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EUROPEAN NETWORK FOR 3D PRINTING OF BIOMIMETIC MECHATRONIC SYSTEMS

CASE STUDY #2

Project Title	**European network for 3D printing of biomimetic mechatronic systems 21-COP-0019**
Output	**IO4 - EMERALD e-case studies for project based learning method used in developing, testing and manufacturing of new biomimetic mechatronic systems by 3D printing technologies**
Module	**Case study #2 – Mechatronic personalized upper limb prosthesis**
Date of Delivery	**August 2023**
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Version	**1.0, 30.08.2023**

Contents

1. Introduction

This document presents a description of a case study realized in the EMERALD project, as part of the IO4 work package. The case was selected on the basis of experience, possibilities, available solutions and access to patients by the team from Poznan University of Technology. Discussions conducted during various EMERALD project meetings were also taken into consideration and feedback of all partners was gathered and implemented.

The case study #2 focuses on a biomechatronic prosthesis, for patients with transradial defect/amputation (functional elbow joint preserved). It was proposed to convert a mechanical prosthesis into a mechatronic device by enhancing it with electrical motors in a low-cost manner, enabling patients to operate the actuated end effector and control its state with use of their forearm stump.

Originally the basic prosthesis model was conceived as part of AutoMedPrint project. More information about the AutoMedPrint project that is the base of the cases can be found on the website – automedprint.put.poznan.pl (Polish language only).

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2. Basic concepts

The concept involves modifying a mechanical prosthetic arm into an electric active prosthetic arm with an 0-1 grip. The prosthesis must be able to open and close the handle. The main idea is to enable patients after upper limb amputation to continue cycling. Therefore, the prosthesis must be adapted to the bicycle handle. In addition, the prosthesis should ensure a firm grip on simple, rigid objects, such as door handles, bottles. Figure 1 shows patients using a mechanical prosthetic hand.

Figure 2.1. Mechanical prosthesis used by various patients

Design assumptions:

1) modification of the mechanical hand prosthesis into an electric, active prosthesis with the possibility of closing and opening the effector.

2) the construction of the prosthesis - simple and capable of 3D printing.

3) the prosthesis controlled by the second, healthy limb. A button mounted on the prosthesis that controls the opening and closing of the handle.

4) assembling the electrical parts, it should fit in the forearm or be attached to the patient's arm.

The idea is that the patient should be able to repair the damaged prosthesis on his own. An important aspect of the design is the price and the speed of delivery of the prosthesis to the patient. The model of the prosthesis is based on scans of the patient's stump. In addition, the design itself is semi-automatic based on functions in MS Excel and Autodesk Inventor Professional.

The work plan includes:

1) Design of the movable prosthetic tip, design of the forearm with the location of electrical components in the CAD environment in Inventor Professional.

2) Selection of electrical components such as motor, servos, batteries, microcontroller. Fabrication of the PCB, soldering of components. Writing a program that controls the prosthesis.

3) Printing of mechanical parts in additive technology.

4) Assembling the prosthesis, conducting tests.

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3. *Case implementation*

3.1. Literature review and premises for the study

Amputation of the upper limb represents a prevalent disability in developed nations, stemming from varied causes including accidents, predominantly affecting men, along with conditions like cancer, vascular diseases, and infections. Lack of one or more limbs may also result from a congenital defect. This range of causative factors leads to varying degrees of limb loss, affecting individuals differently [1]. Such amputations or defects disrupt the intricate neural pathways responsible for relaying both motor commands and sensory feedback from the limb to the brain. This interference greatly impacts an individual's ability to control movements and perceive sensations, profoundly altering their day-to-day functionality [2].

Prosthesis rejection poses a considerable challenge in amputation rehabilitation. Studies emphasize that focusing on personalized prosthesis quality, tailored to individual user specifications, substantially enhances successful fitting, pro-longs prosthesis usage, and minimizes rejection risks. Hence, the feasibility of effortless and cost-effective prosthesis customization stands as a pivotal factor in elevating the quality of life for individuals facing limb disabilities [3,4].

Efforts to develop customizable and high-quality prosthetic solutions aligned with individual needs can play a pivotal role in empowering those with upper limb amputations, enhancing their functionality, and fostering improved societal integration.

The evolution of 3D printing technology revolutionized the fabrication of up-per limb prostheses, offering tailored solutions for amputees. This technology allows the creation of customized prosthetic devices, enhancing the fit and functionality [5]. Utilizing 3D scanning and printing, prosthetists can design prostheses that closely match the patient's anatomy, enhancing comfort and usability. The adaptability of 3D printing facilitates rapid prototyping, reducing manufacturing time and costs [6]. The advantages of 3D-printed upper limb prostheses encompass cost-effectiveness, customization, and accessibility [5]. Customization allows for prosthetic devices that suit individual needs, promoting greater functionality and aesthetic appeal. Additionally, 3D printing enables modifications and adjustments to prostheses without significant expense, contributing to improved patient satisfaction and quality of life [5].

Studies assessing 3D-printed upper limb prostheses highlight the importance of evaluating their efficacy and limitations. While these prostheses offer promising benefits, challenges related to durability, material strength, and long-term user comfort require further exploration [7]. Continuous research aims to address these limitations, enhancing the durability and wearability of 3D-printed prosthetic devices.

In terms of increasing accessibility of 3D printed prosthetics, there is a trend of open-source design for additive manufacturing. Open-source 3D printing initiatives in the prosthetic field aim to promote accessibility and innovation [8]. These initiatives encourage collaboration, enabling the sharing of designs and advancements in prosthetic technology. They facilitate the development of cost-effective, customizable solutions, expanding access to prosthetic devices globally.

