orthosis is saved in STP file
- individual parts (solid bodies) are saved as STL files for 3D printing.

For the design realized in the BRIGHT project, several cases were considered. In the first summer school (2021), an orthosis for a single patient was considered by the students (the patient was a 22-year old female) and task of the students was to create an innovative set of design features (examples in Figure 8).

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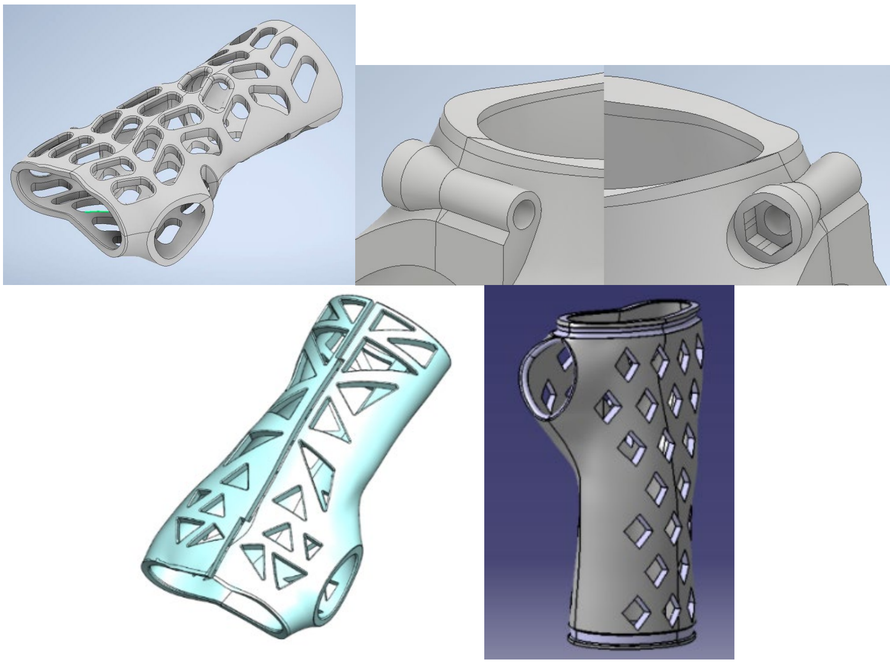

Figure 8. Examples of design features created by the students of first BRIGHT summer school

In the second summer school, the students were given 3D scans of persons present at the site – representatives of consortium partners (teachers and specialists from PUT, Bizzcom and TUCN, 3D scanned during TPM event held earlier in Poznan). The students managed to create customized orthoses and test them with real "patients" (see Figure 9).

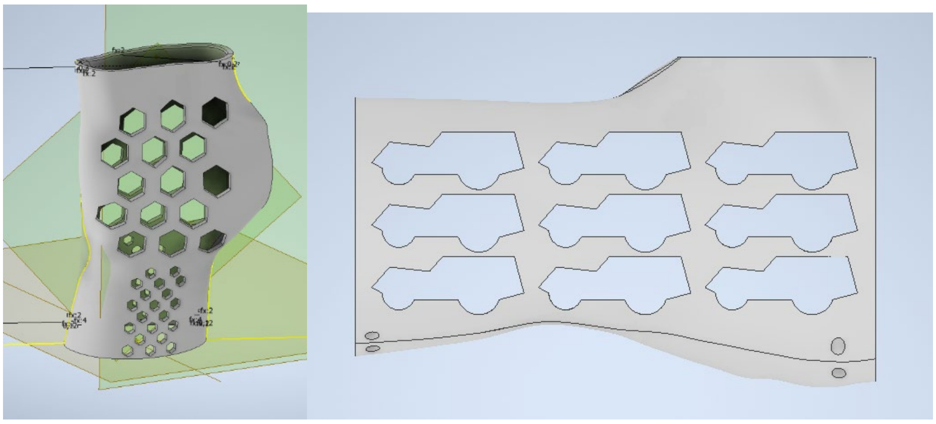

Figure 9. Designs created during the second BRIGHT summer school

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For the webinars realized in IO4, another case study was selected. The patient was a 26-year old man, with an injury to his right wrist, caused by bite of a dog resulting in some bone crush (Figure 10). A full process was undergone and recorded for him (3D scanning shown in Figure 11, finished with obtaining a complete functional orthosis (Figure 12).

