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DESIGN PROCESS OF A MECHATRONIC DEVICE FOR MEASURING THE STUMP STRESSES ON A LOWER LIMB AMPUTEE

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Abstract. *This paper is devoted to the design of process for a low-cost mechatronic device intended for measuring the lower limb amputee stresses. This development is based on a biomechanical analysis and the force data obtained in a gait laboratory, whereof a force and stress analysis over the stump-socket interface could be done. Later, gait critical conditions are simulated for acquiring the theoretical results needed to do a sensors selection (Flexiforce-Teckscan®). Once the selection is done, a sensors mesh is presented as a measuring device, as well as the electronics for signal conditioning and the software for results analysis and presentation. This device is calibrated and validated by means of a testing bench. Finally, the device assembly is done with commercial prosthetic elements, in order to proceed with the critical conditions tests and to get the experimental data. The data is compared with the theoretical results as the designed device validating stage.*

Keywords: *Socket, Stump, Stress, Biomechanics, Interface.*

1. INTRODUCTION

Amputation, It is an outcome that suffers the people in Colombia due to the internal conflict, It is caused by the action of Anti-personnel landmines and Unexploded Ordnance. On the last three decades the action of this devices has left handicapped people of the military forces and civil on rural places. The rehabilitation process its very important for the victims, and the physicians play a key role. One of the most important center to do this, It is the Central Military Hospital (Hospital Militar Central HMC), this hospital receives the greatest number of the victims, and holds the accurate staff for the treatment of injuries and process of the rehab. During the rehab the patients use prosthetic devices. The socket is a part of one of them, that allows to transfer the forces of the leg stump to the rest of the prosthetic device. Making it crucial for recovery.

On this proposal it shows a tool for diagnosis, through of a device that measures the pressure on the socket leg stump interface (Fig. 1), in order to improve the rehab methods and support the best diagnosis for physicians and patients arrived of the HMC (Borrero (2012)).

The number of amputees in Colombia nearly 10309 people (Colombia (2013)), the requirements to enhance the quality on the medical services, are some reason to aid on better medical diagnosis. To achieve these, a study of art is made, looking for the devices which measure the pressure in rehab procedures in order to choose the type of sensor to be used.

Nowadays on rehab, the force and pressure measurement is used for the orthopedic evaluation of gait and definition of the projection line and the plantar reaction. There are devices like podoscope, inked paper, etc, which the goal is to get quantitive information about plantar support by calculating such parameters as surface, maximum pressure, average pressure and center of pressure (Díaz and Torres (2006)).

The gait could be described as a dynamic system, where the reaction force and the surface of contact changes according to the cadence of the patient. During the gait phase, from the back of heel to the lifting of the forefoot, there are forces widely higher than the corporal weight and also generate foot plantar pressure more elevated than stand on natural and relaxed position (Lacuesta *et al.* (2005)).

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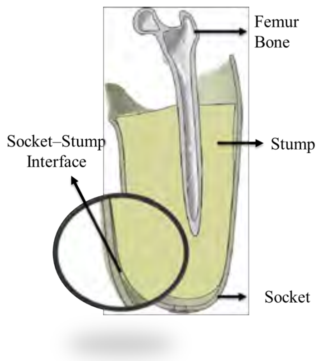

Figure 1. Socket - Stump Interface (Patiño (2011)).

On prosthetic, have been made research on models which describe the behavior of socket stump,through pressure analysis. On 1997, M.Tanaka et al. propose the distributed pressure identification on the socket stump interface for people with lower limb amputation (above knee), they developed a socket model through finite element analysis. The pressure identification was formulated for minimize the elastic energy,the most plausible pressure was sought based on the watched deformation. The Fig. 2 shows the lab test of the socket model. (a). Socket designed and manufactured by finite elements. Fig. 2 (b). Testing laboratory setup. Fig. 2 (c). Pressure distribution (Tanaka *et al.* (1997)).

