Evaluation Plan of a Mechatronic System for Anterior Cruciate Ligament Rehabilitation

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***Abstract*—A great number of disabilities is caused by lower limb injuries, being Anterior Cruciate Ligament (ACL) injuries very common. Research in Robotic and Bioengineering have been addressed to develop robotic systems to carry out automatic processes for the rehabilitation of lower limb injuries or disabilities. However, a comprehensive interdisciplinary evaluation plan for these systems, prior the use on human subjects, was not found in the literature. In this paper is proposed a plan to evaluate a lower limb rehabilitation system, focusing on the knee joint, with an integral approach, where mechanical, electronic and user's safety aspects were taken into account. As a result, it was obtained a plan to assess a lower limb rehabilitation system, focused on ACL rehabilitation where an instrumented and configurable dummy was proposed to evaluate the user's safety.**

***Index Terms*—Rehabilitation robotics, biomechatronics, performance evaluation, exoskeletons, product safety.**

I. Introduction

In Colombia, people in state of disability are 6.3 % of the population, being second in Latin American after Brazil. 29 % of these people have some type of disability for walking or moving [1]. A great number of disabilities is caused by lower limb injuries, being Anterior Cruciate Ligament (ACL) the most commonly injured ligament in the knee [2], 150000 injuries of ACL occurs each year in United States of America and 15000 reconstructions are applied in this country every year [3]. The standard method to treat ACL injuries is surgery and, after that, a rehabilitation process must be carried out.

Research in Robotic and Bioengineering have been addressed to develop robotic systems to carry out automatic processes for the rehabilitation of lower limb injuries or disabilities. Theses developments are focused on active orthosis, also defined as exoskeletons. An exoskeleton is a biomechatronic system coupled outside of the human body to support align, correct placing of extremities or increase of strength, and has actuators to reproduce the body limbs movements. [4], [5]. However, a comprehensive interdisciplinary evaluation plan for these systems, prior to use them on human subjects, was not found in the literature. For example, in [6], torque responses are directly evaluated on one healthy subject, being focused on mechanical tests. On the other hand, in [7] an orthosis is tested on a paraplegic subject with the objective to assess the repeatability of hip and knee trajectories collecting fundamental data about the robot's power consumption but no previous evaluation is reported. Similarly, in other research projects, such as [8], [9], firsts stages of the robot evaluation are performed with healthy subjects, in order to measure the device effectiveness in rehabilitation processes and parameter's values such as inter limb coordination, movement accuracy, efficacy and smoothness.

There are other projects, as shown in [10], where experiments were conducted with a dummy leg on the device in order to estimate its angles and to confirm the right execution of the rehabilitation routines. Similarly, in [11], it was developed an upper limb rehabilitation system and were conducted tests with a mannequin arm, assessing the robot with a dummy weight.

In terms of hardware evaluation, it was found that parameters such as friction and rotational smoothness are assessed to ensure the proper execution of rehabilitation treatments [12], [13]. On the other hand, it was also found the implementation of sensors at the system's joints collecting more reliable data about their behavior, not only depending with the readings of the motor encoders [14]. Other important parameter is the inertia [14], which should be kept low, therefore, several prototypes tend to use a transmission device that drives the joints from a distant location of the actuators [6], [14].

An important aspect observed in numerous projects is the lightweight design of the robots, predominantly in the segments attached to the user [6]. Thus, it is necessary to test structural stiffness in order to give way to possible modifications in the design.

For electrical and electronic test, studies about DC machines have been used for developing the DC motors evaluation, with the revision of the electrical machines books [15], [16] and [17] which show the variables as current, power and torque to have into account to check the DC motor state. Lenz et al. [18] shows the fundamental standard that defines the system boundaries and the environmental evaluation of machine tools and evaluates the energy efficiency.

Other papers have presented works about energy efficiency such as [19], [20], [21], their contribution allow to study evaluation plans for DC motors assessments that have been used in the development of this paper. In the measurement of the power, the method presented by [22] shows an interesting stage that helps in the evaluation of the power consumed by

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rehabilitation systems.

