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EUROPEAN NETWORK FOR 3D PRINTING OF BIOMIMETIC MECHATRONIC SYSTEMS

CASE STUDY #1

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 #1 – Sensorized bicycle prosthesis**
Date of Delivery	**June 2023**
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Version	**1.0, 10.06.2023**

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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 #1 focuses on a biomechatronic upper limb prosthesis, for patients with transhumeral defect/amputation (without functioning elbow joint). It was proposed to convert a mechanical prosthesis into a mechatronic device by enhancing it with sensors, for possible gathering of information on its use and improving the design, as well as closely monitor activities undertaken by the patient for therapeutic purposes.

Originally the prosthesis 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 [1] and in papers [2-4].

2. Case study #1 - methodology

2.1 Research concept and plan

This paper presents a research on new, proposed concept of biomechatronic hand prosthesis A modular 3D printed individualized prosthesis was considered, with its adjustment to needs and preferences of an adult patient and converting static mechanical device into a mechatronic prosthesis, equipped with sensors for monitoring the activities performed by prosthesis user.

The initial concept of the prosthesis was made as part of the project "Automation of design and rapid production of individualized orthopedic and prosthetic products based on data from anthropometric measurements", serving the development of the prototype AutoMedPrint system [2], continuing previous long-term studies by the authors.

The prosthesis has been prepared for continuous and demanding cycling for an adult patient. The modular mechanical prosthesis was originally made for child patients (and successfully implemented, as described in [2] and [3], Figure 1).

Figure 1. Basic concept – low-cost 3D printed bicycle prosthesis made for child patients [3]

Basing on the initial concept of the modular prosthesis model, necessary changes were made to adapt it to an adult. After testing and optimizing the bicycle, the adult mechanical prosthesis was transformed into a mechatronic one through sensorization. The designed prosthesis was 3D printed, assembled and programmed. It was simulated for strength using Finite Element Method and after assembly, testing with the patient was performed. Course of the studies described in this paper with basic characteristics of each stage is presented in the scheme in Figure 2.

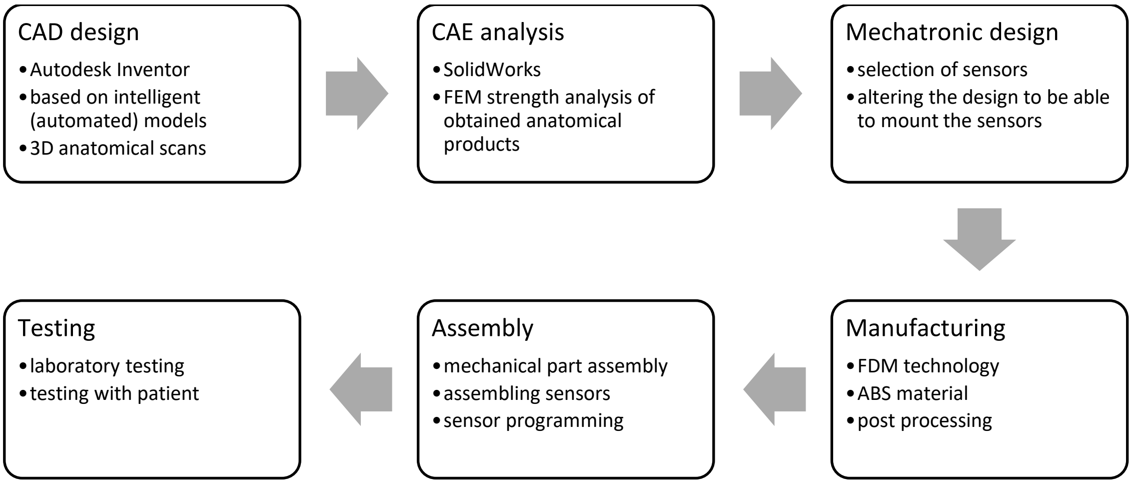

Figure 2. Research stages with basic technical information

2.2 Background – prosthesis design and patient case description

The design was commenced starting off with a project of an intelligent model of the upper limb prosthesis, which is characterized by a modular structure. The device is an integrated whole composed of many elements with unified connections. The model is loaded with anthropometric and configuration data directly from an external Excel file, enabling both the generation of anatomically matched prosthesis components and the manipulation of its variants to create any combination of all parts. Therefore, the model allows for the quick and fully automated production of many configurations of individualized prostheses for the same or many different patients. It is presented in Figure 3 in its basic variant, containing a compressive-release socket (CRS [4]), a forearm with elbow joint and C-shaped end effector with Cardan joint at the wrist.

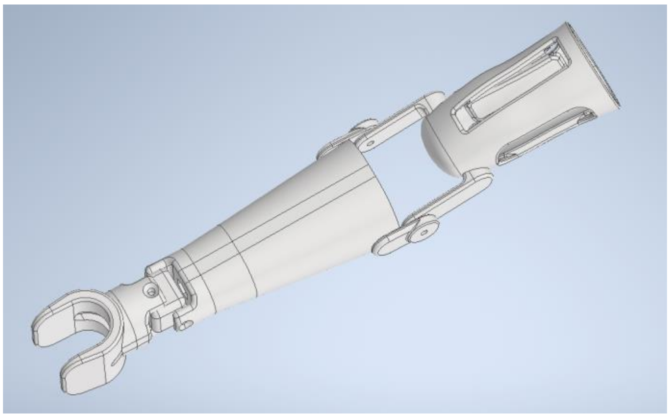

Figure 3. Basic variant of an intelligent CAD model created in Autodesk Inventor [5]

The prosthesis model was adapted to adult patient. A case of 40-year old male patient was selected for the studies. The patient was born without his right forearm (no functioning elbow joint). Both of patient’s upper limbs were 3D scanned (Figure 4) and the resulting data was automatically processed, using AutoMedPrint system hardware and software capabilities (as described in [1-2]).

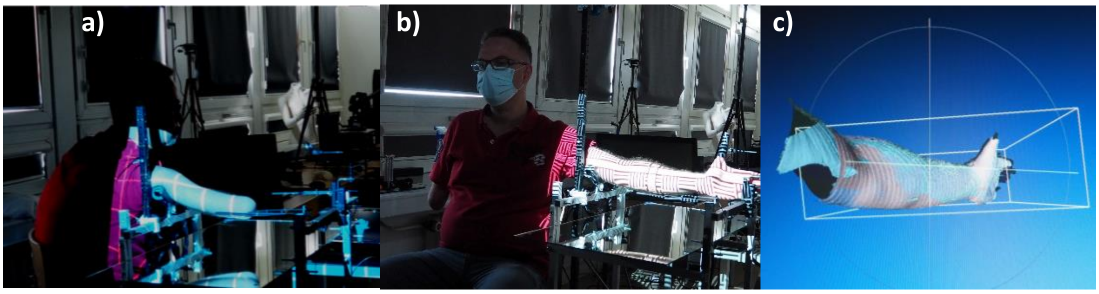

Figure 4. 3D scanning of patient: a) stump; b) healthy arm; c) mesh data during processing

In the preliminary studies, the initial version of prosthesis was manufactured and tested by the patient. After minor corrections (for strength improvement) it was tested in real conditions by the patient riding the bicycle (Figure 5). These tests were positively concluded and the patient was given the prosthesis for longer use, to obtain feedback regarding further construction and use issues.

Figure 5. Tests of initial, mechanical version of the prosthesis, a) laboratory tests, b) usability tests

In the course of numerous tests and subsequent design iterations (considering patient's comments and usage reports, as well as authors' observations), the following modifications have been introduced in the mechanical part of the prosthesis:

1. The CRS socket was modified as a result of removing the movable connection in the elbow joint. It was connected to the forearm rigidly due to too much load in the case of an adult The mounting plane was moved away from the tip of the socket to a properly selected distance, mounting hardware was added to allow connection to the forearm (Figure 6a).
2. The forearm model has been changed as a result of abandoning the movable joint in the elbow joint. It was filled in with material for better strength. Five mounting holes and two access holes were added (Figure 6b).
3. The C-handle has been modified by extending the jaws and narrowing the distance between them. These changes were introduced after patient's feedback - they increased the stability and comfort of cycling. In addition, the connection used in the wrist was abandoned - the lack of a joint resulted in an increase in stiffness with the simultaneous impossibility of rotation. This was possible after adjusting the angles for a given patient and his bicycle (Figure 6c).

