

CONCEPTION, DESIGN AND DEVELOPMENT OF A LOW COST INTELLIGENT PROSTHESIS FOR ONE SIDED TRANSFEMORAL AMPUTEES

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Abstract. *This work presents the conception, design and development of a low cost intelligent prosthesis for one sided transfemoral amputees. The motivation for this study was based on the fact that in Brazil there are approximately 4 million amputees and most of them without any perspective – neither private nor public – to afford purchasing modern prosthesis that allows minimum comfort and life quality. In this work it is presented the conception and development of an intelligent data acquisition system by using sensors (for loads and angular movements) installed on the amputee preserved leg, which is used as a mirror (or pantograph) for the movement of the prosthesis. The prosthesis concept is proposed in order to be inexpensive, functional and to require low level of maintenance. Several simulation and tests are performed: i.e. mechanical strength analysis by using the Finite Element Method, which allows the selection of materials for the structural parts; electromechanical tests for calibration of the sensors and actuators; and finally tests of the electronic circuits for verification of data acquisition, signal conditioning and data transferring. The results show the feasibility of the design proposed. The adopted electromechanical concept enabled the estimated manufacturing cost of the prosthesis to be reduced to about 33% (without discounting import taxes), as compared to the modern prostheses available in the market.*

Keywords: *Rehabilitation, Transfemoral amputees, Intelligent prostheses.*

1. INTRODUCTION

The number people with lower extremity amputations significantly increased in Brazil in the last decades. Automotive accidents and diabetes mellitus should be remarked amongst the main causes of these amputations (Spichler, 2008).

It can be estimated that there are approximately 4 million amputees in Brazil, although the available statistical data related to the people that need any type of rehabilitation equipment are scarce. Most of these people have no perspective – neither private nor public – to afford purchasing modern prosthesis that allows minimum comfort and life quality. For instance, according to Moon et al. (2010), the C-Leg – an intelligent prosthesis developed by Otto Brock – costs around US\$ 50.000,00. It represents nowadays the cost of a small size apartment or house in Brazil, which is unaffordable for most part of Brazilian families.

In summary, two main reasons justify the research in the rehabilitation engineering area for the development of low cost prosthesis: (a) the population aging and the consequent increasing of degeneration diseases that culminate in amputations and (b) the millions of Brazilian amputees that counts exclusively on the public health care system for rehabilitation.

Based on these facts, since the beginning of 1990 decade the Brazilian government (Secretary of Science, Technology and Strategic Resources of the Ministry of Health) has granted multidisciplinary research groups focused on the development of new technologies to improve the quality of life of amputees.

This paper presents the conception, design and development of a low cost intelligent prosthesis for one sided transfemoral amputees. This work is the result of a doctoral research performed at UMC – Universidade de Mogi das Cruzes, SP – Brazil. A detailed description of the information and results presented here should be found in the published thesis by Silva Jr. (2010).

2. DESIGN AND DEVELOPMENT METHODOLOGY

According to Norton (2004), the design methodology is essentially an exercise of applied creativity. Several “design methodologies” have been defined in order to help to organize the “non-structured problem”, that is, the cases in which

the definition of the problem is vague and for those that several solutions exist. Some of these definitions encompass only few steps, and others, a detailed list with up to 25 steps.

In this paper we will present the conception, design and development of a low cost intelligent prosthesis for one sided transfemoral amputees by following the “ten steps design methodology” proposed by Norton (2004), i.e.: (1) Identification of Needs; (2) Background Research; (3) Goal Statement; (4) Performance Specifications; (5) Synthesis; (6) Analysis; (7) Selection; (8) Detailed Design; (9) Prototype and Testing and (10) Production.

In the present work, these steps are organized in different sections as follows: steps (1) to (5) are presented in Section 3: Preliminary Design Phases. Although steps (6) to (8) are common between the design of mechanical parts and the design of the control system, they will be separated in two different sections: Section 4: Mechanical Design and Analysis and Section 5: Control System Design. The step (9) is discussed in Section 6: Prototype and Testing. This project was not yet submitted to large scale production. Therefore the step (10) is discussed here.

3. PRELIMINARY DESIGN PHASES

3.1. Identification of Needs

As stated in the Introduction of this work, it can be estimated that there are approximately 4 million amputees in Brazil. Most part of them is not able to afford purchasing modern prosthesis that allows minimum comfort and life quality. Therefore, it is necessary to development of low cost prosthesis to support rehabilitation of amputees that counts exclusively on the public health care system.