The field encompasses a range of 3D-printed prosthetic models, including functional designs and aesthetically appealing options [6]. These models vary in complexity and features, catering to different user needs and preferences, from simple externally powered bionic hands to more intricate designs like the Limb-Forge aesthetic models.

The current problem in manufacturing advanced bionic prostheses is that they often have too sophisticated designs, while being also enormously expensive, well beyond capabilities of typical patients. This problem is visible both to users, as can be concluded of authors' experiences with patients, and to the scientists and industry representatives [9]. However, switching into low-cost, rapidly manufactured mechatronic prosthetic devices also requires high engineering knowledge and such prostheses usually take long time to be designed, with low chance of translating single use-cases into more serial production.

Due to the problems in the subject, it was decided to use AutoMedPrint solution, allowing for automatic design and manufacture of orthopaedic products, to quickly design a basic version of a low-cost 3D printed mechanical prosthesis, which in a latter phase was re-designed and changed into mechatronic device. This study was conducted to evaluate feasibility of such way of conduct and test if it is possible to build cheap prosthetic devices with actuation possibilities for adult patients, having at least part of the process automated. The paper presents full development and evaluation process of these devices.

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3.2. Materials and methods

3.2.1. AutoMedPrint system and concept of the study

The AutoMedPrint system is used for automatic design and additive manufacturing of selected orthoses and prostheses based on patient anthropometric measurements. The system (Fig. 3.1) consists of a station for 3D scanning and design, a user interface station with applications supporting the scanning process and product configuration, and a station for rapid manufacturing [10].

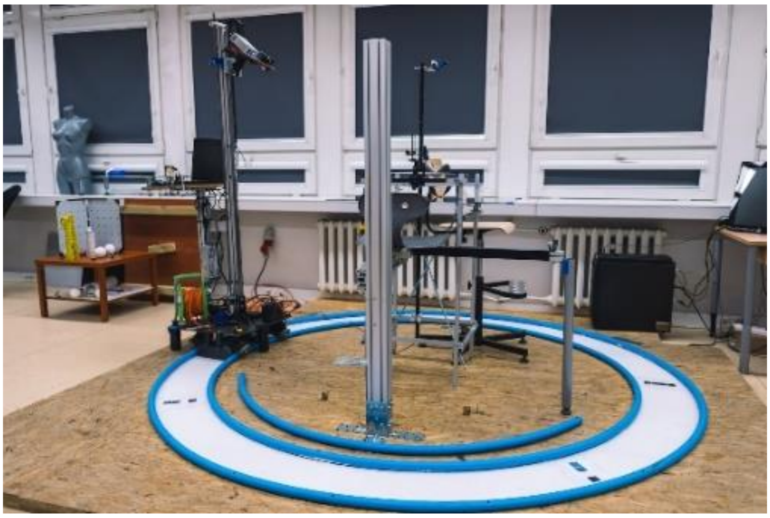

Figure 3.1. The AutoMedPrint system prototype – scanning rig

The design and manufacturing of products is based on 3D data, obtained by 3D scanning of human limbs using a specially shaped rig for placement of both healthy and amputated residual limbs. The data gathering process takes up to several dozen minutes. The time required to produce a finished product, including the design phase can take up to several dozen hours, depending on the type of product [10]. The system allows defining the type of product the patient needs, taking anthropometric measurements using a non-contact 3D scanning technique, automatically designing the product based on the patient's anthropometric data, designing and visualizing the product by the recipient, and preparing and executing the rapid manufacturing process [10]. The system's scheme of operation is shown in Figure 3.2.

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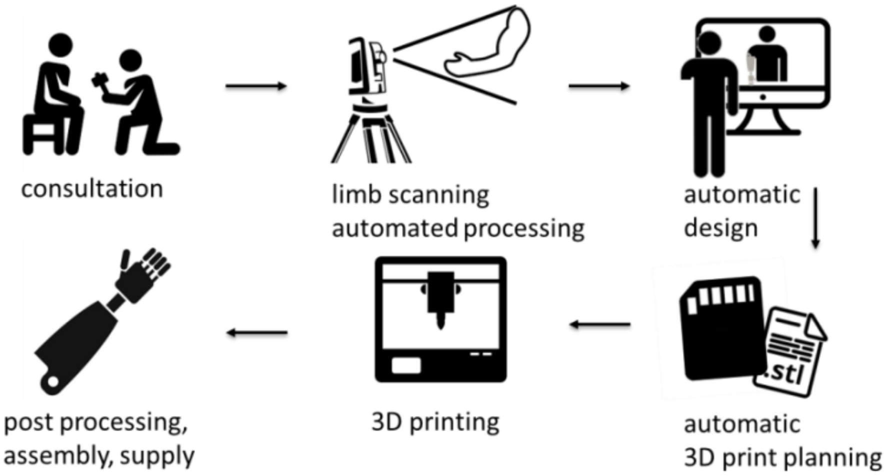

Figure 3.2. Scheme of work of the AutoMedPrint system [13]

The AutoMedPrint system is a solution that has been developed over last years by the team of authors and results of this development are presented in previous publications [10-13]. It gathered some awards such as Polish Product of the Future in year 2022. Currently, development of this solution has many directions, one of them being focused on building cheap, widely available sensorised and actuated devices – biomechatronic prostheses and orthoses.

