



NATIONAL UNIVERSITY OF SCIENCE AND  
TECHNOLOGY **POLITEHNICA** BUCHAREST

**Faculty of Mechanical and Mechatronics Engineering**

Department of Mechatronics and Precision Mechanics

# SUMMARY

# DOCTORAL THESIS

*Research on the fabrication technology of a forearm neuroprosthesis with the command taken from the amputated peripheral nervous system of the patient*

*Cercetări privind tehnologia de realizare a unei neuroproteze de antebraț cu comanda preluată din sistemul nervos periferic al pacientului cu amputație*

**Author:**

Ing. David Cătălin Dragomir

**Scientific Coordinator:**

Prof. Dr. Ing. Octavian Donțu

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## **FOREWORD**

The thesis deals with a subject of particular importance that brings extraordinary progress in recent years in the field of interdisciplinary sciences: the technologies for creating a forearm neuroprosthesis and solutions for interfacing between the human body and computer. The thesis contributes to the development of research regarding the methods for operating the movable parts of a prosthesis made through rapid prototyping technologies, design techniques using CAD software suite, and the characteristics of biocompatible materials used for encapsulating the components of the mechatronic system implanted in a living body.

First and foremost, I would like to express my gratitude to my doctoral supervisor, Prof. Dr. Ing. Octavian Donțu from the National University of Science and Technology POLITEHNICA in Bucharest, Faculty of Mechanical Engineering and Mechatronics, Department of Mechatronics and Precision Mechanics, who guided me throughout my doctoral studies with exceptional scientific and moral attention, providing me with the opportunity to participate in multidisciplinary scientific research projects such as the one entitled 'Forearm Neuroprosthesis Equipped with Artificial Skin and Sensory Feedback' – ARMIN code EEA-RO-NO-2018-0390 as a member of the team where he is the director, and contributed significantly to the development of my research skills and the elaboration of the doctoral thesis.

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I also want to take this opportunity to express my gratitude to my family, who supported and encouraged me in the course of my doctoral research studies in every possible way.

## **CHAPTER 1. THE CURRENT STATUS REGARDING UPPER LIMB PROSTHESES**

### **1.1. The Evolution of Structural and Technological Solutions for Forearm Prostheses**

An upper limb prosthesis is a medical device used to partially or completely replace a missing or incomplete segment, serving a functional and aesthetic role. The first historical source that attests to the existence of such a prosthesis date back to around 950 - 710 B.C., which was discovered in the year 2000 near the town of Luxor in very good condition. The prosthesis replaces the thumb of the lower limb in the mummified body of Tabakentenmut, the daughter of a priestess of that era [1].

In the Middle Ages, advancements in prosthetics moved towards tools other than the hand hook and foot peg. Multiple extensions could now be attached, thereby expanding the functional capabilities of the prosthesis.

### **1.2. Types of upper limb prostheses based on the location of amputation**

Depending on the location of the amputation, the prosthesis that closely replaces the natural limb is classified as follows:

- Partial hand prostheses; when the amputation has affected the entire palm area without its joint and substitutes the grasping function;
- Hand disarticulation prostheses; when the amputation has affected both the palm area and its joint and substitutes the grasping function;
- Forearm prostheses (transradial); when the amputation has affected both the palm area and its joint and substitutes the supination, pronation, and grasping functions;
- Elbow disarticulation prostheses; when the amputation has affected the area from the elbow to the palm and substitutes the elbow flexion, supination, pronation, and grasping functions;
- Arm prostheses (transhumeral); when the amputation has affected the area starting from above the elbow, continuing to the palm, and substitutes the following functions: arm rotation, elbow flexion, palm supination, pronation, and grasping.
- Shoulder prostheses; when the amputation includes the entire shoulder area down to the palm, replacing the functions of shoulder movement, arm rotation, elbow flexion, palm supination, pronation, and grasping.

### **1.3. Neuroprostheses**

#### **1.3.1. Neuroprostheses for the forearm**

Neurotechnology enables the direct capture of a signal from the nervous system, such as movement, touch, or memory. The signal interpretation is done by a computer specially

designed for this purpose, which subsequently transforms it into action on the surrounding environment.

Neuroprostheses consist of:

- The mechanical system of the prosthesis;
- The interface implant between the nervous/muscular system and the prosthesis;
- Electronics and control components.

To enable the transmission of a phantom sensation (simulating the sensation that comes from a region of the amputated limb) to the patient's nervous system, various methods exist:

- Interfacing the prosthesis with the patient's nervous system from the amputated area;
- Interfacing the prosthesis with the patient's brain;

### **1.3.2. Neurotechnology**

At present, the availability of affordable models for the general public is still in its early stages, with the prices for acquiring such prostheses being very high. However, there is ongoing development, and research will continue until the system is stable and the manufacturing cost decreases. Research in the field has shown that the most common amputation is in the forearm.

### **1.3.3. The current state of theoretical research on upper limb neuroprostheses**

Currently, theoretical research is based on the study of neural network behavior and cellular automata to address issues of biocompatibility and regeneration of adjacent tissues to the bio-interface. To enable the integration of this foreign body inside the human body, the material from which the implant is made must be biocompatible, allowing the body to immediately recognize the implant as a part of itself, thus integrating the interface module and excluding the possibility of rejection as a foreign body by the organism.

### **1.3.4. The current stage of experimental research on upper limb neuroprostheses**

The DARPA "Revolutionizing Prosthetics" program involves the development of a neuroprosthesis operated by commands generated using signals extracted directly from the nervous system. As a motto, the project has chosen "near-natural upper limb," referring to a upper limb prosthesis. This program primarily focuses on soldiers who have lost an upper limb due to accidents in war zones, but not exclusively."



