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Bioelectronic transfemoral prosthesis to improve human gait by means of EMG and space-time physical variables

Leverson Beltrán Castro[2], María Camila Parra Aldana[2], Hernando Leon-Rodriguez[1]
[1] Industrial Engineering Department; Pontificia Universidad Javeriana, Bogota - Colombia
[2] Engineering Faculty; El Bosque University, Bogota - Colombia.
{lhbeltran, mcparraa}@unbosque.edu.co, leon.hefrain@javeriana.edu.co

Abstract - This article presents the design and implementation of a bioelectronic knee integrated into a transfemoral mechanical prosthesis manufactured in 3D printing. This device is made to improve the human gait cycle in the lifting, rocking, and support phases. For its implementation, control subsystems were integrated for the spatial variables and the conditioning of native muscle signals generated by the contractions of the vastus and biceps of the stump of a patient with trans-femoral amputation. The readings of the position and angular velocity signals were made through an interface adapted to the non-amputated limb as a response pattern. The scope of this article is defined by the reading, monitoring, control, and improvement of knee movements in a bioelectronic prosthesis in the phases of the human gait cycle. Finally, the importance of reducing the cost of the device is highlighted through the optimization of resources, construction materials, and electronic elements, with a low cost value.

Key Words: Transfemoral amputation, Quality of life, Transfemoral prosthesis, Electromyography signs, and Physical variables.

I. INTRODUCTION

Currently, in Bogota Colombia, there is difficulty in accessing a low-cost bioelectronic prosthesis for adults between 20 and 75 years of age. 80% of these affected adults suffer secondary effects due to the absence of prostheses adapted to their needs and muscular structures [1][2]. Following the above, it was decided to adopt a collaborative posture by implementing a support system for human gait, based on the integration of a bioelectronic knee prototype to a transfemoral mechanical prosthesis made of low-cost materials using 3D printing and buffer systems, to provide moral support and to directly improve the quality of life of people with this disability. This prototype prosthesis is implemented with the aim that the majority of adult patients between 20 and 75 years of age with a maximum weight of 80 kg and a height between 1.60m and 1.80m, can make use of this device.

This article highlights the application of a prosthesis prototype capable of controlling angles and speeds in the patient's gait phases; rocking and supporting. The main objective is to improve the patient's gait cycle, that is, to control the steps in the amputee's gait. [3]

The project article presents the use of the control, sensory, electromyography signal acquisition subsystems and systems for measuring position, velocities, and angular accelerations. Initially, the document presents the functional and detailed design of each of the subsystems that read, actuate, and control the variables in question for the march. Then, the necessary tests are carried out to verify the variables that are affected during the process, if these do not comply with their respective requirement, the appropriate adjustment is made to the subsystem or interface (corresponding set of subsystems).

The bioelectronic knee prototype performed the processes of obtaining a position, velocity, and angular accelerations with maximum values between 45°, 0.8m/s, and 0.25m/s^2 respectively. The control system included data recording for one scan of information for every 10 samples, with these data the necessary algorithm for the Microcontroller software was built. These average values did not exceed a 5% percentage error, which means that this prototype does not generally possible errors in the use process. [4]

The scope of this article ends in the design, implementation, and testing of a transfemoral bioelectronic prosthesis prototype at a low cost compared to current prostheses on the market, which reads, operates and controls movements in the gait cycle. The caveat is made that this project did not involve transfemoral amputees due to the Covid-19 pandemic of 2020.

II. DESIGN AND ANALYSIS PROCEDURE

A. Functional Design

The bioelectronic knee prototype is considered a global system, with each one of the subsystems presented in figure 1. It is taken into account that, for the realization of the prototype, the patient with transfemoral amputation is the main input variable to the system, which is the fundamental basis for the prototype design process. At the end of the design, the patient must finish the process with the transfemoral bioelectronic knee prototype installed on their stump, which represents the output of the system. [5]

The main objective of the system is the emulation or imitation of the human gait cycle in the patient, by reading the positions and angular velocities of the standard limb (non-amputated limb) and the reading of myoelectric signals on the stump to establish the elevation of the limb. Knee on the ground, seen it in figure 2.