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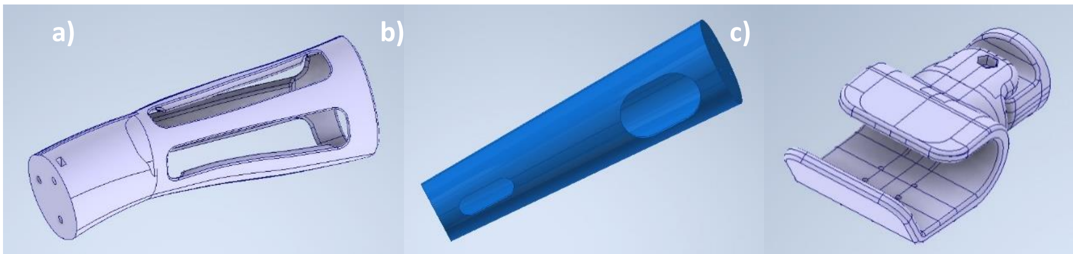

Figure 6. Modifications introduced to prosthesis mechanical parts

The improved prosthesis, well-proven in use, was a base for the actual research on sensor-equipped prosthesis, described in the further parts of this case study.

2.3 Strength analysis

The final design of the prosthesis was subjected to strength analysis prior to equipping it with sensors. ISO 22523 standard was used here – recommended scheme of loading was taken from there [6]. The objective of this test was to evaluate the strength characteristics of the prosthesis by simulating a distal tensile test with the SolidWorks Simulation finite element analysis (FEA) module included in the SolidWorks CAD package. The principle of the test is shown in Figure 7. The prosthesis model was subjected to a distal traction load after being firmly attached to a rigid support that fits inner surfaces of the upper arm. The traction load gradually increases from 0 (zero) to 750 N in five steps. The main purpose of the simulation was to make sure that the prosthesis is safe for the user and detect possible locations of fractures. If the FEM detected any higher stress ratio than the safe rates for the given material, changes in the design would have been introduced.

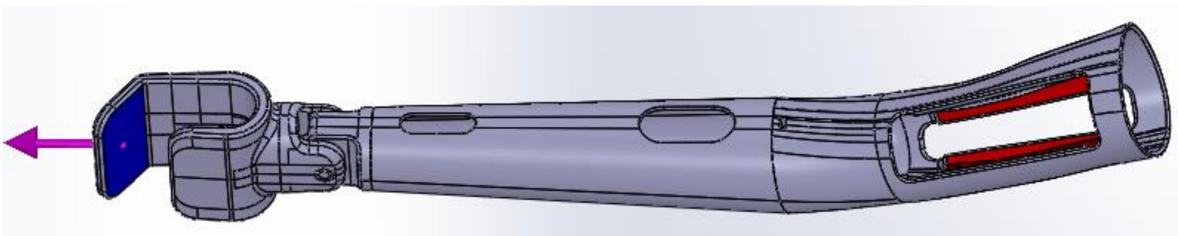

Figure 7. Principle of the distal tensile test simulated for evaluating the strength characteristics of the upper-limb prosthesis (red surfaces – regions where the upper arm is firmly attached to a rigid support; blue surface – support of the traction load)

The following hypotheses were adopted when preparing the finite element model of the tensile test:

- The prosthesis components are made of ABS exhibiting an isotropic linear elastic behavior. Table 1 lists the physical and mechanical properties of this material that are relevant for the finite element model of the tensile test.
- The prosthesis components are bonded together along their contact surfaces.

Table 1. Physical and mechanical properties of ABS (source: "SOLIDWORKS Materials" library)

Mass density ρ [kg/m^3]	Elastic modulus [MPa]	Poisson's ratio [-]	Tensile strength [MPa]
1020	2000	0.394	30

The displacement (deflection), force and stress quantities manipulated by the FEA model are expressed using the following measurement units: displacement (deflection) – millimeter [mm]; force – Newton [N]; stress – megapascal [MPa] (1 MPa = 1 N/mm^2). The FEA test was prepared using the following assumptions:

- locking boundary on inner surfaces of the compressive release prosthetic socket (Fig. 8), compatible with places where the socket firmly sits on patient's arm,

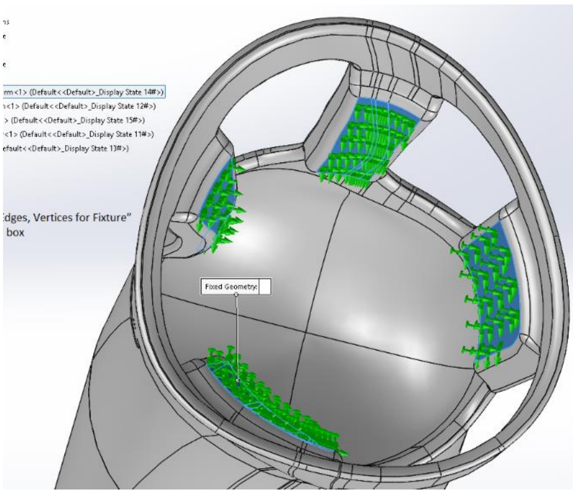

Figure 8. Full locking boundary conditions defined on some inner surfaces of the upper arm

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- five cases of loads (150 N, 300 N, 450 N, 600 N and 750 N), set as a distributed force located in the inner lower surface of the end effector (as visible in Fig. 7),
- tetrahedral mesh, generated using „Fine" setting of the SolidWorks Simulation module, resulting in small size of finite elements for better resolution of results (Fig. 9).

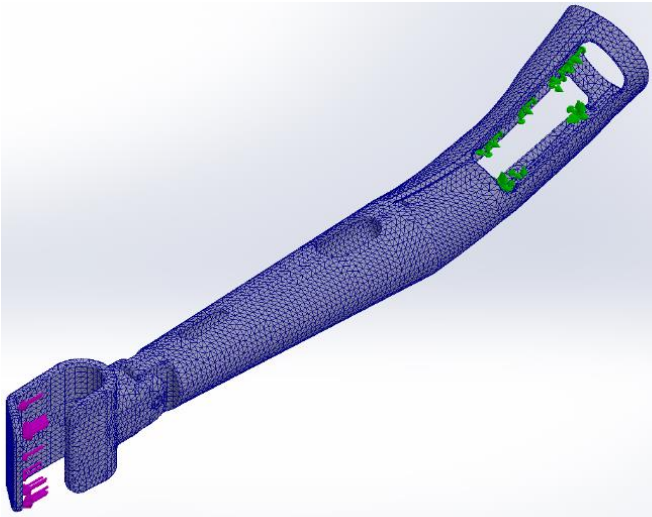

Figure 9. Finite element mesh generated by SolidWorks Simulation

The simulation was conducted using the above mentioned settings. As a method of determining simulated stresses in the prosthesis, von Mises equivalent stress was selected. Values of the stress were checked all over the volume of prosthesis and evaluation was made to find out if the prosthesis is safe for use in the real conditions.

2.4 Concept and design of electronic part

The aim of this part of the presented work was to modify the hand prosthesis in order to create a biomechatronic device, used by human, with monitoring of activities performed in the prosthesis (mostly cycling or similar activities). The main concept was placing an electronic measuring system in the prosthesis, thanks to which it would be possible to determine its operating properties. The detailed purposes of the built electronic system were to:

- enable measurement of the orientation of the upper limb prosthesis in space,
- enable measurement of the force exerted in the prosthesis while riding the bicycle,
- enable storing data on the SD card.

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The device consisted of the following components:

- microcontroller module (Arduino NANO),
- force sensor measuring amplifier module (HX711 with force sensor up to 200N),
- inertial sensor module (BOSCH BNO055),
- Arduino SD card module,
- power source (a USB connected powerbank).

The components were selected to fulfil their role in the simplest possible manner, ensuring robust operation, steady and stable communication, as well as maintaining as low price as possible (as the whole prosthesis is a low-cost project, as mentioned in the research concept). The schematic diagram of the designed device is shown in the Figure 10.

