**NATIONAL UNIVERSITY OF SCIENCE AND TECHNOLOGY POLYTECHNIC BUCHAREST**
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# SUMMARY

# DOCTORAL THESIS

## Cercetări privind conceperea şi dezvoltarea unui membru inferior protetic bionic, controlat cu o cască neuronală

## Research on the design and development of a bionic prosthetic lower limb controlled with a neural headset

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**Keywords**: lower limb prosthesis, 3D printing, brain-computer interface, electroencephalography, functional and non-functional requirements of leg prostheses, tensile test, compression test, bending test, finite element analysis, numerical validation of the finite element model, phantom limb pain, post-traumatic stress disorder, eye movement desensitization and reprocessing therapy.

# CUPRINS

# INTRODUCTION

## TOPIC OF THE THESIS

Since ancient times, people have substituted a missing limb with an object that would help them with their daily tasks and present a close appearance to the natural limb. The first writings in which the use of prostheses is mentioned appear in Aztec mythology, in the 10th century BC [1]. The first lower limb prosthesis was discovered in the 1800s, it was made of wood about 3000 years ago [2].

The evolution of technology has brought countless benefits to humans. Obtaining biocompatible composite materials that are lightweight and durable, together with the design of ergonomic myoelectric prostheses, have raised the standard of developing effective aesthetic prostheses for manufacture. Also, the evolution of devices used in surgery to fix a prosthesis has reached the level where a vascularised composite allograft procedure can restore the patient's life to normal as much as possible. The advantages and disadvantages of using some prostheses depend on cost and the desire of amputees to follow complex surgical procedures.

Biomaterials are a type of natural or synthetic material that can be used to replace an organ of the human body. For example, polylactic acid (PLA) is a biomaterial that is often used in the manufacture of a lower limb prosthesis.

The way a prosthesis is made has kept pace with the evolution of material types. The first 3D printer was made in 1984 by Charles W. Hull [3]. Today, 3D printing is commonly used to make prostheses or components of prostheses. The use of a 3D printer and a biomaterial to print the components of a lower limb prosthesis has advantages and disadvantages. One of the advantages is that the material selected for the manufacture of the components and the printing process is low cost, but this process also comes with some limitations related to the size or design of the parts.

The control mode of a properly fitted electronic prosthesis can be:

- invasive - by implanting sensors on the remaining muscle in the residual limb or placing sensors inside the brain;
- non-invasive - by attaching sensors to the residual limb to capture remaining muscle activity or by placing sensors on the scalp to capture neural activity that controls leg movement.

Controlling a prosthesis to replace a lower limb using neural activity is a novel process in modern research studies.

There are papers in the literature that mention the use of electrical signals from the brain (Electroencephalography - EEG) to fully [4] or partially [5] control a lower limb prosthesis, where each of the proposed systems has certain advantages and disadvantages.

The system designed and presented in this PhD work fills the gaps of the current systems presented in the literature review, by the fact that, through the uniqueness of the implemented system that operates the knee and ankle movement of the foot prosthesis, having also has the advantage of being financially accessible.

Currently, the control of a lower limb prosthesis built from scratch (design, fabrication, assembly and electronic fitting of the prosthesis) using non-invasive brain activity is presented as the first study conducted in Romania.

# IMPORTANCE OF THE THESIS TOPIC

People who have had at least one lower limb amputation need physical and psychological support. The trauma suffered by a person following an amputation often has a devastating effect on psychological health. Most people who have suffered such trauma experience Phantom Limb Pain (PLP), even long after the loss [6].

In addition to helping in treating the associated trauma, amputees need physical help, especially for essential activities: changing clothes, daily personal hygiene, moving around, etc.

Approximately 0,5% of the world's population uses or requires a prosthesis or orthosis. As these people should be able to continue to live as normal lives as possible with the help of the prostheses they use, there is a need to find better solutions for the design, manufacture and use of prostheses [7].

Thanks to the advantages of the superior properties of today's biocompatible materials. 3D printers can print strong, lightweight and flexible components of a lower limb prosthesis.

To avoid complex and costly surgery, a significant proportion of amputees prefer to adopt a non-invasive solution of how to control the prosthesis they are using. After an amputation, the remaining muscles in the residual limb may be damaged in such a way that they can no longer provide signals that can be used later to control the prosthesis. In this context, the use of electrical signals from the brain to control the lower limb prosthesis is highlighted. Brain signals can be captured using a dedicated neural headset, which has the sensors needed to capture the electrical activity of the human brain.

The control of a prosthesis requires the appropriate electronic equipment. Thoughts captured by the neural headset are converted into specific commands to control the movement of the lower limb prosthesis.

Using the neural headset to set specific commands to move the prosthesis requires a series of training sessions. As the loss of a lower limb causes trauma, amputees may require specialist psychological treatment to reduce trauma to train the neural headset. Appropriate treatment can be achieved using an Eye Movement Desensitization and Reprocessing (EMDR) method. In this thesis, an actuator-based EMDR virtual assistant system is described. The system can be used to treat participants with traumatic memories, in our case, people with trauma caused by (partial) limb loss.

EMDR is a psychological therapy designed to treat emotional distress caused by a past traumatic event, most commonly in the treatment of post-traumatic stress disorder (PTSD). In this case, it helps people who have suffered amputations to be able to follow self-treatment to reduce their trauma, using an application that does not require the physical support of a medical specialist.

The topic of the thesis also describes the use of biomaterials to fabricate, assemble and electronically equip a lower limb prosthesis to control it using a dedicated neural headset.

This thesis is the first study in Romania to design and implement a lower limb prosthesis controlled by the power of thought.

# 1 CURRENT STATE OF RESEARCH

## 1.1 Evolution of prostheses

This subchapter presents some general aspects of prostheses that are used to replace missing limbs. In step with the evolution of synthetic biomaterials used in the design and manufacture of prostheses, the technology by which a prosthesis can be controlled by the amputee has also evolved. It has been one step in the evolution of prostheses from the discovery of carbon fibres and myoelectric prostheses to the implantation of a custom-made synthetic limb for a specific individual.