## **1.4. Neural Interface**

### **1.4.1. Biocompatibility problems following the implantation of the signal acquisition module from the patient for prosthetic control**

A bio-interface, as the name suggests, is a device that establishes a connection between the human body and a prosthesis with the goal of enhancing command and control, making the integration of the device into the patient's life as easy and natural as possible.

#### **1.4.2. The current state of theoretical research on the upper limb neuroprosthesis**

At present, theoretical research is based on simulations in the digital environment of cell behaviors in the implant area. Cellular automata are defined that have reactions similar to human tissues in response to stimuli such as foreign bodies, and the system's evolution over time and the reaction of cells adjacent to the implant are observed.

#### **1.4.3. The current status of experimental research on the upper limb neuroprosthesis**

After theoretically proving the possibility of successfully creating such an integrated interfacing system, testing continued on a live apparatus in rodents. When the results were promising and the rejection reaction to a foreign body stabilized, stability was observed, and experiments continued on primates. Currently, ethics committees have approved the implantation of these devices in humans.

### **1.5. Some conditions regarding biomaterials and processing technologies used, imposed by human biocompatibility and medical ethics**

The good quality of implanted neural devices is associated with their small size, biocompatibility, physical softness, but their vulnerability arises from the mechanical and physical mismatch with biological tissue [2].

Implantable wireless interfaces are widely studied due to the significant advantage of eliminating wires, which greatly reduces the risk of infection and electronic noise. However, they have a few disadvantages in terms of electric power consumption, short-range data communication [3, 4, 5, 6] due to attenuation, and limited functionality.

### **1.6. Types of neural interfacing systems for creating the control module of neuroprosthesis**

There are interfaces that capture signals directly from the amputated area by implanting them on the healthy side of the nerve. Electrodes are placed on the nerves, and the signals

describing movement instructions are electrical impulses that can be captured, measured, and interpreted.

Microprobes already produce bio-interfaces placed in the peripheral nervous system and sell them online, with various models used for different types of applications.

### **1.7. National and international legislation regarding the prosthetic care of human patients**

Laws vary from country to country globally, but in 2017, the "NeuroRights" movement was initiated to be applied at the European level when the NeuroRights Foundation was established. It aims to stimulate the regulation of intellectual rights more precisely and specifically. The first objective of the NeuroRights Foundation is to protect the rights of all individuals from potential abuse of neurotechnology.

The five "NeuroRights": [7]

- **Mental Privacy:** Any neural data obtained from measuring neural activity must be kept private.
- **Personal Identity:** Boundaries should be developed to prevent technology from disrupting one's sense of self.
- **Free Will:** Individuals should have ultimate control over their decisions, without unknown manipulation from external neurotechnologies.
- **Equitable Access to Mental Augmentation:** Guidelines should be established both internationally and nationally regulating the use of mental augmentation neurotechnologies.
- **Protection Against Prejudice:** Measures to combat prejudice should be standard for algorithms in neurotechnology.

### **1.8. Design solutions for upper limb prostheses and the issue of biocompatibility**

#### **1.8.1. The current state of upper limb prostheses**

Previous research was conducted in the dissertation, where CAD/CAM methods for rapid prototyping were addressed, used in the manufacture of a customized nasal concha prosthesis. The patient was missing an upper lamella of the nasal concha on the right side. High-fidelity medical imaging data were acquired, which were used to replicate the 'mirror-image' model for the prosthesis. The same procedure will be applied in this work to create the model of the prosthesis fixation sleeve on the amputated forearm and the prosthesis.

#### **1.8.2. A multidisciplinary approach of creating a prosthesis for human use**

The approach to this thesis involves studying solutions from a multidisciplinary perspective to address the proposed theme. Within this research, there is a need to merge engineering to

find a technical solution, with the medical field contributing by defining the natural mechanisms that intersect with mechanical ones, as well as chemistry and biology, enabling the study of biocompatibility between the two merged environments: the natural (medical) and the artificial (technical).

### **1.8.3. Some biocompatibility issues regarding the implantable system for prosthetic control**

The command of the prosthesis is intended to be generated by processing information obtained from the human nerve through a neural bio-interface applied to the peripheral nervous system in the amputated area. This is where the study of biocompatibility between the two environments, the natural and the artificial, comes into play.

### **1.8.4. Some problems of engineering interdisciplinarity and the given solutions**

New interdisciplinary applications can be a new form of art, a new form of learning, a new form of technology, a new way of thinking and approaching future problems. Therefore, these need to be integrated into educational activities by correlating the conceptual, methodological, and practical content of fused domains.

From this perspective, A. Becleanu Iancu stated: 'Interdisciplinarity is a process of cooperation, unification, and unified codification of contemporary scientific disciplines, characteristic of the current stage of scientific knowledge development, in which each discipline maintains its epistemological autonomy, specialization, and relative independence while simultaneously integrating into the global knowledge system' [8].

## **CHAPTER 2. UPPER LIMB PROSTHESIS WITH TENSIONED WORE ACTUATION AND ELASTIC ELEMENT RETURN**

### **2.1. The mechatronic structure of the upper limb neuroprosthesis**

#### **2.1.1. Some issues regarding the design, development, and construction of smart prostheses**

Today, there is a wide variety of hand and forearm prostheses available as commercial products, with different actuation speeds, forces, and degrees of freedom, systems that partially replicate the functionalities of the human hand. Some of the best devices currently on the market include: Forearm and finger myo-prostheses: i-Limb Ultra and i-Limb Digits from Touch Bionics [9]; Exo-prostheses (classic or with wire) from Otto Bock HealthCare GmbH [10];

#### **2.1.2. The mechanical structure of the mechatronic system and the calculation of the gripping forces it generates when grasping an object**

From a kinematic perspective, the mechanical structure of the prosthesis consists of a configuration of rigid elements connected by rotational and translational couplings [11,12]. In this model [13], the rotational couplings ( $J_i$ ) are represented by cylinders (the axis of rotation is the cylinder's axis, for example,  $J_5$  performs supination or pronation); the segments between the cylinders are rigid connectors, some equipped with tactile sensors ( $T_i$ ). This model was used in the kinematic calculation for the mechatronic structure described in this document.