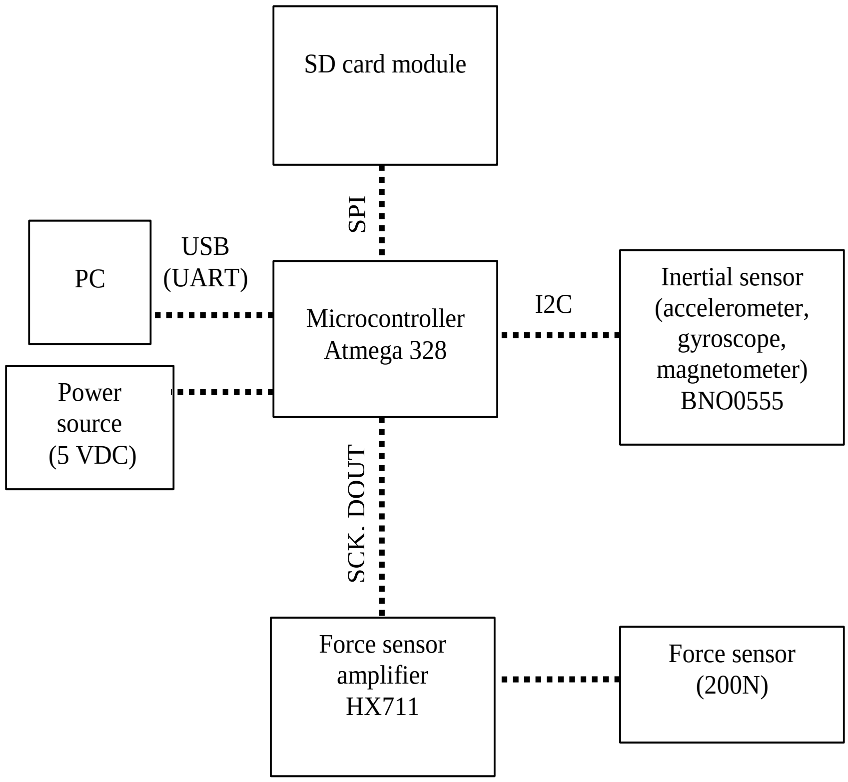

Figure 10. The schematic diagram of the electronic part of the prosthesis

The final mechanical version of the prosthesis CAD model was modified, to be able to fit the electronics of the prosthesis inside it, in a manner allowing steady riding on a bicycle or similar device, without risk of disconnecting or otherwise damaging the components, as well

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as not making them disturb the patient during the activities. The following main changes have been introduced to the design:

- the forearm was modified to enable mounting of the microcontroller, inertial sensor and SD card module inside cavities of the forearm – insets were created with holes, for self-tapping purposes (Figure 11)

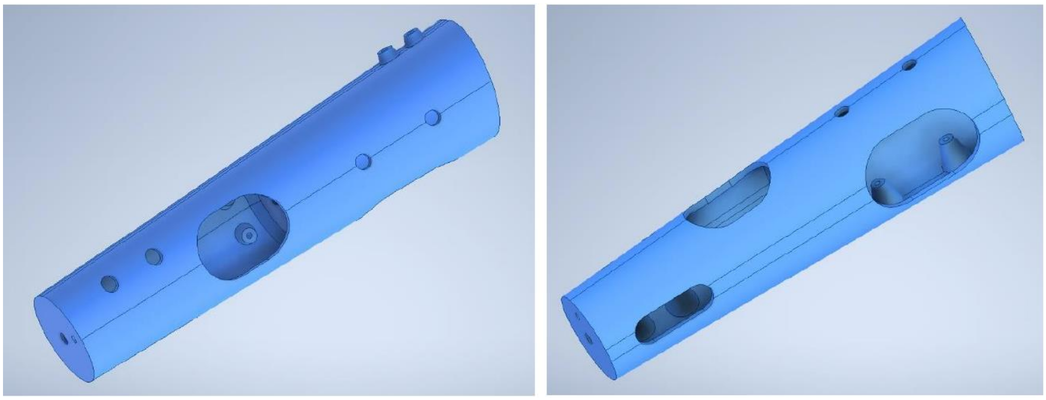

Figure 11. Modified forearm – visible mounting places for electronic components

- at the joint of forearm and socket, insets were added for mounting of the force sensor (beam) – the place (elbow) was selected to easily detect the torques and forces during the bicycle ride
- a number of assembly holes and cable feedthroughs were added to enable unproblematic assembly of the electronic part inside the prosthesis.

Final version of the CAD model of the prosthesis is shown in Figure 12.

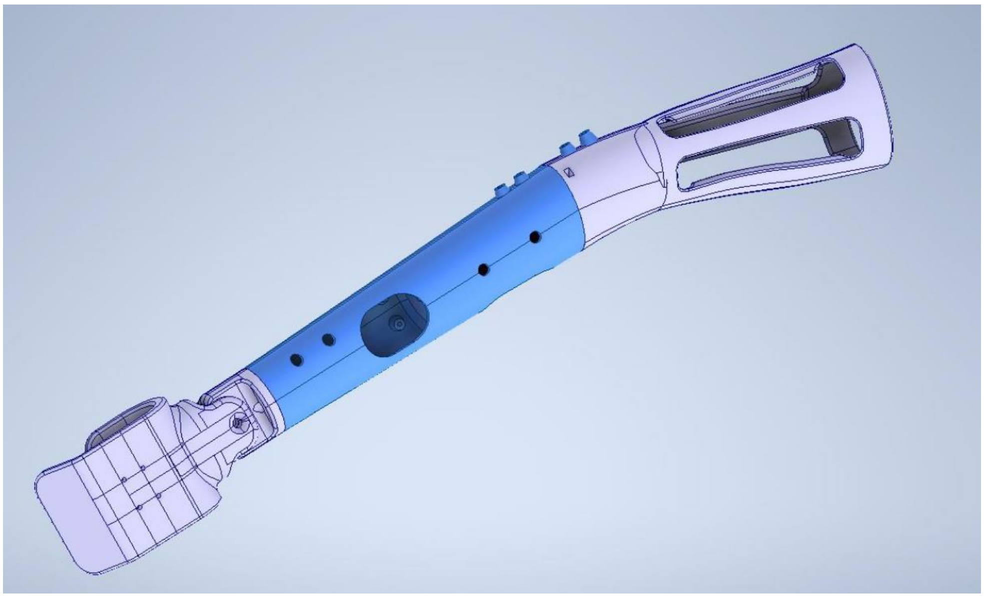

Figure 12. Final CAD model of the biomechatronic bicycle prosthesis

2.5 Manufacturing

The designed prosthesis parts in their final version were manufactured using a Zortrax M300 Dual machine (Zortrax, Olsztyn, Poland). The M300 Dual is an upgraded version of the original Zortrax M300, offering dual extrusion capabilities. Key features of the Zortrax M300 Dual include dual extrusion, large build volume (265 x 265 x 300 mm, with a 0.4 mm diameter nozzle) and compatibility with variable materials, including Zortrax's proprietary filaments as well as third-party filaments that meet the required specifications. This machine can be classified as a semi-professional 3D printer, with an approximate purchase cost of $4 490 (as of 2023).

For manufacturing of mechanical parts of the prosthesis, ABS material was used (Spectrum Group, Pęcice, Poland), in the form of 1.75 mm-diameter filament. Material processing characteristics (based on the material supplier data) are presented in Table 2.

Table 2. Characteristics of used materials and FDM process parameters.

Name	Properties	Process Parameters
ABS (Acrylonitrile-Butadiene-Styrene) Red / black	Density: 1,02 g/cm3 Extrusion temperature range: 240-270 °C	Extrusion temperature: 270 °C Build platform temperature: 90 °C Extrusion velocity: 60 mm/s Number of contours: 3 Number of closing/opening layers: 4/4

Constant material parameters were kept during manufacturing of all parts – layer thickness was 0.2 mm and the internal filling was 30%. The temperatures and extrusion speeds were selected on the basis of the most suitable values recommended by the producer, slightly modified by authors' previous experiences (bringing the most stable process, without layer disjoint, under-extrusion or other typical errors in the FDM process). The values of other manufacturing parameters (not shown in the Table 1) were assumed standard as recommended by machine and material manufacturers.

The printing of the prosthesis was divided into two batches - first the prosthetic socket was printed alone, and then the other elements. The programs were prepared in the Z-Suite program - dedicated to work with Zortax printers. The prosthetic socket was manufactured in the appropriate orientation so as to obtain the best possible quality of the inner surface, which is ultimately in direct contact with the residual limb. The expected print time was 21 hours, and the estimated material consumption was 210 g. The remaining parts of the prosthesis (forearm with holes for electronics, C-handle and cardan) were printed simultaneously, which significantly reduced the production time. The expected print time was approx. 30 hours, and the material consumption was 333 g. Figure 13 shows both prints as simulated in the Z-Suite software and also printer during the process.