Devices like neural headsets can be used to control a bionic prosthetic limb to avoid surgery. Brain-Computer Interface (BCI) can be used to connect the Central Nervous System (CNS) with the bionic prosthesis directly, without the need for a connection to the amputee's peripheral nerves. The low cost and easy maintenance of the neural headset-bionic prosthesis package is an alternative solution for amputees with a low budget.

### 1.1.1 History of prostheses

Throughout history, people's lives have been subjected to severe circumstances, from climate change to bloody conflicts. Humanity has suffered the most from wars, which have not stopped till today. The first prosthesis is mentioned in Aztec mythology and belongs to the god of vengeance and creation, Tezcatlipoca, who is depicted as a man in armour, with some of his body parts replaced with various materials [1].

### 1.1.2 Functional role, advantages and disadvantages of prostheses

In the 1980s, improvements in materials, through the development of technology, allowed to design of lighter and more ergonomic prostheses, and their power supply evolved from the use of compressed gas to rechargeable nickel-cadmium batteries.

Myoelectric prostheses provided a high level of comfort compared to body-operated prostheses because they had no cables.

Research carried out by material scientists has led to the development of carbon fibres, which are biocompatible, synthetic materials that have become part of the structure of very light and very strong composite materials that have contributed to the development of high-tech myoelectric prostheses [8].

## 1.2 Materials used in the manufacture of prostheses

In ancient times, prostheses were made of wood, iron or leather, where such prostheses were heavy and uncomfortable. The switch to the use of biocompatible materials in the manufacture of prostheses has been embraced by all people requiring missing limb prostheses.

Biomaterials are any substance or combination of substances, of natural or synthetic origin, capable of being used over a well-defined period, as a whole or as a part of a system that treats or replaces a tissue, or organ of the human body. A biomaterial is a non-viable material that can be used to create medical devices to interact with a biological system [9].

The proposed lower limb prosthesis, which is the subject of this PhD thesis, will be produced by a 3D printer, using a design in a dedicated application.

## 1.3 Prostheses manufacturing technologies

### 1.3.1 3D printing

Rapid prototyping became increasingly widespread and widely used after 2000 with the development of 3D printing using FDM (Fused Deposition Modeling). The first study on 3D printing technology was published in 1981 by Hideo Kodama, and in 1984 Charles W. Hull produced the first 3D printer, but 3D printing has become increasingly popular as the price of purchasing it has fallen and new 3D printing technologies have emerged [10].

However, in addition to the advantages of 3D printing, it also has some limitations, such as the fact that the parts produced by this method are generally small in size, and additional machining operations are required to obtain the best visual results for their appearance [11].

### 1.3.2 3D printing technologies

According to standard ASTM F2792, there are seven broad categories of 3D printing technologies [12]:

- spraying binder;
- directed energy deposition;
- extrusion of material;
- spraying of material ;
- fusion of powder layers;
- sheet rolling;
- light curing.

## 1.4 The need for specialised help for people using a prosthesis

Prostheses made to replace missing limbs or to replace missing parts of a person's limbs have kept pace with the evolution of technology.

To manufacture a prosthesis today, the parts used to assemble the final product are designed down to the smallest detail. Moreover, prostheses can be controlled using a dedicated neural helmet, in case a person decides not to resort to surgery to replace a missing limb.

Choosing the type of prosthesis and how to control the prosthesis has its advantages and disadvantages.

## 1.5 Methods of controlling bionic prostheses

Many of the current methods of controlling a prosthesis are invasive (surgery is required). These methods use the response of the remaining blunt muscles (proximal muscles that can be reinnervated) to control the bionic prosthesis by converting the muscle response into a control signal adapted for the prosthesis. In this way, neural commands are biologically amplified by the muscles and then picked up by the sensor [13].

The topic chosen for the research involves the use of a non-invasive method to control a bionic prosthetic lower limb. The following presents the technique used in the non-invasive method of controlling the bionic prosthetic limb presented in this PhD thesis.

**Electroencephalography** (EEG) is a non-invasive method of recording an electrogram of the electrical activity generated by the human brain. Electrophysiological signals from the brain are captured using electrodes placed on the scalp [14].

The EEG method underpins the functionality of the Brain-Computer Interface (BCI) technology, which is used to control a bionic prosthetic limb.

## 1.6 Use of brain-computer interface in the control of bionic prosthetic lower limb prosthesis

The original aim of developing the BCI technology was to study the usefulness of using brain signals in human-computer dialogue. At the same time, this goal has generated a new tool for studying the neurophysiological phenomena that govern the production and control of observable neuroelectrical events [15]. Electrodes that can be placed directly on the brain are used to capture electrical signals generated by the brain or on the scalp. Implanting the electrodes in the brain requires one or more surgeries, but the signal obtained is of high quality.

The non-invasive method, which is the subject of this PhD thesis, is where the electrodes are fixed on the scalp, but the signal captured is of lower intensity compared to the signal captured by the invasive method.

## 1.7 Conclusions

The loss of limbs or parts of limbs causes an imbalance in people, both functionally and mentally. To counteract the effects of such losses, since ancient times people have tried to replace missing limbs or parts so that they can continue their work and life with as little loss of functionality as possible.

From rudimentary devices made of wood, iron or leather, whose functionality was minimal, as a result of scientific progress, prosthetics have undergone continuous development and improvement, both in terms of prosthetic functionality and aesthetics.

Nowadays, using EEG technology, the BCI interface can be used to control bionic upper or lower prostheses limb.

A dedicated EMOTIV™ Insight device can be used to capture the electrical signals generated in the brain, which converts the captured signal into commands that can then be transmitted to a bionic lower limb replacement prosthesis.