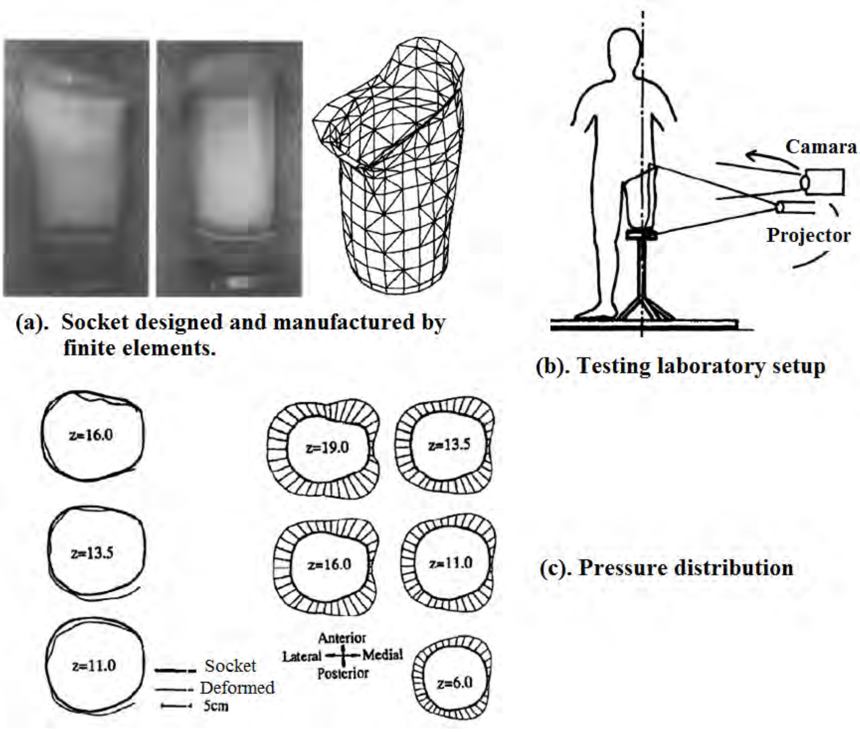

Figure 2. Images taken from experiment and result ofTanaka *et al.* (1997).

Ming Zhang y Arthur Mak made an analysis of force transfer by finite element between the stump and the socket, considering the friction, boundary conditions and no lineal strain. The 2D model developed, has on the sagittal plane of the stump $170\,mm$ height y $185\,mm$ width, the stump and socket properties were assumed as lineal and homogeneous, considering the bone effect, for that reason they included the Poisson value (0.3), Young module $(15\,\mathrm{GPa})$ etc., reference on (Zhang and Mak (1997)). Something important of this work was that they considered the air in the interface, making it into a real approximation to the amputee condition. The simulation was held into ABAQUS software, Fig. 3 shows the the 4 node solid shell used, it had a total of 144 elements and 462degrees of freedom, as outcome they got the pressure distribution and the strain in the interface (Zhang and Mak (1997)).

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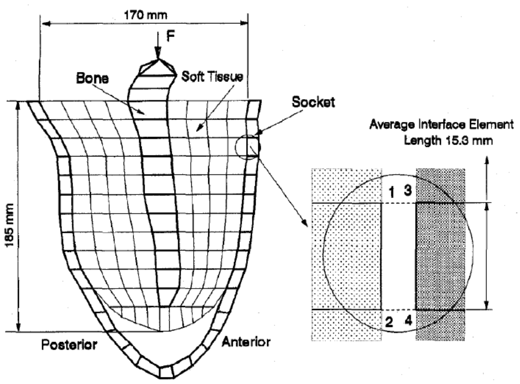
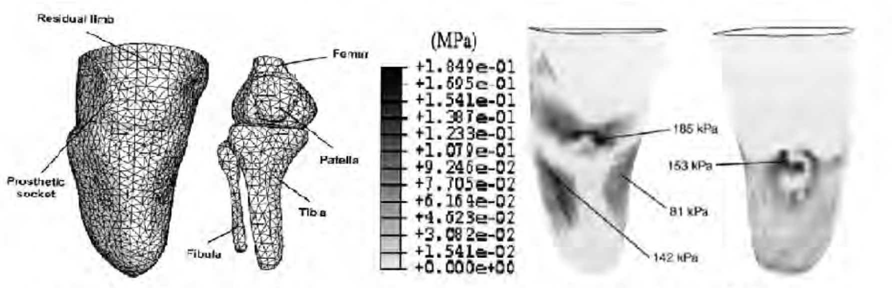


Figure 3. Diagram of simulation conditions and solid element used by (Zhang and Mak (1997)).

