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DESIGN OF A LOWER LIMB PROSTHESIS FOR TRANSTIBIAL AMPUTATION

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Abstract: *This paper falls within the field of rehabilitation engineering, emphasizing the design of a mechatronic prosthesis for the human lower limb, based on input data specific to the user - a patient with unilateral transtibial amputation. A completely designed variant of the prosthesis is proposed, based on two main components which are: human-machine (user-prosthesis) interface and the terminal device. Particular attention was paid to the design and construction of the prosthetic cup as to increase the subsequent chances of user's adaptability to the mechatronic prosthesis.*
***Key words: lower limb, prosthesis, transtibial, biomechatronics*.**

1. INTRODUCTION

The loss of a limb represents a serious disability with a devastating impact on patients, profoundly influencing the quality of their life. A percentage of 90% of new amputations is in the area of the lower limbs, and 52% of these are transtibial amputations, whereas 38% are transfemoral amputations. The main cause of lower limb amputation is disvascularity (72%) while others are infections (8%) and trauma (7%) [1]. Most of the commercially available prostheses are passive [2], based on passive or elastic mechanical elements that do not actively adapt to the gait of the amputees [3], [4]. With the use of these prostheses by the patient, there are a number of limitations such as: low speed and asymmetrical gait, as well as high metabolic consumption [5], [6].

Another issue of lower limb prostheses is related to the prosthetic cup or human-machine interface. Therefore, 48% of people with lower limb amputation cannot adapt to the prosthetic cup [7]. The causes that intervene in the adaptation of patients to the prosthetic cup are related to the suspension, shape and material, and the factors that decisively influence the comfort are: pressure, temperature, volume fluctuations and relative movements [8]. Taking all these data into account, it is necessary and justified to provide prostheses with amputated limb-like characteristics. This paper is focused on two modules of the prosthesis: the prosthetic cup or human-machine interface and the component of the terminal device (Fig. 1).

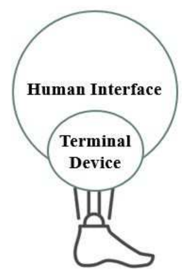

Fig. 1. Components of lower limb prosthetics

2. STATE OF THE ART

The first study proposes an active bionic protection that reduces the metabolic cost and improves the gait of people with transtibial amputation at different walking speeds. The bionic ankle prosthesis is composed of a brushless DC motor, which is mounted in series and parallel to various lamellar springs, ball screw transmission, Lithium-Polymer battery and a leg made of spring sheets. The proposed prosthesis was tested on seven people with amputation compared to their passive protection and seven people without amputation. The result shows that the bionic prosthesis decreased

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metabolic cost by 8% compared to passive protection and walking speed increased by 23% [9].

Developing an active ankle-foot prosthesis that is comparable in shape and weight to the human ankle is the focus of the second study. The prosthesis contains five elements: a direct current motor, motion transmission mechanism, a series spring, a parallel spring and the leg made of carbon fiber. The force control is performed by means of the first three elements, forming an actuator, through the tension or the relaxation of the spring. This subsystem is mounted in parallel with the unidirectional spring. Following tests performed with the series-parallel architecture showed that the prosthesis is able to fulfill criterias regarding the function of the ankles [10].

Thermal management inside the prosthetic cup is the issue that is dealt with by another group of researchers. They have developed a device that aims to maintain a constant skin temperature inside the cup. It consists of heat pipes that are mounted in contact with the lining, having the role of capturing the heat flow and removing it out of the cup for cooling. It also has a finned radiator, with a large coverage area placed on the cooling area and a low-power fan for more efficient heat dissipation. The weight of the entire device is 415 g. By implementing such systems, there is a significant higher degree of comfort experienced by the patient [11].

The relationship between mobility, general satisfaction and the quality of life for people with lower limb amputations is presented in another study. It collected data from 509 people with amputation, who had to complete a questionnaire. The results show that there is a strong correlation between the three components. Therefore, increasing patient mobility leads to increased quality of life as well as overall satisfaction [12].

3. THE LOWER LIMB PROSTHETICS DESIGN

The design of the lower limb mechatronic prosthesis is based on data obtained from the residual limb of a patient with unilateral transtibial amputation. These data are: general data of the patient (Table 1) and geometric data of the residual limb (Fig. 2). The data taken from the amputated person are according to a GDPR agreement regarding the processing of personal data for the purpose of scientific research.