In summary, research carried out on lower limb rehabilitation devices usually tests their prototypes using healthy subjects in order to assess the reliability and functionality of the systems. However, the authors consider that there are not sufficient and exhaustive studies integrating the main aspects of the machine to evaluate the device security and provide an integral plan to be used in lower limb rehabilitation robots.

In this paper is proposed a plan to evaluate the lower limb rehabilitation system Nukawa, focusing on the knee joint, with an integral approach, combining the mechanical, electronic and user's safety aspects. Specifically, for the latter, an instrumented and configurable dummy is proposed in order to emulate the human behavior during rehabilitation routines.

This paper is presented as follows. In section II is described the lower limb rehabilitation system Nukawa. In section III is shown the methodology used for the development of the proposed evaluation plan. In sections IV-A, IV-B, and IV-C the electrical, mechanical, and security tests proposed in order to assess the mechatronical system Nukawa are explained. Section V shows the discussion. Finally, it is presented the conclusion regarding the results and possible future works.

II. Lower Limb Rehabilitation robot Nukawa

A mechatronic system called Nukawa (Fig. 1) is under development at the *Universidad Pontificia Bolivariana*, intended for lower limbs rehabilitation, *i.e.,* hip, knee and ankle therapies. This mechatronic system is product of requirements presented by an interdisciplinary group, formed by physiotherapist and engineers, and has its antecedents in [23]. The mechanical design consists of two limbs, each one composed by a three-link mechanism and an electronic Computed Torque Control (CTC),its implementation was conducted in a first stage as a hardware in-the-loop (HIL), using the Nukawa simulation model without having to use the actual robot.

The three degrees of freedom allows each leg to perform flexion/extension (FE) movements of the hip, FE movements of the knee, and dorsi/plantar flexion movements of the ankle [23]. The design also has three brushless motors in each limb, power drivers, encoders and strain gauges to measure forces.

The joints are, approximately, collinear to human joints, and the system allows to adjust the length of each segment. The knee is a polycentric joint, however a simplification was conducted, as presented by Zoss et al. [24], where a pure rotational joint in the sagittal plane was proposed. The system was designed for people between 1.44 m and 1.85 m and up to 85 kg weight. The angular displacements of each joint were restrict with mechanicals stops. The angular displacement ranges for hip, knee and ankle are shown in Table I.

Nukawa is currently on its last phase of construction, so there are some important requirements to test.

TABLE I
LOWER EXTREMITY RANGE OF MOTION [25]

Joint	Movement	Angular displacement (°)
Hip	Flexion	122 ± 12
	Extension	22 ± 8
Knee	Flexion	134 ± 9
	Extension	-1 ± 2
Ankle	Dorsiflexion	12 ± 4
	Plantar flexion	54 ± 6

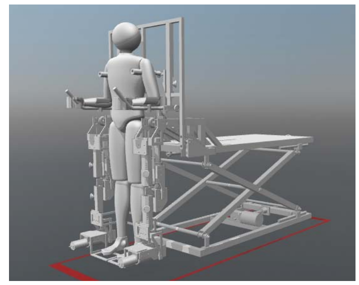

Fig. 1. Sketch of the Nukawa lower limb rehabilitation system

III. Methodology

The evaluation plan developed for Nukawa is based on a literature search about other mechatronic devices for lower limb rehabilitation, including their development, the criterion used in their designs, the hardware evaluation and the implementation of these machines, projects related with rehabilitation and robotic systems. The search covered papers published between 2003 and 2017 on the electronic databases Scopus, IEEE Xplore, Science Direct and Google Scholar. The terms used for the search were lower limb rehabilitation robots, rehabilitation devices, evaluation of rehabilitation machines, gait rehabilitation, robotic safety, dummies in rehabilitation systems, mechanical evaluation in robots, torque analysis in machines,energy efficiency, sensor evaluation, DC machines assessment, electrical machines.