All mechanical components of the structure were 3D printed using a MakerBot Replicator 3D printer [14] and the printing material used was Acrylonitrile Butadiene Styrene (ABS), a biodegradable material suitable for high-resolution printing.

#### **2.1.3. The electrical drive system and the mechatronic control and command block of the robotic arm**

The most common method for controlling the movements of a prosthesis is kinematic control. Although solving the set of equations implemented in the mathematical model can be complex, the solution can also result from physical implementation. Regardless of the model of a prosthesis, whether analog or digital (numeric), it is a reduction of the current implemented model. Various manufacturing stages are presented in the following figure:

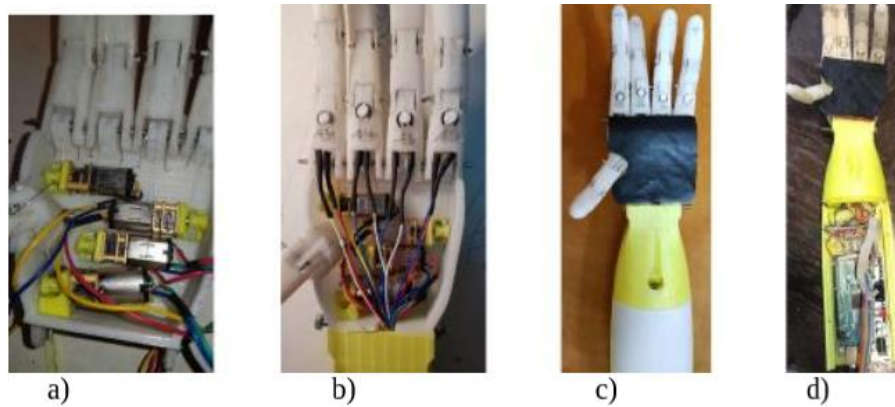


Fig. 1 – Mechanical structure of the prosthesis: a) motors inside the palm for finger flexion; b) pressure sensors mounted on the fingers; c) palm covered with Velostat; d) Arduino board integrated inside the prosthesis forearm

While the elements of mechanical control are located inside the hand, under the palm, the electronic circuits of the control and command block are integrated into the free space of the forearm prosthesis. Implementations use an Arduino board to control 5 direct current micro-motors with brushes that actuate the movable elements of the artificial hand. Extension is practically the gradual release of the flexion of each finger.

#### **2.1.4. Implementing artificial epidermis and pressure sensors for sensory feedback in the mechatronic control system**

The palm of the mechanical structure was covered with Velostat, which serves as artificial skin. Velostat, a polymer film impregnated with carbon, is pressure-sensitive. Its resistance decreases when pressure is applied or when the material is flexed. The electrical resistance of Velostat varies depending on the mechanical pressures applied to it. This material has been used in previous experiments by other researchers to test its application as artificial skin [15].

#### **2.1.5. Testing and results of experiments conducted to test the sensitive feedback system of the forearm prosthesis**

This chapter presents the mechatronic structure of the prosthesis that can be used for patients with forearm amputation (the electronics are included in the artificial forearm area). The artificial hand has 5 fingers with 3 phalanges each, except for the thumb, which has 2 phalanges. Each motor is controlled by a direct current motor that moves the finger into the flexed position. Extension of the fingers is achieved when the motion command is retracted.

## **CHAPTER 3. UPPER LIMB PROSTHESIS WITH TENSIONED WIRE ACTUATION**

### **3.1. Some issues regarding the design, development, and construction of upper limb prostheses with tensioned wire actuation**

In the research stages presented in this thesis, computer-aided design of a new mechanical structure is the next step, aiming to fulfill all the points mentioned as future directions in the previous chapter, materializing in a new functional prototype. This new prototype will be created using the same technological process, namely Fused Deposition Modeling (FDM), which is 3D printing with PLA filament.

### **3.2. Designing the upper limb prosthesis with tensioned wire actuation through computer-aided modeling methods using the Solidworks software suite**

As a method of actuation, this new prototype uses the same operating principle, namely achieving flexion by pre-tensioning a wire wound around the motor axis until the tension in the wire is greater than the force developed by the spring at that moment, thus achieving the flexion movement. When the motor rotates in the opposite direction, the tension in the wire begins to decrease, and when it has decreased enough for the force of the spring to be greater than it, progressive extension is achieved.

### **3.3. Dynamic analysis of the behavior of the upper limb prosthesis with tensioned wire actuation under mechanical stress conditions using the finite element method**

No matter how much one would desire, a prototype will never be a perfect functional model, and depending on the rigor of the manufacturer's expectations, there may be more or less room for prototype optimization. To test the functionality of the prosthetic device in working conditions, computer-assisted simulations were developed using the Solidworks software package. Subsequently, a comparison of the results obtained in the digital environment with similar determinations made on the real model is desired.

Mechanical stresses that occur in the studied structure can be observed, and it can be concluded that there are no structural resistance problems with a 6N grip force, but areas with the highest likelihood of yielding to higher forces can still be observed.