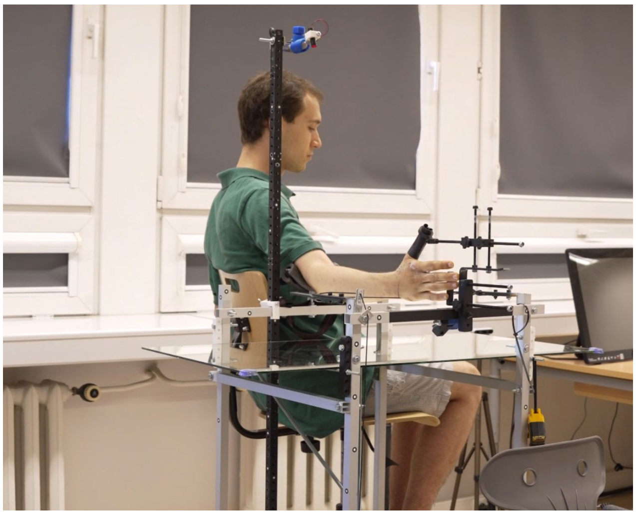

Figure 10. Selected case study – patient with injured hand

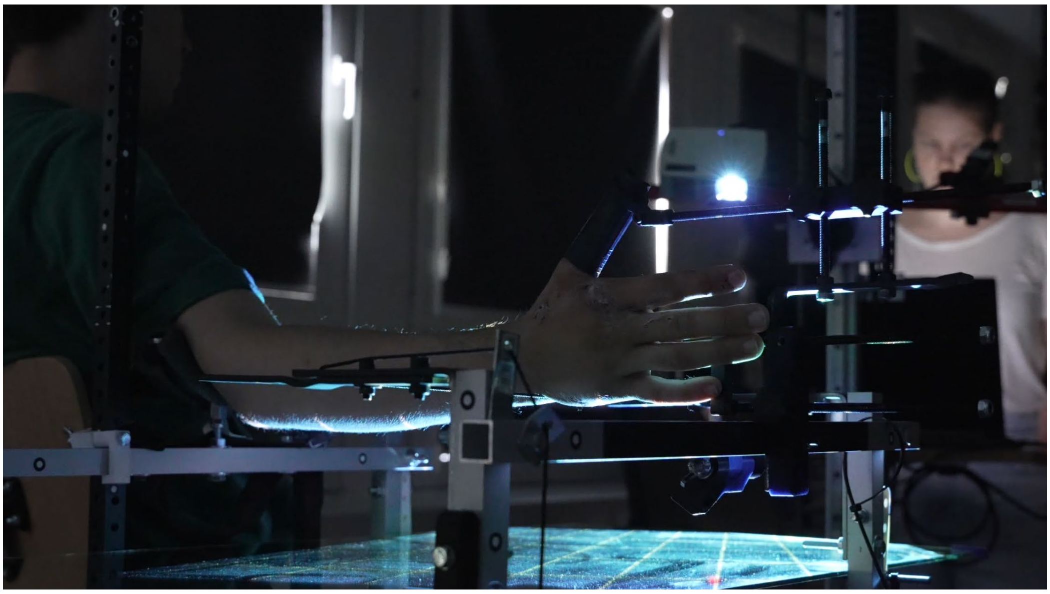

Figure 11. Patient 3D scanning using AutoMedPrint system at PUT

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Figure 12. Orthosis designed for the patient in the scope of O4

3.2 CAE simulations

The main objective of the finite element analysis has been to evaluate the strength characteristics of the wrist hand orthosis by simulating a three-point bending test. The principle of the test is shown in Figure 13. As one may notice, the lower and upper parts of the orthosis are assembled and placed on a support block. The upper part of the orthosis is then loaded by a downward vertical force acting on the red surface patch. This load gradually increases from 0 (zero) to 125 N. The contact between the lower part of the orthosis and the support block takes place along perfectly matching surfaces.

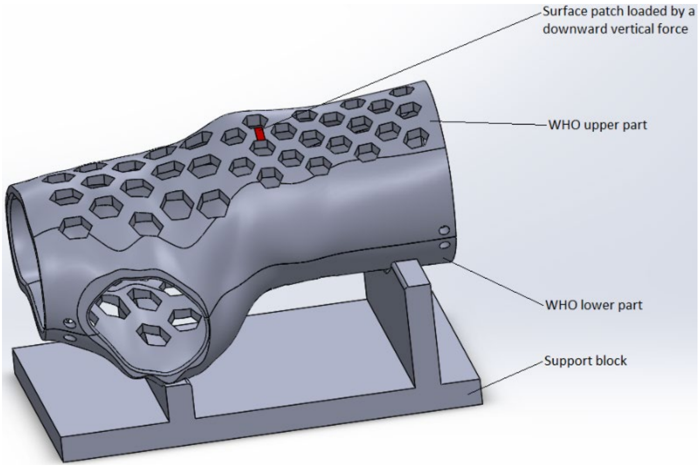

Figure 13. Principle of the three-point bending test simulated for evaluating the strength characteristics of the wrist hand orthosis