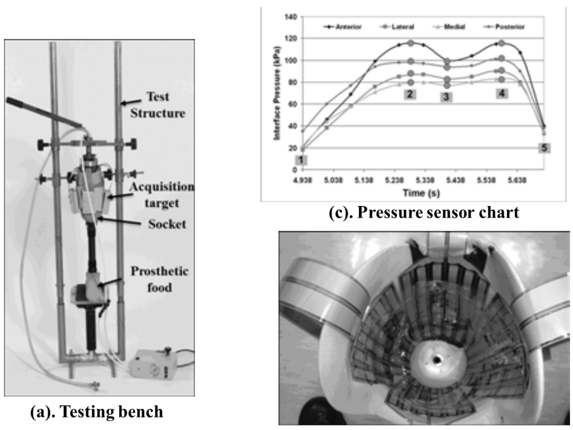
Wilson Lee, Ming Zhang, Jason Cheung y Xiaohong Jia, who developed the model by FEA of the contact interface between the socket and the stump of a transtibial amputee, same as on (Zhang and Mak (1997)), where they copy the element properties of the assembly, modeling each element separately on SolidWorks and imported to the ABAQUS simulation software FEA, the mesh tool used was solid shell 3D tetrahedral, show on Fig. 4 (a), with 22301 elements. The main difference of this research was the preloaded socket by the stump, this cause by the knee patella, allowing an approximation of the strain on different points of the socket, it was watched the pressure distribution on the socket (Fig. 4 (b)).



(a). Modeling and meshing **(b). Result of the simulation**

Figure 4. Simulation and FEA meshing used by (Lee *et al.* (2004)).

On Dumbleton and Buis (2009), on Strathclyde university, Glasgow UK, they designed a pressure measurement device on the lace on 48 trans-tibial amputees, they studied the behavior of the silicone as interface between the stump and the lace, they established which one would be used for testing, they built a testing bench, it shows on Fig. 5 (a), the test results were analyzed statistically and concluded that the pressure exerted by the stump over the socket depends on the alignment made by the physicians to patient amputee, which allow to define the pressures on the front and the back of the residual member.



(a). Testing bench **(c). Pressure sensor chart** **(b). F-Scan Sensor**

Figure 5. Device for measuring pressure implemented in (Dumbleton and Buis (2009)).

The equipment used for pressure measurement were F-scan sensors from Tekscan. The sensor network is composed of four arrays distributed in the socket, carried out a biomechanical analysis it was determined that the anterior, posterior and lateral are where most pressure is exerted on the interface. The sensor distribution is show on Fig. 5 (b). This equipment acquires information for 12 seconds at a frequency of 150 Hz, creating a graph of pressure in the pressure zones (See Fig. 5 (c)) (Dumbleton and Buis (2009)).

2. DYNAMIC OF THE INTERFACE

Devices used to measure pressure, works with the mechanical concept of forces and moments. In this case of study, the forces produced by a prosthetic device with an rigid element (eg prosthetic foot with the ground, where reaction forces and moments are generated by the contact with the ground). This forces are reflected on the interface and therefore on the person. The dynamic event analysis is based on Newton's second law, with the calculation of the forces and moments.

Fig.6 shows the force and moment diagram of the gait, from back of the heel phase on 3D (Cartesian planes (x, y, z)).

