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EUROPEAN NETWORK FOR 3D PRINTING OF BIOMIMETIC MECHATRONIC SYSTEMS

CASE STUDY #4

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 #4 – Personalized mechatronic lower limb orthosis**
Date of Delivery	**August 2023**
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Version	**0.1, 12.06.2023**

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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 #4 focuses on a biomechatronic lower limb orthosis, for patients with conditions and defects in the ankle-foot area (e.g. cerebral palsy, spina bifida etc.), requiring therapy or using orthoses to aid walking. It was proposed to convert a mechanical orthosis into a mechatronic device by enhancing it with sensors and using signals from these sensors for therapeutic purposes – to enhance diagnostics or to control a rehabilitation game, possibly utilizing VR technology.

Originally the orthosis 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] (Polish language only, automatic translation recommended).

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2. Case study #4 - methodology

2.1 Research concept and plan

The main purpose of the project was to create a personalized mechatronic lower limb orthosis based on 3D scans created on AutoMedPrint automatic workstation located in our faculty. The orthosis is equipped with a number of sensors in order to study the movement of the lower limb and foot pressure on the ground. This data is then sent via Wi-Fi to the server connected to the PC where it is saved and then operations are performed on it in order to study the movement. In addition, a rehabilitation application for VR was created.

2.2 Personalization – 3D scanning of selected limbs

In order to create a 3D model of the orthosis for the patient, measurements must be made. For that, AutoMedPrint system was used [1]. An automatic 3D scanner made for measuring upper and lower limbs. The scans were performed on a test (healthy) patient – one of student group members. Both lower limbs were scanned separately. We have made a backup scans of the calf and knee using EINSCAN-PRO scanner.

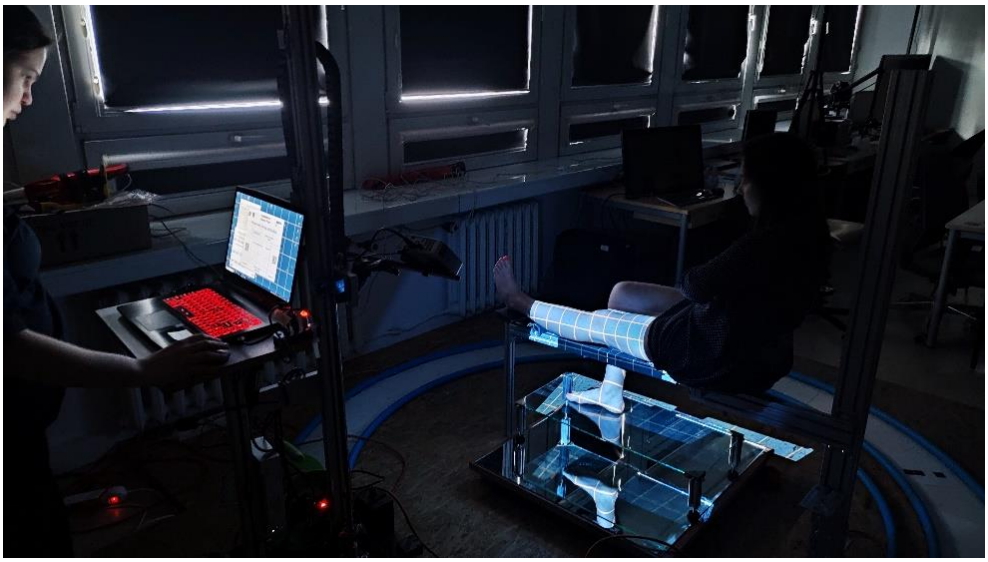

Figure 1. Lower limb scanning process – automatic scanning workstation

The scanning process at the AutoMedPrint station consisted of the following steps:

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1. Station calibration
2. Preparing the station for scanning the lower limb. Equipping it with a mirror and a glass on which the limb lay
3. Launching the unity program - AutoMedPrint
4. Starting the control of the cart on which the scanner is located
5. Performing sequentially six scans at each of the four measurement points
6. Uploading the received scans to the algorithm that combines the scans

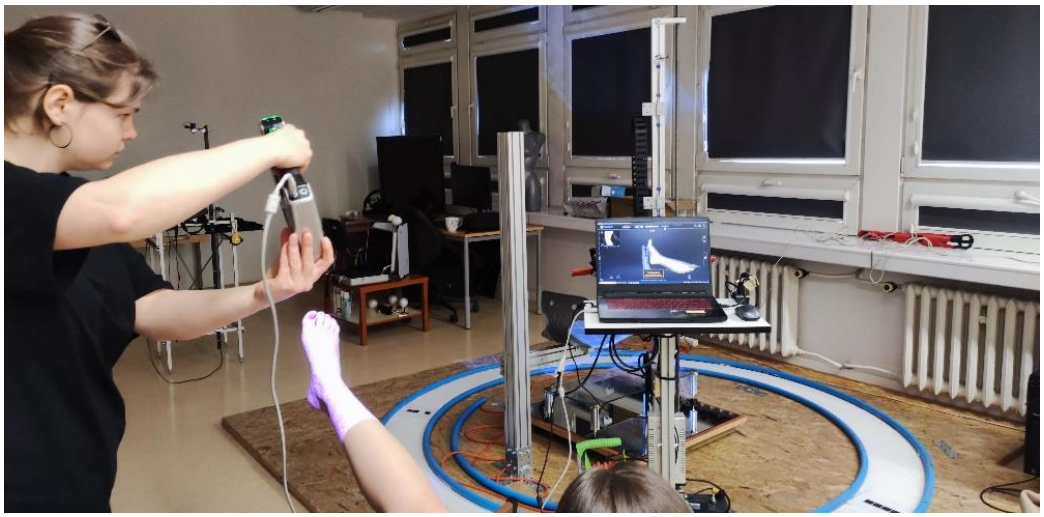

Figure 2. Lower limb scanning process – manual scanner

The scans were also taken with an EINSCAN PRO handheld scanner. The patient was positioned in a sitting position, keeping in mind the 3x90 rule, which involves based on the patient maintaining a right angle at three points: foot-ankle, calf-udo and thigh-to-thigh. The scanner technology does not allow the use of glass, as the laser beam reflects off its surface. For this reason, a measuring station was made and the lower limbs were scanned using it.