No papers were found about integrating different aspects in the evaluation of these kind of devices. Mechanisms, electronics and security are treated separately or barely explained in papers, where the main focus is the implementation of the tests directly on subjects. The gathered information, however, was useful to develop and integral evaluation plan.

21 papers were revised, 13 were used for the electrical evaluation plan and 8 for the mechanical plan. On the security aspect, only 5 papers treated the use of dummies to assess the general behavior of the rehabilitation device [26], [10], [27], [11], [28], without evaluating the robot safety. Particularly, Banala et al. [10] measured the angle in the dummy joints confirming the right execution of rehabilitation paths.

The integral plan presented in this paper was developed according to the literature search, the evaluation of the design requirements over the actual robot, and the previous experience of the authors in mechatronic devices. Although this plan is focused on Nukawa, the principles and the methods here proposed could be extrapolated with few modifications to other rehabilitation devices.

IV. Results

In this section is proposed the evaluation plan resulting from the methodology. It is divided to asses electrical, mechanical and security aspects, each one is described by several tests. A summary is shown in Table II.

A. Electrical evaluation

Several tests must be carried out in order to evaluate optimal electrical operating conditions for Nukawa and collect information about the electrical power consumption, in order to determine the electrical power, required for performing ACL therapies. The electrical evaluation of the prototype consists in taking some measurements verifying the fulfillment of the predefined specifications in the design.

1) Visual Inspection: Initially, the electrical evaluation begins with a visual inspection of all electrical and electronic devices, checking the state of DC motors bracket, cabinet bracket, sensor modules and power units. Subsequently, it is planned to verify the connections of all the electrical and electronics devices checking the correct isolation.

2) Actuation module test: The second step in this evaluation consists in test the performance of the actuators that moves the robot which are in this case Maxon DC motors RE45 (250W) and EC60 (400W). This evaluation verify the movement and the speed of the knee joint according to the range movements presented in Table I. The DC motors are supplied with a regulated DC source of 50V, connected to 220V(AC). A control signal of the desired angles and torques must be sent from the computer to the drivers of the DC motors in order to check if the motion exerted by the motor correspond with the information sent. The current data consumed by the DC motors when performing a movement is recorded for measuring the energy efficiency, which depends of the power supply and the power generated. The data previously taken allows understand the characteristics between speed-torque of the DC motors of Nukawa and determine the optimal operating conditions of the actuators as the maximum load that can support the DC motors and their speeds with different loads.

3) Sensor module test: Another test consists in the evaluation of the measuring modules. The accuracy of the angle in the limbs, measured with position sensors such as goniometers and encoders, must be checked. Moreover, it is programmed to evaluate the configuration of the strain gauges used to measure the joint torques, their position in the shaft and the readings collection. The position data are acquired through a Beaglebone Black, which send the values to the controller. The same steps are used for the torque data, where the acquisition system sends the torque values to control the Nukawa robot. Moreover, it is necessary to check that the values sent to the controller be the same executed by the robot when it makes its movements. With the measurements previously mentioned, some movements constraints are established in the robot for preventing accidents considering the physiological safety of people who uses the robot, avoiding any anomaly in the system. This allows to configure the emergency stop policy of the Nukawa robot, by software and hardware, establishing the maximum range of movement (MROM). The emergency stop by software works automatically when the actuators are in MROM position or if the MROM is exceeded and sends a signal to the DC motors' drivers for braking the movement. If the emergency button is pressed by the person, the Nukawa controller drives the DC motors to the safe position of the robot.

4) Electrical and electronic devices test: On the other hand, the test of the cabinet and the power stage consists in verifying the chassis of the box where the power units have been kept. A variable taken into account at this stage is the temperature and the heat transmission; with this information is obtained the optimal conditions of temperature for operating Nukawa and fitting a place with relevant ventilation for placing the cabinet. Other important parameter in this test is to check the operation of the cabinet ports.

Finally, other stages in the electrical test is the evaluation of the robot's wiring that belongs to the electrical and electronic connections, to measure values such as the level of isolation, humidity, induced voltage and power factor.