# 2 OBJECTIVES AND ORGANISATION OF THE THESIS

## 2.1 THESIS OBJECTIVES

*The main objective* of this PhD thesis is to design and implement a bionic lower limb prosthesis and to investigate how to control it using a dedicated neural headset. EEG-based BCI technology has been used for controlling a lower limb prosthesis by capturing the thoughts of the brain using the sensors in the neural headset. In this way, neural activity can be captured in the form of signals, which are then converted into specific commands. Successful use of the neural headset requires training sessions by the user.

*The secondary objective* of this PhD thesis is to develop a software application that can be used independently by people who need trauma reduction after lower limb amputation. This could be important for them to train the neural headset to control a prosthetic leg successfully.

*The specific objectives* are:

- Study the evolution of materials used in the manufacture of lower limb prostheses, how foot prostheses are manufactured, and the techniques in which these prostheses are controlled over time.
- Conduct a quantitative questionnaire to determine the main improvements that can be made to a lower limb prosthesis.
- Make the elastic and mechanical characterisation of the material used in lower limb prosthesis fabrication.
- Design and implementation of a lower prosthesis limb based on the results of the previous questionnaire and implementation of a neural headset control system for the prosthesis.
- Highlighting the dynamic behaviour of a bionic lower limb prosthesis, equipped with electric actuators, allowing rotational movement of the knee and ankle of a prosthetic foot.
- Reducing the trauma experienced by people who can receive EMDR therapy in terms of neural pathway training.

## 2.2 THESIS ORGANISATION

This PhD thesis is organized into eight chapters, primarily written to implement the main objectives defined above and to demonstrate a concept that is insufficiently researched in Romania.

182 references have been used in this thesis, most of which are part of a highly topical literature.

**CHAPTER 1 - CURRENT STATE OF RESEARCH**, this chapter includes a history of the materials used in the manufacture of lower limb prostheses, methods of prosthesis manufacture, and methods of prosthesis control over time. It also presents reviews and compares the types of biocompatible composite materials that can be used to make a prosthetic leg, the methods of making the components in the prosthesis configuration, and the types of prosthesis control.

Among the biocompatible composite materials, PLA was chosen to implement the lower limb prosthesis presented in this thesis.

EEG-based BCI technique was chosen to control a lower limb prosthesis, to avoid surgery and to not depend on the level of function of the remaining muscles in the residual limb.

**CHAPTER 2 - OBJECTIVES AND ORGANISATION OF THE THESIS**, this chapter presents a description of the thesis's objectives. It also presents the research carried out to implement a system in which a lower limb prosthesis is controlled using electrical brain signals generated by the prosthesis user.

**CHAPTER 3 - DETERMINATION OF USER REQUIREMENTS FOR AN INTELLIGENT SYSTEM FOR MIND CONTROL OF A LOWER LIMB PROSTHESIS**, is a survey that was conducted to determine the functional and non-functional requirements of the proposed system.

Amputees and healthy people participated in the survey. The results of the survey were used to implement a lightweight lower limb prosthesis that is affordable and easy to use.

**CHAPTER 4 - ELASTIC AND MECHANICAL CHARACTERISATION OF THE MATERIAL USED TO MAKE THE BIONIC LEG,** this chapter describes the printing of samples of PLA to test the tension, compression and three-point bending.

To characterise the material from an elastic and mechanical point of view, a state-of-the-art technique - DIC (Digital Image Correlation) was used, which involves capturing images during the test and evaluating the resulting deformations. Based on data obtained from the experiments, a series of results can be obtained, which are highlighted in this chapter.

Practically, the tests have been conducted to determine the elastic and mechanical properties of the 3D printed material - PLA.

**CHAPTER 5 - DESIGN AND IMPLEMENTATION OF A LOWER LIMB PROSTHESIS AND ITS CONTROL USING ELECTRICAL SIGNALS FROM THE BRAIN**, this chapter describes the design, implementation and hardware fitting inside the lower prosthesis limb prototype. The fitting of the prosthesis was achieved by using components that allow remote control of the prosthesis using a dedicated neural headset.

Several tests were performed, on a clinically healthy participant, by training the neural headset to use it to move the prosthetic leg, with a training session taking approximately 20-30 minutes. After creating the profile of the neural headset user, he successfully controlled the lower limb prosthesis using his electrical brain signals.

The present work aims to study the possibility of controlling a prosthetic leg using thoughts, which is why the designed prosthesis was not 3D printed on an adult scale.

**CHAPTER 6 - ANALYSIS OF THE MECHANICAL BEHAVIOUR OF A BIONIC LEG IN DYNAMIC MODE**, chapter six describes the use of kinematic and dynamic analysis methods suitable for the implemented prosthetic leg and presents a simulation of its mechanical behaviour in the dynamic regime using the finite element method.

By printing the lower prosthesis limb components, in terms of their thickness level, the mechanical results obtained indicate a different behaviour of the material depending on the stresses to which such a prosthesis is subjected.

For the experimental model, the dynamic stresses occurring during the movement of the foot were determined and the finite element numerical calculation revealed the occurrence of mechanical stresses below the allowable strength of the prosthesis material.

**CHAPTER 7 - IMPLEMENTATION OF AN EFFECTIVE EMDR SYSTEM FOR THE TRAUMA TREATMENT OF THE PEOPLE THAT USE A LOWER LIMB PROSTHESIS**, this chapter describes the implementation of a software application that aims to reduce trauma for amputees. This application implements EMDR therapy, which can be self-administered by a participant without the supervision of a psychological specialist. Neural headset training requires a stable psyche of the users, hence the need to use EMDR therapy to reduce trauma.

The testing of the application was carried out in collaboration with an NGO (Non-Governmental Organisation), where participants were trained and supervised by specialised clinical staff. The results obtained from self-administration of EMDR therapy were very successful, where the patients' trauma was reduced as a result of the sustained EMDR process.

All the results were also interpreted by psychologists, who confirmed the reduction of trauma. A scientific article was published describing in detail the procedures followed in the implementation and testing of the application responsible for self-administration of EMDR therapy.