Table 1

Data of the amputated person

Age	61 (year)
Amputation type	Transtibial
Amputated limb	Left
Cause	Diabetic Neuropathy
Weight	80 (Kg)
Height	1760 (mm)
Muscle tonicity	Good
Residual limb length	220 (mm)
Length limb non-amputated	500 (mm)

The length of the residual and non-amputated limb were measured from the center of the knee joint to the center of the ankle joint, respectively the distal end of the amputated limb.

Fig. 2. Geometric data collection.

The collection of the geometric data of the residual member was done by using a lot made of plaster and medical gauze, resulting in the negative residual member.

3.1 Design of the Human-Machine interface or the prosthetic socket

For the design of the prosthetic cup, comfort and general perception of the patient are important in order to increase the chances of subsequent adaptation to the prosthesis. For this, a TSB (Total Surface Bearing) type prosthetic cup is chosen, which achieves a uniform pressure on the surface of the residual limb [13]. The first step is making the positive residual member from the negative mold. The negative mold was filled with Vinylpolysiloxane, a silicone material composed of base and catalyst with good fluid capacities (Fig. 3).

Fig. 3. Making of the positive mold

This stage was carried out in collaboration with the Department of Dentistry of the "Lucian Blaga" University of Sibiu.

After obtaining the positive mold, the next stage is the conversion from the physical model to digital one. This is done through 3D scanning, obtaining a mesh of dots based on the positive molding. As to use this mesh in the computer assisted design program, it is necessary to process it in the CATIA V5R20 for reverse engineering program. The 3D scanning took part in collaboration with the company 3D-MSM SRL in two stages (Fig. 4).

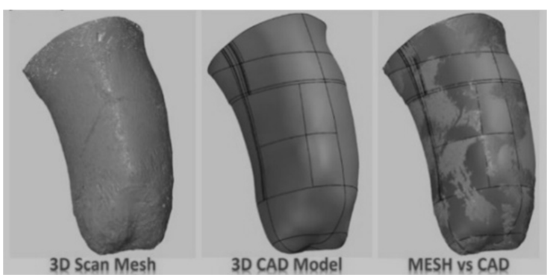
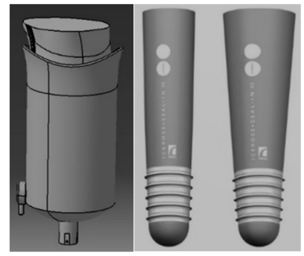


Fig. 4. Residual limb in CatiaV5R20.

Based on the positive residual member, there follows the design of the prosthetic cup in Catia V5R20. The prosthetic cup is designed so, that there is a geometric fit with that of the residual limb. The prosthetic cup assembly is equipped with a vacuum valve, having the role of allowing the elimination of the air flow from the inside when the residual member is inserted, and the connecting pillar that has the role of connecting the prosthetic cup to the terminal element of the prosthesis (Fig. 5a). The vacuum valve works in combination with a hypobaric membrane "Iceross", which consists of five silicone gaskets that seal and create a vacuum inside the prosthetic cup, being mounted on the residual limb (Fig. 5b).



a **b**

Fig. 5a. - Prosthetic socket, **5b. –** "*Iceross*"

The role of this "Iceross" valve and gasket system is to prevent the relative movement between the residual limb and the prosthetic cup. The relative movement between these elements decisively influences the patient's comfort [8]. The connecting pillar has four fins at one end, which are inserted in the walls of the cup. The grip provides good stability eliminating the possibility of detachment while walking. Another important aspect is the possibility to vary its length and so the length of the prosthesis in order to be equal to that of the healthy limb so as not to lead to sensitivities in the area of the sacroiliac joint and spine [14]. Also, the terminal element or active ankle will be connected to the other end. The fastening between the two elements is made with four screws.

3.2 Terminal device design

For the design of the prosthesis there are used active elements that create rotational motion with specific characteristics of speed and torque, as well as the use of elements that store energy and release it when walking. Thus, a Maxon DC brushless motor with a power of 200 W is used and connected to a transmission with toothed belt and ball-screw and a lamellar spring in parallel with the transmission (Fig. 6)

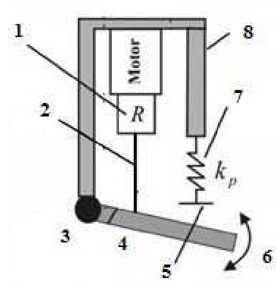


Fig. 6. The structure of the mechanical model: 1 - Transmision, 2 - Ball-screw transmision, 3 - Ankle joint, 4 - Foot, 5 - Spring end, 6 - Foot movement, 7 - Leaf spring, 8 - Housing.