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The following assumptions have been made when preparing the finite element model of the three-point bending test:

a) The lower and upper parts of the orthosis are made from ABS exhibiting an isotropic linear elastic behaviour defined by the following parameters: elastic modulus E = 1990 MPa, Poisson's ratio ν = 0.365, and yield strength Y = 31.2 MPa. The support block is a perfectly rigid body.

b) The lower and upper parts of the orthosis are bonded together along their contact surfaces. The lower part of the orthosis is allowed to slide along its contact surfaces with the support block, the frictional component of this contact interaction being neglected.

The finite element model of the three-point bending test has been elaborated and solved with SOLIDWORKS Simulation in the following sequence of steps (Figure 14):

a) Defining the pressure block as a perfectly rigid body

b) Associating the ABS material to the lower and upper parts of the orthosis

c) Specifying the contact interaction between the support block and the lower part of the orthosis: frictionless sliding contact

d) Specifying the contact interaction between the parts of the orthosis: bonded contact

e) Enforcing a full locking kinematic constraint on the bottom face of the support block

f) Defining a downward vertical unit force applied to the upper part of the orthosis

Note: The actual values of this force have been specified later as load cases (step (h)).

g) Controlling the local and global dimensions of finite elements and generating the mesh

h) Specifying the actual values of the downward vertical force applied to the upper part of the orthosis: 25 N (load case 1), 50 N (load case 2), 75 N (load case 3), 100 N (load case 4), and 125 N (load case 5).

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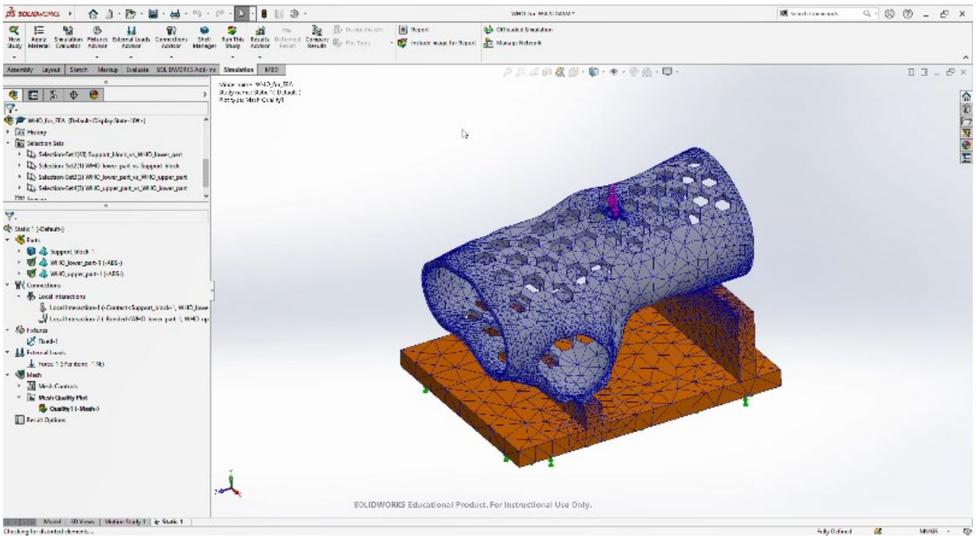

Figure 14 Finite element model of the three-point bending test simulated for evaluating the strength characteristics of the wrist hand orthosis

Figure 15 shows the most important result provided by SOLIDWORKS Simulation: distribution of the von Mises equivalent stress in the lower and upper parts of the orthosis for the fifth load case (testing force of 125 N). The maximum values of the von Mises equivalent stress σeq,max associated to different load cases are displayed on the diagram in Figure 16 to show their dependence on the testing force F. The following conclusions have been formulated after examining the diagram:

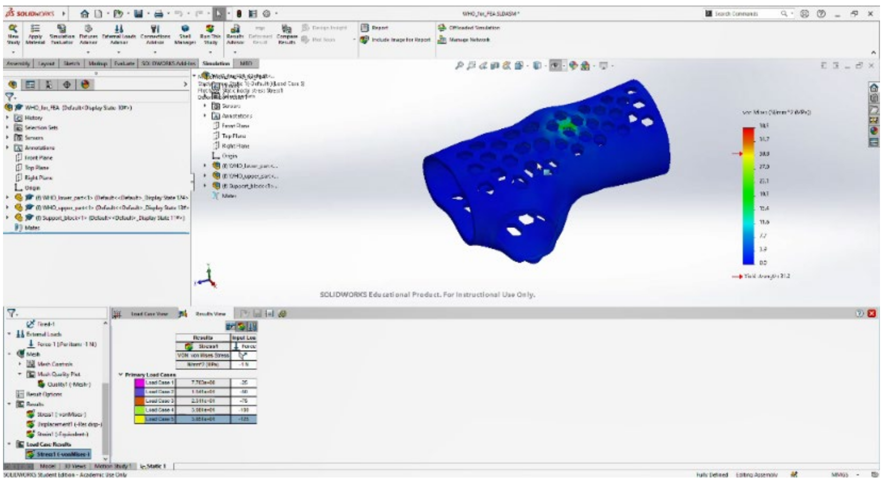

Figure 15. Distribution of the von Mises equivalent stress in the lower and upper parts of the orthosis for the fifth load case – testing force of 125 N

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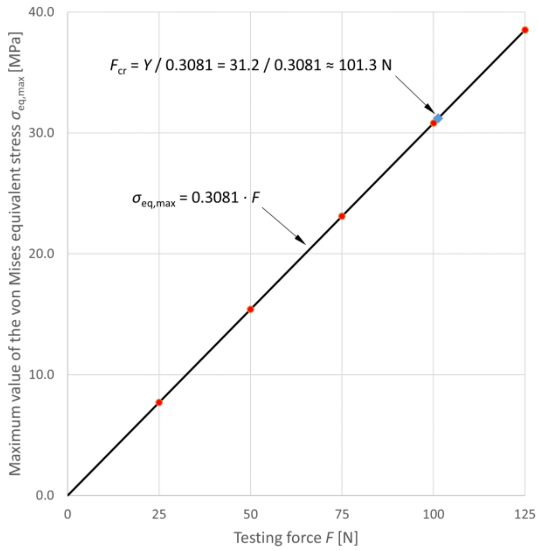

Figure 16. Maximum values of the von Mises equivalent stress associated to different testing forces: red dots – numerical results; black path – linear regression; blue diamond – testing force at which the maximum value of the equivalent stress equals the yield strength

a) The mechanical response of the orthosis is well approximated by means of the linear regression $\sigma_{eq,max} = 0.3081 \bullet F$ (see the black path displayed on the diagram in Figure 16).

b) This regression can be used to determine the testing force at which the maximum value of the equivalent stress equals the yield strength of the ABS material: 101.3 N (see the blue diamond displayed on the diagram in Figure 16).

The CAE simulations were also performed by the students of both summer schools, with excellent results.

3.3 Manufacturing

For the 3D printing, FDM technology was used. For most cases, FlashForge Creator Pro machines were used (Figure 17). In the second summer school, on-site prints were realized using Prusa i3 MK2 (Figure 18).

The FDM process utilized standard settings – with layer thickness of 0,25 mm and 30% of internal filling. The used materials were PET-G, PLA and nylon, with their temperature and velocity settings as recommended by their respective producers. Different colors were used, mostly white, blue and orange.

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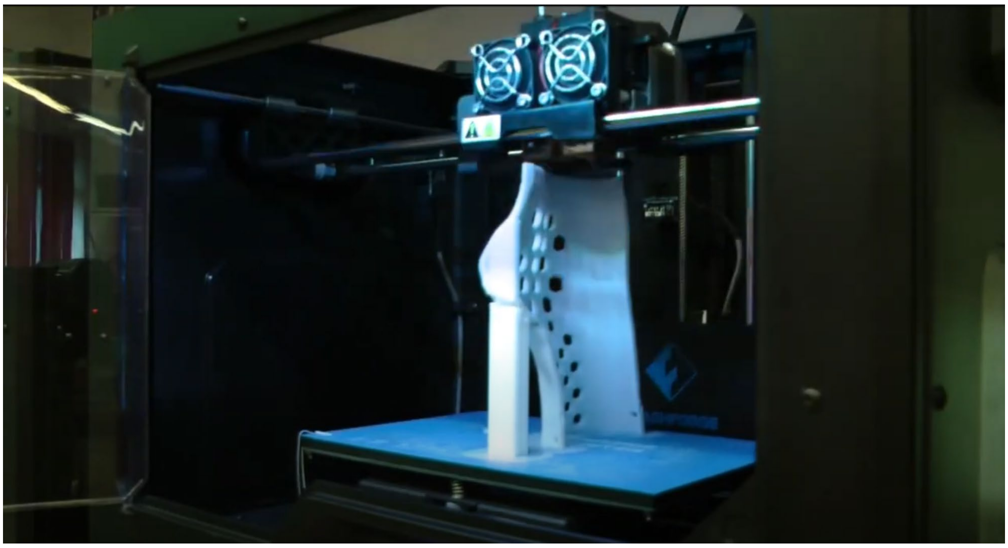