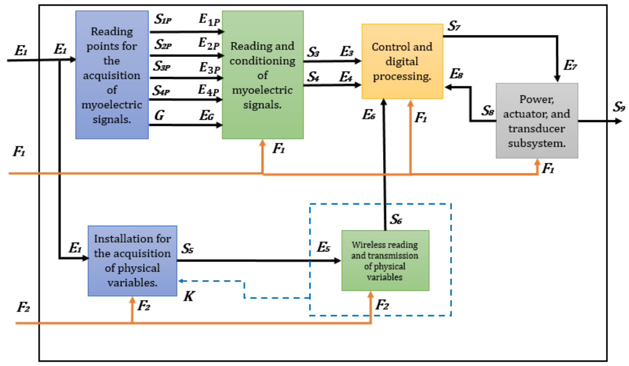

Figure 1. Summation of system functions. Own.

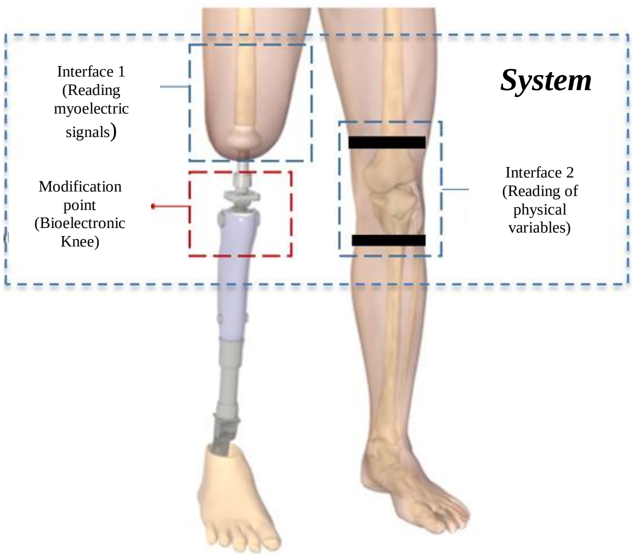

Figure 2. Location of electronic interfaces for reading electrical and physical variables in the patient. [6]

B. *Mathematical analysis of the System*

- *Static Analysis*

In the same way, it is important to highlight the behaviour of the subsystem that reads the physical variables (Θ, $\dot{\Theta}$, and $\ddot{\Theta}$) when the knee joint exerts a tension force on the point of rotation [7]. This force is produced when the gait cycle is performed. With the Solid Works simulator, the design structure is analyzed in a study by applying a force of 50N on the point of rotation, since this point is an articular joint and is prone to generating a higher torque than in the other fixed joints. The force value is an approximation of the limit that the patient could generate at maximum torque on the joint at the point of rotation. [8]

In Figure 3, the area where the 50N force is applied is shown; indicating that, in the gait cycle, the point of rotation with the position transducer coupling will be the elements with the greatest wear and friction. The right image shows a maximum modulus of elasticity of 2.85 MN/m^2 on the aluminium plates, this presents 10% of the elastic limit of the aluminium plate [9]. The left image shows the rotation point displacement of 14.8µm with a force of 50N.

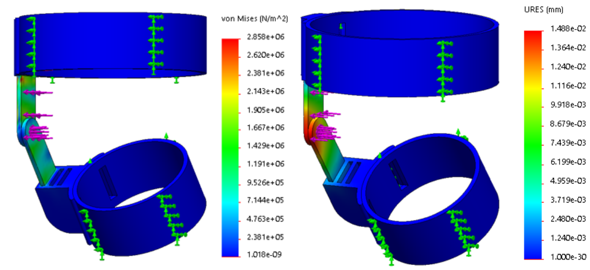

Figure 3. Simulation analysis of stresses N/m^2; (Right) and displacement in mm; (Left) when a maximum force of 50N is applied. *Solidworks pack.*

In Figure 4, the area of the ABS where the greatest displacement is applied is presented. The images, right and left, show a stretch ΔX between 157µm and 313µm on the ABS when a tensile force is applied on the rotation point of 50N.