The main objective of this project is the development of a low cost active prosthesis for one sided transfemoral amputees. The idea is to submit the final project to patent registry in INPI (Instituto nacional de Propriedade Intelectual) and authorize the use to the Brazilian public health care system and other non-profit institutions that help and support amputees in their rehabilitation.

3.2. Background Research

The recent advances in biomedical engineering technology have led to the construction of intelligent prostheses. See for example the recent reviews by Herr et al. (2005), Dollar and Herr (2007) and Herr and Kornbluh (2008).

The main differences in the prostheses design are in their dumping systems, since an adequate dumping allows fast transitions in stride velocity, which increases the amputee autonomy. There are three main kinds of dumping systems: passive, semi-active and active. In Figure 1 are presented prostheses with different types of dumping systems.

According to Herr et al. (2005) the users of variable dumping prostheses report less muscle fatigue and smooth movement than the others with mechanical passive dumping. In addition microcontrolled intelligent prostheses improve the dumping performance as function of stride velocity transition. Therefore, it can be demonstrated that intelligent prostheses reduce less oxygen consumption in walking in a wide range of velocities.

On the other hand, the cost of intelligent prostheses is yet too expensive, since they have high aggregated value due to the high end technology applied. According to Moon et al. (2010), the C-Leg – an intelligent prosthesis developed by Otto Brock – costs around US\$ 50.000,00, which is unaffordable for most part of Brazilian families.

As discussed previously, these facts have motivating the Brazilian government to grant multidisciplinary research groups focused on the development of new technologies to improve the quality of life of amputees with affordable cost.

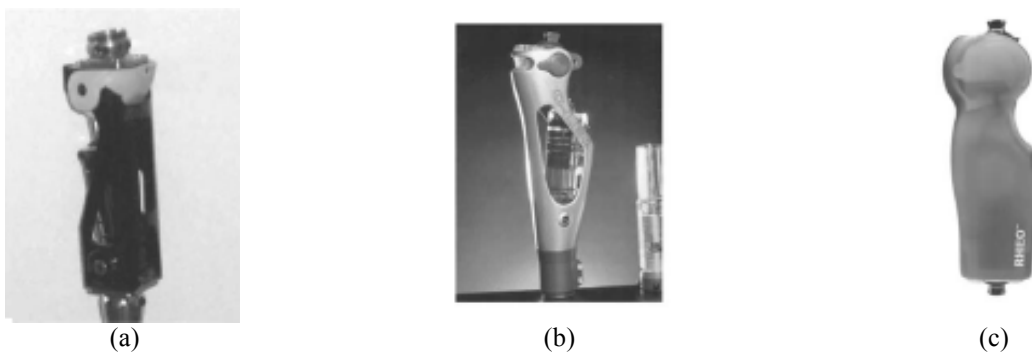


Figure 1. (a) Mauch SNS prosthesis with mechanical damping, (b) C-leg prosthesis with variable hydraulic damping and (c) Rho prosthesis with magneto-rheological damping. Adapted from Herr et al. (2005).

3.3. Goal Statement and Performance Specifications

Any study that aims the treatment of patients that use prosthesis or orthoses must be based on the normal human walking gait. Figure 1 presents schematically the human walking gait through one cycle, beginning and ending at heel strike.

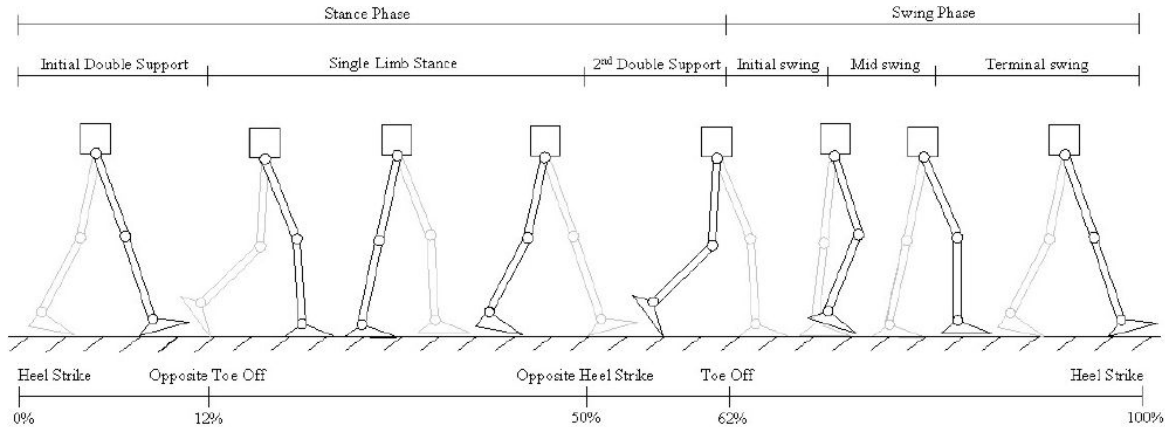


Figure 2. Human walking gait through one cycle, beginning and ending at heel strike. Percentages showing contact events are given at their approximate location in the cycle (Dollar and Herr, 2007).