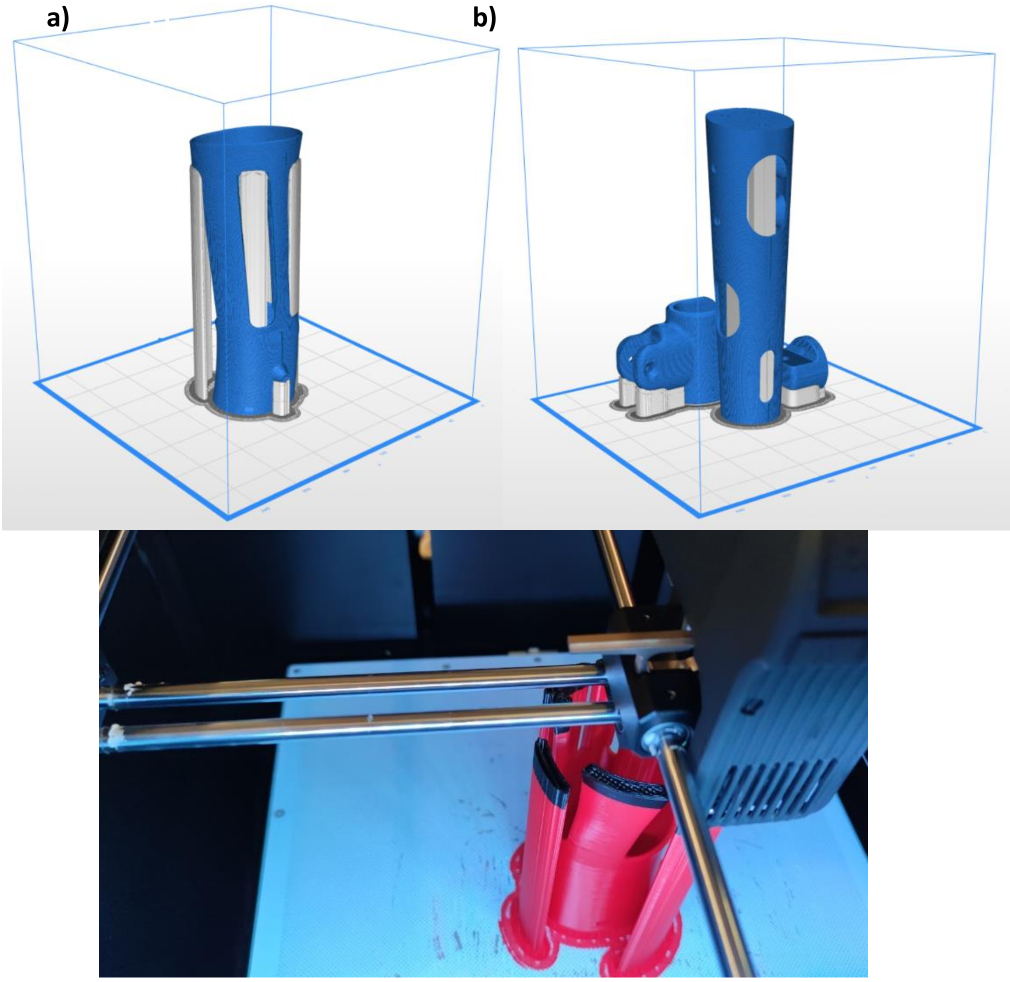

Figure 13. Printing processes of the mechatronic prosthesis, a) planned batch #1; b) planned batch #2; c) batch #1 during printing

The manual post processing of the obtained products was limited to the simplest activities: support removal, basic manual grinding and thermal removal of excess strings of material. The produced parts were visually assessed during and after the process to check for major defects that would make them unusable and minor defects that would require certain processing in order to make the prosthesis functional or more comfortable. They were further used for assembly of complete prosthesis.

2.6 Assembly and programming

The most important components of the mechanical part of the construction were produced using additive manufacturing methods and then assembled into the final product using standardized connecting elements, such as screws and nuts. During the assembly, only basic workshop tools, such as metric wrenches, pliers, and screwdrivers were used.

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The assembly of the electronic part was more complex and time-consuming. Due to the significant criterion of the prosthesis cost, generally available and inexpensive electronic components were used. The terminal outputs were soldered into the Arduino module (Figure 14). The same was done with the BNO055 module (accelerometer, gyroscope, and magnetometer). In order to ensure better connection and reduce disturbances resulting from the assembly method, the force sensor was directly soldered into the HX711 amplifier module (Fig. 15).

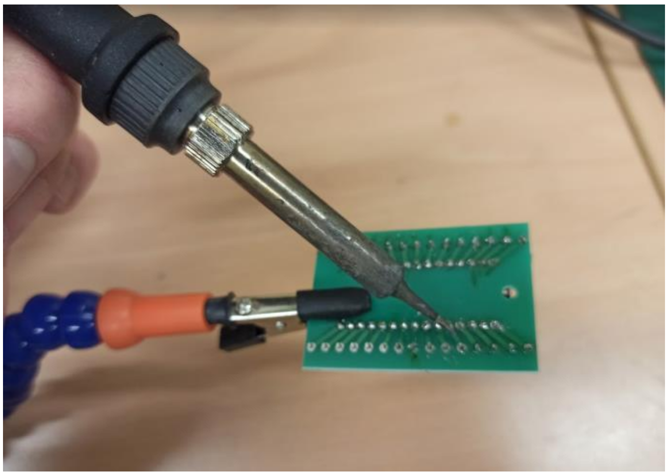

Figure 14. Terminal outputs soldered to the Arduino module.

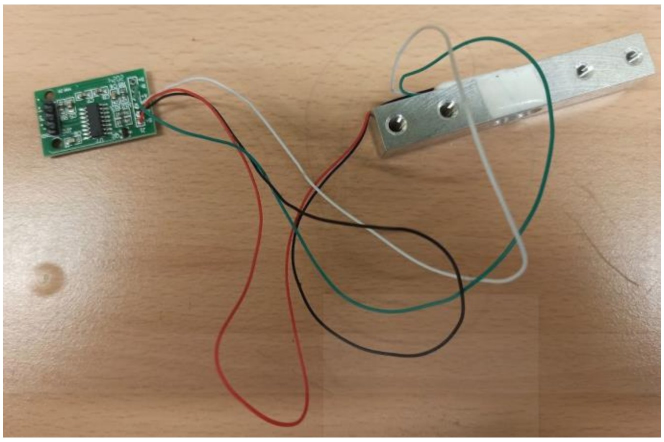

Figure 15. Force sensor soldered to the HX711 module.

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Finally, the electronic components were connected to each other according to the diagram shown in Figure 16. Components ready for connection and basic testing are presented in Figure 17.

The electronic components were connected to the mechanical part of the prosthesis using screws and adhesive connections. The major volume of parts of the electronic system was able to be housed within the cavities of the forearm of the prosthesis. The force sensor had an initial pre-tension due to the small variations in mounting hole spacing between the CAD project and additively manufactured parts, which was then taken into account by the data collection method.

Powering the electronic system requires two different voltages. The SD card reader operates at a voltage of 3.3V, while all other components require a voltage supply of 5V. The battery power is connected to the Arduino module via the USB connector, which converts them to the appropriate values for each of the connected modules.