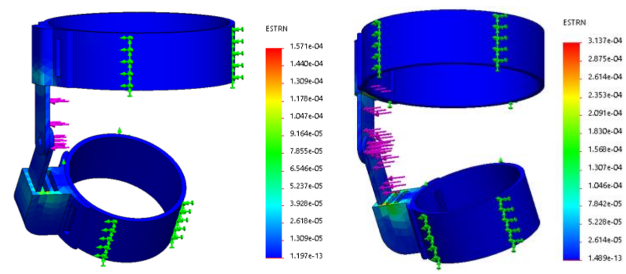

Figure 4. Simulation analysis for the displacement of the ABS with a force of 50N applied to only one arm (right) and displacement of the ABS with a force of 50N applied to the two arms (left). *SolidWorks pack.*

According to the requirements, the length of the prosthesis will be between 0.3m and 0.45m with a maximum weight of 3Kg. It has to:

$$\tau = F \cdot d = m \cdot \alpha \cdot d$$

Replacing values:

$$\tau_1 = 3Kg \cdot \frac{9.8m}{s} \cdot 0.3m = 8.82Nm$$

$$\tau_2 = 3Kg \cdot \frac{9.8m}{s} \cdot 0.45m = 13.23Nm$$

We calculate the mechanical and electrical powers:

$$P_{m1} = P_{e1} = \frac{\tau_1 V_1}{d_1} = \frac{8.82Nm * \frac{0.5m}{s}}{0.3m} = 14.7W$$

$$P_{m2} = P_{e2} = \frac{\tau_2 V_2}{d_2} = \frac{13.23Nm * \frac{1.5m}{s}}{0.45m} = 44.1W$$

Finally, the current required for the actuator powered at 24V is:

$$I_1 = \frac{P_{e1}}{V} = \frac{14.7W}{24V} = 612.5mA$$

$$I_2 = \frac{P_{e2}}{V} = \frac{44.1W}{24V} = 1.83A$$

The motor parameters must be between:

$$612.5mA < I < 1.83A$$
$$14.7W < P_e < 44.1W$$
$$8.82Nm < \tau < 13.23Nm$$

- *Dynamic Analysis*

In this section, the dynamic analysis of the bioelectronic prosthesis prototype is presented. This study is carried out to obtain the speed and acceleration variables in each of the three Cartesian axes (X, Y, and Z), taking into account the limiting angles in flexion and extension of the knee. [10] [11]

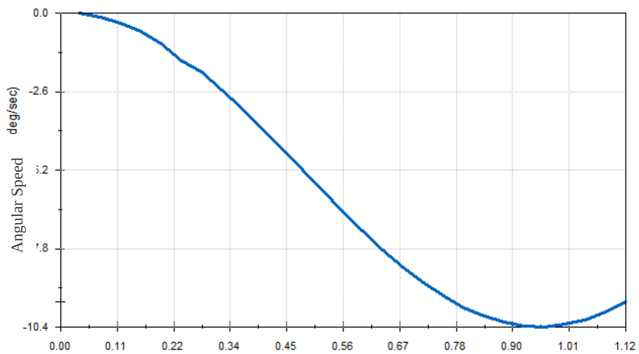

Figure 5. Results of angular velocity in the X-axis; *Solidworks pack*.

For the angular velocity in the X-axis, which is presented in figure 5, its behavior is oscillatory, that is, as the knee has a movement about a point of rotation, it behaves like a pendulum in the gait cycle. The angular velocity during a step is equivalent to 10.4°/s, by trigonometry, the patient will be able to walk 15.7cm/s.

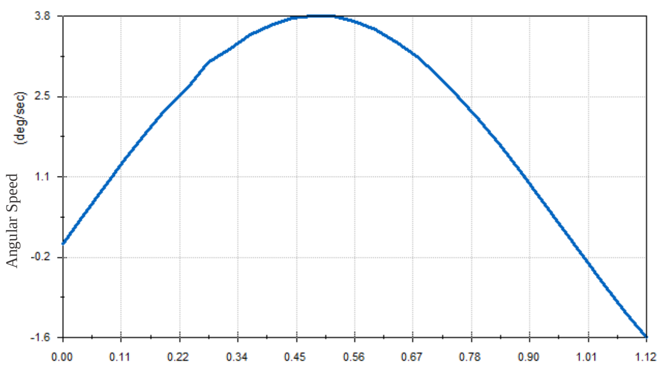

Figure 6. Results of Angular velocity in the Y-axis; *Solidworks pack*.