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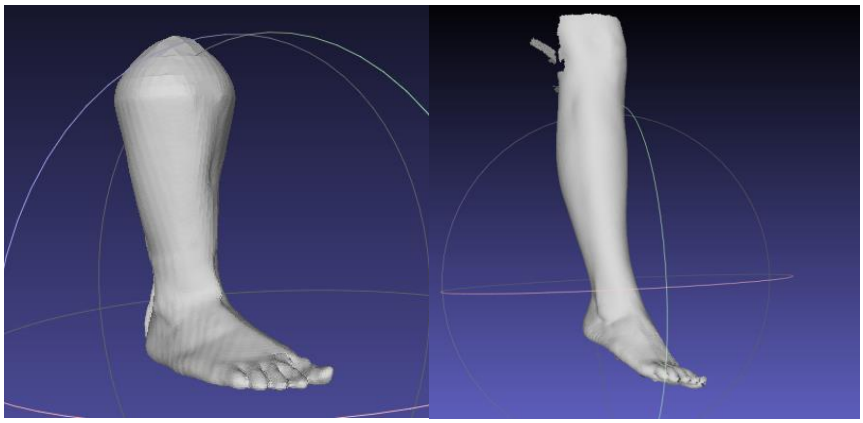

Figure 3. Lower limb cleaned scan from AutoMedPrint – David SLS-3 scanner (left), EINSCAN (right)

2.3 Background - orthosis design

The 3D model is based on previous iteration of an orthosis which construction proved to be the most reliable and comfortable for the patient. Hybrid modelling was used, basing on wireframe, then surface and finally 3D solid, based on points extracted from the scan. Methodology of creating the model is shown in Figure below.

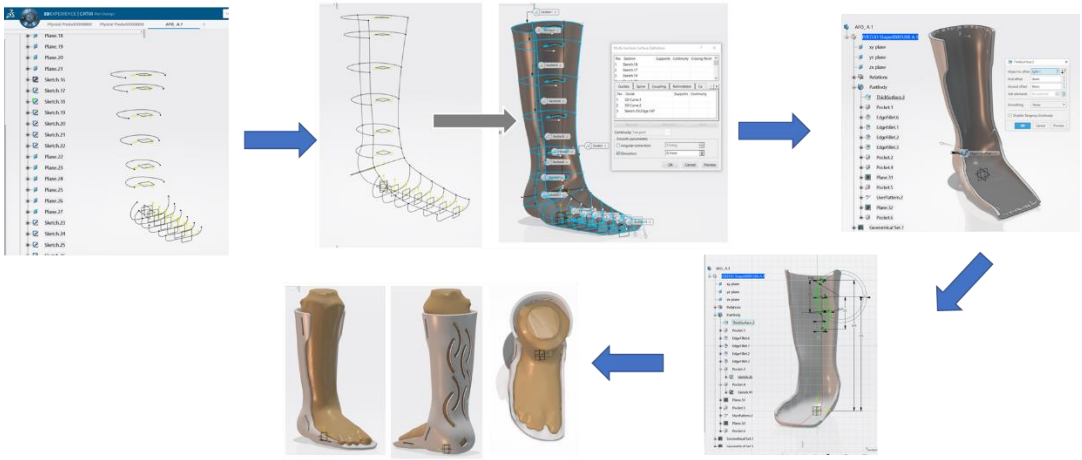

Figure 4. Methodology of creating the lower limb orthosis model based on personalized scans, based on work presented in [2]

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Figure 5. Mechanical orthosis produced for previous patients [2]

First shell test models were made to test the fit of the printed orthosis to the patient's limbs in reality. Models are shown Figures below.

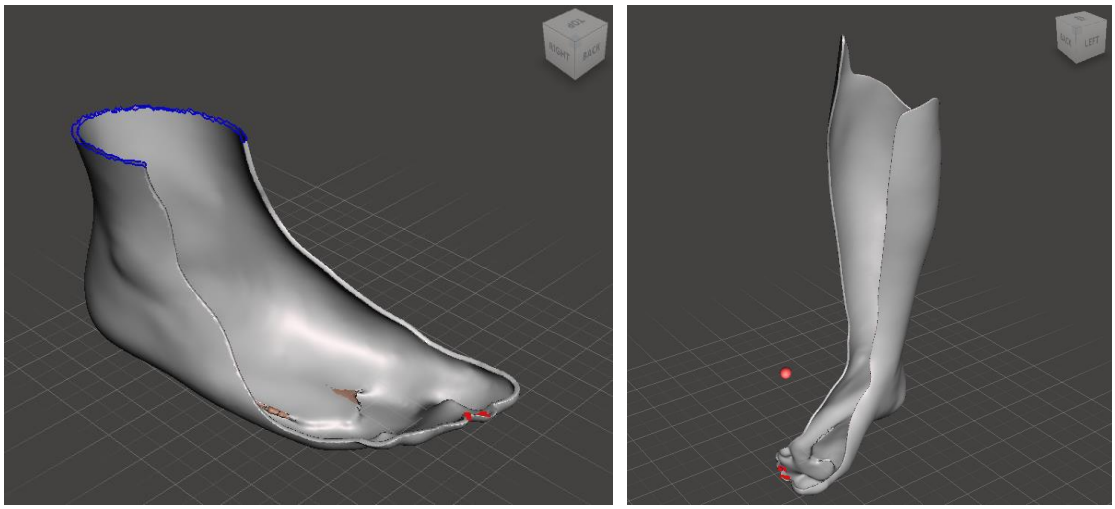

Figure 6. Shell orthosis model: short and long version

Work on the model and the electronic system of the AFO orthosis continued in parallel. The dimensions of the sensors and the electronic system were collected, and the final model of the patient's AFO orthosis was made based on them.