**CHAPTER 8 - FINAL CONCLUSIONS. CONTRIBUTIONS AND PERSPECTIVES**, this chapter presents the main conclusions obtained during the implementation of the system in this PhD thesis. Also, both the original contributions of the author of the thesis and the new directions for further scientific research focused on the topics addressed in this PhD thesis, are mentioned.

# 3 DETERMINATION OF USER REQUIREMENTS FOR AN INTELLIGENT SYSTEM FOR MIND CONTROL OF A LOWER LIMB PROSTHESIS

## 3.1 Use of EEG-based BCI technology

In this chapter, a quantitative questionnaire is presented to determine the functional and non-functional requirements of the users, as well as how they want to interact with the lower prosthetic limb system. Participants' responses will be considered as the basis for the system design.

The aim of this quantitative questionnaire is to determine the functional and non-functional requirements for the lower prosthetic limb prototype that we intend to build. The prototype should be made of lightweight, low cost, and to be controlled by mental commands using a dedicated neuro headset.

Some of the disadvantages of lower prosthesis limbs that are currently in use are their high cost, the high mass of some materials and the difficulty of controlling them. Prostheses could help many people who have had lower limb amputations regain some functionality to perform their daily activities. Although they look increasingly attractive, prostheses offer less than half the capabilities of a human leg. Because of the inefficiency of these prosthetic activities, amputees often reject them due to high stress, leading to exhaustion and frustration [16].

In quantitative research, solutions and observations are transformed into numerical data and then analysed and interpreted through statistical analysis processes.

The findings of these studies are often used to conclude important elements of interest to individuals, like parameters that indicate links between theoretical ideas or the significant impact of experiments and practices [17].

To identify and evaluate the functional and non-functional user requirements for a prosthesis leg system that is intended to be built, this quantitative research was created. The results of the responses' analysis are used to determine user requirements.

## 3.2 About the questionnaire and sampling

This questionnaire was made to define the functional and non-functional requirements of amputees to fulfil all their needs in controlling a prosthetic bionic lower limb. This questionnaire targeted four groups of people: prosthetic limb technicians, engineers, physicians, and lower limb amputation surgeons.

To ensure the survey is as comprehensive and accurate as possible, it has been sent to a wide range of respondents. There were 40 people who took part, and they all answered questions from one of three sets. Each set had both multiple-choice and short-answer questions:

- In the first group, the backgrounds of the participants were determined;
- The second group includes questions for leg amputees only;
- The third group include questions to identify the functional and non-functional requirements of the user.

## 3.3 Analysis of the obtained results

In this article, we apply a quantitative exploratory approach to verify the user's functional and non-functional requirements for operating the prosthetic lower limb controlled by the mind. The interests and suggestions of the users have been considered, along with suggestions of the specialists and conclusions from the related works.

*A. Participants' background*

In terms of participants' occupations, 58.5% were engineers, 9.8% were amputees of at least one lower limb, 7.3% were prosthetic technicians, 4.9% were doctors, while 19.5% were from other professions. 66% of the participants were Romanian, 29% Iraqi and 5% Turkish, according to their nationalities.

Regarding age, 2.4% of survey respondents were under 18 years old, 24.4% were between the ages of 18 and 30, 46.3% were between the ages of 31 and 40, 14.6% were between the ages of 41 and 50, 7.3% were between the ages of 51 and 60, and 4.9% were over 60 years old. 26.8% have a doctoral degree, 31.7% have a master's degree, 31.7% have a bachelor's degree, 4.9% have a vocational/technical degree, 2.4% have a high school diploma, and 2.4% have a different sort of speciality.

## 3.4 System demands

The functional and non-functional requirements of the user have been determined based on the results analysis of the questionnaire. The system design implementation of the prosthetic lower limb should take these needs into account. User specifications for the mind-controlled prosthetic lower limb prototype are as follows:

- Build prosthesis lower limb using lightweight materials;
- Use wireless technology to control the prosthesis leg;
- Make the prosthesis leg to be able to simulate the classical movements of a human leg;
- Provide training for amputees to control the prosthetic lower limb;
- Safety requirements should be included in the prototype;
- Increase the accuracy and the speed performance of the prototype;
- Usability, reliability, flexibility and maintainability requirements should be included in the system.

Based on the respondents' opinions, the most important functional requirements are to have the classical movements of the human leg and to use lightweight materials in the system that is intended to be built.

According to leg amputees' complaints, the system should be built out of lightweight materials considering other features like:

- flexibility;
- biocompatibility;
- durability;
- wear resistance, high temperature and high impact resistance.

Regarding non-functional requirements, it is necessary to build the prototype with good accuracy and response time, which are very important as performance requirements.

Related to reliability requirements, it is necessary to reduce failure in the system's performance by building a reliable system.

The prototype should be easy to learn, operate and interact with by leg amputees who have a low level of education to ensure the usability requirements of the system.

By considering flexibility requirements, the system should be configured and easy to adapt to different environments according to leg amputees' expectations.

The system should be easy to improve and repair with less time, taking into consideration the battery lifespan. The software used by the system should be error-prone according to safety requirements.

## 3.5 Conclusions

Controlling applications using EEG-based-BCI is a new area of research where a lot of studies can be done, particularly in the medical field.

The purpose of this survey is to report the results of a quantitative research questionnaire developed to ascertain and verify the functional and non-functional needs of the anticipated design and construction of a mind-controlled prosthetic lower limb.

The questionnaire was published online, where 40 participants (leg amputees, engineers, physicians and prosthetic limb technicians) answered the questions of the questionnaire. The responses of the participants have been analyzed and represented graphically.

Those responses have revealed some disadvantages and issues of the current prosthesis lower limb used by leg amputees, problems like heavyweight, movements, and control difficulties. Most of the respondents proposed improving the control and movements of the prosthesis leg since the analysis of the results showed that several leg amputees are not satisfied with their prosthesis lower limb.

This questionnaire will help ensure that the user's needs are considered while designing and building the prosthesis leg which will help alleviate present issues with the prosthetic lower limb system.