All the tests previously mentioned must be taken carefully, so the personnel who makes these tests must carry their safety equipment for protecting their integrity. These tests must comply with the electrical measurement standards such as the ISO 14955 standard [18].

B. Mechanical evaluation

The authors propose four different types of mechanical assessments for Nukawa, which are conceived to provide an overview of the joints' behavior and the general performance of the robot.

1) Joint inspection: Firstly, an inspection of the couplings between the actuator drive and the joint needs to be developed determining the maximum backlash presented, mainly on the bevel gears of Nukawa. It is considered the use of Biometrics twin axis goniometers (SG 150) and inertial measurement units (IMU) from Xsens (MTi-300) to obtain the information of the angles and general behavior of the robot. In particular, the joint is situated with the actuator in 20 different positions covering its total range. On each position, the respective leg segment is moved manually between the minimum and maximum movable range finding the backlash presented. A value between $\pm 0.1^{o}$ is desired in order to reduce the position error in the latter links of the kinematic chain and produce smooth transitions when changing the rotational direction on the rehabilitation paths.

The measurements taken with the IMUs determine the possible constructive deviations on the axes that could cause movements in planes different to the sagittal. Primarily on the knee, these deviations could exert excessive forces on the lateral collateral ligaments (LCL). Therefore, movements in the frontal plane should be kept within ± 5 mm, according to the criteria of physiotherapists of our research team.

The instrumentation implemented in the previous evaluation is also used for the confirmation of the angular range of the joints, comparing the value obtained with the ones commanded, also confirming that the software and electrical limits do not reduce the expected range (see Table I). Furthermore, their mechanical limits must be assessed in the worst possible

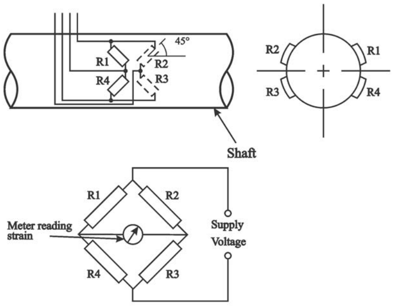

Fig. 2. Implementation of strain gauges to measure joint torques

TABLE II
SUMMARY OF TESTS

Evaluation	Trial	Test
A. Electrical	1	Visual Inspection
	2	Actuation module test
	3	Sensor module test
	4	Electrical and electronic devices test
B. Mechanical	1	Joint inspection
	2	Torque measurements
	3	Friction and Smoothness test
	4	Inertia and structural stress
C. Security	1	Knee Rehabilitation Exercises
	2	Dummy Instrumentation
	3	Testing the System with a Dummy

scenario where a loss in control of the actuators and the failure of the electrical limits, drives the leg's parts to hazardous positions for the user.

2) Torque measurements: To measure the joints' torque is planned the use of strain gauges in a full Wheatstone bridge located in the shaft of the joints in a 45^o configuration, as shown in Fig. 2. The tests comprise the evaluation of 20 movements for each joint, covering different configurations of the robot, which include the use of the three joints, *e.g.*, the torque presented on the knee in the flexion and extension movements is affected by the hip angle. It is pointed out, that these configurations are developed on stand-alone routines in the motors and others using an instrumented dummy. It is also planned to use 2 or 3 types of dummies with different weights and sizes in order to evaluate the right execution of assistive and resistive exercises, and the dynamic torque presented. The results obtained on these tests will be also compared with the values calculated in the design.

3) Friction and Smoothness test: For friction test the actuator's torque is increased gradually in steps of 1 Nm until achieve a rotation in the joint. Besides, the lack of bearings could also produce different friction values depending on the robot's configuration, thus 15 to 20 positions should be evaluated covering the entire range of motion of the joints, being repeated the experiment 10 times, in order to obtain an accurate average friction for each joint.