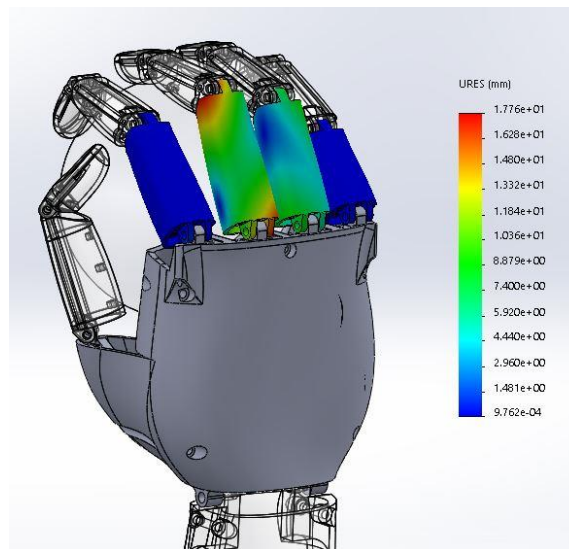


Fig. 2 - Dynamic simulation of the mechanical structure during object grasping (PLA)

Blue indicates the smallest elongations in the studied structure; Green indicates average elongations in the studied structure; Yellow indicates parts that are weak in mechanical resistance, areas that require improvement in future prototype versions. Red indicates a major problem in the structure, often indicating the first part to fail.

### **3.4. Testing and optimizing the upper limb prosthesis with tensioned wire actuation, designed and manufactured**

#### **3.4.1. The adaptability of the human patient and nerve retraining following limb amputation and prosthetic fitting**

Simulations of gripping actions were run, resulting in areas of reduced strength during operation, which were improved, resulting in a new optimized 3D model. This structure was fabricated using additive rapid prototyping technologies, namely thermoplastic extrusion or melt filament modeling. The next step was practical functional testing.

#### **3.4.2. Some issues regarding Open-Source prosthetic types produced through additive technologies**

Due to the accessibility of additive manufacturing technologies such as thermoplastic extrusion and the equipment (3D printer) and filament, several models of upper limb prostheses have emerged and are freely available to the general public by various groups, with the first being from OpenBionics, a company founded with the help of crowdfunding actions, which is a technique for funding projects using online resources derived from

crowdsourcing. [16]. To compare all emerging open-source models, the E-Nable platform was established. [17].

### 3.4.3. Computer-aided design methodology for creating the functional model of the forearm prosthesis

To design an artificial hand that matches both aesthetically and functionally, certain constraints must be considered, which the designer must define at the beginning of the product development process. [18]. These constraints may relate to size, the functions that this system must perform, the chosen methods of electrical actuation, the shape and appearance of the final product, but last but not least, defining the degrees of freedom of the mechatronic system to be created.

### 3.4.4. Computer-assisted simulation results and 3D model optimization for the forearm prosthesis

A series of simulations were conducted using Solidworks Simulation software to detect areas of weak strength during operation. The scenario used is as follows: the robotic hand grasps a sphere. This object was chosen because the force generated by its grip decomposes into multiple directions, testing the entire assembly in various ways.

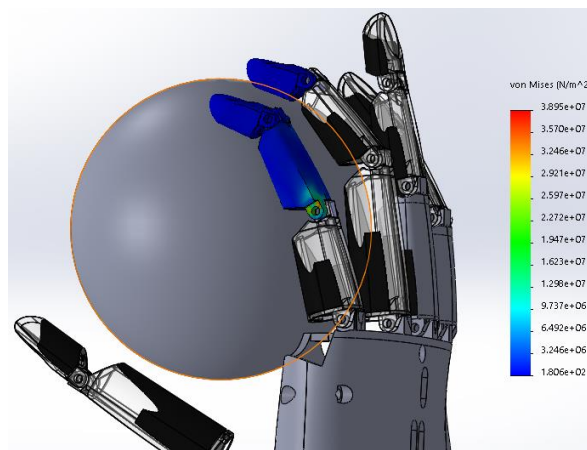


Fig. 3 - Simulation results (increases in stress values measured in  $N/m^2$  are symbolized from blue to red)

An area of increased stress and deformation is observed in the gripping areas between the two phalanges; this area needs improvement by applying extra material to increase the grip strength. The grips were reinforced, and the simulation was run again.



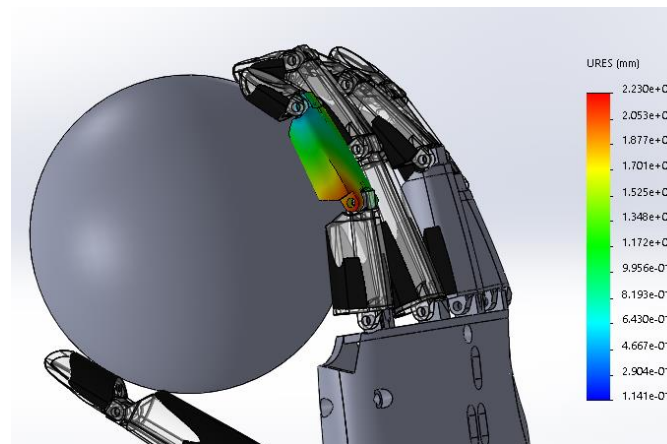


Fig. 4 - Simulation after applying the modifications (increases in deformation values measured in millimeters are symbolized from blue to red)

After reinforcing the area, the reddish color indicating the area of increased stress is no longer concentrated at a point, specifically the grip between the two phalanges, but the improved design disperses stress from the gripping areas onto the phalanx, providing increased resistance compared to the previous model.