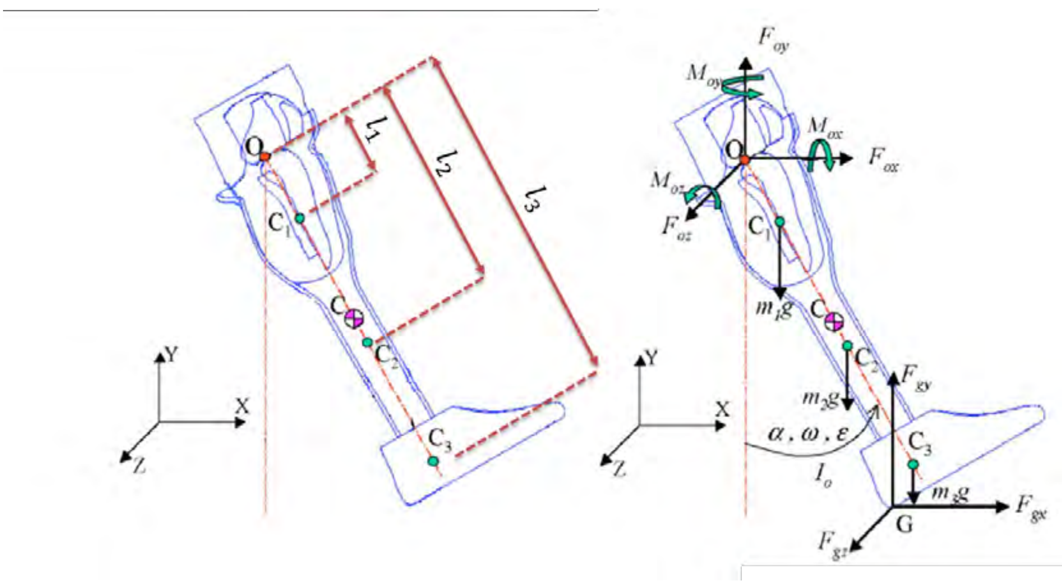


Figure 6. Diagram of forces and moments (Jia *et al.* (2004)).

Equation (1) shows the knee rotation by the sum of moments with respect to the origin$O$. see Fig.6.

$$M_{oz} - m_1 g l_1 \sin(b) - m_2 g l_2 \sin(b) - m_3 g l_3 \sin(b) + F_{gx} y_G + F_{gy} y_G = I_o f \quad (1)$$

where, b is the angular displacement on sagittal plane; $m_i (i = 1, 2, 3)$ are the stump masses, socket with the tube and prosthetic foot respectively; $l_i (i = 1, 2, 3)$ are the distances from the center of mass to the origin$O$.

Equation (2) shows the sum of moments x regarding O.

$$M_{ox} + F_{gz} y_G + F_{gy} z_G = 0 \quad (2)$$

Equation 3 shows the sum of moments y regarding O.

$$M_{oy} + F_{gz} x_G + F_{gx} z_G = 0 \quad (3)$$

Equations (4, 5 y 6) shows the sum of forces on the different coordinated axis (x, y, z).

$$F_{ox} + F_{gx} = (m_1 + m_2 + m_3)(rf\cos(b) - rp^2\sin(b)) \quad (4)$$

$$F_{oy} + F_{gy} - (m_1 + m_2 + m_3)g = (m_1 + m_2 + m_3)(rf\sin(b) + rp^2\cos(b)) \quad (5)$$

$$F_{oz} + F_{gz} = 0 \quad (6)$$

The variable p is angular velocity, f is angular acceleration and r is the distance from the origin to the center of mass of the entire model.

According to Jia *et al.* (2004), previous equations describes the interface dynamic.

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3. SENSOR NETWORK DESIGN

Based on the Eq. 4, Eq. 5 and Eq. 6, has been determined that the maximum force exerted on the interface was $26,1\,N$ and corresponds to the force F_{ox} (Jia *et al.* (2004)). The previous work results (IV Latin American Congress on Biomedical Engineering (2007)), where they established gait pressures of a transfemoral amputee, at 32% of the amputee bodyweight. Proposal is to use the Flexiforce A301 pressure sensors from TeckScan.

These are manufactured with two layers of substrate film (polyester). Each layer, a conductive material (silver) is applied, followed by a layer of sensitive pressure ink. The two substrate layers are joined by an adhesive to form the sensor. A silver circle on the top of the sensitive ink is the hotspot detection. The conductive material extends from the detection area to the other end of the sensor, forming the leads. The chart 1 shows the physical properties, which allow the position of the sensor array into the socket without interfering with the motion of the person using it, by its thickness and overall dimensions (Mejía *et al.* (2010)).

Table 1. Properties and Performance of Flexiforce A301 .