Future research will focus on developing a prototype system for mind-controlled prosthetic lower limbs utilizing non-invasive EEG-based BCI that is affordable, accurate, and intelligent to meet the demands of leg amputees.

# 4 ELASTIC AND MECHANICAL CHARACTERISATION OF THE MATERIAL USED TO MAKE THE BIONIC LEG

## 4.1 Experimental tests

### 4.1.1 Equipment used

Considering the information presented in subchapter 1.2, which related to the implementation of a lower prosthesis limb, and without losing sight of the information obtained from the quantitative questionnaire presented in chapter 3, it was decided that the parts of the lower prosthesis limb would be made by 3D printing, from PLA [18], [19], it being a bioabsorbable biopolymer produced from renewable, non-toxic raw material [20].

The selected solution, in terms of the material chosen to make the prosthesis leg, is the fact that PLA is considered a good material for medical applications [21].

At a later stage in the development of the prosthesis leg, this material will come into contact with the human body, the main objective of this PhD thesis being focused on general scientific research into a modern and efficient method of neural control of the lower prosthesis limb studied.

Since the lower prosthesis limb is primarily stressed in tension, compression and bending during gait was considered necessary to perform experimental tests on all three mechanical stresses, and generate useful information for finite element numerical modelling (elastic characteristics of the PLA).

The PRUSA i3 MK3S+ 3D printer was used to print the samples required for mechanical testing.

To determine the elastic and mechanical properties of this material (PLA), three types of samples were made, specific to tensile, compressive and bending stresses, according to the relevant standards.

The universal testing machine INSTRON 8872 from the material strength laboratory of the National University of Science and Technology Politehnica Bucharest was used for tensile and compression tests [22].

For compression testing, the INSTRON 8772 system required the use of compression adapters.

The INSTRON 8801 system was used for the bending tests and was considered ideal due to the accessories present in its hydraulic pans.

Digital image correlation (DIC) of the tensile, compression and bending tests was performed using the Dantec Q400 system.

All mechanical tests were performed at a speed of 1 mm/min.

### 4.1.2 Tensile tests for samples

In the case of the 10 samples printed for tensile testing, the X-axis in the direction of stress (uniaxial direction) was considered, following the ASTM D3039 standard [23], suitable for tensile testing of materials of this type (considered orthotropic materials).

The fact that the tensile test material broke in the narrow area of the specimens, with the neck section positioned at an appropriate distance from the hydraulic machine's extension parts, shows that the tests performed were correct.

The Bluehill 3 testing system was used as software in the INSTRON machine configuration.

### 4.1.3 Compression tests for samples

For the compression test, 10 samples were also made following the requirements of the standards in force.

The following properties are determined by the compression test: modulus of elasticity in compression and equivalent compressive stress.

The determination of the modulus of elasticity in compression of the material studied was performed similarly to the modulus of elasticity in tension, calculating the slope of the linear-elastic portion of the characteristic curve.

### 4.1.4 Bending tests of samples

For this type of test, 10 samples were made.

The bend test is performed until the specific linear deformation of the sample reaches 0.05 mm/mm (according to the standards) or until the specimen breaks.

### 4.1.5 Digital image correlation technique

The Dantec Q400 system allowed the study of the three types of specimens subjected to experimental tests (tensile, compression, bending) using the DIC method. By comparing images of samples captured by the system's cameras, the system makes it possible to observe and analyse a 3D field using a non-contact optical approach to measure specific deformations, stresses and vibrations for almost any material [24].

## 4.2 Conclusions

In this chapter, the elastic characteristics (modulus of elasticity and coefficient of transverse contraction (Poisson's ratio)) and mechanical characteristics of the material (PLA) are considered for the practical implementation, and numerical analysis of the lower prosthesis limb which is the subject of this work is determined experimentally.

After the implementation and mechanical testing in tension, compression and bending at three points of 10 samples (3D printed) for each type of mechanical test, it can be considered that a complete and correct elasto-mechanical characterisation of the investigated material has been performed.

Using DIC technology, it was possible to observe how the material fails for each sample tested, as well as how strains and stresses are located and then fail.

# 5 DESIGN AND IMPLEMENTATION OF A LOWER LIMB PROSTHESIS AND ITS CONTROL USING ELECTRICAL SIGNALS FROM THE BRAIN

## 5.1 System Components

This section presents the design, used materials, and implementation of the proposed system. The implemented prosthetic leg is not designed to be used by a human; it is only a proof-of-concept system's prototype for further research purposes.

In the future part of this thesis (chapter 6), some testing will be done on this prosthetic leg by creating a special support to measure how the leg reacts to forces.

### 5.1.1 Lower limb prosthesis

After the analysis carried out in subchapter 3.1, using the dedicated application SolidWorks (CAD application - Computer Aided Design), a prosthetic system containing three elements was designed: foot-planetary zone, calf and knee.

## 5.2 System implementation

The system consists of several parts, and they are connected as follows: the neuro-headset EMOTIV Insight is connected to the computer via Bluetooth, the computer is connected to the Raspberry Pi 4 via Secure Shell Protocol (SSH), and Raspberry Pi 4 is connected to the prosthetic lower limb through the GPIO pins.

## 5.3 System testing

The testing of the system was conducted using EEG signals recorded from a healthy male subject. To enable the subject to control the prosthetic lower limb, the subject must wear the headset and train two commands to provide the necessary control for the movements. Emotiv BCI application has been used for the training process, where each command has been trained 40 times. The duration of each time is eight seconds.

The training session takes about 20 minutes. After the training, the subject was asked to control and do flexion, extension, plantar flexion, and dorsiflexion movements of the prosthetic lower limb using his thoughts.

## 5.1 Conclusions

The use of the EEG-based BCI method is relatively a new direction of research, particularly in the medical domain. This paper presents the design and implementation of a mind-controlled prosthetic lower limb prototype. The materials used to create the prosthetic device are both robust and lightweight materials.