Figure 17. 3D printing of orthosis using FlashForge Creator Pro machine

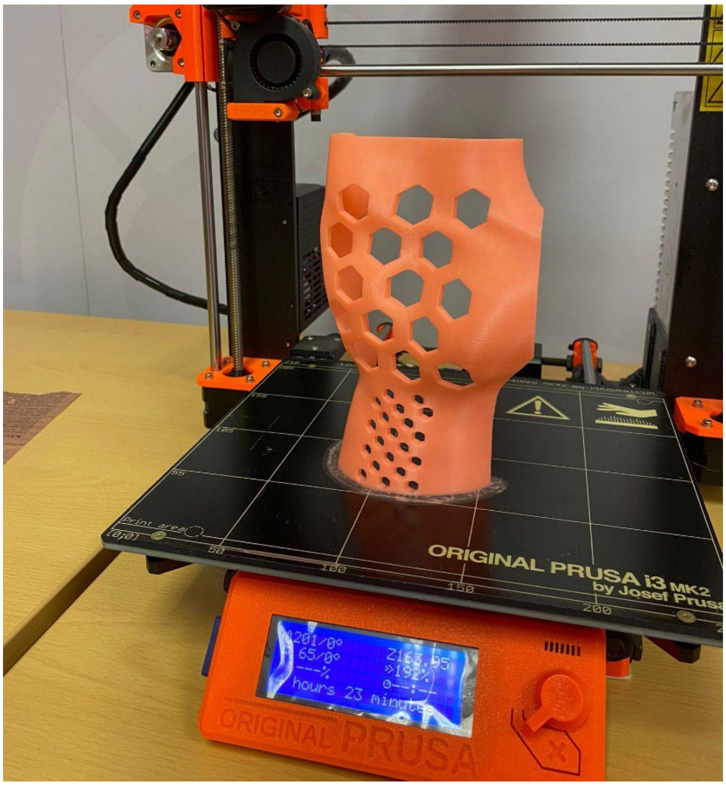

Figure 18. 3D printing of orthosis with Prusa machine

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Figure 19. Post processing of the orthosis (support removal, lining with foam etc.)

Post processing included removal of support structures, polishing the orthosis to remove sharp edges and rough surfaces, lining parts of orthosis with foam for more comfortable use and adding mounting elements to keep the two parts together (plastic cable ties + velcro straps). It is shown in Figure 19.

3.4 Testing

The testing of the orthosis is divided into non-destructive testing and strength tests. The strength tests mimic the three-point bending test, as in CAE simulations. The orthosis was put in an universal testing machine, with a special 3D printed fixture. Then it was loaded until it broke (Figure 20). Figure 21 shows results of the test – broken orthosis and force-deformation diagram. These tests have been made during the summer school 1.