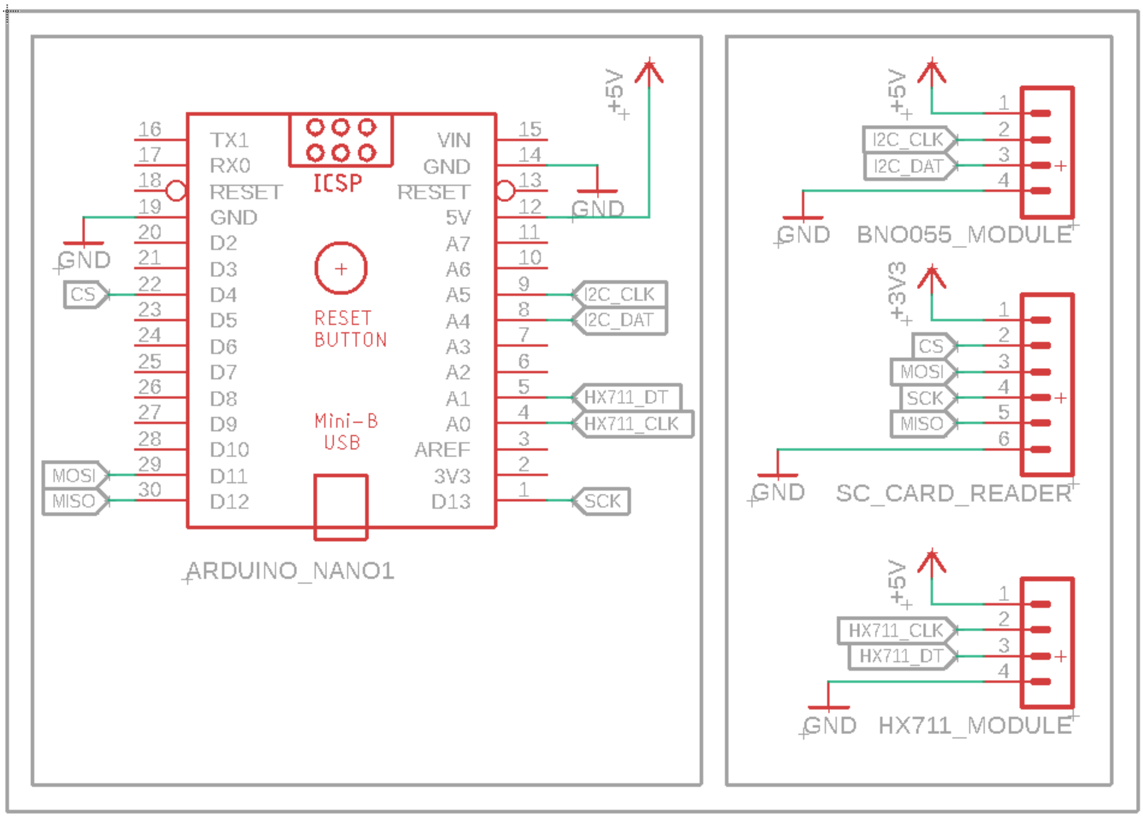

Figure 16. Wiring diagram of the electronic system of the prosthesis

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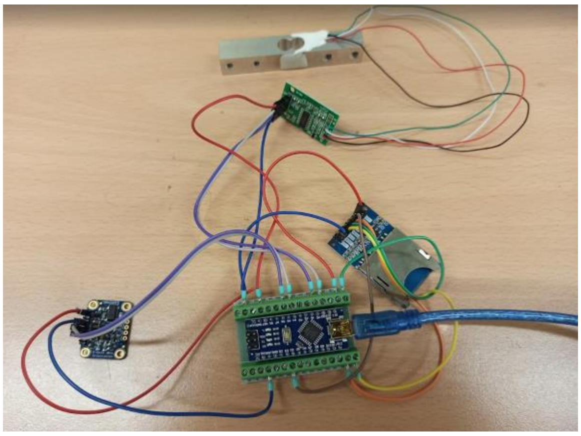

Figure 17. Complete electronic part – all elements connected

The programming of the control code for the prosthetic electronic component was accomplished using the Arduino programming environment version 1.8. The use of pre-existing libraries such as "SPI", "SD", "BNO055", "Wire", and "HX711" significantly simplified the entire process. Although the Atmega328 microcontroller used in the project has the capability to run timers, data collection from the sensors could also have been accomplished easily using cyclical loops.

The BNO055 inertial sensor module had to be initialized before the working loop. Its main advantage is the ability to directly convert quaternion or Euler angle values from the sensor without the need for microcontroller filtering. The I2C bus was used to connect the sensor, allowing reading of different data including absolute orientation, angular velocity, linear acceleration, or temperature.

All measurement data are read by the microcontroller program and sent serially to be eventually stored on the SD card. The datafile consisted of lines. Each line started with a timestamp, followed with three recorded Euler angles, followed with a recorded force value (Fig. 18).

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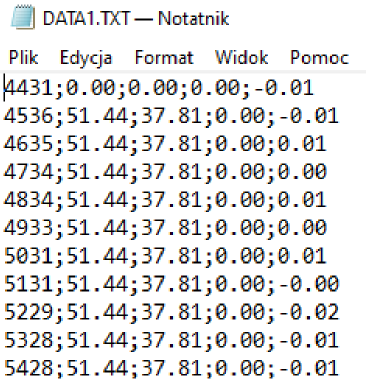

DATA1.TXT — Notatnik

Plik Edycja Format Widok Pomoc

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Figure 18. Structure of the data file

2.7 Testing procedure

The first phase of testing was laboratory procedure, realized without patient. Initially, the prosthesis was connected to the power source – a powerbank – via USB cable (Fig. 19).

Figure 19. Prosthesis during laboratory tests with power source connected.

During that phase of tests, sample data was recorded. The prosthesis was tested by the researchers, by moving it around in various random patterns and applying various forces, simulating resting on handlebar, static loading (slight bending and compression) as well as dynamic loading (slight hitting). To generate the visualization of the data, MatLab software was used. After confirming proper recording of sensor data, further tests were planned and realized.

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The second phase of testing involve working with patient. First stage was fitting tests, where the prosthesis was tested by the patient for comfort, weight and general fit. It was also compared to a purely mechanical prosthesis, to check if adding the electronic components influenced the use comfort and easiness.

In the second stage of patient testing, the patient was invited to perform tests on actual device. An electric scooter was used as a reference vehicle. In the first attempt, the patient wore the prosthesis and tried it with the vehicle, to check if everything is correct mechanically. Then, after slight modifications were introduced to the angular position of the end effector (to adjust the prosthesis for the specific vehicle, used by the patient for the first time), the patient performed actual testing with data recording. It consisted of three separate tests:

1) static test with up-down movement of the prosthesis towards the vehicle handlebar (Figure 20),

2) static test with right-left movement of the prosthesis along the vehicle handlebar (Figure 21),

3) dynamic test - ride along a straight route, of approximately 25 meters – but the patient was asked to drive in a circular manner (simulating maneuvering around obstacles).

During both static and dynamic tests, data sets were recorded by the prosthesis sensors. These data sets, similarly as in the case of laboratory tests, were visualized using MatLab and compared, to check if the recordings match the actual course of patient's movement.

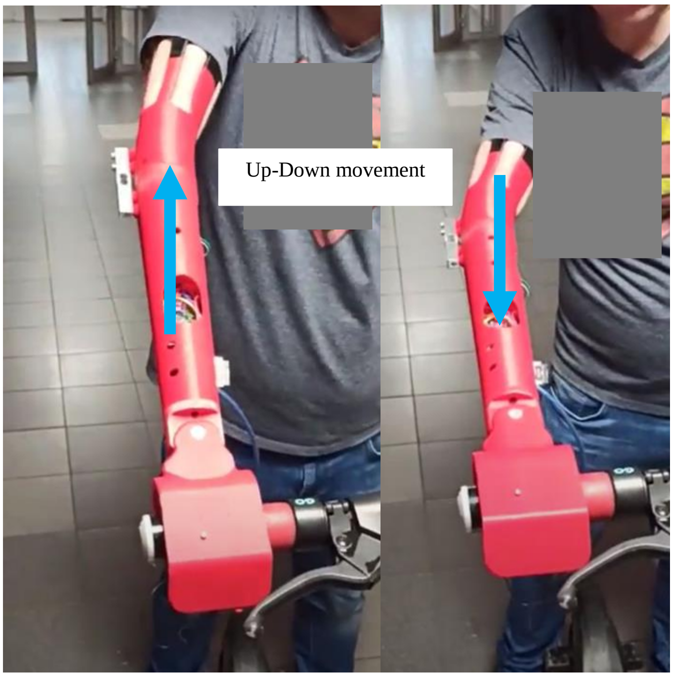

Figure 20. Static test #1 – up-down movement

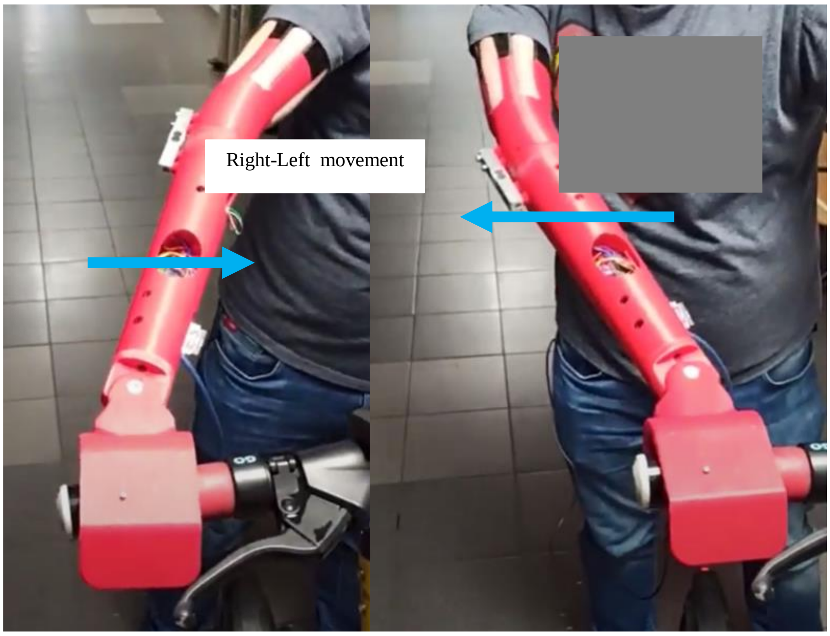

Figure 21. Static test #2 – right-left movement

3. Results

3.1. Strength simulation results

The main results of FEM calculations are presented in Figure 22 (fifth, highest case of loading – 750 N) and Table 3. The table presents the maximum values of the von Mises equivalent stress $\sigma_{eq,max}$, the maximum deflections d_{max}, and the traction forces F corresponding to different load cases.