The concept of the study presented in the paper assumes converting a mechanical device – a simple mechanical prosthesis, part of AutoMedPrint scope of operation – into a mechatronic one, by adding actuation in two axes (wrist rotation and gripper closing and opening) possible to be operated by buttons located in the prosthetic forearm. The plan of the realized activities is as following:

1. 3D scanning of the patient and building mechanical prosthesis using automated capabilities of AutoMedPrint system.
2. Design of mechatronic, actuated prosthesis in two separate variants using mechanical prosthesis as a basis.
3. Manufacturing of mechanical and electrical part and assembly.
4. Testing and expert evaluation of two concepts.

These stages will be described in more detail in further chapters of this study.

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3.2.2. Patient case description and manufacturing of mechanical prosthesis

The case was based on one of the test patients of the AutoMedPrint system. The patient was a 40-year old male with a missing forearm, with the functioning elbow joint (transradial amputation). The work was realized completely remotely, without meeting the patient, thanks to involvement of the Polish division of the e-Nable foundation. The stump was 3D scanned using a Structure Sensor portable 3D scanner, by an external specialist (not belonging to the team of the authors). Two positions were assumed – with straight and bent elbow. The data sets consisted in two separate triangular meshes, as presented in Figure 3.3.

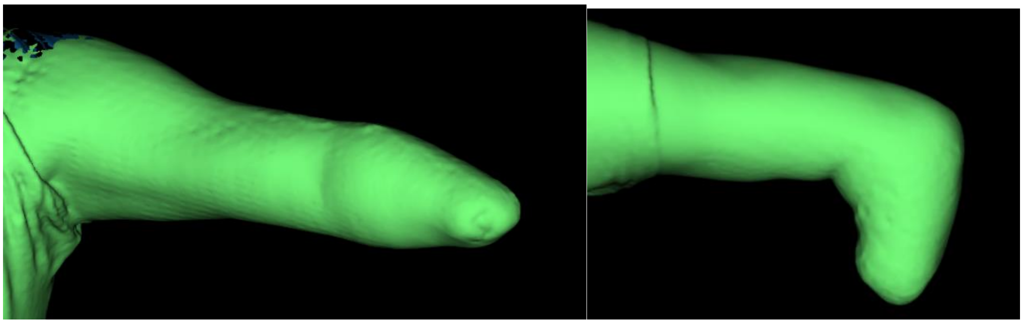

Figure 3.3. Input data of the basic patient – 3D scanned stump in two positions (obtained thanks to courtesy of e-Nable Polska foundation)

These data sets were used in the AutoMedPrint system as an input – after putting them in a correct coordinate system (by rotation and translation operations in MeshLab software), automated data extraction algorithms were run and the most important measurements were taken - lengths, widths, heights in specific areas of arm, with a total of eleven dimensions taken in the basic procedure. Two missing dimensions – lengths of forearm and hand – were assumed using available scans of another 40-year old male, already in AutoMedPrint database, and confirmed by checking appropriate anthropometric atlases.

Using the measurements realized on the mesh, basic version of a mechanical prosthesis (using the proprietary design, as in the patent claim [14]) was designed and 3D printed using Fused Deposition Modelling technology, out of PLA material. The prosthesis was then assembled and sent to the patient for fitting and testing, which was realized successfully – as presented in Figure 3.4b.

Figure 3.4. Mechanical prosthesis, a) design [15]; b) printed product tested by the patient

The prosthesis proven itself to be usable, but for the patient it lacked gripping possibilities to be more useful in daily life. That is why it was decided to create and prototype a mechatronic design, with possible actuation. The mechatronic conversion was realized in the scope of a diploma thesis [15] in scope of the EMERALD project. The thesis contains more detailed descriptions of all the design and manufacturing operations. It will be shortly presented in the following chapters of this study.

3.2.3. Design of mechatronic actuated prostheses

The first step of the mechatronic conversion of the original mechanical prosthesis was concept work. The following assumptions were made:

- actuation should allow both wrist rotation and closing/opening of the prosthetic gripper,
- all electronic components should be contained within the forearm part,
- control of the actuation should be realized through monostable buttons,
- actuators and electronic components should be as cheap as possible to obtain a working and usable prosthesis.

As a result of design work, consulted with experts in mechatronics, physiotherapy and biomedical engineering, two concepts were originated and decided to be subjected to prototyping and further evaluation.

In the first variant, a bilateral opposition of opposing robotic “fingers” is employed, meaning that both parts of the gripper are set in motion during opening. The specified maneuver is executed through a direct current motor. A worm gear (with 1:100 ratio) is mounted on its shaft, transmitting rotary motion to the wormwheel. The wormwheels are connected to the manipulators; thus, they are activated during motor rotations. The motor is installed in the wrist. Additionally, a servo mechanism is mounted in the wrist, rotating the entire wrist around its axis. The servo mechanism, PCB board, and power supply are installed in the forearm. Design of this variant is shown in Figure 3.5 – only the forearm, as the prosthetic socket (the part mounted on patient's arm) was not changed from the original mechanical prosthesis.