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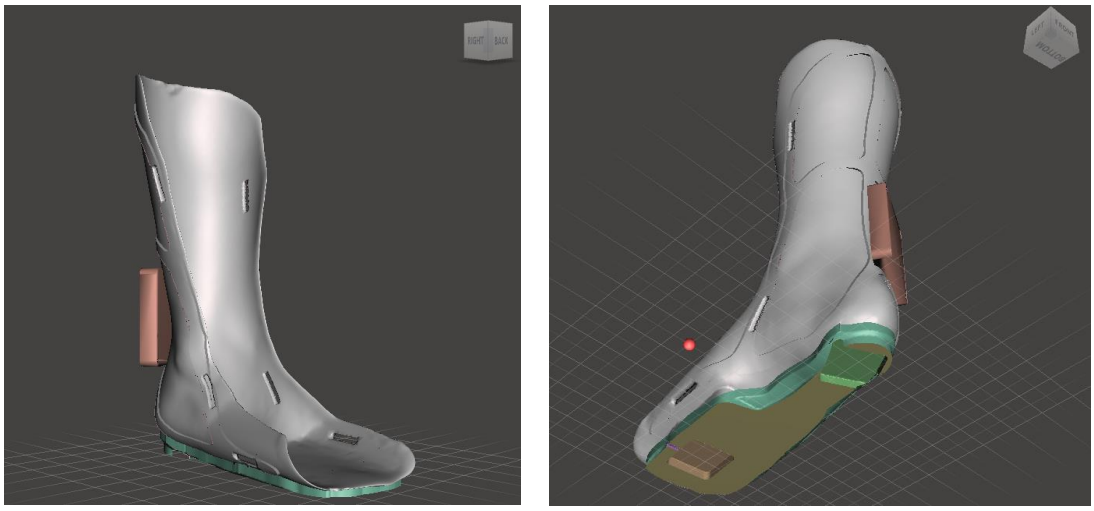
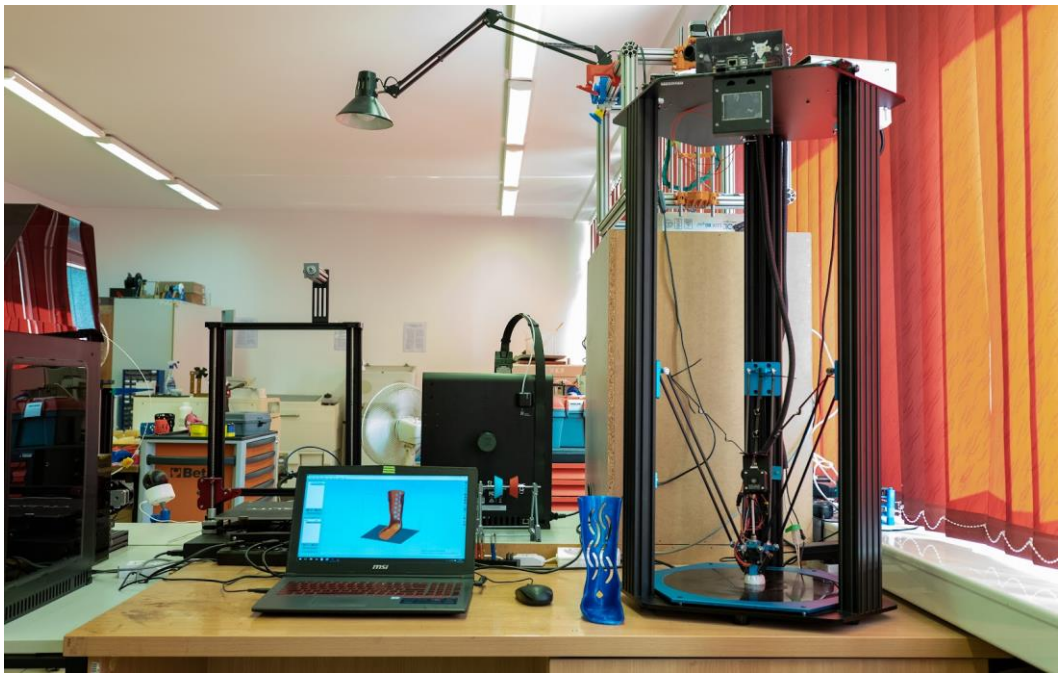


Figure 7. Final update of the model including the electronic system

The model was updated by adding space for strain gauges, located under the main support points of the foot, shown in green, and the mounting of the electronic system, shown in red in Figure 7. The orthosis was designed so that it could be printed in a one step.

2.4 Manufacturing

The designed orthosis was 3D printed using Fused Deposition Modelling, in several processes using 3D printers available in EMERALD consortium partner laboratories. We tested and picked the material for the 3D printing of the orthosis. We tested a handful of materials (more information on this topic can be found in the previous papers by the authors [3,4] and also in current studies – unpublished yet). We picked composite material PETG. Due to relatively large volume of print, especially height, larger FDM printers were selected – Zortrax M300, as well as delta kinematic machines FLSun Super Racer.



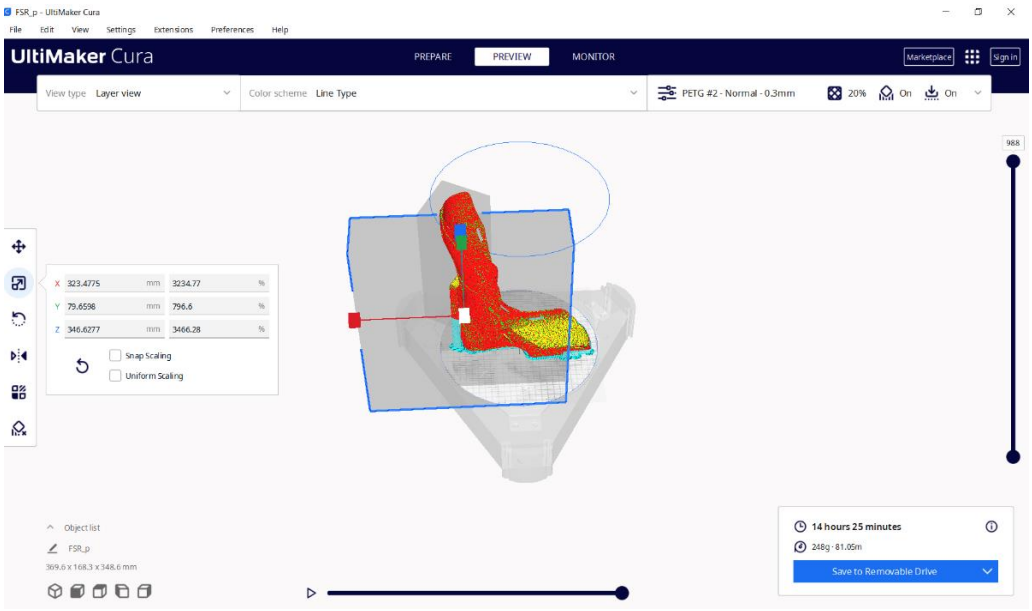


Figure 8. FDM machines for printing of high orthoses (FLSun, Zortrax machines visible)

2.5 Design of electronic part

The selected logic module is the ESP32-DevKit microcontroller, equipped with a built in module for WiFi communication.