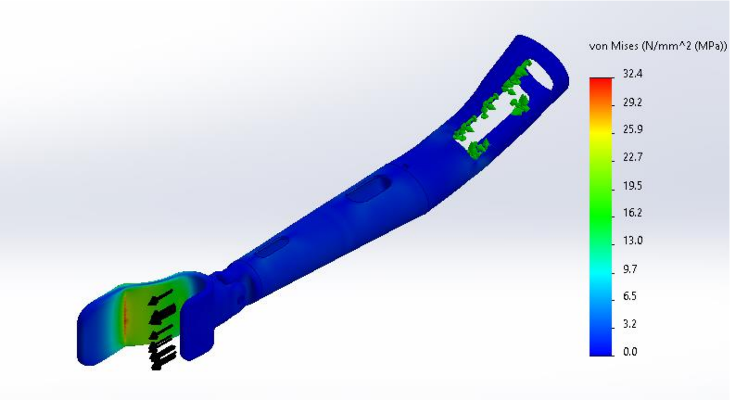

Figure 22. Color map showing the distribution of the von Mises equivalent stress at the level of the entire assembly (fifth load case: traction force of 750 N)

Table 3. Traction force, maximum value of the von Mises equivalent stress, and maximum deflection corresponding to different load cases

Load case	Traction force F [N]	Maximum value of the von Mises equivalent stress $\sigma_{eq,max}$ [MPa]	Maximum deflection d_{max} [mm]
1	150	6.48	2.263
2	300	12.97	4.525
3	450	19.45	6.788
4	600	25.93	9.050
5	750	32.42	11.310

The plots in Figures 21 and 22 show the dependencies $\sigma_{eq,max}$ vs F and d_{max} vs F, respectively. Both diagrams allow noticing that the mechanical response of the prosthesis is linear. In fact, the dependencies $\sigma_{eq,max}$ vs F and d_{max} vs F are well approximated by the regressions

$$\sigma_{eq,max} = 4.323 \cdot 10^{-2} \cdot F, \quad (1)$$

and

$$d_{max} = 1.508 \cdot 10^{-2} \cdot F, \quad (2)$$

respectively (see the black lines in Figures 38 and 39).

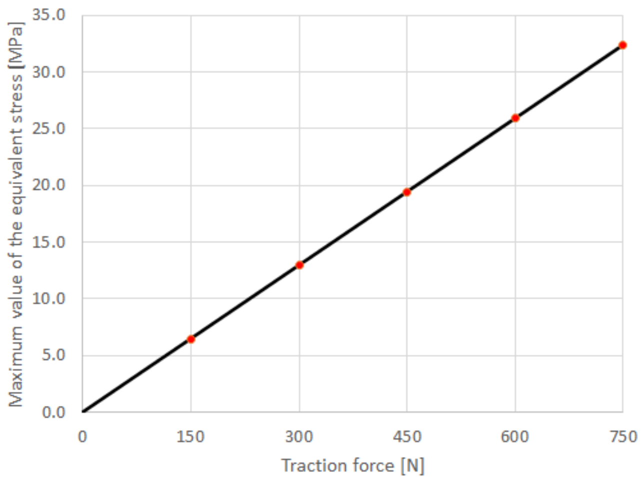

Figure 23. Dependence $\sigma_{eq,max}$ vs F: red dots – numerical results taken from Table 2; black line – linear regression defined by Eq (1)

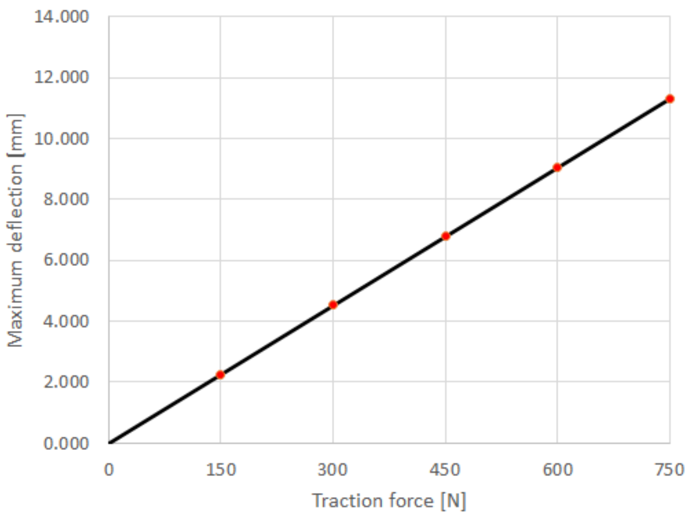

Figure 24. Dependence d_{max} vs F: red dots – numerical results taken from Table 2; black line – linear regression defined by Eq (2)

It can be easily seen in Table 2 and Figure 38 that $\sigma_{eq,max}$ equals the tensile strength of the ABS material (30 MPa – see Table 1) for a traction force 600 N < F_{cr} < 750 N. This critical load results from Eq (1) as soon as the replacement $\sigma_{eq,max}$ = 30 MPa is made:

$$F_{cr} = 30 \cdot 100 / 4.323 = 693.96 \text{ N.} \tag{3}$$

When interpreting results, two main considerations need to be taken into account:

1. The load of 750 N is impractical and will probably never occur while using the prosthesis as intended. It would require an equivalent mass of ~75 kg to hang off the prosthesis end effector, which would be impossible to bear by the patient and the socket would probably slide off the stump first before the prosthesis was actually damaged.
2. The simulation does not consider dependency of properties of ABS material manufactured using FDM technology on layered deposition process parameters, such as build orientation or layer thickness and many others, noted in many publications [7]. The real tensile strength of ABS (as well as impact and bending strengths) would be therefore significantly lower than the declared values by the producer, depending mostly on build orientation and also other process parameters.

Also, it is important to notice that only one loading scenario was considered in the analysis – with other load types and locations, different areas of prosthesis could be in danger of breaking. Special attention should be paid to the wrist joint area, as the nut and bolt connection could be also a weak point when loading the prosthesis.

As such, effective recommended load, in authors' opinion, should not exceed the third load case (450 N) and the equivalent stress in prosthesis mechanical parts made using FDM technology should not exceed 20 MPa, to avoid risk of breaking or otherwise damaging the prosthesis mid-activity. The force sensor should be able to answer what are the real loads during the prosthesis use.

3.2 Manufacturing and assembly results

All the parts were manufactured successfully at first attempt. As expected, the printing time was about 21 hours for the socket and about 33 hours for the other elements, with the material consumption also generally compatible with the initial estimation. The obtained model required additional post-processing consisting in removing the supports produced during printing. All the parts were manufactured in a stable manner, without any large errors or deformations. Minor problems occurred at one end of the forearm (contact surface with the socket part) – it was slightly deformed and needed some manual post processing for better fitting and strength.

The assembly process started with putting together mechanical parts of the prosthesis, starting from the end effector (modified C-shape), with a simplified wrist joint connecting it to the forearm part. The assembled module is presented in Figure 25.

Figure 25. Prosthesis forearm and end effector assembled together.

The second step was putting together the electronic system and placing it inside cavities of the forearm. At this step, some adjustments were made to assure better fitting and also access to the mounting elements, so that disassembly of mechanical components of the prosthesis is possible without removing the electronic part (easy access with tools). Also, cable feedthroughs had to be made slightly wider, to accommodate for the cable connections between modules. These efforts are presented in Figure 26.

Figure 26. Assembly of electronic components – putting microcontroller in central hole.

In the three cavities in the prosthesis forearm, the following electronic components were placed:

1) the first narrow hole near the wrist was used for SD card reader and output of USB cable for power source (Figure 27a),
2) the second, central hole at the forearm was used as a hosting place for the main microcontroller (Figure 27b),
3) the third, widest opening near the connection to the socket was used to mount the force sensor controller and the IMU device (Figure 27c).