Physical Properties	
Thickness	0.208 mm (0.008 in.)
Length	25.4 mm (1 in.)
Width	14 mm (0.55 in.)
Sensing Area	9.53 mm diameter (0.375 in.)
Substrate	Polyester (ex: Mylar)

Typical Performance	
Linearity (Error)	< ±3%
Repeatability	< ±2.5% of full scale
Hysteresis	< 4.5 % of full scale
Drift	< 5% per logarithmic time scale
Response Time	< 5 µsec

The sensor works as a variable resistance on an electric circuit. When there is no load over the sensor, their resistance is very high (higher than $5M\Omega$); when force is applied on the hotspot, the resistance decreases. When connecting an ohmmeter to the two output pins of the sensor connector and apply a force to the detection zone, you can see the change in resistance (Mejía *et al.* (2010)).

A network sensor was designed, It allows to measure the pressure in the socket, this design has 5 force sensors, which established a hotspot for estimate the pressure on the grid. Each sensor is connected to electronic conditioning system, this grid is made of a sheet of acetate, thanks to its flexibility and low thickness Fig. 7 shows the dimensions of the grid.

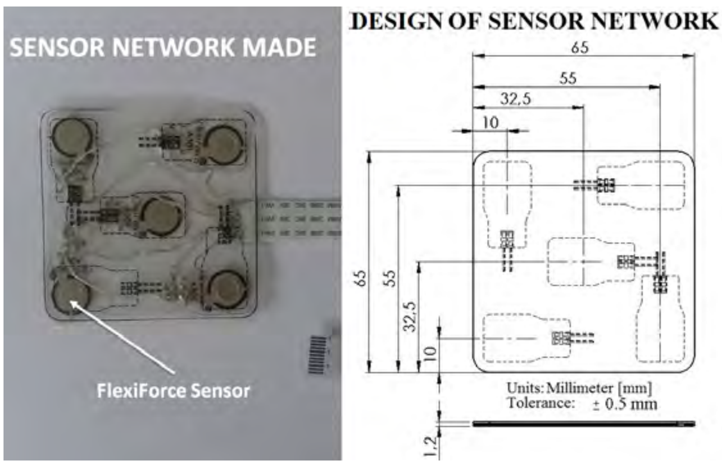

Figure 7. Design and sensor network made.

The electronics for signal conditioning of each sensor implemented was based on manufacturer's recommendations, which states that you must use an operational amplifier in inverting amplifier configuration by adjusting the resistance $R2$ to determine the gain configuration. Fig. 8 shows the electronic network sensor circuit. A simulation was made to determine the resistor R2 and obtained a value of $85\,k\Omega$, allowing the sensor to have a voltage output range from 0 to 8V.

Additionally, the sensor calibration machine shown on Fig. 9, was designed to calibrate the sensors. This allows vertical movement, thus ensuring that the discs (weights), located at the top, transfer the weight directly above the sensor. The machine performs the movement through linear bearings, which help to decrease friction. It also has support structures for stability and restrict horizontal movements. A piece was made, which controls the area of the sensor application, and so to determine the pressure on the sensor.

A National Instruments acquisition card NI 6010 NI USB was used, in order to obtain the data from each sensor (see chart. 2).

An experiment was designed to determined the measurement error, in the mechatronic device, which is based on statistical analysis, according to the hysteresis of the sensors, allowing to achieve calibration of each sensor using the

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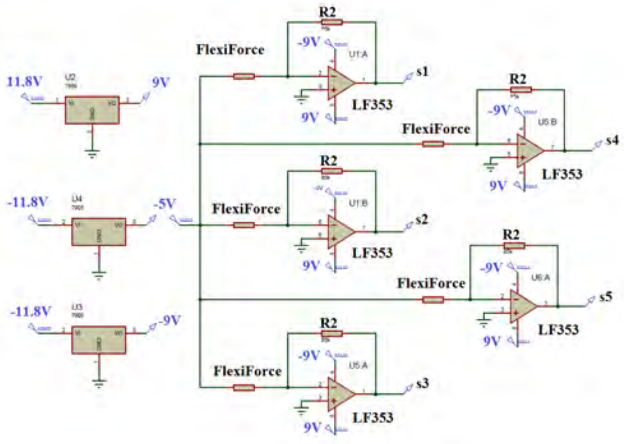

Figure 8. Electronic Network Sensor Circuit.