The using of biomechanical parameters (see for instance, Figure 3) to analyze the human gait is important to allow the adequate programing and prosthesis control. Therefore, the comparison of non-amputee data with amputees allows the improvement of prostheses fitness and comfort for different users.

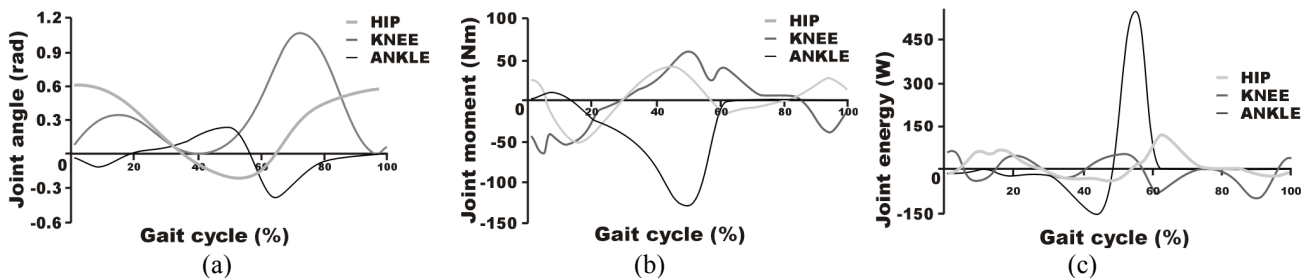


Figure 3. Biomechanical data for lower member in a stride cycle of a non-amputee in a complete gait cycle (100%): (a) joint angle, (b) joint moment and (c) joint energy. Each curve represents: hip, knee and ankle joints. Adapted from Popovic et al. (1999).

3.4. Concept Definition

The prosthesis design has been conceived in order to be as low cost and light weight as possible. All mechanical components were selected based on their prompt availability in the national market, in order to make the maintenance, parts repair and replacement easy and low cost. In addition, the system must work with affordable energy consumption.

The main mechanical subsystem of the prosthesis is the knee articulation. This mechanism is active based on a microcontrolled micro-motor (with an embedded 1:20 rotation reduction gear train) plus a worm gear pair. Since only some gear teeth are in contact, when they wear or crack the gear should be rotated and mounted again which increases the durability of the system.

The ankle system is passive. It is composed by a five-link mechanism and a helicoidal spring to absorb shocks and act as a returning system.

The Figure 4 presents the first sketch of the prosthesis concept in what the main mechanical parts are presented, i.e.: the foot sole with the main contact areas; the main knee structure, worm gear mechanism and micro-motor; and the details of the ankle link and spring mechanism.