In figure 6, the angular velocity is presented in the Y-axis, the knee has a movement over a maximum rotation point of 3.8°/s exerted by the biceps muscles. Taking into account the actuator of the prosthesis will only move on the X-axis, the angles observed on the Y-axis are only deviations exerted by the patient when walking, and that will not affect their gait.

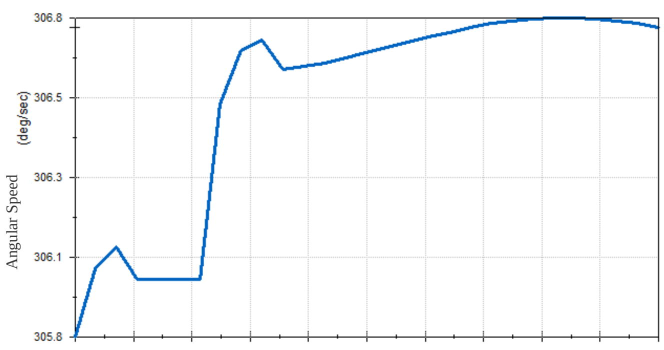

Figure 7. Results of Angular velocity in the Z-axis; *Solidworks pack*.

Figure 7 presents the angular velocity in the Z-axis, its behavior is incremental as the patient raises the leg. It is important to clarify that the simulation of the speed in the Z-axis is a maximum of 305.8°/s, however, the maximum angle of elevation of the knee will be 90° (horizontally at the waist). This speed will depend on how much elevation the wearer of the transfemoral prosthesis wants to give it.

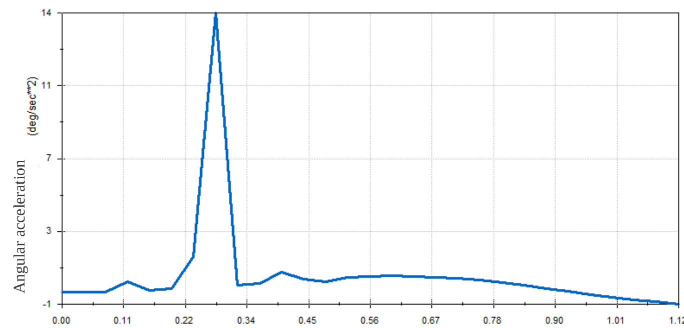

Figure 8. Results of Angular acceleration in the X-axis. *Solidworks pack*.

Similarly figure 8 is showing the angular accelerations, for example: for the X-axis, will be maximum in 1/3 of the time of the patient's gait. At this point, the patient begins the lifting phase to the support phase on the floor. The maximum value of this acceleration is equivalent to 14°/s^2, by trigonometry the patient will be able to walk with a maximum acceleration of 21.13cm/s^2.

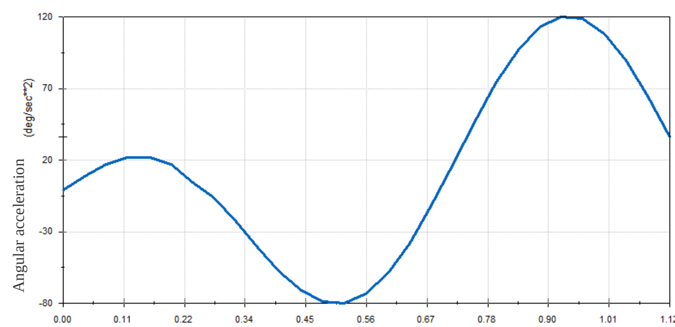

Figure 9. Results of Angular acceleration in the Y-axis. *Solidworks pack*.

For the angular acceleration in the Y-axis, it is shown in figure 9 that its behavior is oscillatory, that is, since the knee has a movement over a maximum rotation point of 120°/s^2 exerted by the biceps muscles, it follows Note that the actuator of the prosthesis will only move in the X-axis, the angles that are observed in the Y-axis are not taken as a control variable.