### **3.4.5. Technology for processing the functional prototype for the forearm prosthesis**

Considering that the new model indicates increased resistance compared to the previous one, the manufacturing process begins with 3D printing. A Ultimaker 2+ 3D printer with PLA filament was used for this purpose. All parts were printed at medium printing speeds, averaging 60 mm/s. The nozzle diameter is 0.4mm, and the layer height is 0.2mm. The parts are printed, and their assembly begins. All targeted functions have been incorporated into a general algorithm that is loaded into an Arduino Mega 2560. The algorithm is capable of accessing functions automatically, allowing the system to have more natural movements in this way. As an initial state, the system is in complete rest, and at the beginning of operation, an algorithm defining the desired grasping movement type is selected by entering a value from the keyboard. This is made possible by connecting the system to a computer through the Arduino's serial port.

### **3.5. The technology for processing the functional prototype for the forearm prosthesis**

It should be noted that the tolerances of the additive manufacturing process are easily influenced by external factors such as humidity and ambient temperature, and the parameters of the 3D printing process must be memorized and used consistently each time. Small variations in these parameters lead to significant changes in the structure of the final product

or the appearance of defects. The recommendation is to perform tolerance tests before designing the assembly, and these tolerances should be included in the design from the beginning.

As future directions for optimizing the functional model, improving the couplings between the phalanges to reduce friction and increase grip strength is desired so that the assembly is more robust and capable of handling larger masses, thereby extending the lifespan and expanding the range of objects that can be gripped.

Another direction is the use of superior-quality motors compared to the current ones, which will increase the performance coefficient of the entire system and make it possible to adapt an algorithm optimized for speed and precision of movements, thus achieving an overall more performant prosthesis.

Creating a robust mechanism for transmitting motion from the motor to the fingers and abandoning the tensioned wire to increase the system's resistance, which will broaden the field of application.

Implementing an additional degree of freedom for the thumb, thus increasing the robot space of the thumb and, at the same time, expanding the range of objects that can be grasped.

## **CAPITOLUL 4. UPPER LIMB PROSHESIS WITH RIGID ROD ACTUATION**

### **4.1. Advantages of the rigid rod actuation method and reliability enhancement**

The mechatronic system we designed, built, and tested, which constitutes an upper limb prosthesis, continues the previous research with a new approach aimed at achieving the same set of functions that the system needs to fulfill, but in a different and optimized way. By constructing the mechanism with multiple rigid rods, the disassembly procedure in case of system failure is greatly simplified. The rods were properly sized according to the robotic space that the finger needs to cover, allowing for better control of finger trajectory during grasping. The new mechanism also provides superior mechanical resistance compared to the previously designed system. The novelty lies in simplifying the system by using a new mechanism that is easier to manufacture but more efficient in controlling progressive movements. This new concept is pursued to increase the system's reliability without increasing manufacturing costs.

### **4.2. Analysis of basic grip methods and defining the degrees of freedom required for the forearm prosthesis to function**

A real human hand has 27 degrees of freedom. Next, we calculate the degrees of freedom required for the mechatronic system to perform the six grips explained above.

- Cylindrical grasping is achieved by flexing the four fingers opposite the thumb, and the thumb itself, so each finger requires 3 degrees of freedom, plus the thumb which opposes the other four, resulting in:

$$3 \text{ (degrees of freedom)} \times 4 \text{ (fingers)} + 2 \text{ (thumb)} = 14 \text{ (degrees of freedom).}$$

- Two-fingered grasping is achieved by flexing the index finger and the thumb, so the index finger requires 3 degrees of freedom, and the thumb requires 2 degrees of freedom, resulting in:

$$3 \text{ (degrees of freedom for index finger)} + 2 \text{ (degrees of freedom for thumb)} = 5 \text{ (degrees of freedom).}$$

- Four-fingered grasping is achieved by partially flexing the four fingers opposite the thumb, so each finger requires 3 degrees of freedom, which results in:

$$3 \text{ (degrees of freedom)} \times 4 \text{ (fingers)} = 12 \text{ (degrees of freedom).}$$

- Three-fingered grasping is achieved by flexing the index, middle, and thumb fingers, so it requires:

$$3 \text{ (degrees of freedom)} \times 2 \text{ (fingers)} + 2 \text{ (thumb's degrees of freedom)} = 8 \text{ (degrees of freedom).}$$

- Spherical grasping is achieved by flexing all fingers as in cylindrical grasping, so it requires the same:

$$3 \text{ (degrees of freedom)} \times 4 \text{ (fingers)} + 2 \text{ (thumb)} = 14 \text{ (degrees of freedom).}$$

- Lateral (card) grasping with two fingers is achieved by fully flexing the index and middle fingers, followed by flexing the thumb until the object is grasped, so it requires:

$$3 \text{ (degrees of freedom)} \times 2 \text{ (fingers)} + 2 \text{ (thumb's degrees of freedom)} = 8 \text{ (degrees of freedom).}$$

Research on the types of mechanisms used to actuate the mobile parts of a prosthesis is already conducted [19] but new models are emerging every day. Considering the constructive solutions used mainly in prostheses already available to the general public, these mechanisms can be classified as follows:

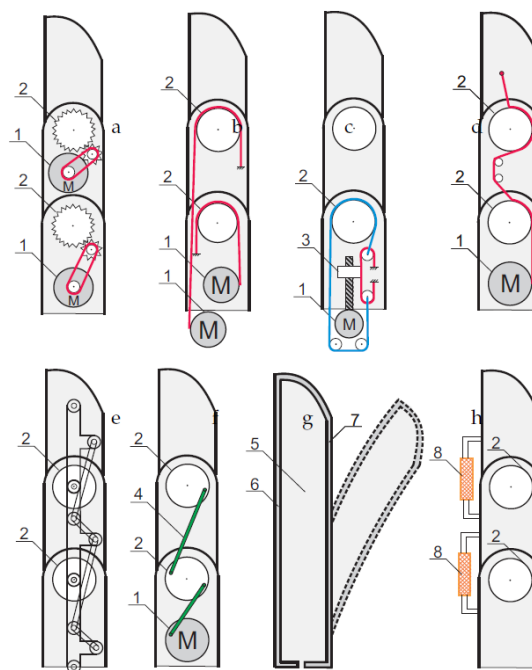


Figure 5 - Types of mechanisms for finger actuation in a prosthesis

- (a) Direct gear transmission, (b) Fully tendon-driven mechanism, (c) Inverse tendon-driven mechanism, (d) Sub-tendon-driven mechanism, (e) Rigid linkage system, (f) Rod-driven joints, (g) Pneumatic actuation, (h) Pneumatic/hydraulic muscles

In this studied system, we aim to implement a rod-driven mechanism as it meets the degrees of freedom requirements imposed on the system to perform the six basic grips mentioned earlier.

### 4.3. The implementation of the modular mechanism in the mechatronic system of the prosthesis

For better troubleshooting in case of a malfunction, we have designed the modular assembly of the system's components. A modular approach not only makes it easier to troubleshoot or replace faulty parts but also allows for system improvement by leaving room for the installation of auxiliary systems. To maintain the anatomical appearance of a real hand, different mechanisms specific to each finger will be designed and sized accordingly.

This mechanism has been appropriately resized for each finger to ensure the movement characteristic, and for the manufactured mechanism to function.

### 4.4. Calculation memorandum of the driving forces for the fingers of the forearm prosthesis

The system is based on three rod-driven mechanisms that are actuated successively. The first rod will actuate the second one with the help of a secondary rod by transferring the forces coming from the linear motor. The second rod, in turn, will actuate the third one through another secondary rod that transfers the actuating forces from the motor. To determine the actuating forces that the motor needs to develop for the assembly to move, we observe the force distribution in the finger mechanism and calculate values of frictional moments in the couplings that connect the constructive elements of the robotic finger mechanisms. Figure 6 illustrates the forces in the studied mechanism:

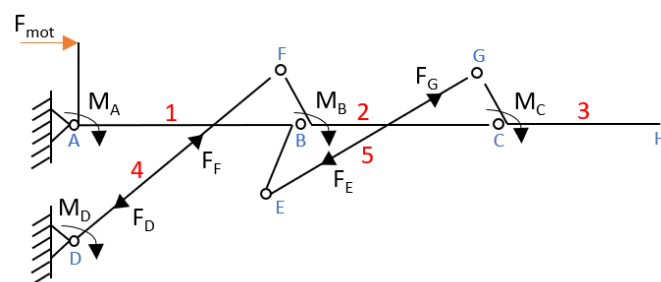


Figure 6 - Force distribution in the mechanism when applying an actuating force from the motor

Having all the necessary data to calculate the minimum force that the motor needs to develop, it can be calculated as follows:

$$F_{mot} * [A] > F_e * [AB]$$

$$F_{mot} * 9[mm] > 14,4[N] * 27[mm]$$

$$F_{\text{mot}} > (14,4 * 0,027) / 0,009$$

$$F_{\text{mot}} > 43\text{N}$$

To ensure proper grasping and prevent objects from falling out of the prosthesis, the linear motor must be capable of developing a force of at least 43 N. Several motors have been studied, and a model that comes with multiple options for the transmission ratio and meets the requirements of the studied system is the "PQ12-R Micro Linear Servo" produced by Actuonix with a transmission ratio of 100:1, capable of developing a force of 50N.

#### **4.5. Creating the 3D model of the prosthesis using computer-aided design (CAD)**

The selected linear servo motor is compact and can be easily integrated into a modular design. In addition to being able to develop a force of at least 43 N, it needs to be relatively small so that when four motors are grouped for the fingers opposite the thumb, the system's dimensions do not exceed those of a real hand. The process of building the 3D model starts with the finger mechanism, integrating a motor attachment while keeping modularity in mind for easy troubleshooting or possible future enhancements.

#### **4.6. Results obtained and their interpretation for the rigid rod actuation version**

Before finalizing the simulation and design phase, it is essential to ensure that the necessary requirements are met, attempting to identify any issues at this stage. Detecting design or production errors at this stage is crucial and shortens the total time for creating a functional prototype since correcting errors after the product is designed or produced is much more challenging.

## **CHAPTER 5. METHODS OF INTEGRATING TECHNOLOGIES FOR CREATING AN UPPER LIMB NEUROPROSTHESIS WITH SENSORY FEEDBACK**

### **5.1. Sensory feedback and its role in generating control commands for neuroprostheses**

To meet the needs of people with disabilities, state-of-the-art technologies provide solutions that not only match but also offer the potential for augmentation beyond natural limits. Whether it's the upper limbs or other parts of the human body, by integrating miniaturized technologies into a complex, tested, and optimized system, it becomes possible to overcome certain physical limitations.

#### **5.2. The component elements of the forearm neuroprosthesis system**

The studied system is an upper limb neuroprosthesis, specifically designed for individuals with forearm amputations. The system consists of two subsystems: the robotic arm and the neural interface, each divided into multiple components. [20]

**5.2.1. The robotic arm** itself comprises various components, including a mechanical system for motion, electric actuators (linear motors), data processing electronics, and power supply (batteries). Its purpose is to perform everyday movements.