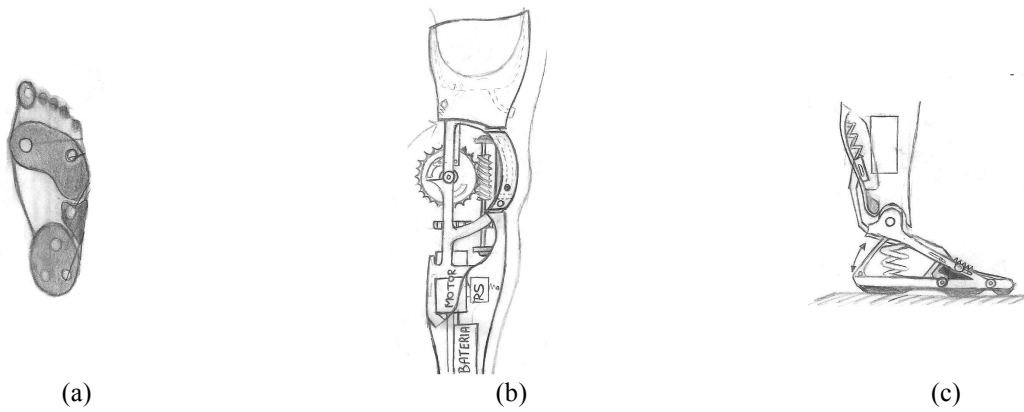


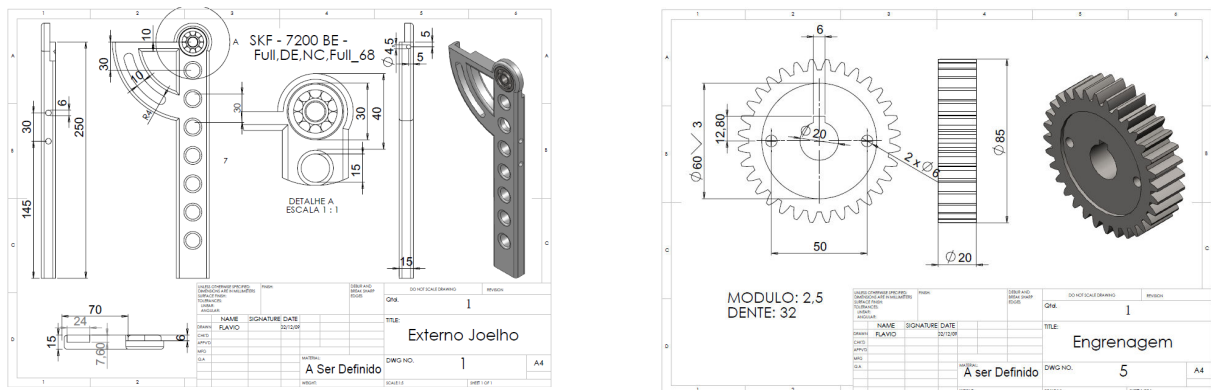
Figure 4. First hand sketch of the prosthesis concept showing its main parts: foot sole (a), knee mechanism (b) and ankle mechanism (c).

4. MECHANICAL DESIGN AND ANALYSIS

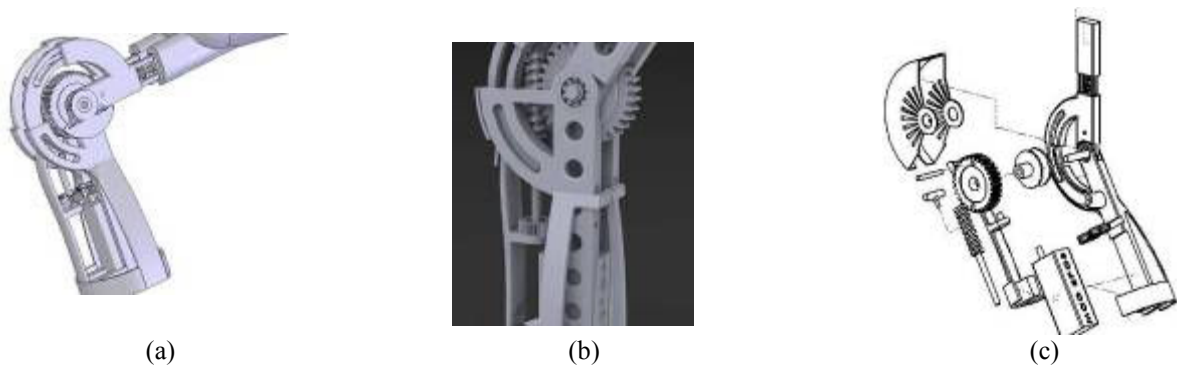
In this section it is presented the geometrical design of all the parts of the prosthesis and the stress analysis by using the Finite Element Method (FEM).

4.1. Geometrical Design

The geometrical design has been performed in the CAD (computer aided design) software SolidWorks®. In Figure 5 it is presented two samples of 2D drawings quoted and detailed for production. Figure 6 shows 3D views of the prosthesis and an exploded view of the main parts composing the knee articulation. At last, in Figure 7 are presented two overall 3D view of the complete assembly of the prosthesis parts.



(a) (b)
Figure 5. 2D drawings quoted and detailed for production.



(a) (b) (c)
Figure 6. 3D views with details of the knee main parts and mechanism.



Figure 7. Overall 3D views of the prosthesis assembly.

4.1. Stress Analysis

The stress analysis of the main knee and leg parts has been performed with help of the CAE (computer aided engineering) software ABAQUS®, which is a dedicated multipurpose FEM package. The ankle and foot parts have small geometrical details that jeopardized the import process and mesh generation of the in ABAQUS®, therefore these parts were analyzed within the native FEM code available SolidWorks®.