Similarly, the friction is related with movement smoothness, the measuring of this parameter consist of commanding a constant angular speed in the motors of 45^o/s, 90^o/s and 120^o/s, separately. The tangential speed profile of the joints is obtained for each experiment through goniometers and IMUs, where it is primarily evaluated the smoothness over the total articular range of the joint. However, the test comprises the execution of 10 different movements with diverse starting and ending points. With the gathered information, is evaluated the ratio between the peak tangential speed and the mean speed, the number of peaks and optionally the spectral-arc length (SAL), which is a novel approach that has been proven to be reliable when used in ACL subjects [29]. Furthermore, it is also intended to observe the response of the system when executing different sequences on the actuators, in this way it is expected a critically damped or over-damped response, producing smooth movements on the system.

4) Inertia and structural stress: With respect to the leg inertia, the theoretical values are set to be confirmed with the data obtained from the torque tests and the angular speed and acceleration from the IMUs in the rehabilitation sequences evaluated and mainly in the independent movement of the leg's segments. Moreover, the implementation of strain gauges in different parts of the robot will allow the evaluation of the stress on its structure, being also used the dummy with the maximum weight of the intended users of the machine, to assess its robustness. Specifically the strain gauges are located 10 mm to 20 mm from the joint where the maximum possible deformation could be presented.

5) Other parameters: Parameters such as accuracy, precision, repeatability and resolution, are also thought to be assessed in Nukawa with the same instrumentation used in the previous tests. The first three parameters are evaluated in each joint with steps of 5% the total articular range, starting from maximum extension or flexion. The experiment is repeated 20 times, with the purpose to be statistically significant. On the other hand, resolution is measured with a position control scheme of the system, increasing gradually the joint angle, seeking the minimum value executable. On these tests are also covered intra-session and inter-session evaluations in order to have more reliable data about the possible changes of the robot performance in different situations. Finally, errors will be evaluated with the mean squared error (MSE)

The adaptability of the robot for different user heights is also planned to be evaluated with the dummy, confirming the correct attachment of its limbs to the machine and mainly the alignment of the mechanical axis with the patient's joints. Furthermore with the use of dynamometers will be assessed the strength of the movable parts that allow multiple configurations on the robot.

The plan also covers the evaluation of the movement, torque and acceleration of the device in the event of a sudden loss of control or energy during a rehabilitation sequence that goes in cohesion with other security tests.

C. Security evaluation

In order to ensure users integrity during rehabilitation routines, security tests should be carried out before using it on human subjects, focused on the evaluation of the kinematic human variables, *i.e.,* angles and velocities of the joints.

In this work, a basic anatomical model, *i.e.,* a dummy, is proposed to be instrumented with angle sensors in order to carry out security assessments of the mechatronical system, emulating the anatomical human behavior of the lower limbs. As it is mentioned above, this work is focused on the knee joint security assessment. However, hip and ankle movements are taken into account due to their movements are used during knee rehabilitation processes. Therefore, the instrumentation and tests carried out in the knee joint can be easily extended to the hip and ankle joint of the anatomical model to evaluate its security.

The methodology proposed to carry out the security assessment of the mechatronic system is developed in three stages as shown in the following subsections.

1) Knee Rehabilitation Exercises: At this stage, is imperative to have the support of expert physiotherapists, in knee rehabilitation, to establish tests that allow the evaluation of the system security. Furthermore, it is necessary to identify exercises and positions that are commonly used during knee rehabilitation processes.

In order to evaluate Nukawa, six rehabilitation exercises focused on the ACL rehabilitation are proposed, according to works developed previously by [30]. In Table III are presented the selected exercises for the rehabilitation system security assessment. Moreover, the exercises were selected taking into account the following criteria: Exercises that can be performed by Nukawa; exercises that only present movements on the saggital plane; exercises that are repeated at least in two phases of the rehabilitation; resistive, active and passive exercises.

The selected exercises are intended to be used in a dummy with the purpose of emulating real knee rehabilitation therapies. Finally, it is recommended to refer to [30] for more detailed information about the exercises.