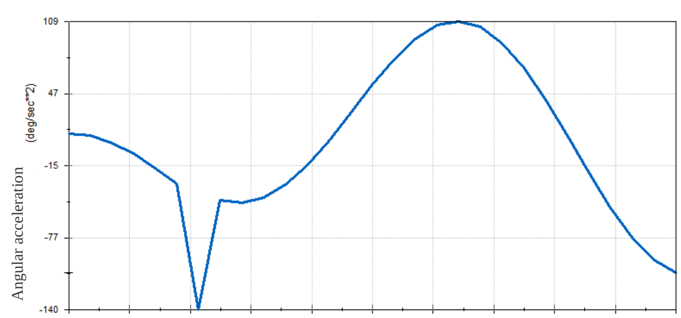

Figure 10. Results of Angular acceleration in the Z-axis. *Solidworks pack*.

For the angular acceleration in the Z-axis, it is observed in figure 10 that its behaviour is variable as the patient raises the leg. It is important to clarify that the simulation of the acceleration in the Z-axis is a maximum of 109°/s^2, however, the maximum angle of elevation of the knee will be 90° (horizontally at the waist). This acceleration will depend on how much elevation the wearer of the transfemoral prosthesis wants to give it.

III. IMPLEMENTATION

On figures 11 to 13 this section is presented the implementation of each of the subsystems, interfaces, and integrations of the project is presented, through particular and general photographs, depending on the number of processes necessary to reach the equivalent implementation of the subsystem in question.

For the implementation of the integrations, each of these was taken and coupled through wired and wireless machine-to-machine interfaces for some subsystems. With the implementation of each of the subsystems, we proceeded to integrate all of the above into the global system. [12]

Figure 11. Implementation of the "Physical Variables Reading Interface" structure built in PLA with elastic bands.

Figure 12. Mounting of the actuator and Encoder on the mechanical prosthesis.

It is important to note that the response time of the control system on the actuator is less than 100ms. These values were measured through the use of the serial monitor and the approximate calculation of the baud rates recognized by the used Microcontroller STM32F103C8 of 64 bits. [13]

Figure 13. Implementation and actual gait test (without patient) of the transfemoral bioelectronic prosthesis.

IV. RESULTS AND REQUIREMENTS CHECK

The results and graphs of the variables measured in the verification of the established requirements are presented in Table 1. The Figures 14 and 15 show the average degrees angle of the joint mechanism of knee movements with respect to the sampling time in the patient's gait cycle. These values were obtained for each of the system interfaces. Initially, for the interface for reading physical variables, the graph seen in figure 14 was obtained, which approximates a linear trend between the angle and the sampling time, this is due to the linearity of the transducer. On the other hand, for the actuator interface (knee) the graph seen in figure 15 was obtained, which approximates a linear trend between the angle and the sampling time; this is due to the linearity of the Encoder of the control system.

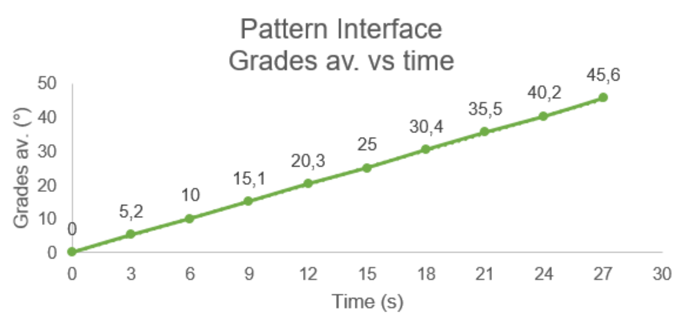

Figure 14. Graph of average degrees concerning the sample time performed every 3 seconds for each test for the standard interface.