The loads used to calculate the stresses in the components were based on the work reported by Paul (1970). In this paper it was considered a 60kg male subject, 1.83m height and walking with a velocity approximately 2.1m/s.

In order to update the loading conditions to real Brazilian population biotypes and to allow some safety factor to stresses, the original loads reported by Paul (1970) were scaled by considering a 90kg male subject of same height and same walking velocity.

The stress analysis results are presented in Figure 8. Critical stresses in the parts in the conditions analyzed are below 90MPa. Based on the stress results, the material selected for the structural parts is the aluminum alloy AA5052-H32 (hardness HB60, 193MPa yielding limit, 228MPa ultimate stress limit and 117MPa fatigue limit at 5×10^8 cycles. Ref.: <http://www.matweb.com>). Other material alloys should be considered for this application, for instance stainless steel or titanium, but the cost should be a limiting factor.

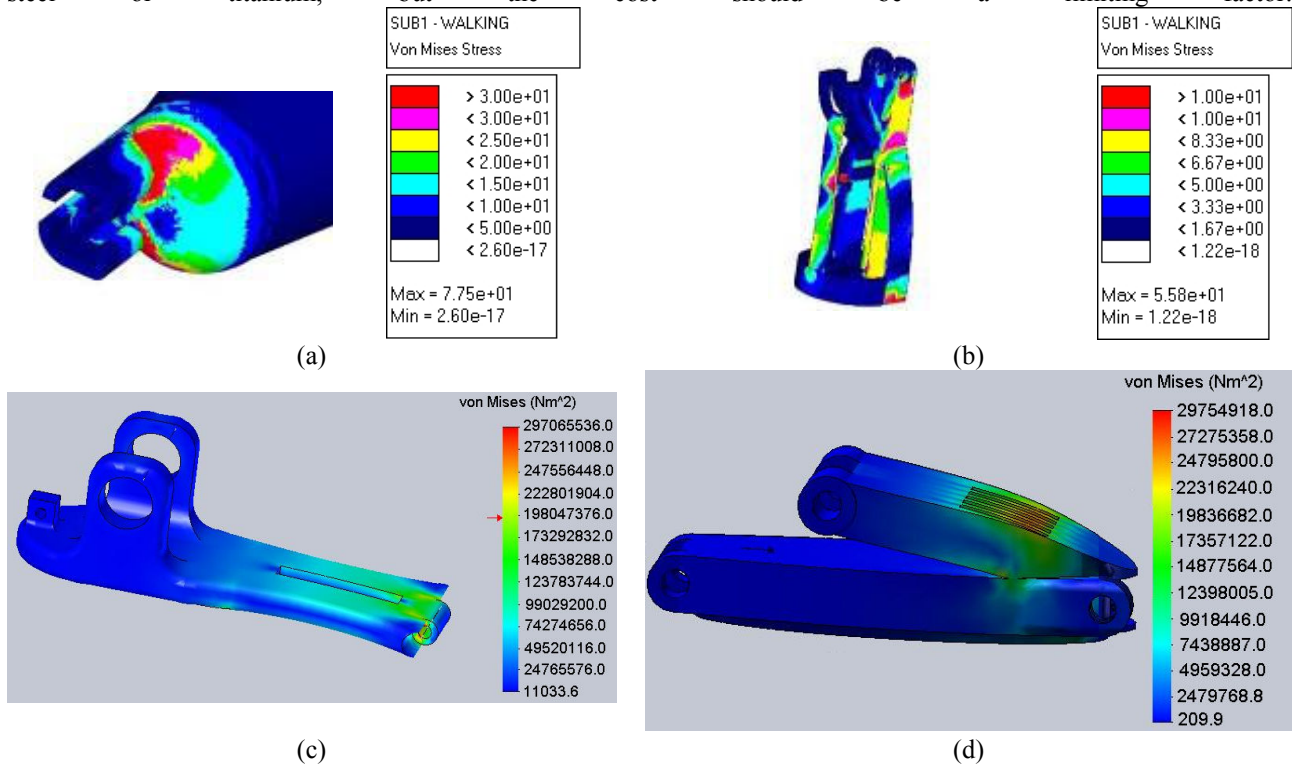
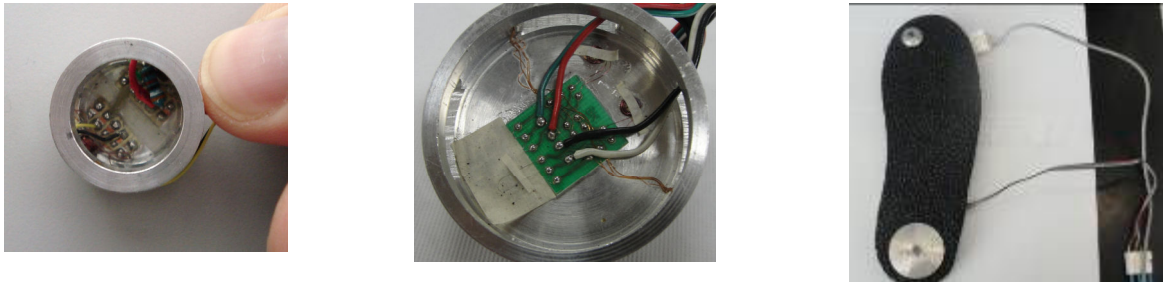