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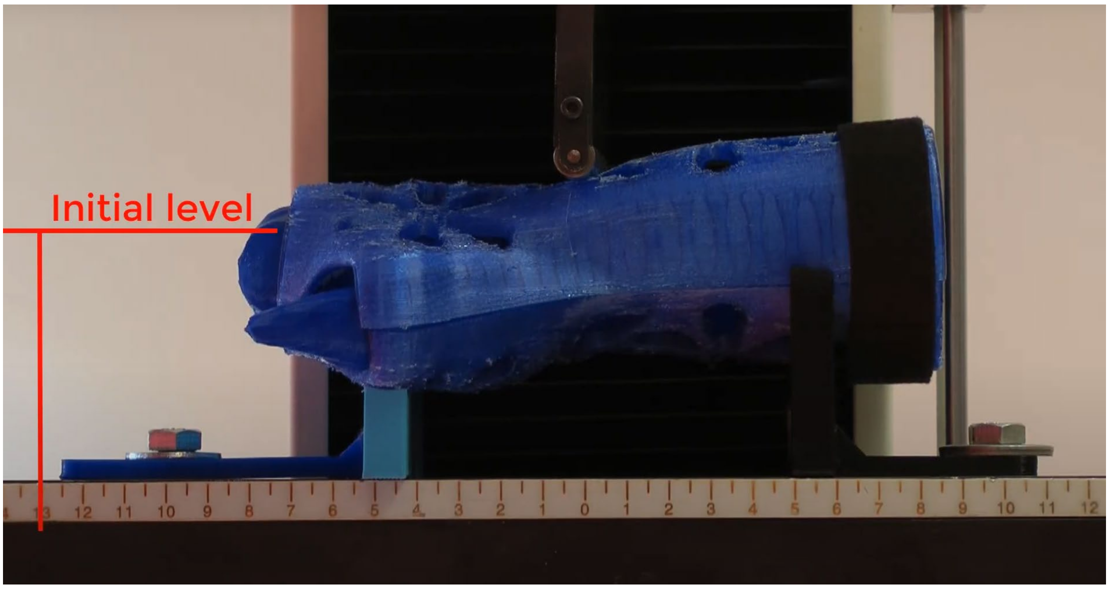

Figure 20. Strength test of orthosis made by summer school participants - course

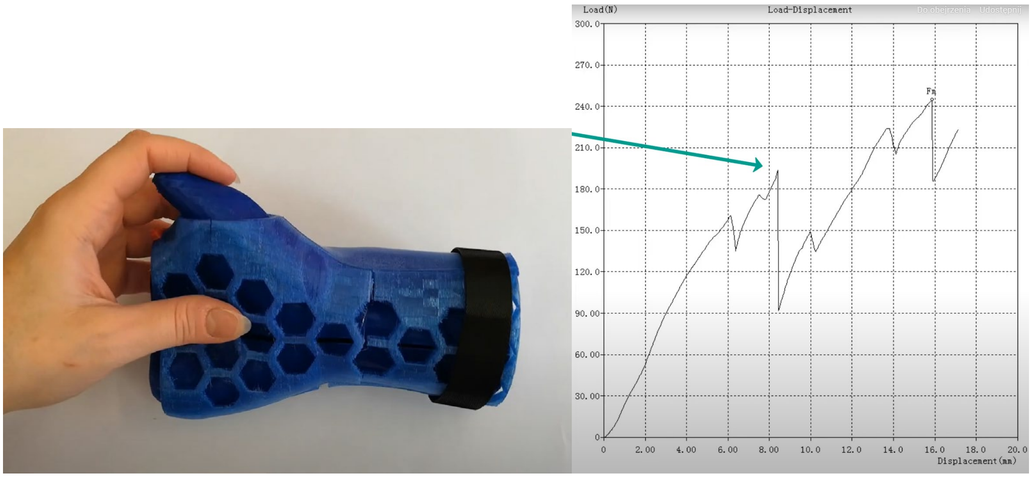

Figure 21. Strength test of orthosis made by summer school participants – broken orthosis, diagram of tensile test

The non-destructive part involves accuracy testing done with use of 3D scanning (Figure 22). First, the orthosis is 3D scanned, then the data is processed in appropriate software (GOM Inspect in this case) to generate a colorful deviation map, for accuracy check (Figure 23).

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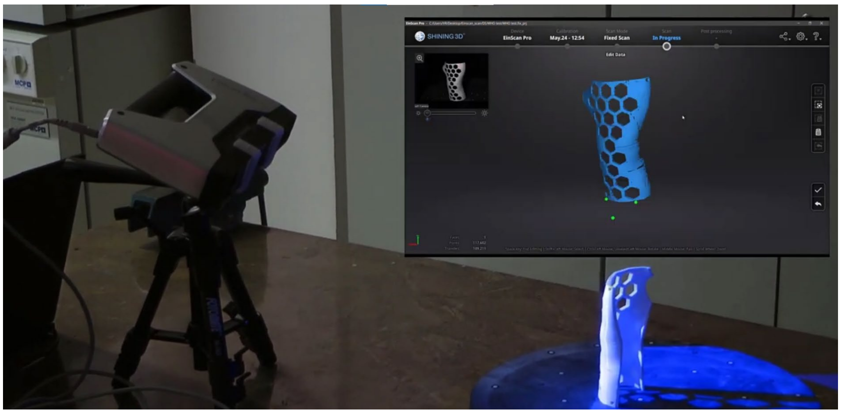