The subassembly (motor, transmission and lamellar spring) creates mechanical energy that it transmits through the transmission to the lamellar spring in order to tension it. When walking, the mechanical energy accumulated in the lamellar spring will be removed to propel the person forward.

The connection between the terminal device and the prosthetic cup is made by rigid connection of two mechanical elements: the connecting pillar to the prosthetic cup and the fixing element to the terminal device (Fig. 7).

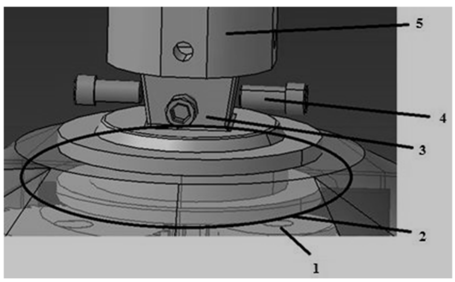


Fig. 7. The connection between the prosthetic cup and the terminal device: 1- Housing, 2- Clamping channel, 3- Fastener, 4- Screw, 5- Connecting pole.

The fastener is connected to the housing of the terminal device by using a square channel on its entire circumference which helps to eliminate relative movements. The fastening element is present with inclined walls on all four sides to achieve a fastening as well as a centering of the entire prosthesis.

The drive system (Fig. 8) has the main role in the propulsion of the prosthesis and has been designed with elements that have a high efficiency rate, precision and silent operation, important features of the prosthesis.

The elements used in the design of the drive system are important in the field of mechatronics. The thermal management of the electric motor was taken into account, so an aluminum radiator is mounted on the entire surface of the motor. Another issue was the protection against moisture, solved by mounting an accordion-type protection along the length of the ball screw, making it possible to compress or extend with the movement of the ball screw.

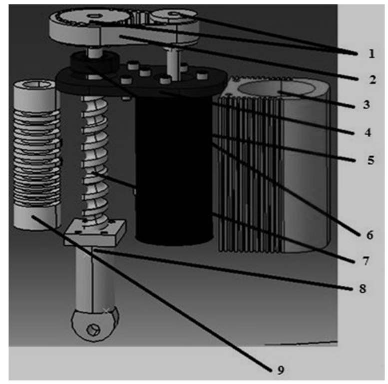


Fig. 8. Drive system: 1 - Gear, 2 - Timing belt, 3 - Heat sink. 4 - Clamping plate, 5 - Motor, 6 - Radial bearig, 7 - Ball screw, 8 - ball nut, 9 - Accordion type protection.

The actuator is connected to the ankle joint by the ball screw and the nut (Fig. 9).

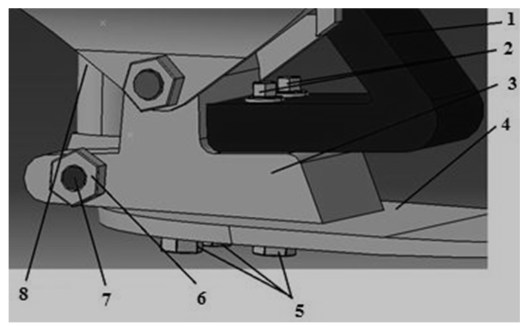


Fig. 9. Ankle joint: 1- Lamellar spring, 2- Clamping screws, 3- Ankle joint, 4- Foot, 5- Clamping screws, 6- Screw, 7- Ball nut shaft, 8- Ball nut.

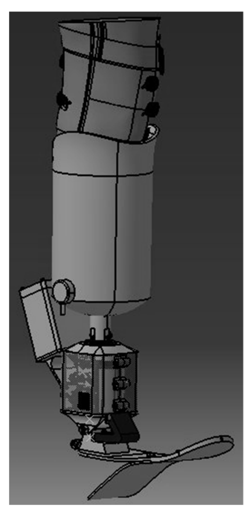


Fig. 10. The design of the prosthesis

The ankle joint is composed of a single component to which the lamellar spring, the housing and the ball nut are attached.