Figure 8. Stress contour plots for different parts analyzed.

5. CONTROL SYSTEM DESIGN

The control system of the prosthesis has been conceived to be based on the amputee preserved leg. An intelligent data acquisition system by using sensors (for loads and angular movements) was installed on the amputee preserved leg, which is used as a mirror (or pantograph) for the movement of the prosthesis. The choice was to install two load cells on the shoe sole and an angular position encoder on the knee of the preserved leg, in order to measure the different gait parameters as indicated previously in Figure 3. The sensor signals are sent to a PIC microcontroller to activate the prosthesis.

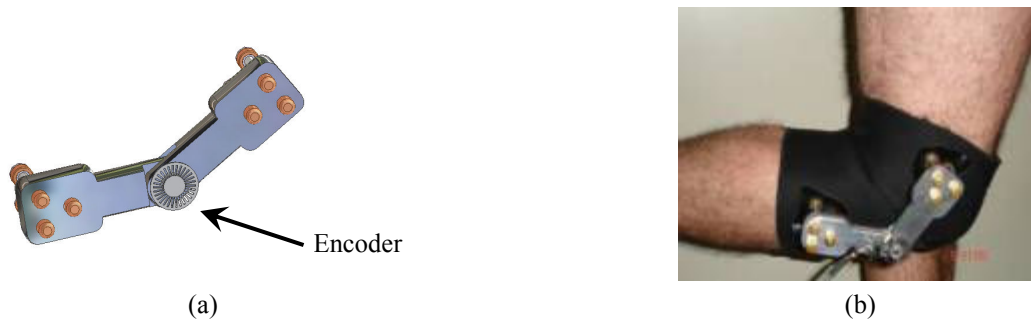
Figure 9 presents the load cells used. They were installed below in the regions with higher pressure in the foot sole during the gait phases: the hallux (20mm diameter) and the heel (50mm diameter).



(a) (b)

Figure 9. Load cells: (a) diameter 20mm (b) diameter 50 mm. In (c) is shown the load cells installed on the shoe sole below hallux and the heel.

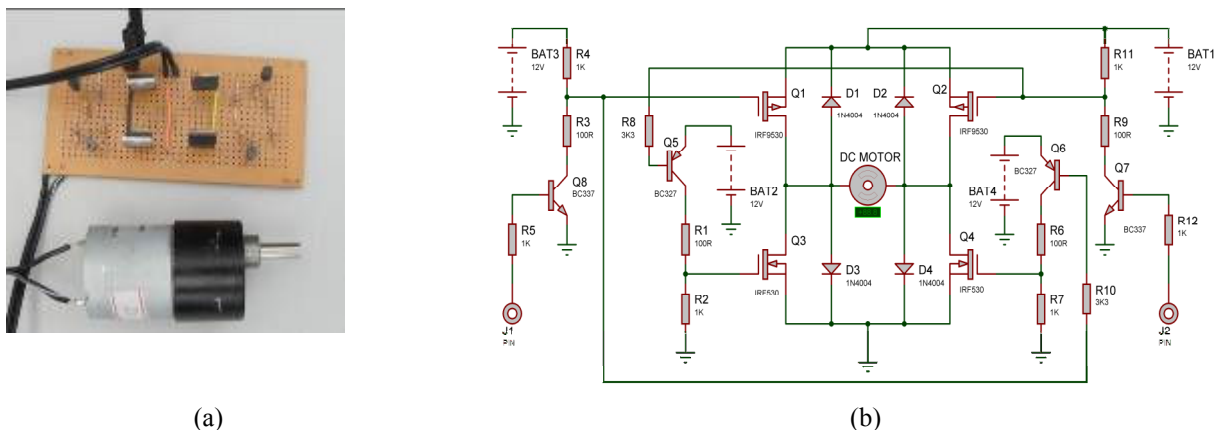
Figure 10 presents the angular position encoder used. This system has been designed and constructed by a group of undergraduate UMC students under supervision of professors Fumagalli and Rosa (Fumagalli and Rosa, 2008). This system allows monitoring both the angular position and velocity of the preserved leg knee.