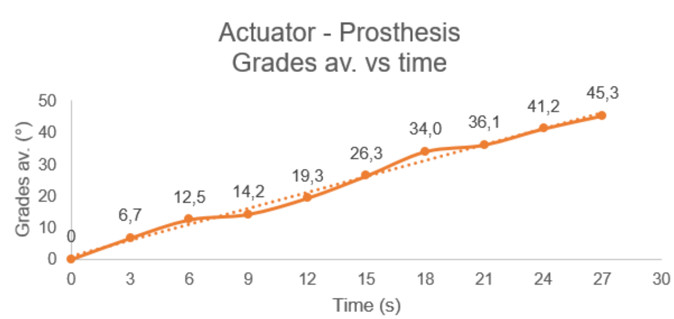

Figure 15. Graph of average degrees versus the sample time performed every 3 seconds for each test for the actuator or bioelectronic knee.

The type of compliance obtained by verifying the operating conditions is presented in Table 1. It is important to highlight that "Partial" indicates that the requirement meets between 80% - 90%, this compliance percentage is calculated by giving it an importance value regarding the impact that the requirement has on the prototype's operation.

Table 1. Compliance with the functional and quality requirements of the system: “Bioelectronic knee prototype”.

Operation requirement	Complies	Fails	Partial	Observations
Emulate the gait cycle	X			Gait movement but no patient test
Interface 1 Myoelectric	X			If you have the EMG signal interface
Physical variables interface 2	X			If you have the physical variable's interface
Conditioning of EMG signals between 10uV and 5mV	X			Avg = 10mV per muscle contraction
Reading Voltages for Lift (Actuator Start)	X			Reading done on the seated volunteer
Control of the actuator in phases of travel			X	Actuator control but not running
Position and speed measurement by Interface 1 while running			X	Position: 0 and 70° flexion and extension. Speed: measured without gear
Integration of the knee in the prosthesis	X			Integration through mechanical adjustment
Movement of the knee in the sagittal plane (0 to 70 °)			X	Movement: between 0 and 45°
Speed measurement by Interface 2 while running		X		Running speed measurements were not made
Weight of the mechanical prosthesis: 3kg ± 10%	X			Weight: 2.1Kg
Interface 2 Weight: 300g ± 10%	X			Weight: 220g
Angle max. extension: 90 ° ± 10%			X	Max angle: 50°
Angle max. bending: 90 ° ± 10%			X	Max angle: 50°
Angle max. per stride opening: 45 °			X	Angle max: 50°, but not in the gait cycle

With the data obtained in the graphs presented in Figures 14 and 15, an approximation is made by using the average of variables as the final result of the test, the percentage of error (%E), and the standard deviation (σ) with respect to the expected value. The mean absolute error was 1.55° with a deviation of 1.32° and an average percentage error of 8.7%.

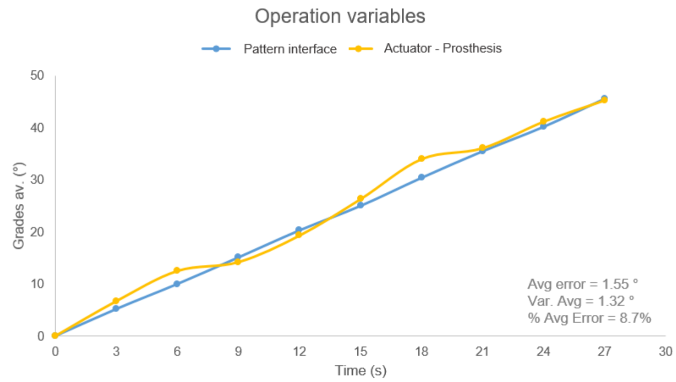

Figure 16. Graph of the operating variables: average degrees with respect to the sample time performed every 3 seconds for each test.

With the graph in figure 16, it can be inferred that the requirements involved for the fulfilment of objectives, ranked from highest to lowest impact in the implementation process, are presented in table 2.

Table 2. Variables of operation for the fulfilment of the requirements of greater value.

Higher value requirements	Result
Degrees and angular position	Between 0 and 45 °
Walking speed	Between 0.5 m/s and 0.8 m/s
Compliance with quality requirements	≤10%
EMG signal conditioning	Impulse of muscle contraction.
Actuator control system	Positioning and speed of the knee between 0 and 45 °

Figure 17 shows the result of the initial proportional control system that was obtained when performing the gait cycle tests. Initially, the angular position signals were read by eliminating digital noise [14]. With the digital low pass filter, there is a noise reduction factor of 0.05, with this factor the control signal on the input and output of the position variables was improved.