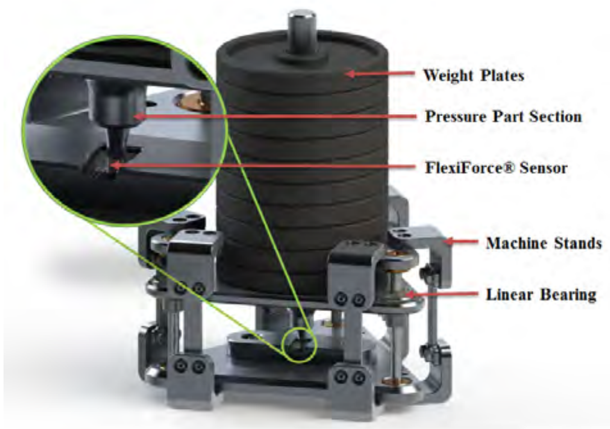

Figure 9. Sensor Calibration Machine.

Table 2. Calibration data table of Flexiforce A301.

Weight [kg]	**Voltage [V] FlexiForce 1**	**Voltage [V] FlexiForce 2**	**Voltage [V] FlexiForce 3**	**Voltage [V] FlexiForce 4**	**Voltage [V] FlexiForce 5**	**Voltage [V] FlexiForce AVG**
0	$0,07 \pm 0,32$	$0,06 \pm 0,33$	$0,07 \pm 0,30$	$0,06 \pm 0,30$	$0,07 \pm 0,26$	$0,07 \pm 0,28$
1,16	$0,93 \pm 0,32$	$0,82 \pm 0,33$	$0,95 \pm 0,30$	$0,85 \pm 0,30$	$0,92 \pm 0,26$	$0,89 \pm 0,28$
2,37	$1,69 \pm 0,32$	$1,58 \pm 0,33$	$1,66 \pm 0,30$	$1,56 \pm 0,30$	$1,55 \pm 0,26$	$1,61 \pm 0,28$
3,44	$2,45 \pm 0,32$	$2,44 \pm 0,33$	$2,62 \pm 0,30$	$2,48 \pm 0,30$	$2,41 \pm 0,26$	$2,48 \pm 0,28$
4,68	$3,31 \pm 0,32$	$3,36 \pm 0,33$	$3,31 \pm 0,30$	$3,30 \pm 0,30$	$3,38 \pm 0,26$	$3,33 \pm 0,28$
5,73	$3,94 \pm 0,32$	$4.09 \pm 0,33$	$3,85 \pm 0,30$	$3,93 \pm 0,30$	$3,94 \pm 0,26$	$3,95 \pm 0,28$
6,92	$4,78 \pm 0,32$	$4,70 \pm 0,33$	$4,60 \pm 0,30$	$4,63 \pm 0,30$	$4,61 \pm 0,26$	$4,66 \pm 0,28$
7,95	$5,32 \pm 0,32$	$5,34 \pm 0,33$	$5,54 \pm 0,30$	$5,53 \pm 0,30$	$5,53 \pm 0,26$	$5,45 \pm 0,28$
9,25	$5,11 \pm 0,32$	$5,95 \pm 0,33$	$6,29 \pm 0,30$	$6,32 \pm 0,30$	$6,45 \pm 0,26$	$6,22 \pm 0,28$
10,87	$7,02 \pm 0,32$	$7,08 \pm 0,33$	$7,11 \pm 0,30$	$7,24 \pm 0,30$	$7,16 \pm 0,26$	$7,12 \pm 0,28$
12,23	$7,87 \pm 0,32$	$8,11 \pm 0,33$	$7,78 \pm 0,30$	$8,05 \pm 0,30$	$7,65 \pm 0,26$	$7,89 \pm 0,28$

ji-square method (Eq. 7) (Box *et al.* (2008)). Chart 2 shows the error value of each sensor.

$$\frac{\sum(y_u - n)2}{\sigma 2} \sim x_n^2 \tag{7}$$

Equation (8) determines the average sensor behavior, this was obtained by making the average data from five sensors for each weight by a linear regression of the data shown in chart 2.