(a) (b)

Figure 10. Details of the geometrical design of the knee mechanism.

Figure 11 presents the micro motor 37JB6K/3530-1250 used to activate the prosthesis knee movement and the respective H-bridge driver circuit. The nominal micro motor specifications are: voltage: 12VDC, rotation: 4300rpm, current: 330mA, output power 1.8W and torque: 40gcm. The micro-motor is equipped with a 1:20 reduction system.



(a) (b)

Figure 11. DC micro motor and H-bridge circuit driver.

Figure 12 presents a flowchart with the block diagram of the control system and Figure 13 presents the main digital circuit used for the control system. The microcontroller used is a model 18F425, with 8 10bits analogical input channels. In order to verify the sensors signals, it was used a LCD display.

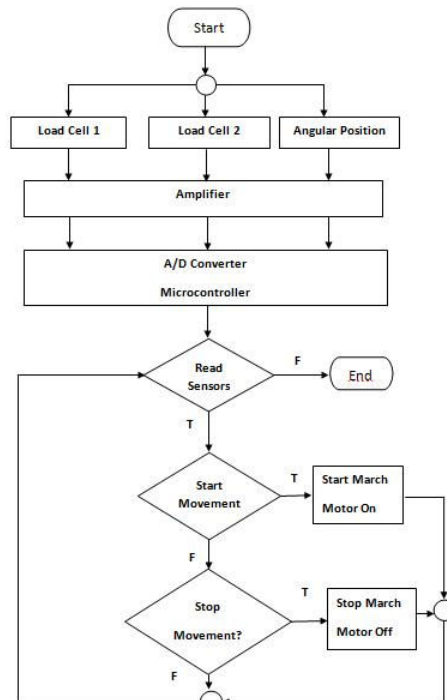


Figure 12. Flowchart with the block diagram of the prostheses control system.