2) Dummy Instrumentation: At this stage, a dummy is necessary to perform the selected tests defined previously in order to emulate the interaction between a human and the machine, during real rehabilitation therapies, and to assess how could be affected the people integrity. In this phase, it is planned to select a realistic dummy to reproduce similar movements of the human knee, *i.e.,* flexion and extension in the saggital plane.

Once the dummy is selected, it must be instrumented to measure variables such as angles, velocities and accelerations. In this work, electrogoniometers are proposed to measure these variables on the dummy's knee. In previous works carried out by the authors, were used the wearable body sensing platform BiosignalPlux powered by Plux® to collect these variables.

The authors plan to use BiosignalPlux because it allows to gather and send to the computer real time information of various sensors by means of bluetooth communication. Moreover, it is proposed twin axis goniometers (SG150) in order to capture the dummy's knee angle during flexion and extension movements. The angular velocity and acceleration of the dummy's knee can be obtained with the first and second derivative of the angular displacement, respectively.

TABLE III
ACL REHABILITATION EXERCISES [30]

Trial	Exercise
1	Elevation of straight leg
2	Unilateral leg press
3	Knee assisted extension
4	Knee resisted extension
5	Knee resisted flexion
6	Displacement of heel on bed

During the goniometers placement on the dummy's leg, it is suggested to review the work carried out by Piriyaprasarth et al. [31], where they reported the importance of use the standard attachment protocol and standardized measurement procedures. On the other hand, it is recommended to follow some of the recommendations of the goniometer and torsiometer operating manual [32] from Biometrics Ltd ®.

3) Testing the System with a Dummy: In order to assess the feasibility of the mechatronical system, using the articulated anatomical model, it is imperative to have the support of a physiotherapist expert in ACL rehabilitation processes. This work counts with the guide of a physiotherapist with Biomedical Engineering specialization to perform each of the exercises selected and mentioned in the Table III.

The movements will be recorded with the commercial acquisition device BiosignalPlux. During each exercise the expert must conduct the movements the best way possible, *i.e.,* so that the movements emulate a subject during the rehabilitation processes. Subsequently, it is planned to compare the measurements collected and the movement exerted by the knee of the dummy in order to check the movement accuracy of the system in the knee joint, *i.e.,* the pre-recorded signals will be the target input to the mechatronical systems and the signals measured on the dummy's knee will be the output.

Integral Square Error (ISE) [33] and the Root Mean Square Error (RMSE) will be computed, between the input and output signals mentioned above, for each test carried out with the six exercises. Assessing whether each joint movements are within the range of motion (ROM) is mandatory [30].

Finally, the capability of the control scheme to react to external perturbations will be tested. These type of perturbations can be made with known external forces in known positions.

V. DISCUSSION

The evaluation plan is a stage that should be fulfilled previous the execution of tests in persons and, further, on ACL injured patients. Nevertheless, the plan developed could be also implemented on other kind of similar rehabilitation devices. It is possible to use the evaluation plan presented and to adapt different instrumentation, like accelerometers to collect data information. In that case the angular and velocity displacement can be calculated with the first and second integration, respectively.

The performed tests on Nukawa will allow to create a preventive maintenance plan in accordance with the obtained results in the mechanical and electrical tests.

On the other hand, the evaluation plan can be also used with the objective of designing an improved version of the rehabilitation robot Nukawa and aid in new projects related with lower limb rehabilitation systems.

CONCLUSIONS

This paper showed an integral plan to evaluate the lower limb rehabilitation system Nukawa for Anterior cruciate ligament (ACL) rehabilitation. It was proposed a different approach, in comparison with reported evaluation methods for this type of systems, where are not taken into account an integral assessment that includes mechanical, electronic and user's safety aspect.

It was concluded that an instrumented and configurable dummy can be useful to emulate, approximately, the human behavior during knee rehabilitation, in order to obtain ethical endorsement to carry out test with human subjects.

Additionally, it is proposed an evaluation plan that can be extended to assess the hip and knee joint of Nukawa. Also, it can be used to assess similar robotics systems.

Immediate future work, consist in applying and assessing the proposed plan in the actual robot Nukawa.

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