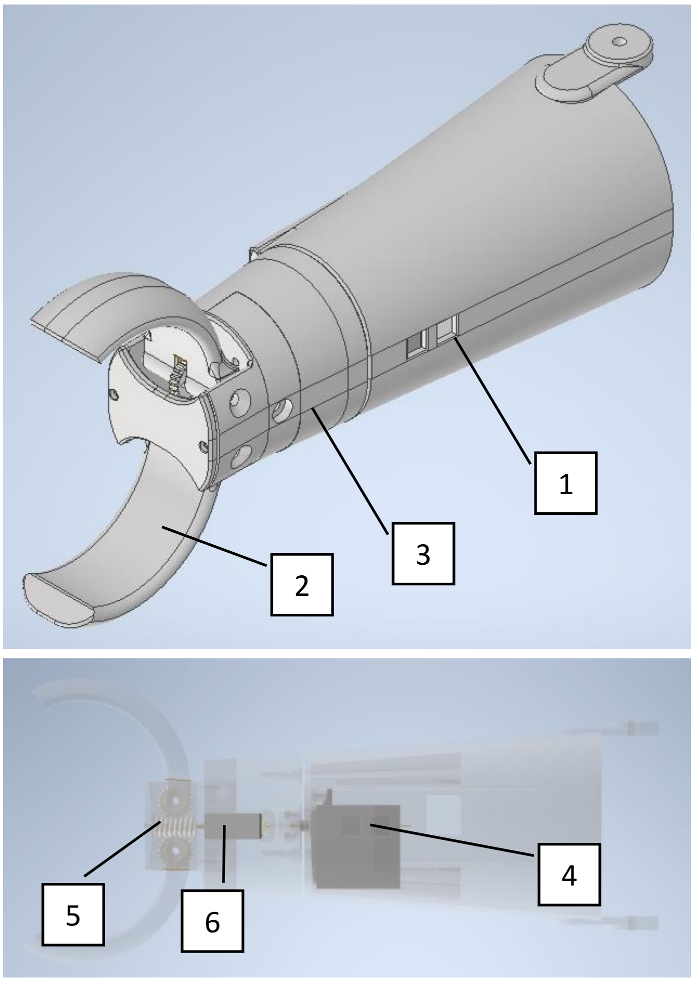

Figure 3.5. Mechatronic prosthesis – variant 1, basic elements: 1) forearm; 2) gripper; 3) wrist; 4) servo mechanism Feetech FT5325M; 5) worm gear; 6) motor HP 100:1 - Pololu 2214

The second prototype of the prosthesis is based purely on servo mechanisms (without motor and worm gear). Opposing fingers in this variant operate based on the servo mechanism's motion principle. An additional distinction involves the movement of only one lower manipulator, while the upper one remains permanently attached to the prosthesis. The opening of the lower gripper part has been programmed to occur in two stages. There are three positions for the gripper: closed, half-open, and fully open. This variant is presented in Figure 3.6. It is noteworthy that it has much less mechanical components (3D printed parts) than the first variant, due to lack of gearbox and need for making a proper encasing and mounting for the DC motor.

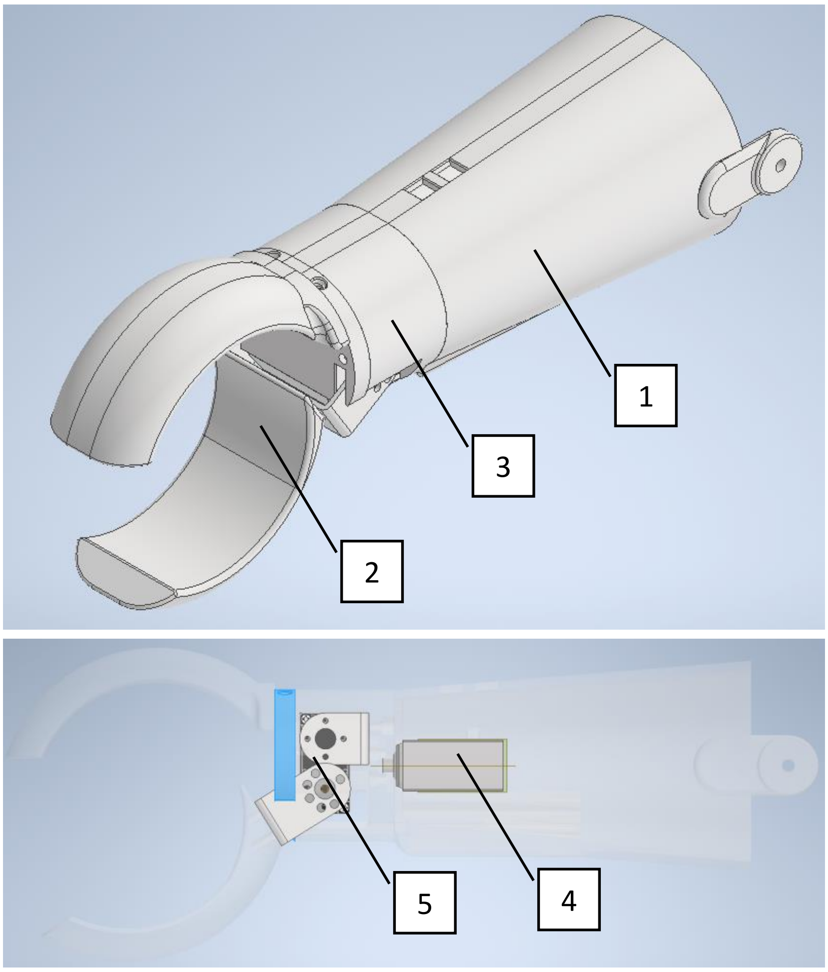

Figure 3.6. Mechatronic prosthesis – variant 2, basic elements: 1) forearm; 2) gripper; 3) wrist; 4) servo mechanism Feetech FT5325M; 5) servo mechanism Feetech FC-SRB-002

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In terms of other electrical and electronic components, the following were used in the prototype:

- Arduino Nano board (Atmega328),
- controller and encoders for the electric motor,
- monostable buttons for control,
- 9V battery as power source,
- power converters,
- custom PCBs.