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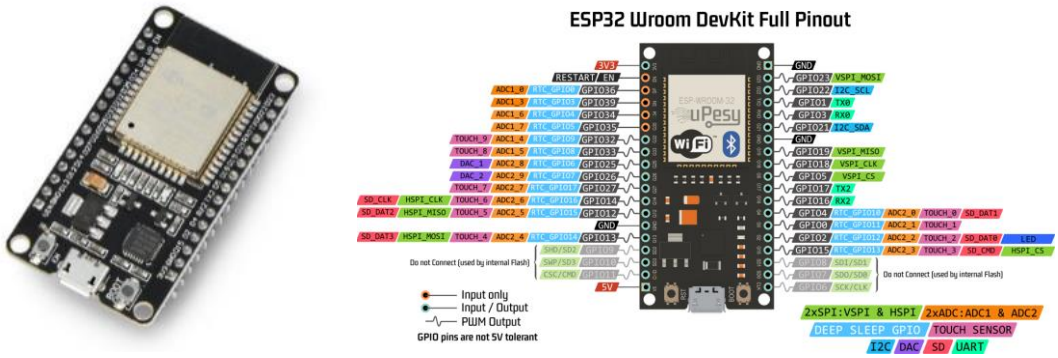

Figure 9. ESP32 Microcontroller

A system equipped with the LSM6DSO six-axis gyroscope with accelerometer from SparkFun was used to take motion measurements.

Figure 10. Sparkfun IMULSM6DSO 3 axis accelerometer and gyroscope

The pressure force of the sole of the foot on the ground will be measured by a system of two strain gauge beams, designed to measure pressure not more than 50 kg, and an HX711 analog digital amplifier.

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Figure 11. HX711 ADC amplifier

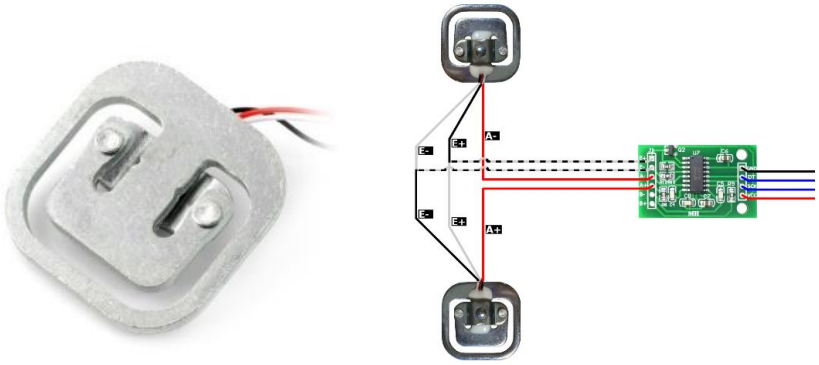
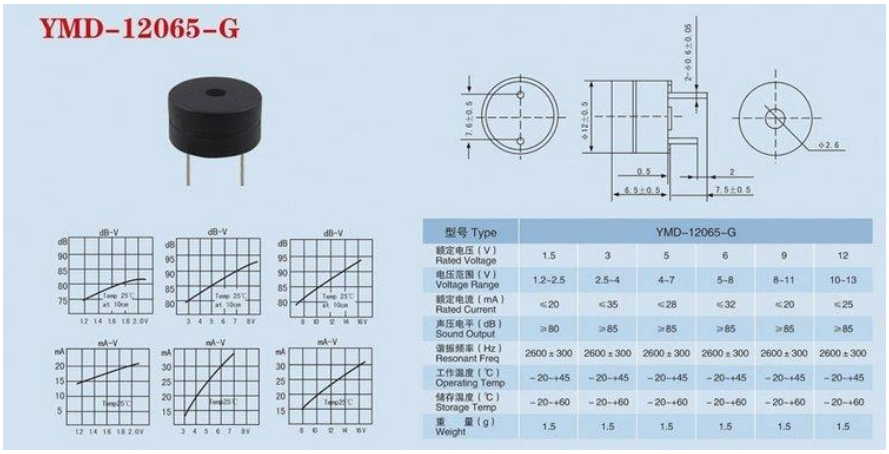


Figure 12. Tensometer

The element that communicates the operating status of the device with the user is a piezoelectric buzzer powered by 3.3V.



型号 Type	YMD-12065-G					
额定电压（V）Rated Voltage	1.5	3	5	6	9	12
电压范围（V）Voltage Range	1.2-2.5	2.5-4	4-7	5-8	8-11	10-13
额定电流（mA）Rated Current	≤20	≤35	≤28	≤32	≤20	≤25
声压电平（dB）Sound Output	≥80	≥85	≥85	≥85	≥85	≥85
谐振频率（Hz）Resonant Freq	2600±300	2600±300	2600±300	2600±300	2600±300	2600±300
工作温度（℃）Operating Temp	-20~+45	-20~+45	-20~+45	-20~+45	-20~+45	-20~+45
储存温度（℃）Storage Temp	-20~+60	-20~+60	-20~+60	-20~+60	-20~+60	-20~+60
重　量（g）Weight	1.5	1.5	1.5	1.5	1.5	1.5

Figure 13. Buzzer

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Based on the catalog notes of the selected components, an electronic schematic of the microcontroller's connections to the LSM6DSO and HX711 IMUs was made. The schematic was made in Autodesk Eagle application. Communication between the chips takes place using I2C and SPI interfaces.