##### **5.2.1.1. The mechanical system of the upper limb prosthesis**

The mechanical system includes a mechanism with rigid rods, protective casings, and a tensioned wire mechanism with elastic return for the thumb.

##### **5.2.1.2. The electric drive system of the robotic arm**

Two types of electric motors were used. Micro linear servo motors Actuonix PQ-12R with a 6V power supply and a reduction ratio of 63:1 were used for all fingers except the thumb. These motors are capable of delivering a maximum torque of 45 N, sufficient for mimicking real hand capabilities. [21]

##### **5.2.1.3. The control and command block of the mechatronic system**

The control and command of the prosthesis are generated using an Arduino development board and a Pololu DRV8838 driver for brushed motors. The Arduino board is suitable for this application, requiring only a few outputs for system control. The four linear servo motors are controlled using digital signals directly from the Arduino board, with integrated internal positioning systems.

#### **5.2.2. Neural Interface**

The neural interface is composed of several components, including electrodes, nerve mounting support, and attached electronics. A flexible substrate made of polyimide and Cr/Au traces was used to ensure biocompatibility. Its purpose is to capture neural signals

from the peripheral nervous system, necessary for generating commands to control the prosthesis.

### **5.2.2.1. The electrodes for neural interfacing between the patient and the prosthetic device that was created**

The implantable subsystem consists of the neural implant and internal electronics. The neural implant comprises electrodes with metal contacts, metal traces, and a flexible substrate. [22] A reference electrode is also included to collect both alternating impulses. The manufacturing process for the electrodes involves several steps, including substrate preparation and metal deposition. [23]

The manufacturing technological process of the electrodes includes the following steps:

Step 1. Substrate preparation: The substrate is a 0.2 mm thick polyimide (Kapton) film.

The polyimide base is dimensioned into layers measuring 100 mm x 100 mm. It is placed on a glass support and its edges are fixed with adhesive tape. Dry cleaning is applied using O<sub>2</sub> plasma with the RIE (Reactive Ion Etcher) equipment. Process parameters are as follows: Power = 100W; Pressure = 20Pa; Oxygen flow rate = 40 cm<sup>3</sup> / min (sccm); Time = 40 seconds [24].

Step 2. Metal deposition:

The gold layer was obtained using the sputtering deposition technique [25].

- Exposure to photoresist at 2500 rpm HPR;
- Heat treatment at 90 degrees Celsius for 1 minute;
- Photolithography M1 (Au);
- Deposition of Cr / Au 20/200 nm;
- Separation and dicing process.

### **5.2.2.2. The electronic system attached to the neural interfacing module**

To process the neural signals and transmit them to the main processing system (Arduino), an electronic module is attached subcutaneously. This module acts as a Bluetooth transmitter, enabling data transmission through tissues without the need for external wires, reducing the risk of infection.



### **5.3. Some issues regarding the biocompatibility of materials for encapsulating mechatronic systems**

Biocompatible materials are used to cover the implant's components, ensuring they can be implanted without causing a foreign body reaction. Two biocompatible materials, Gelatin Methacryloyl (GelMA) hydrogel [26] and Silastic RTV 9161 elastomer [27], were chosen for this purpose.

#### **5.3.1. Medical-grade hydrogel, Gelatin Methacryloyl (GelMA) for encapsulating mechatronic systems**

GelMA, a high-collagen hydrogel with biocompatible compounds, was chosen to cover the implant components. It imitates natural cells, ensuring biocompatibility. [28]

#### **5.3.2. Medical-grade silicone, Silastic RTV 9161 elastomer, for encapsulating mechatronic systems**

Silastic RTV 9161, a medical-grade silicone rubber, was used to encapsulate the implant. It offers excellent dielectric properties, resistance to moisture and oxidation, and is suitable for protecting electronic devices from malfunction.

#### **5.3.3. Bio-printer BioX, CellInk, and the bio-printing process for creating the encapsulation enclosure of mechatronic systems**

A BioX bio-printer from CellInk was used for fabricating structures using GelMA. Precise control over parameters such as extrusion pressure, chamber temperature, printing speed, and structure consistency is essential for 3D bio-printing. [29]

#### **5.3.4. Some issues regarding the necessity of encapsulating the mechatronic module with Gelatin Methacryloyl (GelMA)**

Electrodes are encapsulated with GelMA [30], to create a 1mm thick rectangular cover, ensuring that the material imitates the surrounding tissue, enhancing biocompatibility.

#### **5.3.5. Encapsulation of the mechatronic module with medical-grade elastomer Silastic RTV 9161**

Silastic RTV 9161 [31], was used to encapsulate the mechatronic module. A custom-sized mold was fabricated to incorporate the entire subassembly.

### 5.3.6. Comparative results of encapsulating the mechatronic module with Gelatin Methacryloyl (GelMA) and the elastomer Silastic RTV 9161

Conductivity measurements were conducted before and after encapsulation with both materials. Results indicated that GelMA has minimal impact on conductivity, ensuring that low-current functionality remains undisturbed. [32]

### 5.4. Some issues that have arisen in the development of the forearm neuroprosthesis

Before implanting the system in humans, testing was conducted on animals, specifically pigs, due to the similarity of their peripheral nervous systems to humans. These tests were approved and carried out to assess functionality. [33, 34]