The assembly required using standard manual and power tools. Also, to some electronic connections needed to be reinforced by soldering.

In the final stage of the assembly, the socket was assembled together with the other parts. This was made mechanically, with screws. After joining the parts together, the force sensor was screwed to the both parts. As there were slight discrepancies in mounting hole distances between project and printout, the force sensor had an initial pre-tension, which was then accounted for in the data gathering algorithm. The complete prosthesis is shown in Figure 28.

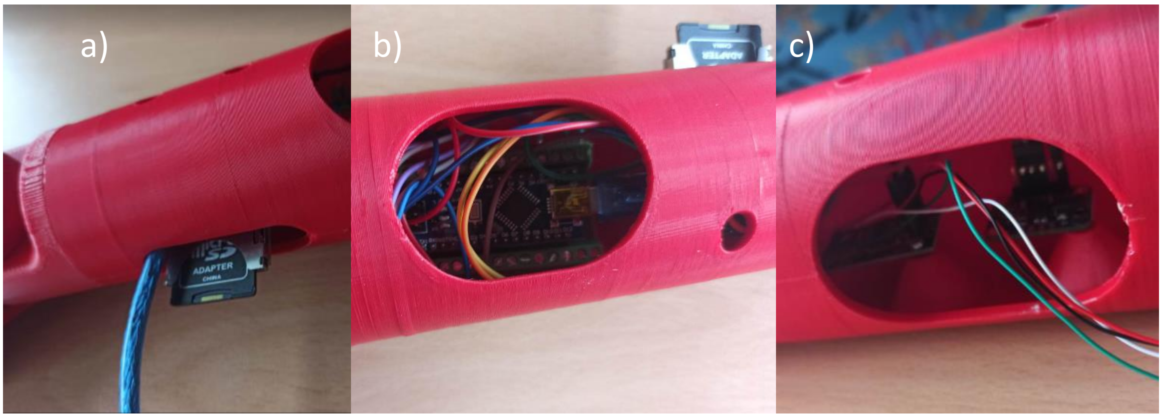

Figure 27. Electronic measuring system mounted in the prosthesis, a) SD card reader and power input, b) main microcontroller, c) IMU and force sensor electronics.

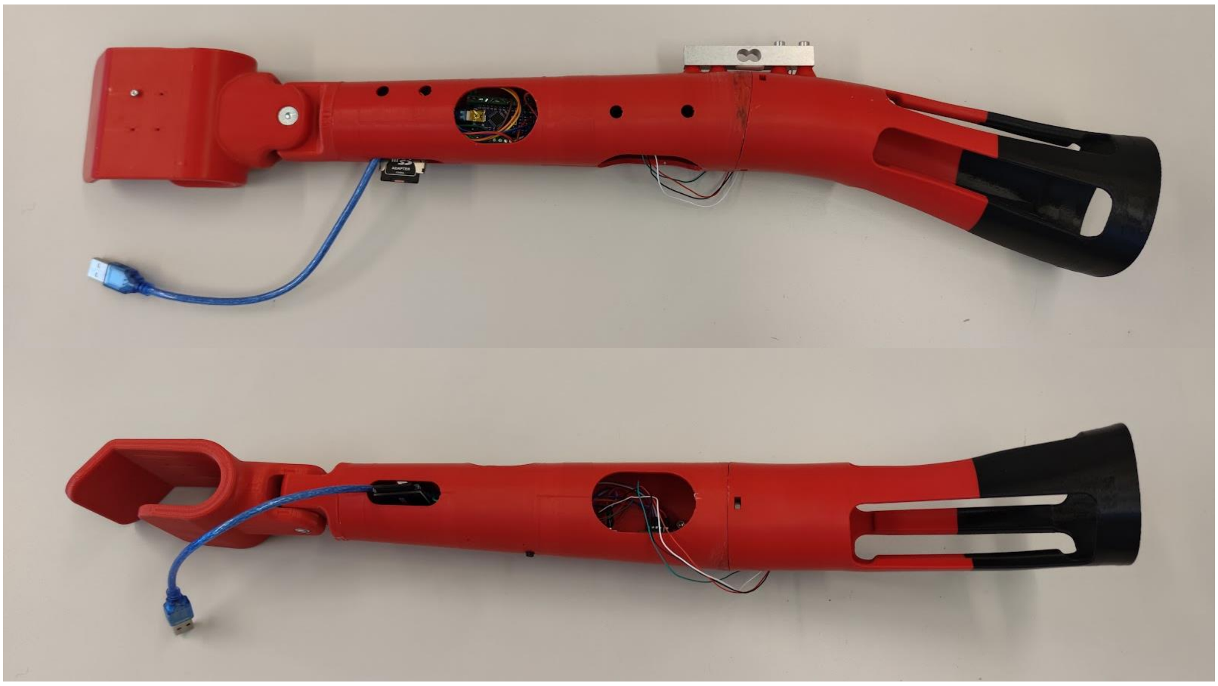

Figure 28. Complete assembly of the mechatronic prosthesis

Table 4 contains summary of working times of subsequent stages of prosthesis development as assumed for a single patient, excluding the design phase.

Table 4. Summary of working times

No.	Stage	Time elapsed [h]
1.	3D scanning and data processing	0.5
2.	3D printing of parts	54
3.	Post processing and mechanical assembly	0.5
4.	Electronic part assembly	1
5.	Coding and testing	6
6.	Assembly of electronic and mechanical part together	1
	Total	63

3.3 Testing results and discussion

The data obtained from laboratory testing (two exemplary courses) are presented in Figures 29 and 30. It is visible that all the events were registered correctly, both in terms of

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position and force change. It is noteworthy that the registered forces with simulated usage are very low (not exceeding 4 N). However, no dynamic scenarios (such as hitting against hard objects, or lifting a heavy weight) were considered at this point, so that was to be expected.

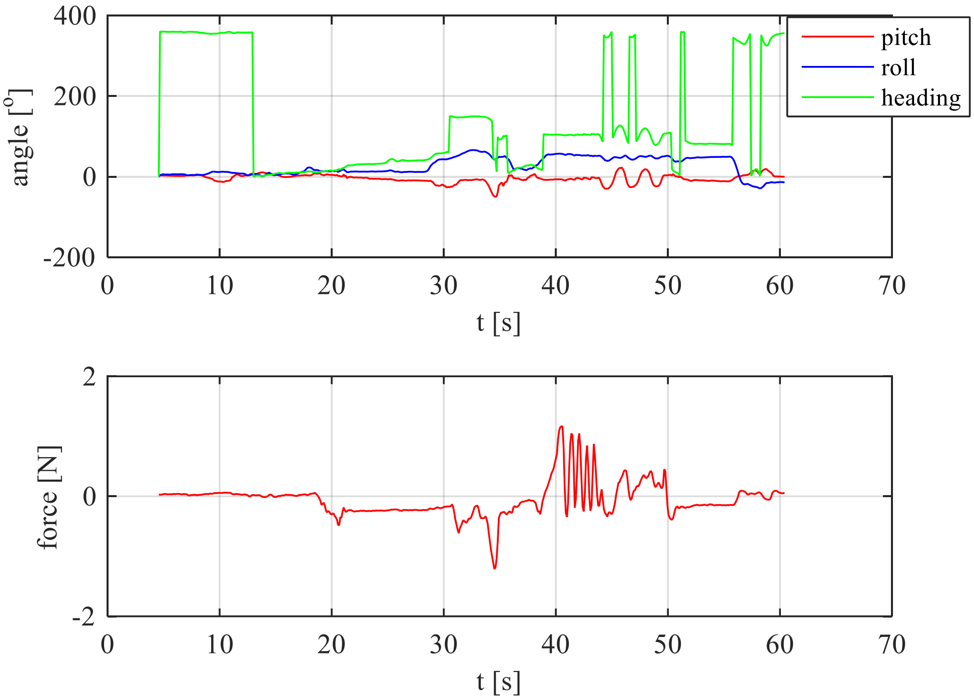

Figure 29. Sample data collected during laboratory tests – course #1.