Except the PCBs, widely available and cheap electronic components were used for building the electronic circuit of the prosthesis. The PCBs customized for variant 1 and 2 of the prosthesis are shown in Figure 3.7. They were made by the thermal transfer method, in laboratory conditions. Figure 3.8 presents schematics of the complete prostheses in both variants.

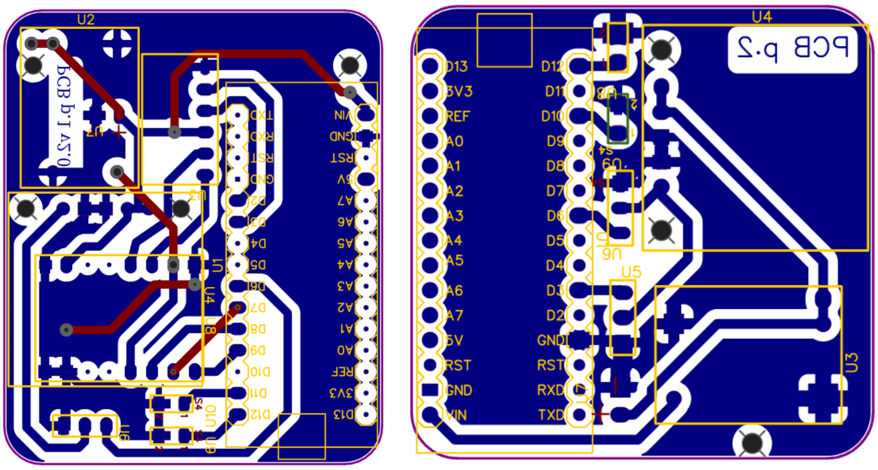

Figure 3.7. Custom Printed Circuit Boards for variant 1 (left) and 2 (right) of the mechatronic prosthesis

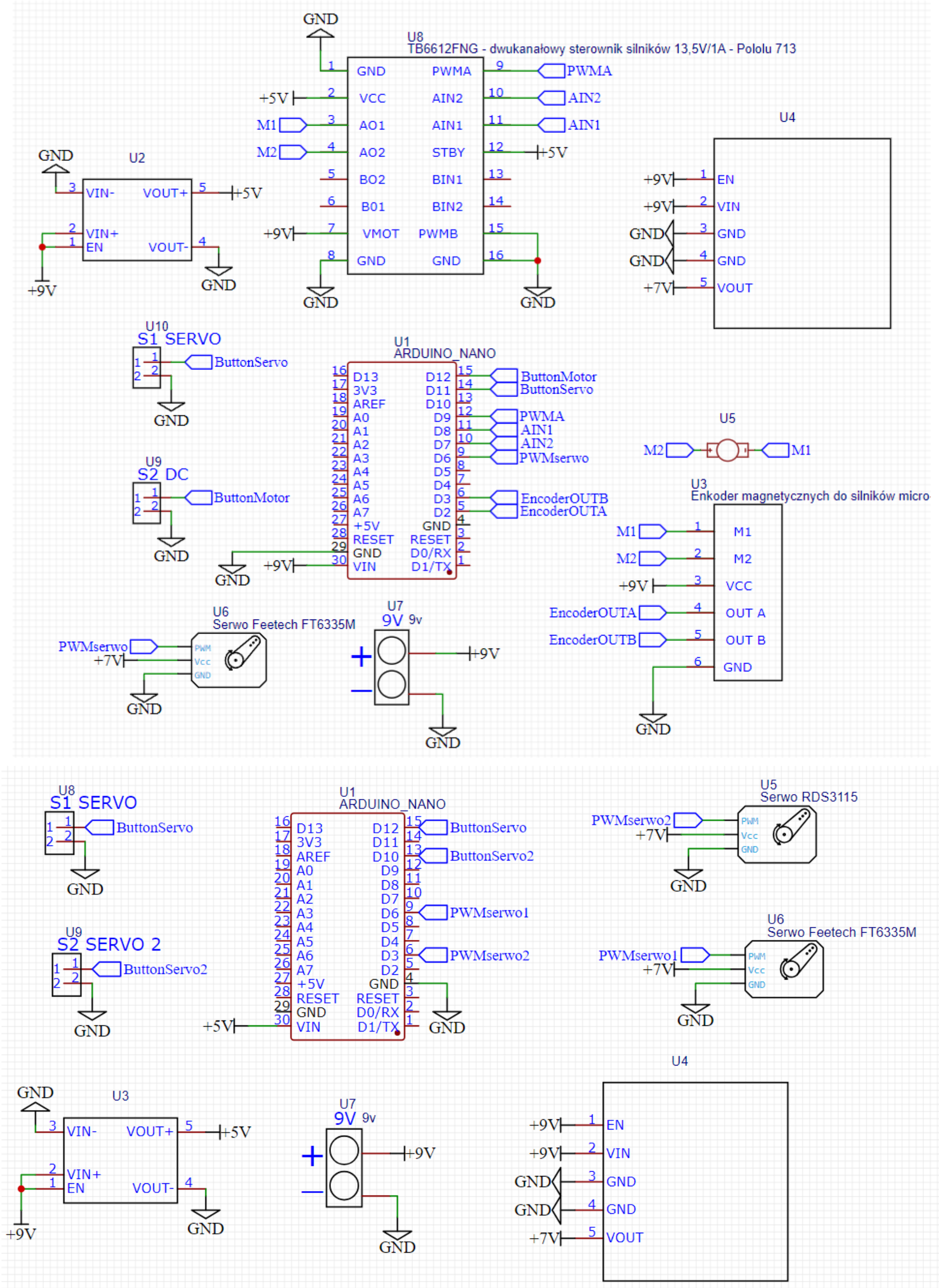

Figure 3.8. Schematics for variant 1 (top) and 2 (bottom) of the mechatronic prosthesis