$$Weight = 1,549 \cdot Voltage - 0,2764 \tag{8}$$

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Figure 10, shows the curve of data obtained from the sensors and the average thereof, as well as the linear regression obtained

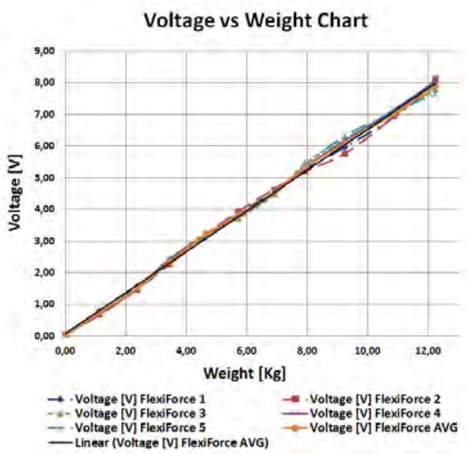

Figure 10. Sensor Response to Different Weights.

4. TEST BENCH

In previous work (Jimenez *et al.* (2012)), we performed the design of a machine for structural testing of prosthetic devices, following the international standard ISO 10328, which determines the critical load conditions which lower limb prostheses must be submitted. A pneumatic system with closed loop control system for testing was implemented, according to the requirements of the standard. The standard establishes different test arrangements, which recreate the heel support and standing off. These are configurations in which the maximum pressure occurs on the interface.

In this paper, In this paper, a user interface was designed for the elaboration of the tests according to standard, where there was a static test heel support setup, allowing us to reproduce a critical moment in the gait of the amputee. For purposes of understanding the test, established an amputee with a weight of 80 Kg.

According to Lacuesta *et al.* (2005) in gait, there has been a value of 120% of the weight. Therefore, set the pneumatic actuator force to a maximum value of 96 Kg.

Based on the work (Jimenez *et al.* (2012)), the system was adapted to test the sensor network designed, the overall system architecture is shown in Fig 11

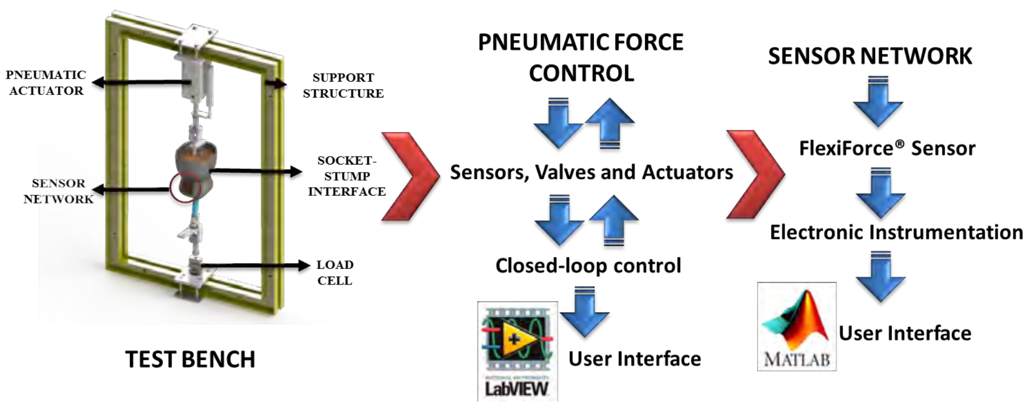

Figure 11. Proposed architecture.

The user interface designed, was performed for the mechatronic device (See Fig12) in order to visualize pressures in the network obtained during the test sensor, according to the standard. On the left you have a graph of the pressures on the five grid sensors, acquiring real-time information. This allows to establish the area where most pressure is exerted, this is shown by the red color of the graph. On the right, you can find a chart with the value of the pressure, presented in all sensors, and in which is recorded a historic maximum pressure generated.