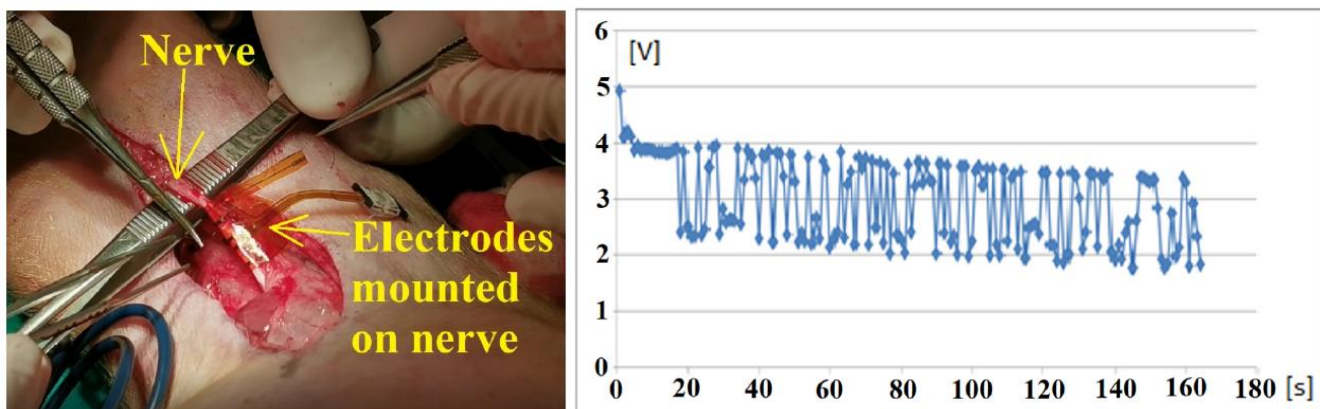


Fig. 7 - The electrode mounted on the nerve and the signal obtained after stimulation

Because the issue of biocompatibility has been addressed and the system can function through commands received from the user's nervous system, the assembly of the prosthesis is presented in detail, from the flow of information to the grasping motion.

The neuronal impulse is captured at the level of the nerve branch by the gold electrode on the Kapton film and is then transmitted and processed by the electronic block attached to the implant. [35]

After the neuronal impulse has been captured, filtered, and processed, transformed into electronic information, it can be further transmitted to the peripheral system of the prosthesis. The construction of the functional prototype of the prosthesis begins. The Anycubic 4Max Pro 2 printer is used for system fabrication. [36] The first 3D printed parts are the components of the finger mechanisms. These are manufactured one by one, as there

are relatively small dimensional differences, making it easy to confuse and assemble them incorrectly, resulting in a malfunctioning mechanism.

#### **5.4.1. The need for optimizing the mechatronic system of the prosthesis**

Tests focused on joint play and optimizing friction in the finger mechanisms to minimize lateral play and ensure smooth grasping.

#### **5.4.2. The electric drive system, control, and operation of the prosthesis**

The four fingers opposing the thumb use linear servo motors for actuation [37], while the thumb uses a brushed motor [38] with position feedback. The linear motors are controlled directly via Arduino, while the brushed motor is controlled through a DRV 8838 motor driver.

#### **5.4.3. The operating algorithm for grasping a cylindrical object**

To grasp a cylindrical object, the system undergoes initial preparation to compensate for dimensional variations. Flexion of the fingers begins and continues until pressure sensors detect contact with the object.

#### **5.4.4. The problem of low adhesion on the surface of the phalanges**

The use of PLA for the functional prototype resulted in low adhesion to objects. A solution was found by applying a layer of silicone to increase friction between the phalange surfaces and objects.

#### **5.4.5. Preparation for grasping a cylindrical object**

The system was programmed to grasp cylindrical objects like plastic bottles. Measurements of the object were taken, and digital values for motor control were correlated to achieve a desired gripping pressure.

#### **5.4.6. Velostat pressure sensors fabrication steps**

Pressure sensors with Velostat were fabricated to automate position control of the motors during object interaction. These sensors are placed in contact areas between the prosthesis.

#### **5.4.7. Advantages of the forearm prosthesis that was fabricated**

One of the main advantages is that the prosthesis is controlled using signals captured from the patient's peripheral nervous system, making the control more natural and intuitive over time, closely resembling the use of a real hand.

## **CHAPTER 6. CONCLUSIONS REGARDING THE UPPER LIMB PROSTHESIS, ITS USAGE ON HUMAN PATIENTS AND DEVELOPMENT PERSPECTIVES FOR THE FUTURE**

### **6.1. Conclusions on the reliability of the prosthesis and its control system and some problems with its use in human patients**

After the prosthesis is attached to the patient, there is a period during which the brain will adapt to the new system integrated into their life, which is meant to ease their daily actions. This adaptation period can last between 1 and 3 months, during which the user gets accustomed to the system, and their brain adapts to the interaction between the commands given by the patient's nervous system and the actual movement response of the prosthesis.

### **6.2. Current stage of budgets allocated to global prosthesis manufacturing**

Limbs amputations are a global medical issue with an alarming increase in recent years. The World Health Organization and the International Society for Prosthetics and Orthotics declared a decade ago that "50 million people (0.5% - 0.8% of the world's population) have lost a limb, with 30 million located in Africa, Asia, and Latin America." [39]. *Advanced Amputee Solutions* [40] predicted that the number of people with limb amputations in the USA will reach 3,600,000 by 2050.

### **6.3. Future development perspectives for upper limb prostheses**

Further research is needed to optimize the system and program it to perform the six basic grips. The neural stimulation system can also be used to provide sensory feedback to patients who have a paralyzed area, for example, by connecting the neural interface module to a healthy nerve region that still transmits signals. [41]

The possibilities for development are numerous, as this system can be used to rehabilitate an amputated area or an area where the nervous system is affected. Once the materials of the implantable system provide the necessary biocompatibility to prevent the body from rejecting it as a foreign object, one of the most complex issues associated with these types of systems is overcome, but the interpretation of nerve signals recorded from nerves remains just as challenging.

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