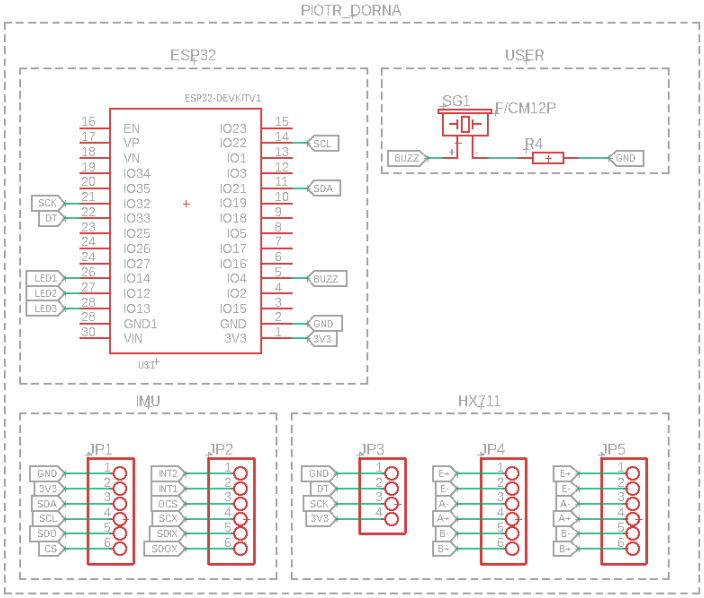

Figure 14. SCH connection diagram

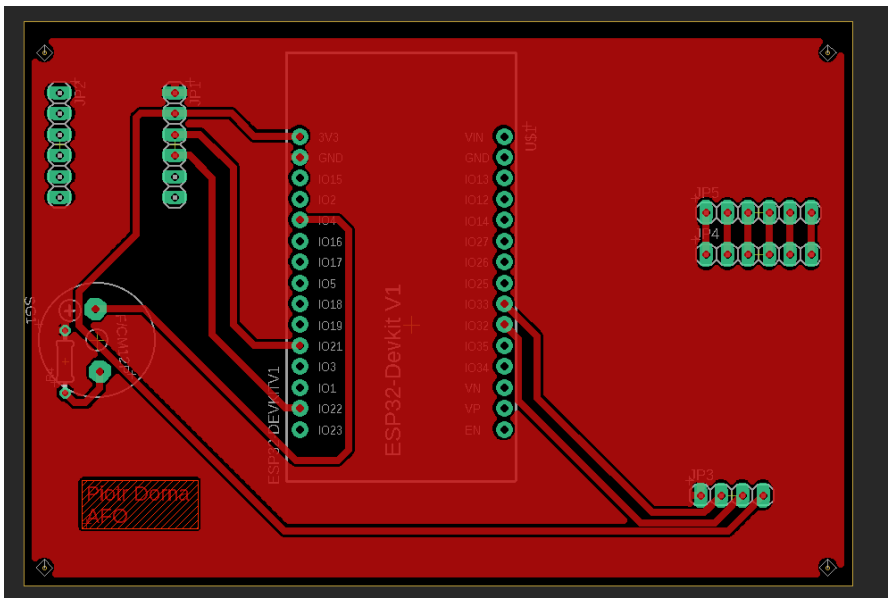

Figure 15. Designed PCB

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The program part of the project can be divided into three sections. The first is to program two ESP32 microcontrollers responsible for collecting data from the AFO chip. The program controls the I/O pins, reads the data from the sensors, subjects it to simple operations - filtering, calibration, and sends the collected data to the server in the form of a data packet. The next section is to program the server, which is the third microcontroller used in the project. The server receives data from the AFO1 circuits and AFO 2, then performs further operations on them, filters the data and in the form of a ready packet of data from both AFOs it sends via USB to a PC. The last element that makes up the software part is to write a program on a PC, whose task will be to collect data from the server, write this data to a file, and read the data in real time in the Unity environment, on which the rehabilitation application will be implemented. The programming language used to write the programs on both the microcontroller and computer sides was C++.

2.6 Assembly and programming

The created wiring diagram of the electronic components included on the board can be found in Figures 16. After the functional prototype (Figure 16 left), the board was made using the THT method (Figure 16 right). Figure 17 shows the complete electronic circuit for mounting on the AFO orthosis.

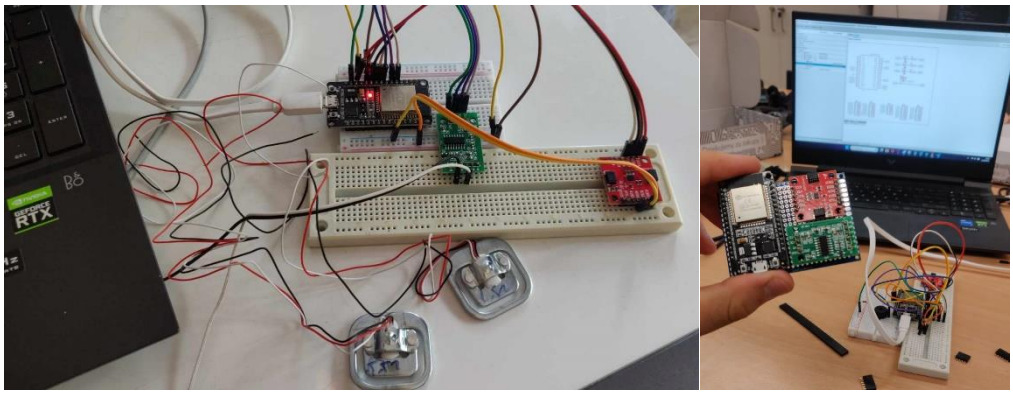

Figure 16. Functional prototype and process of making an electronic circuit

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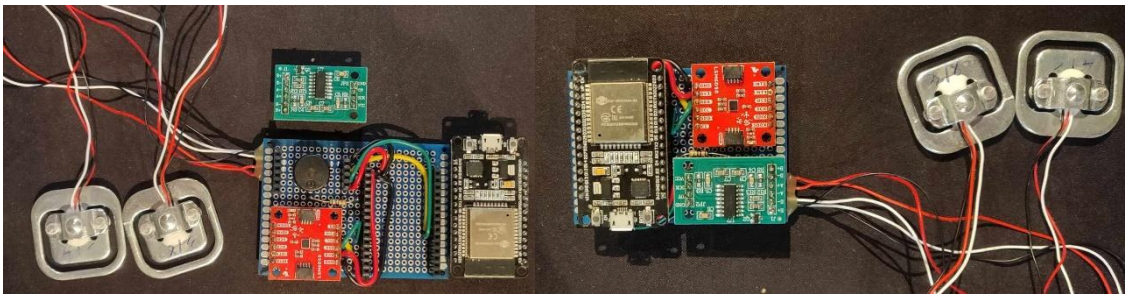

Figure 17. Layout of system components

2.7 Testing procedure

Testing of the functional mechanical properties of the orthosis took place while the patient performed typical movements associated with moving. The patient performed transitions, bends and other typical movements using the stabilization provided by the orthosis.