# 6 ANALYSIS OF THE MECHANICAL BEHAVIOUR OF A BIONIC LEG IN DYNAMIC MODE

## 6.1 Sisteme care oferă o cinematică eficientă

The purpose of this work is to highlight the dynamic characteristics of a lower prosthesis limb, as an alternative to existing passive or mixed systems. The proposed system has been realized at the level of an experimental laboratory model.

The prosthesis consists of a knee actuated by a servomotor and an ankle also actuated by a servomotor. The solution, to be developed in the future, is intended to be used as a prosthesis for people whose lower limb (from the knee down) has been amputated or to equip a medium-sized humanoid robot. To set the prosthesis in motion, a system/frame was made that also has a stepper motor for longitudinal movement. An actuation was also performed on the two servomotors with the help of a neural headset. The primary intention is to create a prosthetic prosthesis that can be operated with the help of brain waves.

## 6.2 Materials and methods

The experimental tests carried out in the present research consisted of the determination of the material characteristics, the displacement along the longitudinal axis and the vibrations at two points on the foot. The experimental setup for testing the bionic leg is shown in fig. 6.2.

### 6.2.1 The technology of making the leg

The component elements of the bionic prosthesis after the design phase were processed in a specific language for the PRUSA i3 MK3 3D printer.

From a constructive/assembly point of view, we have the following:

1. Sole:
    a. Foot (monobloc piece made of PLA);
    b. Motor attachment bushing, positioned next to the ankle (aluminium);
    c. Fixing screws between the bushing and the foot (steel).
2. Calf:
    a. Gamba (monobloc part made of PLA);
    b. Sole drive actuator (considered aluminum);
    c. Actuator mounting bolts (steel);
    d. Motor mounting bush, positioned next to the knee (aluminium);
    e. Clamping screws between the bushing and the shank (steel).
3. Knee:
    a. Knee (monobloc piece from PLA);
    b. Calf actuator (considered aluminium);
    c. Actuator mounting bolts (steel).

The inside of the calf and foot were printed with 30% infill and the outer walls with 1mm thickness. Due to this aspect, the two components were geometrically modelled separately. Figure 6.4 shows the outside of the calf (transparent) printed with 100% fill and the inside (opaque) with 30% fill.

### 6.2.2 Kinematics

To estimate the forces in the leg joints, linear motion laws for the rotation angle of the output shaft were imposed on the actuators. Thus, in an interval of 5 seconds, the shaft of each servomotor rotates by an angle of 20 degrees. The resulting kinematics are simple if a schematization is adopted. According to this schematization, the velocities and accelerations of the prosthesis components are determined.

To highlight the movement described by the above laws, three-way accelerometers (PCB Piezotronics 356A43 S/N LW348378) were used. Accelerometers were attached to the foot in two positions: on the sole and on the axis of the calf-foot joint.

### 6.2.3 Simulation with the finite element method

ANSYS software was used for finite element modelling. The modeling was performed for a transient regime, using the Transient Structural module.

The contacts used between these components are as follows:

- For the sole:
  - A „frictionless” type for the contact between the foot and the clamping bush with the servomotor;
  - A „bound” type for the rest of the contacts.
- For the calf:
  - A „frictionless” type for the contact between the calf and the clamping bush with the servomotor in the knee and the contact between the foot actuation servomotor and the calf;
  - A „bound” type for the rest of the contacts.
- For the knee:
  - A „frictionless” type for the contact between the knee and the calf actuation servomotor;
  - A „bound” for the rest of the contacts.

Between the sole and the calf and between the calf and the knee, respectively, "revolute" connections were defined between the shaft of the actuators and the connecting bushings.

### 6.3 Conclusions

The prosthetic devices aim to reproduce the fit-angle profile of a healthy human during locomotion. A lightweight, energy-efficient joint can decrease peak actuator power and/or energy consumption per gait cycle, while adequately meeting profile-fitting constraints.

In this chapter, the dynamic characteristics of a bionic leg with electric actuators with rotational motion are highlighted. 3D printing technology was used to make it, and servo motors were used for the joints. A stepper motor was used for the horizontal movement.

From the analysis of the results obtained, it can be concluded that the prosthesis resists dynamically without problems.

# 7 IMPLEMENTATION OF AN EFFECTIVE EMDR SYSTEM FOR THE TRAUMA TREATMENT OF THE PEOPLE THAT USE A LOWER LIMB PROSTHESIS

## 7.1 EMDR therapy

Among patients who suffered an amputation, approximately 80% reported Phantom Limb Pain (PLP) [6], [25]. Nearly half of PLP patients report experiencing daily pain [26]. Although a pain treatment would be best, studies have shown that acting on pain does not help in most cases [27]. Significant correlations were found between PLP intensity and central factors like cortical remodelling and somatosensory memory formation [28]–[30].

EMDR is an eight-phase psychological therapy designed to treat emotional distress caused by traumatic events from the past, most frequently in PTSD. Studies have shown that EMDR therapy is efficient in the treatment of PLP [31]–[35].

During the therapy, the clinician uses diverse bilateral stimuli like a light that changes positions, the alternation of sounds between speakers, or the vibration of devices held by the patient in their hands, to help the client process a distressing experience.

## 7.2 Materials and system implementation

The system offers a multi-actuator implementation of the EMDR protocol:

- Video stimulus using a rendered ball on a graphical display;
- Audio stimulus simulating a moving sound source;
- Tactile stimulation using vibration motors placed on the user using bracelets - stimuli are synchronized to maximize the effectiveness;
- A chatbot for communicating with the user according to the EMDR protocol, allows the system to function autonomously, i.e., in the absence of a therapist.

The proposed system is composed of the following modules: video, audio, tactile, and chatbot, which can work independently or together, depending on the user preferences and deployment options.