3.2.4. *Manufacturing, assembly and programming*

Most of the mechanical elements of the prosthesis were made using FDM additive technology. This technology was used due to the idea of this work - the production of low-cost prostheses that are easily accessible to users. The prints were made of the basic filament, i.e. PLA material, with standard parameters (layer thicknesses between 0.2-0.25 mm, with infill percentages and contours adjusted to specific parts individually, using author's experience, between 25-35%). Two types of 3D printers were used during production. The first one is FlashForge Creator Pro. It is a machine with a closed working space and a heated table. The second printer is Ender 3 – low-cost printer with open working space. For the FlashForge machine, Simplify3D slicer software was used to plan the printing, while for Ender it was IdeaMaker. Figure 3.9 shows process planning in the slicer software, while Figure 3.10 presents FDM printing of selected components.

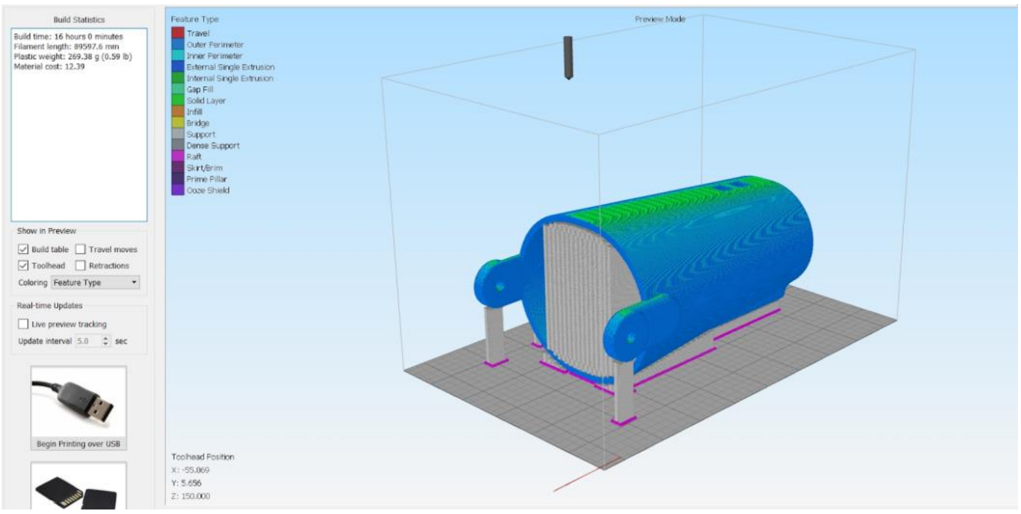

Figure 3.9. FDM process planning for the forearm part, Simplify 3D software

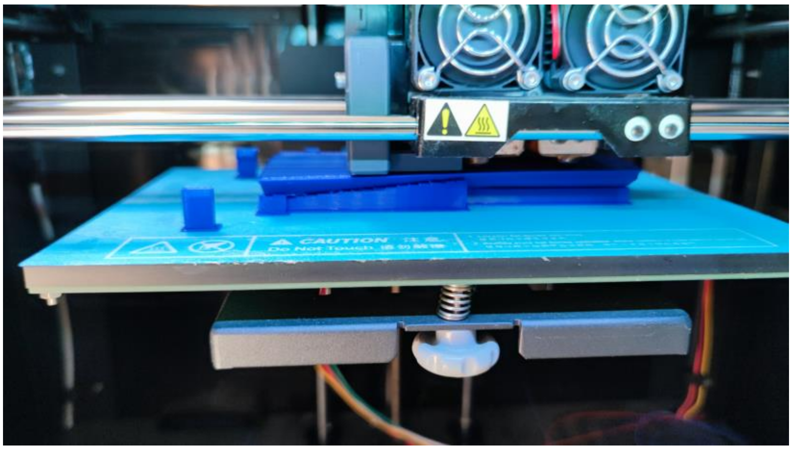

Figure 3.10. FDM 3D printing process (FlashForge Creator Pro)

In addition to FDM technology, PolyJet technology was also used to produce elements. It was used to produce a worm gear, which was used in the first variant of the prosthesis - the PolyJet process was used due to its small size and the need to precisely reproduce the geometry of the gear outline. The worm gear was produced in two copies (in case of damage during tests). In the final product, it could be replaced with a metallic worm gear (ready component, available for purchase). For PolyJet printing, Stratasys MediJet J5 machine was used, with a default UV resin – DraftWhite, with default settings (layer thickness 18 µm). The process was planned using GrabCAD software on a computer connected directly to the printer. After printing, waterjet was used to clean the printed parts of the support structure. Figure 3.11 presents the printed parts.

Figure 3.11. Parts printed using PolyJet technology (Stratasys MediJet J5)

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The main elements during the assembly of the prostheses were M2, M3 and M4 screws. It was decided to use Bossard BN1052 threading inserts to install the screws. Thanks to them, prosthesis can be screwed and unscrewed without excessive wearing of threads in the polymer material. Figure 3.12 shows both prosthesis variants at various stages of assembling.