The housing of the terminal device is designed in two symmetrical parts which are connected in the lateral parts by means of six screws, three on

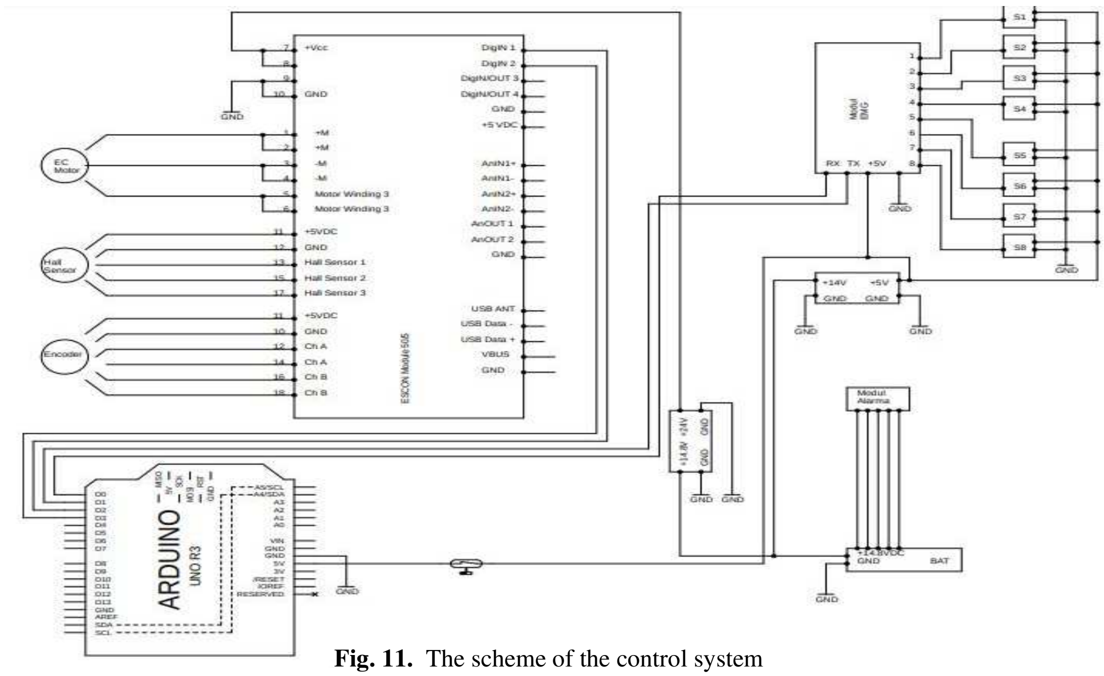


Fig. 11. The scheme of the control system

each side. The housing is designed to protect the electronic and actuating elements against shocks and moisture.

The projected foot prothesis consists of two components and the chosen material is carbon fiber. The foot behaves like a lamellar spring that stores energy and releases it when walking, giving people the feeling of pushing, also damping to the shocks of contact with the ground (Fig. 10).

3.3 Control system

The intended diagram of the control system was made in the *Circuit Diagram Web Editor* program, this being an online program for making the electrical circuits (Fig. 11). This chapter together with the component of experimental simulation and the results' analysis will be dealt with in more depth in a future separate paper.

The main control element of the prosthesis that captures the EMG signals are flexible myoelectric sensors that are 80 μm thick and is mounted in the areas of interest of the limb muscle group (anterior tibial, lateral gastrocnemius, posterior tibial, long peroneal) in order to achieve the flexion and extension movement of the leg [15]. The main control elements of the prosthesis contain an Arduino Uno development board and a Maxon motor driver. The battery is a Lityu-Polymer type with a capacity of 5500 mmAh.

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4. CONCLUSION

In this paper, a mechatronic lower limb prosthesis for transtibial amputation was proposed. The prosthesis is designed as to have a high degree of comfort in order to increase the patient's chances of adaptability to the prosthetic cup and finally to the prosthesis. Collaborations with different specialists, companies and institutions offer this paper a multidisciplinary character by using modern technologies. Future research directions are mainly based on the development of a functional model of this prosthesis, equipping it with conventional or unconventional actuators, as to meet the need for power and the application of the concept of animatronics, giving the prosthesis an appearance as similar as possible to the natural limb.

5. ACKNOWLEDGEMENT

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Proiectarea unei proteze de membru inferior uman pentru amputaţie transtibială

Rezumat: Lucrarea de faţă se încadrează în domeniul ingineriei de recuperare şi propune proiectarea unei proteze mecatronice pentru membrul inferior uman bazată pe date reale preluate de la o persoană cu amputație transtibială unilaterală. Se propune o variantă complet proiectată a protezei, bazată pe două componente principale care sunt interfața om mașină și dispozitivul terminal. S-a oferit o atenție deosebită proiectării şi realizării cupei protetice pentru a creşte şansele ulterioare de adaptabilitate a utilizatorului la proteza mecatronică.

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