Figure 22. 3D scanning of orthosis for accuracy testing

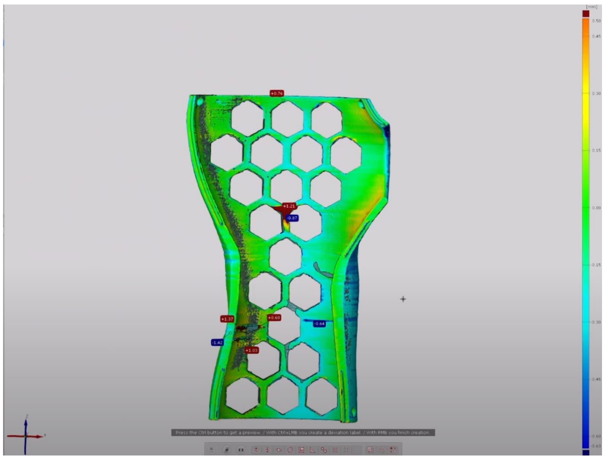

Figure 23. Accuracy check – colorful deviation map

Also, tests with patients were made for fit and functionality. First of all, virtual tests were made using the MeshLab software (Figure 24). The real patient fit tests are shown in Figure 25 and 26.

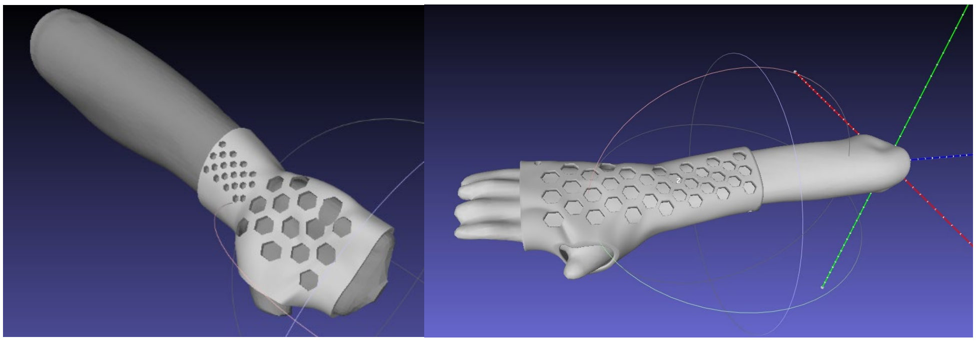

Figure 24. Virtual fit tests in MeshLab

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Figure 25. Fitting test with patient (IO4 webinar)

Figure 26. Fitting test with patients (2022 summer school)

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3.5 VR solutions

For the wrist hand orthosis, the product configurator was created and it can be used to select the basic features of the product. It has been tested and used during TPM event in Poznan (Figure 27).

Figure 27. WHO 3D configurator (AutoMedPrint system)

During the BRIGHT summer school, students were asked to prepare VR configurators of their own, using the generated products. Example of their work in the Unity software is shown in Figure 28 and 29.

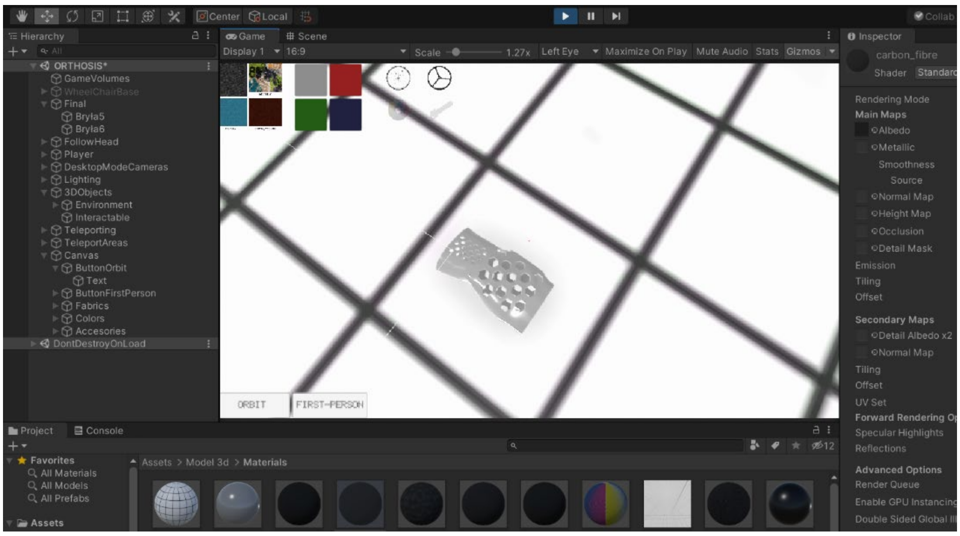

Figure 28. Creation of VR configurator of the orthosis by the summer school students