Figure 3.12. Assembly of prosthesis, variant 1 (left) and 2 (right)

Programming of the prostheses was realized in the Arduino IDE environment, a dedicated program for Arduino boards. The program for variant 1 provides interactive control of the servo and DC motor using two buttons. When the servo control button is pressed, the servo rotates 90 degrees in one direction or returns to its home position if already rotated. The second button starts the DC motor and changes its direction of rotation. The program monitors the number of encoder pulses during rotation. The motor stops after a certain number of revolutions.

The program for variant 2 allows to control two servomechanisms using two buttons. When the first button is pressed, the first servo rotates in a specific sequence. After the first press of the button, the gripper opens halfway, then the jaws are fully opened, after the third press, the servo mechanism returns to halfway opening, the last sequence is the closing of the grippers. Then the cycle repeats. The full opening of the gripper is 60 degrees. The second button controls the second servo, which rotates between 90 and 180 degrees each time it is pressed. The program uses button debouncing to prevent accidental presses and eliminate the effect of button vibration. Both servos are initialized at specific positions and controlled by buttons.

3.2.5. Methodology of evaluation

The manufactured prototypes were evaluated by a group of 5 experts – mechatronic engineers, biomedical engineers and mechanical engineers, with industrial and/or scientific expertise in building of mechatronic and prosthetic devices. In the first part of evaluation, both models of prosthesis were tested and operated, as well as visually and structurally evaluated. Then, the experts filled a survey. In the first part of the survey, there were questions asked about specific features of each of two variants, answered in 5-point Likert scale. The questions were:

1. The prosthesis has good aesthetics.
2. The prosthesis has the appropriate gripper functionality.
3. Prosthesis is well designed to grip hard things (e.g. door handle, bottle)
4. Prosthesis is well adapted for cycling.

The second part of the survey included two questions about movement ranges of grippers and wrists of both prosthesis variants. Three answers were possible (too broad, too narrow, appropriate). In the last part, 4 comparative questions were asked, where the experts had to choose between the two variants. The questions were:

1. Which prosthesis concept better meets the design requirements?
2. Which prosthesis concept has greater comfort of use?
3. Which prosthesis concept is rated as more reliable in performance?
4. Which prosthesis concept should be referred for further development work?

At that stage of development, patient was not involved in testing and evaluation of the produced prototypes.

3.3. Results

3.3.1. Manufacturing, assembly and functional testing

The manufacturing processes ran without greater disturbances. In one attempt at manufacturing a gripper part using Ender machine, it failed due to layers not joining to each other at one point. The other prints were successful, with minor errors and defects visible at the surfaces of parts. Also, some damages were found, most notably a broken extension for elbow coupling. These defects can be easily fixed with proper post processing (e.g. grinding, gluing etc.). Times of manufacturing, however, were slightly larger than the planned times (in the case of forearm – almost one hour longer than according to the created program). All the notable defects are presented in Fig. 3.13.

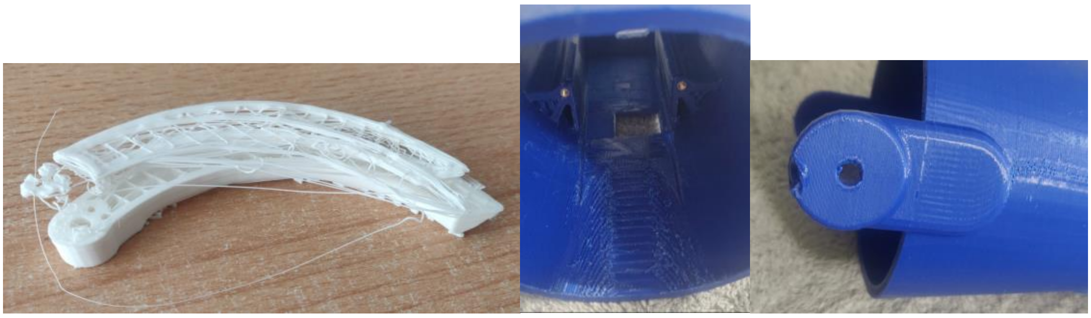

Figure 3.13. Defects of FDM manufacturing processes (from left to right: malformed gripper, surface defects of forearm, broken and glued elbow coupling extension)

The assembly of the both variants was possible and realized without problems, with parts fitting each other with acceptable dimensional and shape accuracy. The assembled prostheses are shown in Figure 3.14.

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Figure 3.14. Assembled prostheses (without the – arm part), variant 1 (top) and 2 (bottom)

The created programs were also verified successfully in numerous tests. The programmed sequences of opening and closing were realized without disturbances or blockings. When testing gripping and lifting of hard, relatively heavy objects, it was noted that both variants are able to do it, as shown in Fig. 3.15. However, variant 2 seemed to be better suited to such tasks – variant 1 mechanisms had tendencies to block. Moreover, worm gear printed using PolyJet was quickly subjected to wear, which caused it not to operate properly. Seemingly, friction resistance of UV resin used in this technology is too low. Another observation is that the used 9V battery has too low capacity – it only allowed for less than 20 minutes of continuous operation. Instead, a powerbank should be used, with greater capacity than the battery.