The test of the device's operation consisted of conducting a check of the correct functioning of the various systems, while collecting data during the patient's movement.

The patient, with the AFO orthosis in place, performs two tasks. The first is to walk on a flat surface in a straight line. The data recorded by the app is evaluated. The second task is for the patient to assume various positions of the orthosis, while studying the behavior of the virtual model. The data was collected by the built rehabilitation application. The rehabilitation application was made in the Unity environment. In order to execute it, the BioIK plugin was used and modified. The BioIK plugin enables prediction of body behavior, based on data related to the pivoting of the system elements that make up the

on the skeleton of the digital character. The data collected by the application from the server is stored in a database and assigned to the virtual model. In this way, visualization of the patient's movement in virtual reality is realized.

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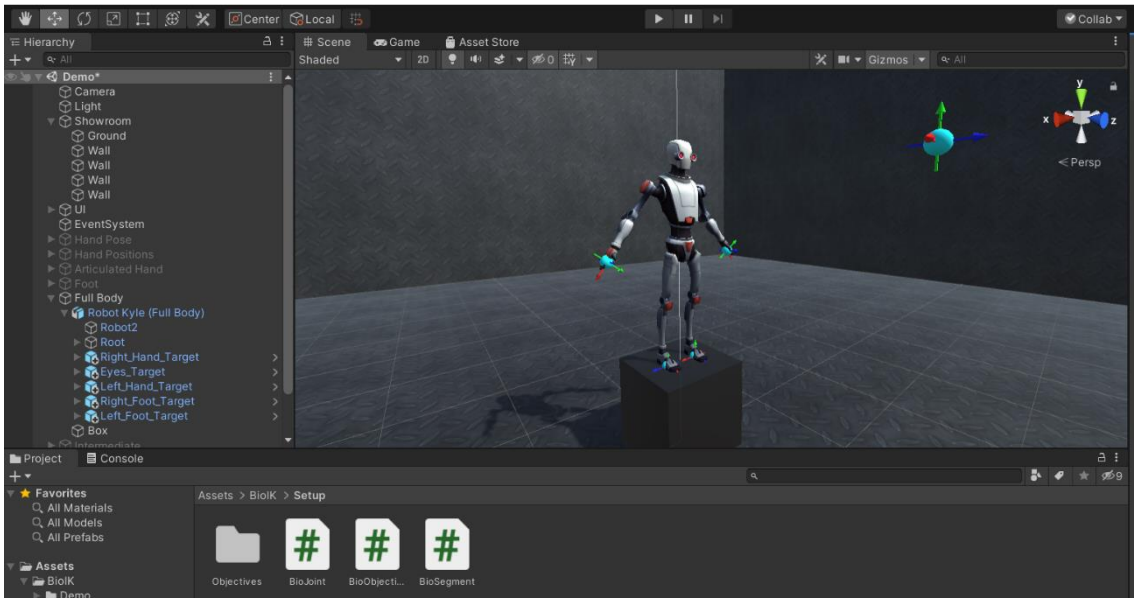

Figure 18. Unity environment

```
// Update is called once per frame
void Update()
{
    IMUdata = port.ReadLine();
    IMUdata = new Vector3(0+calX,0+calY,0+calZ);
    transform.localRotation = IMUdata;
}
```

Figure 19. Reading/Assignment of values from IMU

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3 Results

3.1 Manufacturing and assembly results

The result of the 3D scanning, design and modeling process are 3D models of the AFO lower limb orthoses, which were made based on the 3D scans collected. Each of the orthoses were designed separately. The time required to manually design two orthoses was within five working days. The results of designed orthoses is in the figures below.

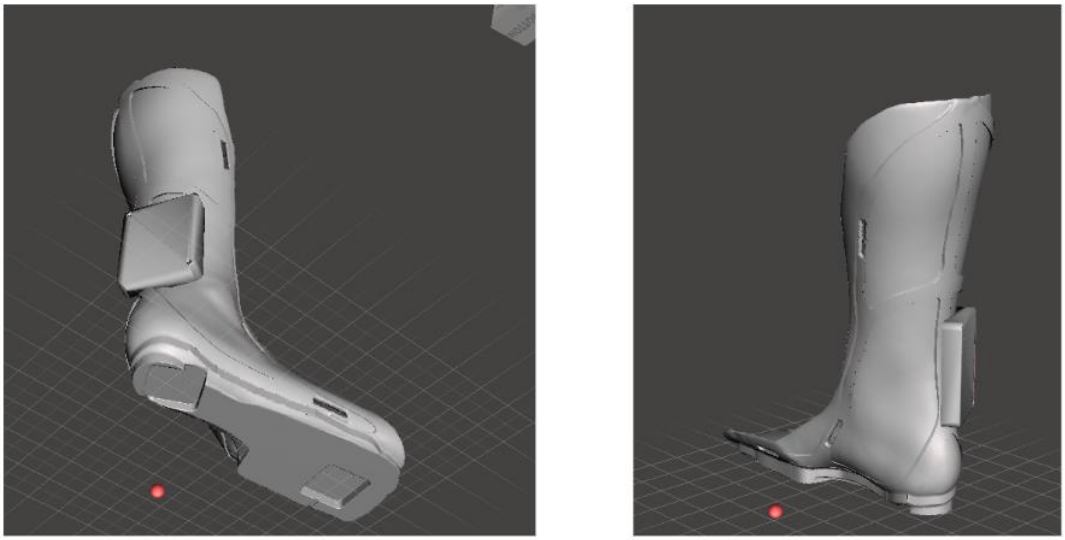

Figure 20. Result of designed AFOs

The orthoses were fitted to the patient's lower limb dimensions. During the additive manufacturing process, a material flow problem was encountered. This problem, was noticed on both FLSUN V400 printers. Initially, it was assumed that the wrong printing parameters had been selected. After changing the parameters, increasing the nozzle temperature, decreasing the print speed and making a second attempt, the print result was almost identical. The second printout failed. There were a large number of defects on the printout. The structure of the print was unstable. The orthosis was considered waste.

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Figure 21. Results of first and second NOK printed orthoses

Therefore, the decision was made to change the nozzle to a new one of the same diameter and to clean the PTFE tube. On the third attempt to make the print, the orthoses were successfully printed. However, a defect appeared in the orthosis, which definitively identified the source of the issue. Examination of the breakpoint of the layers revealed intramaterial defects in the form of impurities and air cells appearing in the printed layers.