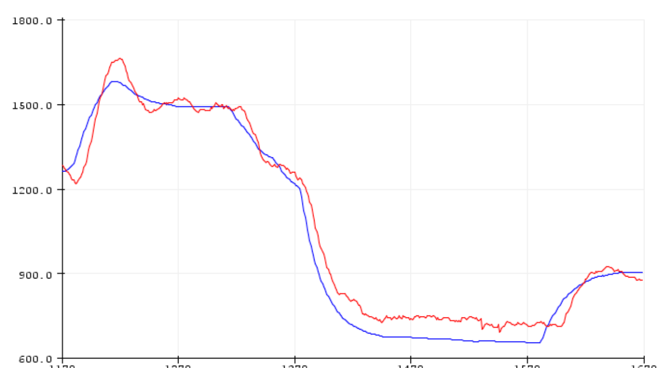

Figure 17. Results of angular position measurements using the control system. Graphic with digital low pass filter for noise elimination.

Figure 18 shows the result of the initial proportional control system that was obtained when performing the gait cycle tests. Initially, the angular velocity signals were read with digital denoising.

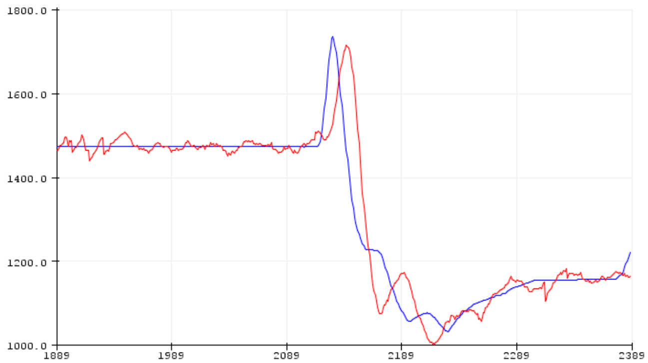

Figure 18. Comparison of the results of the position and angular velocity measurements using the control system.

Figures 19 and 20 show the result of the impulses of the EMG signals produced by the continuous muscular contractions given by a voltage pulses, these signals are produced by muscle contractions. Initially, continuous muscle contractions are performed; where the volunteer performs a contraction on the Vastus Intermediate approximately every second as presented in figure 19. Furthermore, rapid muscle contractions are performed to observe the behaviour of muscular exhaustion using the voltage drop in the impulse as presented in figure 20. [15]

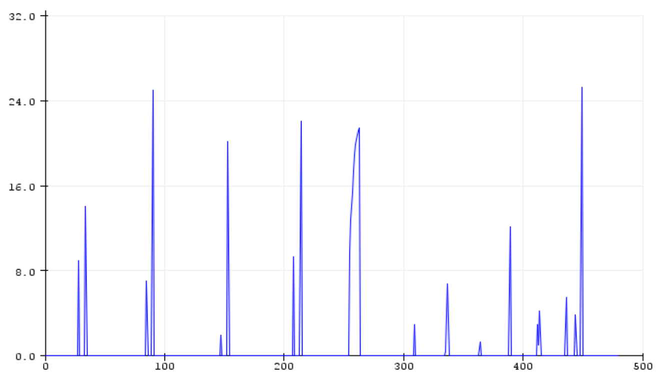

Figure 19. Impulses of the EMG signals produced by the continuous muscular contractions of the volunteer.

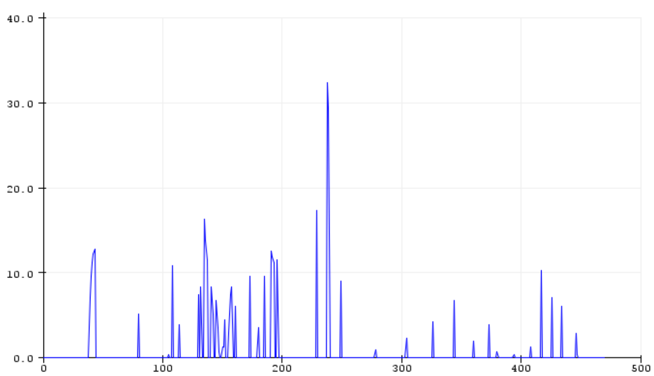

Figure 20. Impulses of the EMG signals with repetitive muscular impulses to verify the voltage drop due to muscular exhaustion.