Figure 3.15 Functional tests, variant 1 (left) and 2 (right)

3.3.2. Evaluation results

The main results of evaluation, in terms of answers to the 4 Likert scale questions, are presented in Table 1 and Figure 3.16. In terms of questions about the movement ranges, no detailed results will be shown – surveyed experts assumed that the range is appropriate, in exception of gripper of variant 1, where the opening is assessed as too wide by some experts. Figure 3.17 presents answers to the final questions, where the surveyed experts had to select one variant of two.

Table 1. Evaluation results – function of prostheses

	1-Aesthetics	2-Gripper function	3-Grasping hard objects	4-Cycling
Variant 1	4.0	4.0	4.2	4.0
Variant 2	4.0	3.0	4.6	4.4

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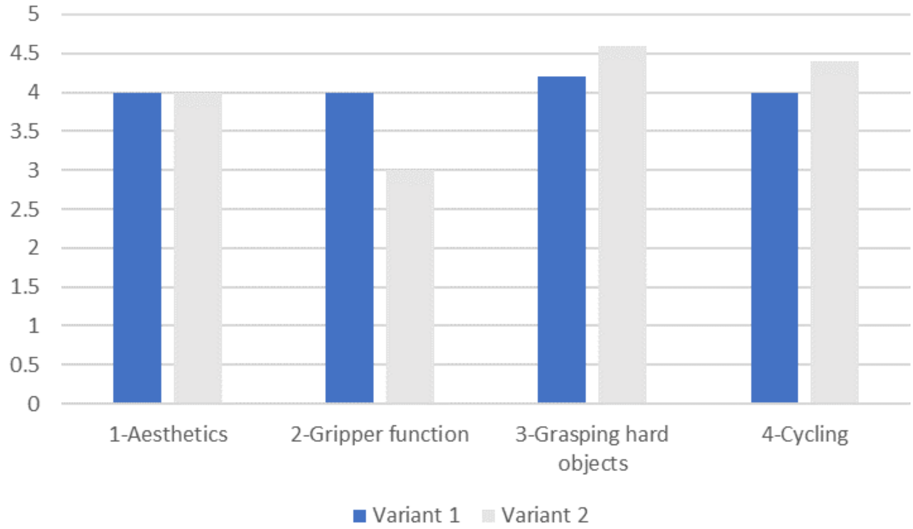

Figure 3.16. Prosthesis evaluation results in a group of experts – functions

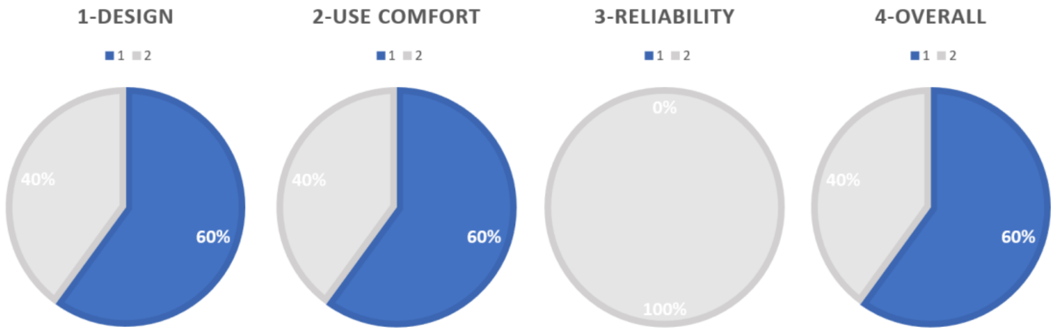

Figure 3.17. Prosthesis evaluation results in a group of experts – general evaluation

Analysing experts' opinions, the following observations can be made:

1. The aesthetics of both variants are at the same, acceptable level.
2. Variant 1 has better gripper functionality, although its range of opening is slightly too large.
3. Variant 2 was evaluated as slightly better for both grasping of hard objects and cycling than variant 1, which is a bit in contrary to the answers to question 2. However, it may point out that the variant 1 has more universal gripper, usable for many other purposes.
4. In terms of fulfilment of design requirements and use comfort, variant 1 was selected a bit more frequently than variant 2.

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5. Variant 1 was evaluated as unreliable, with 100% answers in that question pointing to variant 2. It is understandable, due to fact of wear of polymeric worm gear and blockades of mechanism – which can however be counteracted by using metallic gears to prevent it.
6. Most experts pointed the variant 1 as the one that should be selected for further work and development, however it was not unequivocal – as such both variants could be considered worth developing.

The variant 1 is a device that is more complex than variant 2 – it has more parts and also more potential sources of malfunction. In the overall assessment it is also more expensive to make. Variant 2 is simpler and economically more effective, while still having a possibility to fulfil most requirements of the patients. As such, the evaluation is not unequivocal and both variants need to be further developed and tested, most of all, with patients, to test if the prosthesis could be actually usable in daily life. A potential solution might be integration of both variants, to obtain a third variant with advantages of both initial solutions.

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4. Summary

In conclusion, the results of the study showed that it is possible to build a low-cost mechatronic actuated upper limb prosthesis using partially automated workflow and cheap 3D printers. The constructed prosthetic devices are fully functional, with certain disadvantages and problems that can be solved in further design iterations. It is intended to do so in the further work, also considering improvements to the control method of the prosthesis gripper and wrist – current method is a very basic one and it would be advisable to test some other methods more intuitive for the patient (such as use of myoelectric control or touch buttons located in the stump socket).

Future work will focus on development of more robust, reliable and usable prosthetic devices, tested along with potential patients (both adults and children), with maintaining of the automated design approach and low-cost rapid manufacturing.

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