## 7.3 Conclusions

In this paper, we described an EMDR virtual system based on video, tactile, and audio actuators used to treat anxiety, distress, and negative emotions associated with traumatic memories. Based on the results obtained, an autonomous EMDR intervention is a clear possibility. Our study evidences the efficacy of an EMDR intervention for those who cannot have access to immediate psychological support, thus enabling their autonomy. Moreover, the established protocol was tested and positively confirmed in providing the necessary guidance for an efficient administration. As a result, it could be considered as a tool of self-support for people experiencing mild symptoms of PTSD.

As a result of this research, amputees can make a session of EMDR treatments to subsequently train a dedicated neural headset to control a lower limb prosthesis.

# 8 FINAL CONCLUSIONS. CONTRIBUTIONS AND PERSPECTIVES

## 8.1 General considerations

The PhD thesis entitled „***Research on the design and development of a bionic prosthetic lower limb controlled with a neural headset***" has as its main objective to investigate how to control a lower prosthesis limb using a neural headset that interprets the user's thoughts to move the prosthesis.

This work aimed to design and implement a lower prosthesis limb made of lightweight material with adequate tear strength. Initially, the demonstration of the present concept did not seem to be successful, highly interdisciplinary scientific research has shown that a prosthesis leg can be neuronally (mentally) controlled without the need for surgical intervention on the amputee.

To achieve this final point, it was necessary to study several interdisciplinary knowledge, like strength of materials, robotics, mechanics, mechanisms, materials science, materials technology, experimental methods, numerical computational methods, computers and information technology, electronics, prosthetics, psychology, etc.

## 8.2 Final conclusions

In ***chapter 1 - „Current state of research"***, the current state of information in the literature on the modalities and materials used in making a lower prosthesis limb was presented. As a summary of this chapter, the following conclusions can be mentioned:

1. Any kind of amputation causes a physical and mental imbalance in a person, which is why people have tried to replace missing limbs to live as close to normal as possible.
2. Originally, prostheses were made of wood, leather or iron and were made mainly for their functionality, with aesthetics taking second place.
3. The evolution of mankind has left its mark on the methods of making a prosthesis and on the materials used to make them.
4. Research over the years has brought to light biomaterials, which offer numerous advantages in their use for the manufacture of prosthetic legs like high mechanical strength, resistance to exposure to different environments, lightweight, flexibility and, last but not least, aesthetic appearance much closer to that of natural limbs.
5. The emergence of 3D printers has been an important step in the manufacture of prostheses, by increasing production speed, obtaining parts (structures) with a high degree of complexity, reducing costs, etc.
6. Almost 0.5% of the world's population requires a prosthesis or orthosis (according to a WHO study) to perform their daily activities.
7. The evolution of prostheses has reached a point where they look as close as possible to a normal limb, through the use of allograft (a vascularised composite), greatly improving the functionality of the missing limb to allow amputee lives an active, natural life with prostheses.
8. Prosthetic control can be done invasively (using nerves left in the residual limb that would need to be reinnervated by surgery) or non-invasively (using EEG signals from the brain).
9. The use of electrical signals from the human brain avoiding costly and dangerous surgery (required to place sensors on the brain), can be achieved through the use of a dedicated

neural headset containing sensors attached to the head, which are necessary to capture the brain activity of the amputee.

10. Choosing the solution of using a neural headset, through which a 3D printed lower prosthesis limb could be controlled, is the essential aim of the research presented in this PhD thesis.

***Chapter 2 - „Objectives and organisation of the thesis"*** includes the general and specific objectives defined for the development of this PhD thesis. A summary description of each chapter has also been provided.

***Chapter 3 - „Determination of user requirements for an intelligent system for mind control of a lower limb prosthesis"*** presented an online survey with a quantitative questionnaire to determine the functional and non-functional requirements of the proposed system. The survey was carried out by consulting 40 respondents from different backgrounds (amputees, engineers, doctors and prosthetic limb technicians). The results obtained from the quantitative questionnaire can be concluded in the following points:

11. EEG-based BCI technology is relatively new in scientific research and is very useful, especially in the medical field.
12. Highlighting the functional and non-functional requirements for the lower prosthesis limb.
13. All the answers of participants were analysed and graphically represented, thus highlighting some advantages and especially some disadvantages of current lower prostheses limbs like heavy, difficulty in movement and control, low reliability, etc.
14. The majority of participants specified the need to improve the control and movement of a prosthesis leg.
15. The responses from this survey helped in selecting the material from which the lower prosthesis limb could be 3D printed to implement the system designed by the PhD student.

***Chapter 4 - „Elastic and mechanical characterisation of the material used to make the bionic leg"*** describes the mechanical tests performed on 3D printed specimens made of PLA and presents the results obtained from these tests (tensile, compression and three-point bending).

The following points can be concluded from this chapter:

16. From the tensile test, the elastic and mechanical properties of the 3D printed PLA material can be obtained and the failure mode of the specimens could be observed.
17. The compression tests revealed the deformation of the specimens and allowed us to find out their elastic and mechanical properties.
18. Three-point bending revealed how the side wall of the specimen under load broke and helped to determine the elastic and mechanical properties of the material used in the practical implementation of the scale model of the prosthetic limb.
19. Knowledge of the elastic and mechanical properties of the 3D printed material can help to better design the components used to make the prosthesis leg.
20. The elastic and mechanical properties presented in this chapter are needed for the numerical simulation of the motion behaviour of the prosthesis leg.

***Chapter 5 - „Design and implementation of a lower limb prosthesis and its control using electrical signals from the brain"*** describes the design and implementation of the lower prosthesis limb, the corresponding hardware equipment of this prosthesis, and its control using a dedicated neural headset.

This chapter focused on the hardware fitting inside the prototype and control of the prosthesis, while the next detailed description of the design and 3D printing of the prosthesis leg is presented in the next chapter.