Figure 22. Successful printing of orthoses

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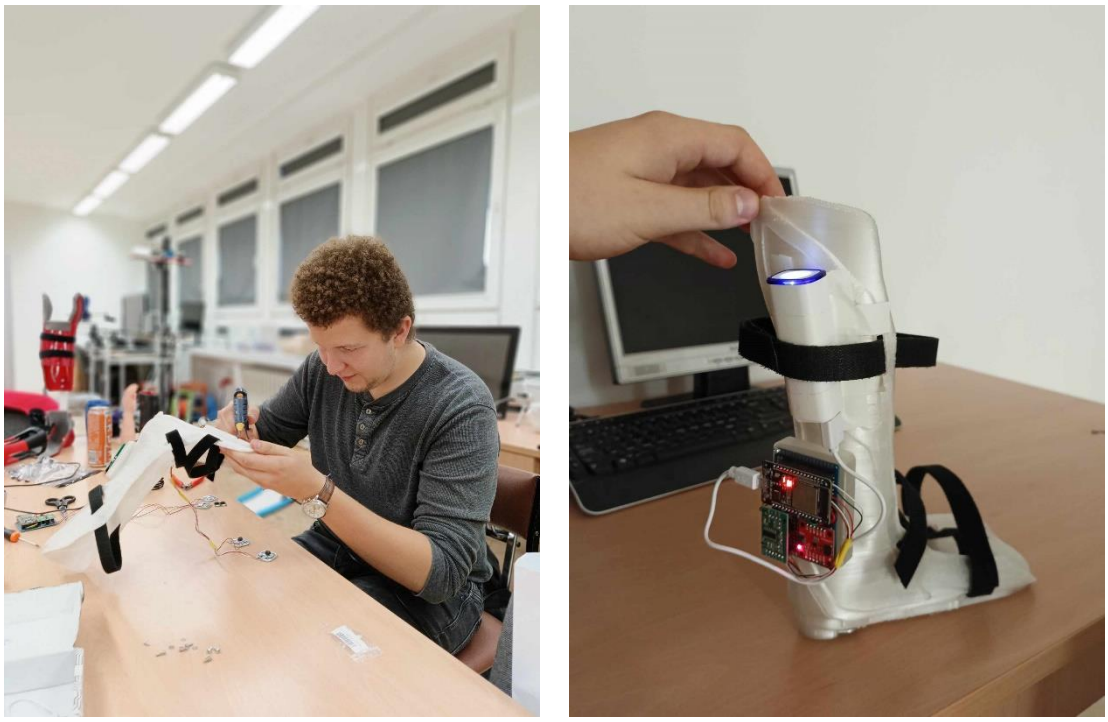

Figure 23. Assembly process and prepared mechatronic AFO orthosis

3.2 Testing results and discussion

The finished lower limb orthoses were tested separately for the left and right legs by the patient. The AFO mechatronic orthosis of the right limb was tried on first. The patient confirmed that the orthosis did not pinch, and stiffened her ankle joint well. The strength of the orthosis was tested by transferring her entire body weight to the orthosis and walking. The orthosis lived up to its claims. Accordingly, after the successful fit test, data collection was started according to the established experimental plan.

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Figure 24. Fitting of the AFO orthosis of the right limb

Figure 25. Walking - the process of data collection

Next, the AFO mechatronic orthosis test was performed for the left limb. As in the first study, the test began by checking the fit of the orthosis. The orthosis did not pinch the patient. During the strength test, the structure of the orthosis broke, making further testing impossible.

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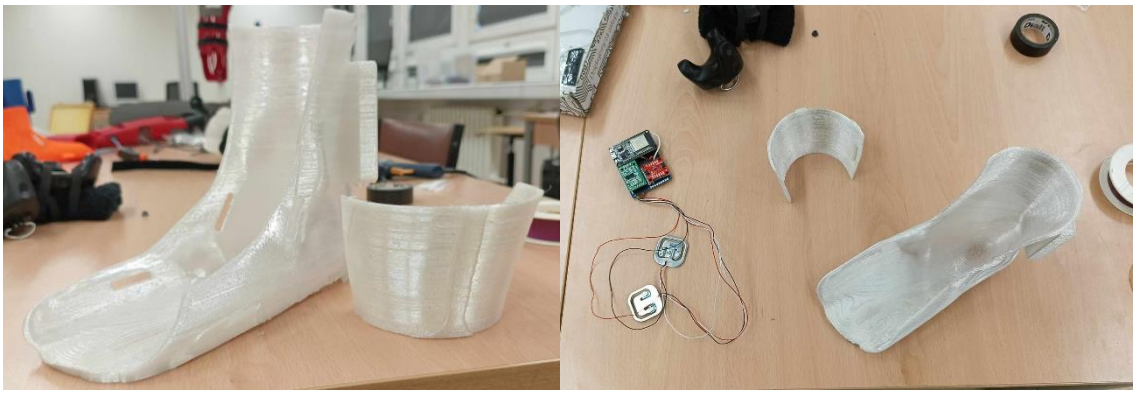

Figure 26. Damaged orthosis as a result of testing left lower limb AFO orthosis

The data collected during the experiment is shown in the graphs below. Figure 27 shows the IMU sensor data processed by the rehabilitation application, and Figure 28, data from the strain gauge system and ADC.