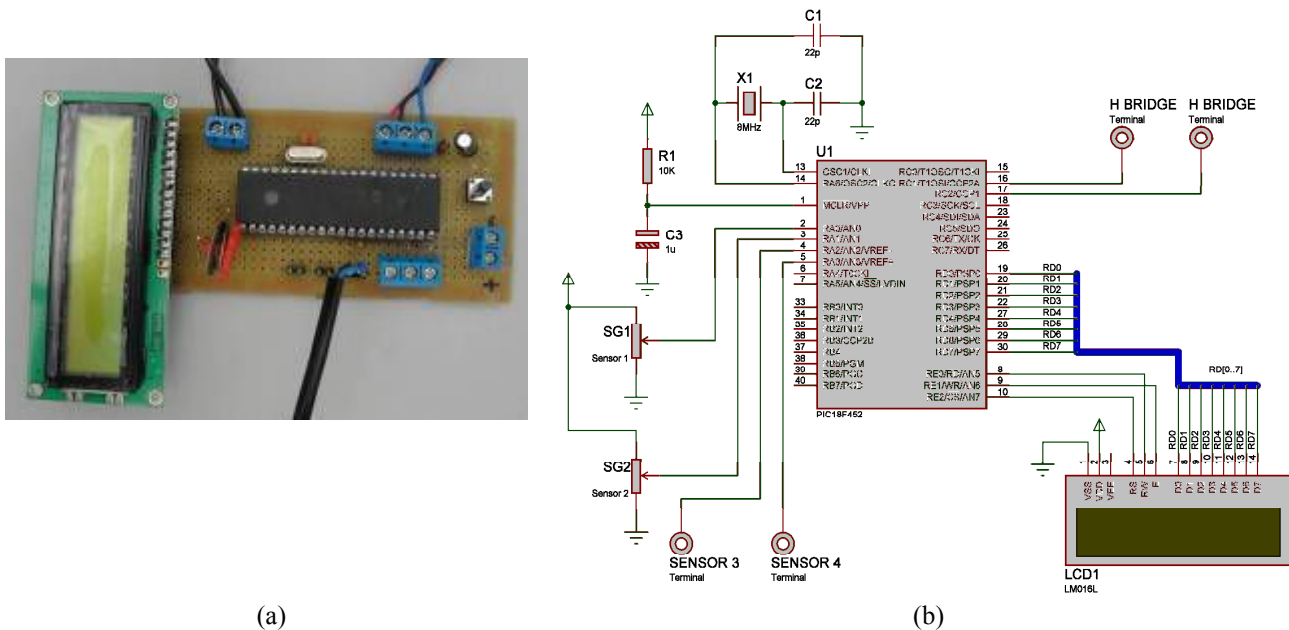


Figure 13. Control system main digital circuit.

5.1 Input and Output Results

The input data from sensors gate type strain that are located in the following positions: two in the foot plant, one in the big toe and a heel area of the preserved leg. The prosthesis has a resistive sensor positioned in the region of the knee joint that allows the determination of the angular position of the joint. The acquired signals are the analog type with a range of 0 to 5V DC, being acquired by the microcontroller analog channels of 10bits, and has a resolution of 4.887 mV per digital word. The reference tension from analog converter are (VREF) and (VREF-) 5 and 0V respectively.

Applies the equation

$$(V_{in} - V_{REF-}) \cdot \left(\frac{1023}{(V_{REF+}) - (V_{REF-})} \right)$$

to calculate the value of the digital converted in

relation to the analog variable acquired. This way the outputs data has the following behaviour to 0V analog 0 in digital value ; to 5V in analog value it presents 1023 in digital value. Digital signals are allocated in integral variables created in the source code of the compiler C to the microcontroller, when signals from the sensors located in the regions of the big toe, the heel and the prosthesis reach the reference values of the control algorithm to start the march at that time the power drivers will be activated to start the motion from the joint of the prosthesis. When the joint of the prosthesis reaches the end of the course of the motion the sensors of the prosthesis, the big toe and the heel region will be in the reference position which allow the power drivers to bring the joint to its original position. The response time of the analog channel of the microcontroller is programmed to perform the acquisition every 1.6 μ s.

6. PROTOTYPING AND TESTING

In order to verify the main system characteristics and performance, a prototype has been constructed. The foot parts were machined by using a CNC system and are presented in Figure 14.



(a)



(b)



(c)

Figure 14. Foot parts were machined.

Figure 15 presents the test apparatus mounted to verify the system performance. At this design stage no tests with humans has been performed. The load cells were calibrated by considering a 90kg subject.



Figure 15. Apparatus to test the prosthesis components.

In the tests performed all the system components worked integrated without noise and distortions. Although the behavior of the system is considered satisfactory at the present stage, it was designed an additional angular movement sensor to be installed in the prosthesis knee to check if the correct motor movement is transmitted to the prosthesis. This additional sensor is presented in Figure 16. The sensor was installed on a leg prototype made by using two PVC pipes and an articulation.



Figure 16. Additional angular position sensor to be installed on the prosthesis.

More than 100 test repetitions have been performed with different march conditions: uniform velocity, sudden stops, sudden acceleration and deceleration. The system works smoothly and the response time observed is adequate to provide comfort to the amputees.

The results show the feasibility of the design proposed. The adopted electromechanical concept enabled the estimated manufacturing cost of the prosthesis to be reduced to about 33% (without discounting import taxes), as compared to the modern prostheses available in the market.

Further research is needed in order to improve the system characteristics, performance and robustness in a wide range of applications and usage. Also, production of the system in large scale was not investigated. In addition, it is necessary to test the system with humans and verify the level of comfort and fitness.

7. CONCLUDING REMARKS

This work presented the conception, design and development of a low cost intelligent prosthesis for one sided transfemoral amputees.

Several simulation and tests are performed: i.e. mechanical strength analysis by using the Finite Element Method, which allows the selection of materials for the structural parts; electromechanical tests for calibration of the sensors and actuators; and finally tests of the electronic circuits for verification of data acquisition, signal conditioning and data transferring.

The results show the feasibility of the design proposed. The adopted electromechanical concept enabled the estimated manufacturing cost of the prosthesis to be reduced to about 33% lower than imported active prostheses.

Further research is needed in order to improve the system characteristics and verify the production feasibility in large scale. In addition, it is necessary to test the system with humans to confirm the results with prototypes.

The documents needed to patent registry are under preparation and the submission of this design to INPI should occur near in the future.

8. ACKNOWLEDGEMENTS

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