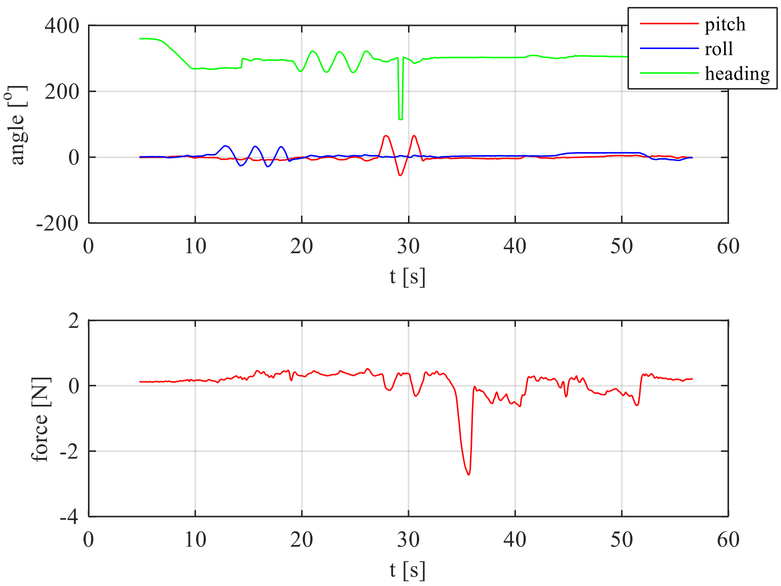

Figure 30. Sample data collected during laboratory tests – course #2.

The tests with the patient went without disturbances, the prosthesis worked as expected and was comfortable for the patient, who was able to operate the vehicle without any problems. However, it was observed by the patient and the researchers that the electronic parts (especially the beam and SD card reader) stick outside the prosthesis main shell and could interfere with the clothing (long sleeves). Also, proper covering would be needed to prevent damage to the electronics via unfavorable atmospheric conditions (such as rain or snow).

The photographs of this testing phase are shown in Figures 31 and 32.

Figure 31. Initial try-on of the biomechatronic prosthesis.

Figure 32. Tests of the prosthesis with the patient.

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The data was gathered properly, without any breaks and improper data points. The data plots recorded from two static tests and the dynamic test (ride) are presented in Figures 33-35.

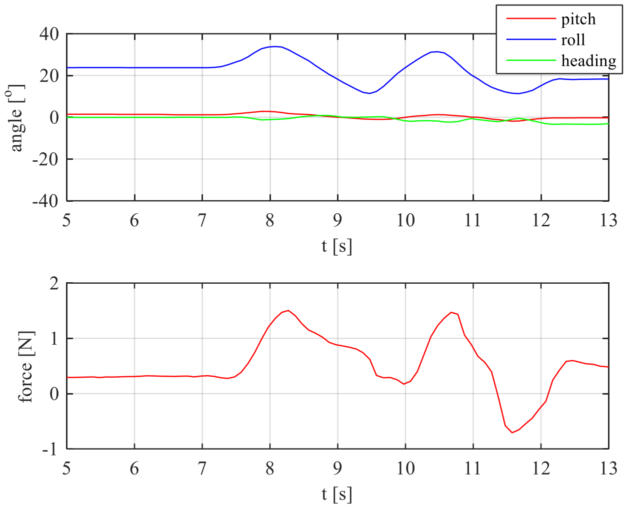

Figure 33. Data registered in static test #1 – up-down movement

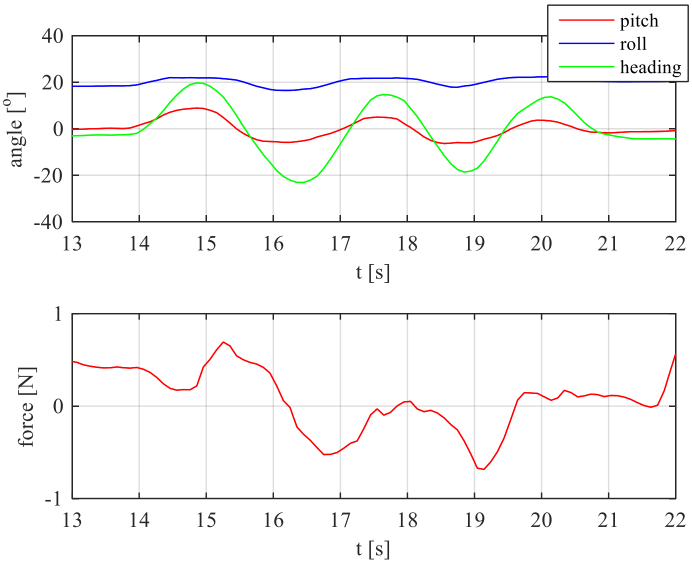

Figure 34. Data registered in static test #2 – right-left movement

In the Figures 33 and 34, it is clearly visible that the nature of realized movements was different, by analyzing the IMU data – and they correspond closely with real observed movements. Also, the force sensor readings are compatible with the IMU data – moments when the patient encountered resistance of the handlebar and changed the direction of the movement are clearly identifiable.

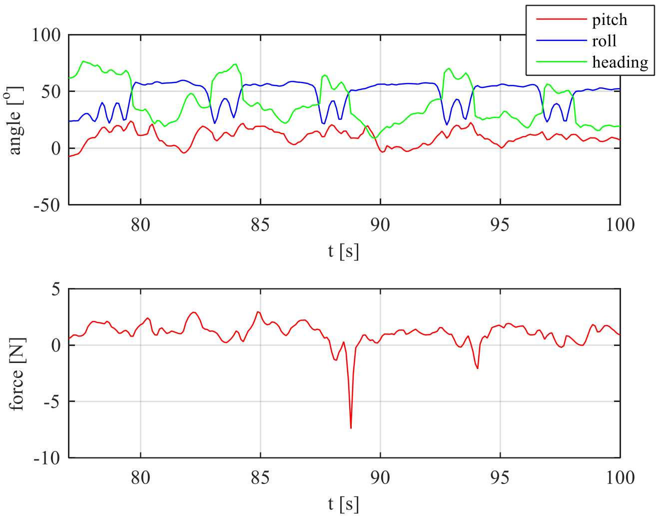

Figure 35. Data registered in dynamic test (test drive)

In Figure 35, nature of patient's movement can be also easily guessed from the Euler angles patterns recorded in the plot. The force changes also correspond closely with the movement. A single visible dip was a threshold that patient encountered in the middle of the test drive path.

It can be observed, that the registered force during the test drive is considerably higher than in any other test – however it is still very low (not exceeding 10 N). As such, use of prosthesis in that manner is completely safe. However, the conditions in the test were also "safe" – the patient did not drive very fast (no faster than 10 km/h), and did not encounter any serious terrain obstacles or height differences that might caused higher forces to occur. Further tests and more results are needed – the patient was given a prosthesis and the results will be gathered and used in other experiments by the authors.

To sum the results up, it should be stated that the obtained sensor data represented the measured activity in an expected manner. As such, the tests were finished at that stage. The prosthesis with its sensors can be considered as a successful prototype – idea of low-cost personalized 3D printed bicycle prosthesis equipped with sensors for registering the course of driving was proven to be viable and will be continuously developed.

4. Conclusions and future work

The presented device must still be considered a prototype that needs further refining and improvement. Electronic components need to be hidden inside the prosthesis and protected from the atmospheric conditions. A suitable location must be found for the battery pack (so far it was carried by the patient in his pocket). The sensors arrangement must be also thought of more carefully – possibly the force sensor could be moved to wrist-forearm joint, or another sensor could be added, to gather force data from various directions. In the software part, live streaming and visualization of results could be obtained by adding a Bluetooth or Wi-Fi module and connecting the prosthesis with a dedicated mobile application. All these improvements are considered and will be pursued in further iterations of the device.

In terms of accessibility and easiness of production, the concept of low-cost sensor-equipped prosthesis was successfully confirmed. Very simple and accessible electronic components were used and they fulfilled their role. Time of assembly and programming did not exceed one working day. The longest (and most costly) part of the process is 3D printing of the parts, that took total of 54 hours. It could be done considerably shorter by using parallel manufacturing with several machines – however, single large parts such as the socket still take more than 20 hours to produce and that time would be difficult to reduce significantly. It is safe to assume that after automating the design (as done by authors in previous research cases) it would be possible to deliver working prostheses in one week – which is still a very short time when comparing to commercial personalized specialized prosthetics.

It can be assumed, basing on patient's positive feedback and authors' experiences to date, that the personalized design of low-cost 3D printed prosthesis with sensors could be an invention that could change approach to amateur sports (especially cycling) by disabled people lacking one of their upper limbs, especially when they are also missing the elbow joint. Such prostheses could be automatically designed and produced cheaply, allowing wide groups of patients to regain capabilities of undertaking sports and other activities safely and comfortably. That is why this direction of research is promising and must be continued.

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