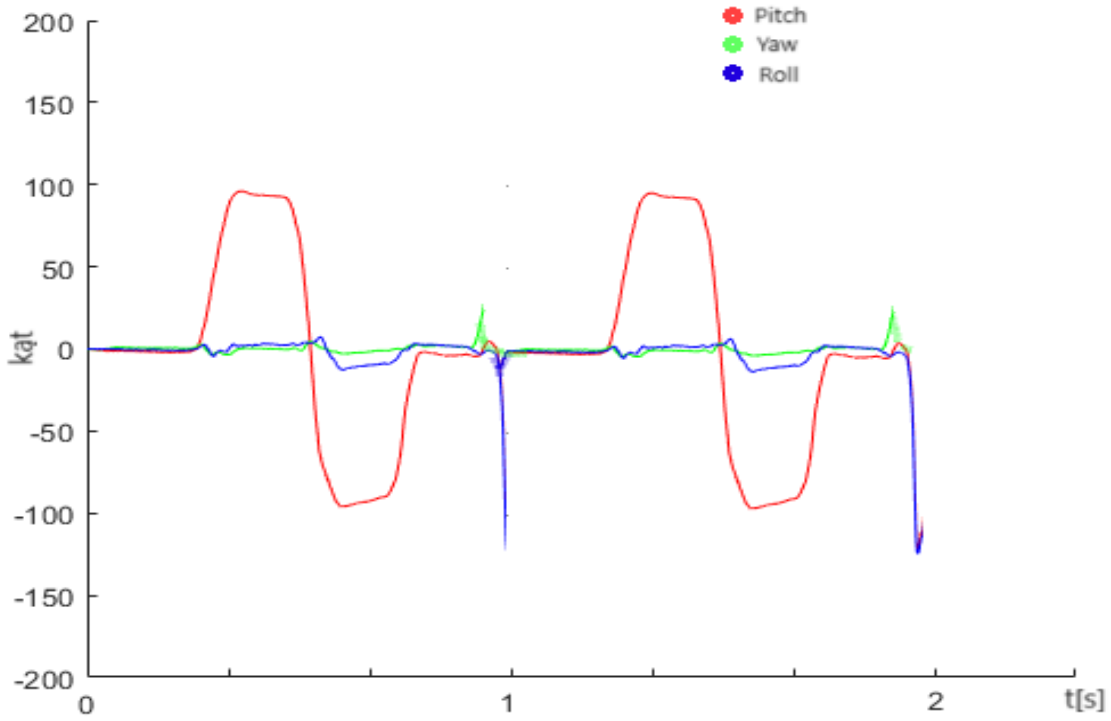

Figure 27. Graph of collected measurements of orthosis deflection

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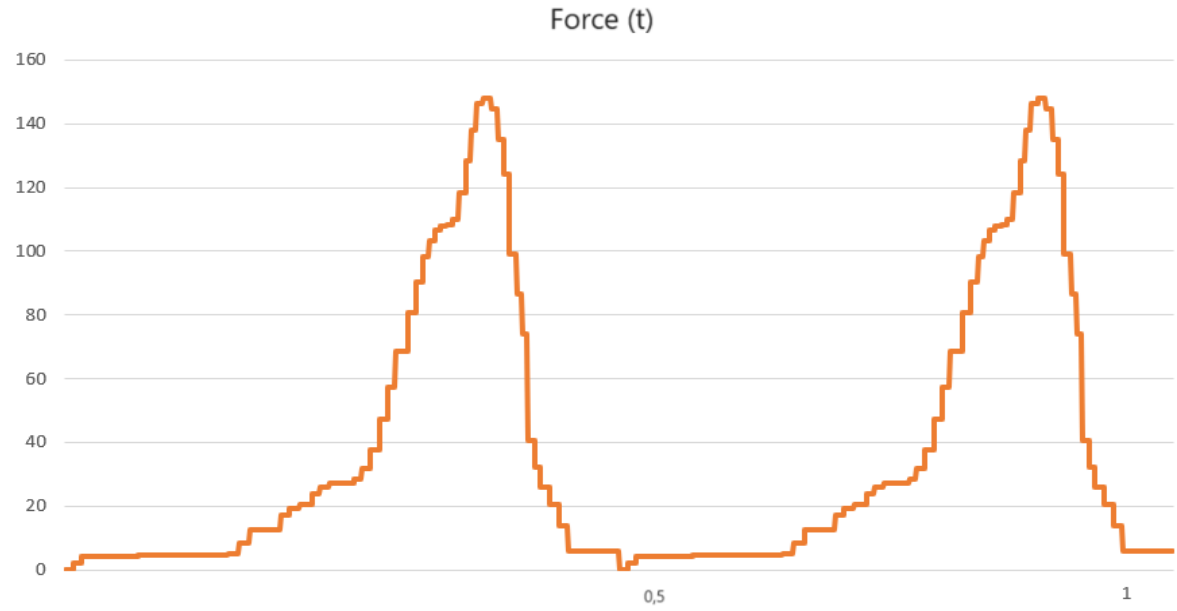

Figure 28. Graph of the collected measurements of the pressure force of the sole of the orthosis

The result of the project is a platform designed to study the patient's movement parameters with the parallel provision of a rehabilitation platform, which includes: two custom-made AFO orthoses equipped with electronic circuits, software on the side of microcontrollers, server and computer. The design and modelling part of the orthoses, electronics and software, achieved design success. The addictive manufacturing process did not achieve full design success.

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4 Conclusions and future work

Many defects - air pockets and impurities - were noted in the structure of the print. The selected 3D printing parameters were correct. The technological part on the side of the FLSUN V400 3D printer was not the source of the defects.

The defects found in the print must have been created before the design was manufactured using the additive method. The blame for the resulting defects is therefore likely to lie mainly with the contaminated PET-G material. It was assumed that the material was exposed to external factors such as moisture and dust. When the material was heated in the extruder, steam appeared due to the heating of the damp material, which caused the material to weaken and caused a "fog" effect in the material. The filament must have been stored in poor conditions, or the defects had already appeared during production.

In future versions of the project, it would be advisable to use better quality filament. A good suggestion for an update would be to use a high-performance PET-G+CF composite filament or high-performance materials such as PEEK or PEKK and polycarbonate (PC). Other manufacturing technology, such as powder sintering (SLS) or Jetted Photopolymer technology, could also be considered. The electronic system works properly, and the data read from the sensors correctly and definitively determines the movement of the orthosis as well as the amount of pressure. The creation of a database and further study of the data can be used to improve the patient's rehabilitation process by being able to continuously track progress.

Future research and development work should focus primarily on using an automated orthosis modeling system to offset the costs associated with time-consuming manual design. Investigating material strength and addictive manufacturing technologies could positively influence future iterations of the design.

The rehabilitation application would need to be expanded to include interactive elements in such a way that full immersion of the patient during the rehabilitation process is possible. Gamification of the rehabilitation process could have a positive impact.

The fusion of 3D scanning and addictive manufacturing technologies is finding applications in medical applications. The correct design of an automated orthosis manufacturing system is capable of revolutionizing the medical market. The price of solutions available on the market is high. The project has proven that there is room to reduce the price of smart medical supplies.

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Literature

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