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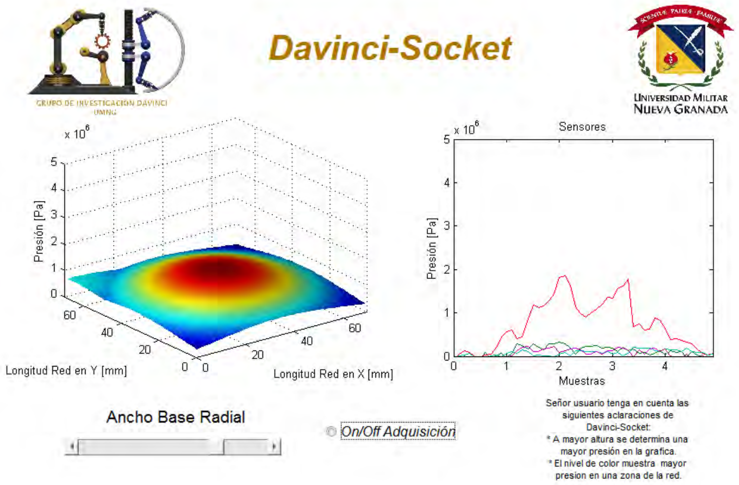
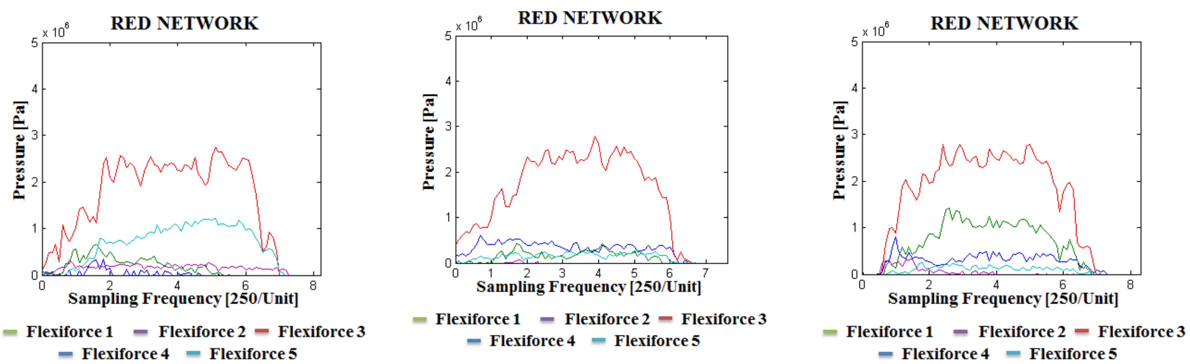


Figure 12. Sensor Network Software.

5. RESULTS

As a result, the pressure was recorded with the prosthetic device in the test bench. where 3 tests were performed to the device. For each test we used a socket of a transfemoral amputee. Based on the foregoing, stump was fabricated with the characteristics of human skin according to the literature (ballistic gel).

Figure 13, shows the values recorded by the network sensors, which shows that the center sensor is where it is exerting greater pressure.



Test 1 Test 2 Test 3

Figure 13. Pressure chart of device.

The reported values of the test are shown in Tab 3.

Table 3. Test results.

Test	**Pressure Max [MPa]**
1	$2,53 \pm 0,13$
2	$2,59 \pm 0,13$
3	$2,44 \pm 0,13$

According to the information accessed Dumbleton and Buis (2009), states that the maximum pressure is generated in the anterior region, in an area of pressure sensed $1\,cm^2$, this is the maximum value, 32% of body weight. Based on the above it was established that the pressure in pascals is equal to $2,51\,MPa$ with an error of $0,12$.

Performing the calculation recorded by the device designed, it was established that the area of pressure is equal to $0.2827\,cm^2$, and that the perceived weight percentage of the sensor network in this area is equivalent to 9.04% of bodyweight. The value obtained was $2.53\,MPa$, with an approximate error of $0,13$.

The comparison between the results of the studies reported in the literature, and the device designed, determine that the device is consistent with that reported in the literature, and their measurements are accurate.

Added value to the device as designed, is its low cost, also serve to support the medical diagnosis, in terms of the pressures on the interface. It shall identify possible errors in the manufacture of the socket, or pathologies of the amputation.

These anomalies in the stump-socket interface can cause skin damage or interfere with the rehabilitation of an amputee patient.

It was also determined that the device, its physical properties, will not affect the progress of an amputee when used.

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