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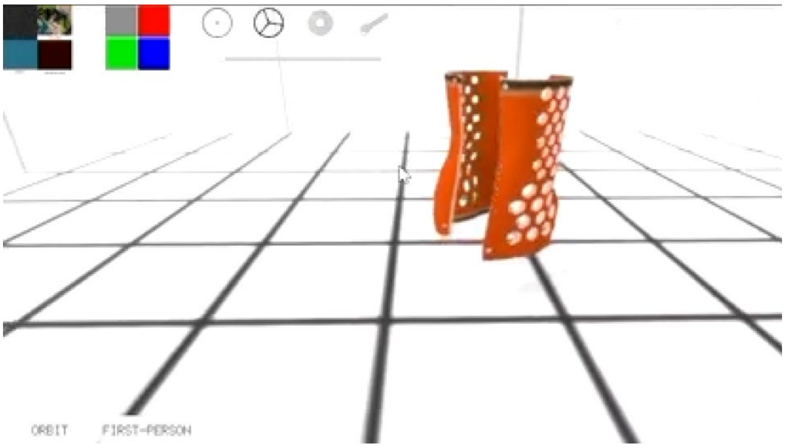

Figure 29. VR configurator in use, created by the summer school students

3.6 Dissemination results

The orthosis case has been successfully used as a main educational case study throughout the whole BRIGHT project. It allowed students to get considerable knowledge and skills related to customized 3D printed medical products. More than couple dozens of students had the experience with design, 3D printing, simulation and testing of the customized orthosis during both summer schools as presented in the Final dissemination report of the BRIGHT project. Educational materials in the project were prepared on that basis (CAD, VR, CAE instructions and educational videos) and were used with great feedback. The orthosis is also a case used now in education at BRIGHT partner universities, within student projects, laboratories and diploma theses as specified also in the Final dissemination report of the BRIGHT project. Its impact is therefore very high.

Of the cases generated specifically for the BRIGHT project, the feedback by patients, experts, specialists and doctors were generally positive.

Also it is to be mentioned that automated design based on customized scans represents definitely one praised capability, as it allows truly individualized design in a very short time – summer school students were able to obtain complete products in less than a week of work, starting with next to no knowledge on the subject. This proves that the automated design technology is ready for implementation.

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The AutoMedPrint system itself (in which the orthosis is a case study) was named as Polish Product of the Future 2022 and has gained considerable media attention, also thanks to the international aspect of the system use in the BRIGHT project. During the project itself, the case was also a subject of conference publications that have been presented at the Manufacturing conference 2022 (and part of the Springer book edited by prof. Górski and prof. Pacurar) as stated in the Final dissemination report of the BRIGHT project, as well as the HTIC 2022 conference in Zabrze (part of upcoming Springer book).

The concept of the orthosis is also a basis in another project – EMERALD (financed by Norwegian grants, project in which TUCN is the coordinator and PUT (Poland) and BIZZCOM partners in the BRIGHT project are also part in the consortium of the EMERALD project) – for another case study, in which the orthosis is being converted into a mechatronic device – a VR game controller for improved rehabilitation process, this important aspect being also specified in the Final dissemination report of the BRIGHT project.

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4 Conclusions

The presented case study pertains to an innovative orthotic device that can be quickly designed by people without high engineering competences and printed on most FDM printers. It was designed and prepared by representatives of Poznan University of Technology. Its educational value is very high. The model was used in educational activities in BRIGHT project, first and foremost as a case study in the BRIGHT summer schools realized in 2021 and 2022. It is a versatile and flexible device, and a perfect example for students to work with design of simple, 3D printable, customizable orthotic devices. For educational effect, all the stages were realized in product development, starting from design for specific patients, through CAE simulation, 3D printing (with experimental phase), destructive and non-destructive tests, fitting, as well as VR. Positive feedback was obtained from some patients and doctors. The case was also used to integrate partners from all institutions involved in the project and it is going to be widespread scientifically, by means of research papers.

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