The most relevant conclusions of this chapter are the following:

21. As a relatively new area of research, the EEG-based BCI method is becoming increasingly popular with amputees, as they no longer require dangerous and costly surgeries.
22. The 3D printed lower prosthetic limb prototype, made of PLA material, has two degrees of freedom, sufficient for flexion, extension, plantar flexion and dorsal flexion movements.
23. To perform the movements of the prosthesis leg, the following hardware were used: Raspberry Pi 4, two servomotors, a motor driver module, external power supply (this alternative is sufficient to demonstrate the concept of neural control of the prosthesis), and an EMOTIV Insight headset which was used to control the prosthesis with the power of the mind (this was responsible for capturing electrical signals from the brain and the computer is responsible for converting them into specific commands, which could then be used to control the lower prosthesis limb).
24. Testing the implemented system was performed by a healthy, male participant who used the neural headset to train two commands necessary for the movement of the prosthetic leg.
25. Compared to other advanced headsets, which contain many electrodes, the performance of the system is relatively good, in terms of the EEG signal obtained from the EMOTIV Insight neural headset, because, it provides the desired decoding and processing for brain signals.

***Chapter 6 - „Analysis of the mechanical behaviour of a bionic leg in dynamic mode”*** aims to study the dynamic behaviour of the prosthesis leg, equipped with electric actuators with rotational movement, the conclusions of this chapter are:

26. Vibrations in the mechanical system (both from the experimental results and the finite element model), occurring during motion, occur when the prosthesis leg is moved from the equilibrium state to the motion state by the acceleration of the servomotors embedded in the prosthesis at a rotational speed of 0.069 rad/s.
27. To reduce vibrations, it will be necessary to investigate the fatigue behaviour of components made of PLA by 3D printing, where vibrations can be partially reduced by hardware.
28. Control of lower prosthesis limb components can be improved by using angular displacement sensors (encoders), thus reducing the effort of comparing experimental data with analytical or numerical data.

***Chapter 7 - „Implementation of an effective EMDR system for the trauma treatment of the people that use a lower limb prosthesis”*** presents a virtual EMDR system that is useful in treating anxiety, grief and negative emotions associated with traumatic memories using video, touch and audio devices. The conclusions of this chapter are:

29. The EMDR-based system was implemented to be self-administered by a user suffering from PTSD, where the established protocol was successfully tested on 31 participants.

30. The functionality of the system follows the eight essential phases of EMDR, with the AI-based chatbot being ideal for using the system autonomously, this chat is the advantage of the prototype over other applications made for administering EMDR therapy.
31. Another advantage of the implemented prototype is given by the accessibility of the use of the EMDR procedure by people with disabilities. Thanks to the different stimulation methods (visual, audio, tactile) embedded in the system.
32. The system presented in this chapter can customise the interaction with the patient, according to the patient's characteristics.
33. Individuals who have suffered limb amputations are still having trauma that can affect the training of a dedicated neural headset, the headset required to control the missing prosthesis limb. Therefore, a system that provides the possibility of self-management with EMDR therapy is necessary for reducing the trauma of amputees.

## 8.3 Contributions and perspectives

The main objective of the PhD thesis entitled ***„Research on the design and development of a bionic prosthetic lower limb controlled with a neural headset”*** was to study how to control a 3D designed and printed lower prosthesis limb controlled via a dedicated neural headset.

**The personal contributions** presented in the development of the implemented prosthetic system, both at a theoretical and practical level, can be considered as follows:

a) Deep study of similar works in the literature regarding the type of material, how prostheses are made, and how to control a bionic lower prosthesis limb.

b) To present a quantitative questionnaire, that will highlight the problems of lower prostheses limbs used in these days. The results of the questionnaire are the basis for the selection of material used in the manufacture of the prosthetic leg.

c) To characterise as much as possible the elastic and mechanical properties of the material used in the practical production of a scale model of the prosthetic leg.

d) Design (using a dedicated software application) and manufacture of a prosthetic leg (small scale) using a 3D printer.

e) To provide appropriate hardware equipment for a lower prosthesis limb to control it by the user's thoughts. Brain activity is captured using a dedicated neural headset, based on EEG-based BCI technology.

f) Analytical approach to the kinematics of the prosthetic leg, according to an appropriate schematisation of it, to determine the velocities and accelerations of the prosthesis components.

g) Determine experimentally the accelerations of the prosthetic leg using two accelerometers (placed on the sole and the axis of the joint between the leg and the sole) and compare the results obtained with those of an analytical nature.

h) Analytical approach to the dynamics of the prosthetic leg to determine the reactions in the joints. For their estimation, linear motion laws were imposed on the servomotors for the rotation angle of the output shaft.

i) Making dynamic numerical modelling and simulation of the implemented system, using the finite element method, to determine the state of deformation and stress in the prosthetic leg that occurs during the movement.

j) Local numerical analysis, on a substructure of the prosthesis, located in the knee area, to determine the state of tension and deformation of all the constituent elements of the considered area (yoke, bushings and screws), taking into account, as loads, the reactions in the analysis previous.

k) Implementation of an autonomous EMDR therapy delivery system to reduce trauma to limb amputees, with the ability to train a dedicated neural headset to successfully control a lower prosthesis limb.

Considering the results obtained in this PhD thesis, the following **research perspectives** (numerical, software, hardware and experimental) can be considered in the future to optimise the current system:

a) Improve the design of the current prosthesis by adding fingers and allograft tissue external to the prosthesis to have an appearance as close to the natural limb as possible.

b) Replace the external power supply with a battery-powered device to be embedded in the prosthesis leg calf.

c) Use of multiple servomotors, to provide the lower prosthesis limb multiple degrees of freedom.

d) Eliminate the computer from the system, when the Emotiv Cortex API will fully support the Linux operating system, which will allow the Rasberry Pi to manage all the processing parts and control the actions of the prosthetic leg.

e) Making a human-scale prosthetic leg for testing on a person who has had a lower limb amputation.

f) Use of dual-shaft servomotors, allowing a cylindrical joint on both sides of the yoke, and a passive joint coaxial with the servomotor shaft, on the opposite side of the yoke, to increase the rigidity of the assembly and reduce the level of vibration arising during movement.

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