V. DISCUSSION

For the measurement of the speeds in the gait cycle, a patient was necessary, due to the contingency it was not possible, and therefore, it is considered that the requirement does not comply. However, velocity measurements in a simulated environment (tests) could be implemented. The measurement of the speeds in this process was carried out by holding the actuator fixedly vertically, where only its main axis moved. After firmly holding the actuator, its speed was measured using the accelerometer and the serial monitor of the Arduino IDE, resulting in 0.5m/s at 0.8m/s. This measurement method is close to the actual walking speed of the patient since it is always in the lifting phase. [16]

With each of the functional and quality requirements, the emphasis was placed on obtaining the quantitative result of the angular positions between 0 and 45°, for flexion and extension equivalent to 8.7% error over the established maximum, angular velocities between 0 and 0.8m/s equivalent to 0% error over the established interval and accelerations dependent on the speed of the patient (the volunteer for this case). These magnitudes occupy a high degree of importance in the functionality of the system, regarding the fulfilment of the requirements, but the qualitative data define the visual behaviour of the system, for example, the direction of the actuator, the indicator lights, and the response of data reception. Digital control system when the master member changes its behaviour, the location of the reading interfaces on the patient, etc. In the graph presented in figure 16, an approximation is made by using the average of variables as the final result of the test, the percentage of error (%E), and the standard deviation (σ) concerning the expected value. The mean absolute error was 1.55° with a deviation of 1.32° and an average percentage error of 8.7%. All the requirements mentioned above fulfil their functionality.

Regarding the operating time of the system (EMG and control interface), the battery life requirements about the speed of the march do not meet. In the first instance, the control interface does not have the adaptation of the prototype on the stump of the patient, this leads to not being able to carry out the walking tests with the prosthesis installed. The uptime for this interface is not known. However, according to the calculations carried out, it is assumed that its duration is in the interval from 1.23h to 3.7h for torques of 8.82Nm and 13.23Nm respectively.

Most devices on the market that use rechargeable battery sources do not include a backup battery for various reasons, for example, its high cost, the life cycle is longer compared to other non-rechargeable batteries, etc. [17] The condition of non-compliance of the lack of a backup battery is given to the high cost of this type of battery, equivalent to 340 thousand Colombian pesos. Hence, only one battery is used in the device.

On the other hand, the total cost of the bioelectronic knee prototype had initially been budgeted at a value of 2,500,000 Colombian pesos (COP) equivalent to approximately 600 US dollars. By optimizing resources, the cost of electronic components, PCBs, construction materials, and elements such as actuators and sensors, at the end of the implementation, and efficiency of 178% was obtained, equivalent to a total of 1'400,000 COP of the budgeted value. Currently, there are transfemoral bioelectronic prostheses on the market with minimum values of 18'000,000 COP equivalent to 5000 dollars [18]. The prices of these prostheses vary depending on the utilities of the patient; some are designed with more complex electronic systems than others.

VI. Conclusions

The design and simulation of the bioelectronic knee prototype fully fulfilled its operation through the construction of the 3D system in CAD platforms, the simulation, and study of static, dynamic, torques, forces, and resistance of the materials on the structures of the prototype.

Similarly, in the implementation and testing of the bioelectronic knee prototype for transfemoral mechanical prostheses, the results of the physical variables that fulfil the function of reading, operating, and controlling the gait cycle were obtained. For example, the reading of the angular position is carried out to obtain the exact opening distance of the transfemoral prosthesis concerning the torso using the movement of the standard member; this opening is at 45° as its maximum value of over the initial position of the sagittal axis. For the patient's gait cycle, the reading of the signals of the quadriceps muscles in the stance phase and the hamstring muscles in the swing phase produces the change in the records of the amplitude data in which the patient decides it does start the gait cycle by generating its muscle contraction or it stops.

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