System for supporting and fixing body segment for nukawa lower limb rehabilitation device

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Abstract. The objective of this study was the design of a system of supports and fixations for the Nukawa, an exoskeletal system of lower limb rehabilitation controlled through robotics and surface electromyography. The supporting system was developed emphasizing lumbar support, hand support, and fixation mode, grip, and suspension, in order to generate ideal ergonomic conditions for the use of Nukawa by the average population. In this context, this work developed a design proposal linking the exoskeleton with a modular orthosis type system, based on the study of body shapes and segments (cineanthropometry). The elaboration of the parts and the functional verification of the prototype considered design requirements of the Nukawa and recommendations from medical staff. Design stages also involved the specifications of the additive manufacturing, and the analysis through finite element software. The generated prototype is an intuitive system, where all the components interact to execute the rehabilitation process, with the least possible risk for the patient.

1. Introduction
The research and development of new technologies in biomedical engineering, has brought with it applications in robotics focused on the area of rehabilitation, enhancing the skills of therapists and facilitating the process of patient recovery. Such is the case for dynamic orthoses [1] and specifically, exoskeletons. However, for the correct use of this type of rehabilitation systems, the anthropometric, biomechanical and ergonomic analysis must be considered, taking into account the positions, the alignment of the patient and the intervention protocols when performing each of the rehab exercises.

Although the purpose of orthopedic devices is to provide support and complement the rehabilitation processes, the prolonged use of them in a frequent and disciplined manner can generate changes affecting the recovery processes positively. This effect appears mainly in diseases and injuries related to the muscle-skeletal system and in those derived from alterations of the nervous system, usually affecting the functionality of patients. Within this context, Table 1 presents a relation of fixation systems for rehab devices, classified according to their main features and development level.

In the local context, most of the fixation and support systems that accompany biomedical and rehabilitation devices are generic and standardized, since aspects such as the design of their shapes, comfort, and safety are ignored in their elaboration. However, the recommendation for the design of this type of tools is to characterize them to avoid the appearance of injuries and muscular fatigue during their
use. The correct characterization will make them more efficient elements to execute the repetitions of the recommended exercises properly [2,3].

| Team/company/country | LS | SH | Position | A | Work in process |
|----------------------|----|----|----------|---|-----------------|
| Lokomat/              |    |    |          |   |                 |
| Hocoma/              |    |    |          |   |                 |
| Switzerland          | Yes| Yes| No       | No| Yes             |
|                      | Yes| Yes| Yes      | No| Yes             |
|                      | Yes| Yes| No       | Yes| Yes             |
| Erigo/               | Yes| No | No       | Yes| No              |
| Hocoma/              | Yes| Yes| No       | Yes| No              |
| Switzerland          | Yes| No | No       | Yes| No              |
| Rewalk/              | Yes| Yes| Yes      | No| Yes             |
| Rewalk robótica/     | Yes| Yes| No       | Yes| No              |
| USA                  | Yes| Yes| Yes      | No| Yes             |
| Motion maker/        | Yes| No | No       | Yes| No              |
| Swortec/             | Yes| Yes| No       | Yes| No              |
| Switzerland          | Yes| No | No       | Yes| No              |
| Mind walker/         | Yes| No | No       | Yes| No              |
| Space applications/  | Yes| No | No       | Yes| No              |
| Belgium              | Yes| Yes| No       | Yes| No              |
| Knexo/               | Yes| No | No       | Yes| No              |
| Vrije Universiteit Brussel/ | Yes| No | Yes | No| Yes            |
| Belgium              | Yes| No | No       | Yes| No              |
| Lopes/               | Yes| No | No       | Yes| No              |
| University of Twente/| Yes| No | No       | Yes| No              |
| Netherlands          | Yes| No | No       | Yes| Yes             |

LS: Lumbar support. SH: Support hands. A: Accessibility. P1: Recumbent. P2: Seated. P3: Standing. W1: Commercial. W2: Research. W3: Portable. W4: Stationary.

This article presents the methodology for the design of the fixation and support system included in the Nukawa rehabilitation exoskeleton, a device currently under development at the Universidad Pontificia Bolivariana (UPB). The implemented design proposal allowed the linking of the exoskeleton to a modular orthosis type system, based on the study of corporal cineanthropometry. The link improved the adaptation and positioning of the patient in the robot for the comfortable and secure execution of the rehab exercises. With the methodology used, it was possible to demonstrate how the Nukawa design requirements, the criteria for the use of health personnel, the specifications of the additive manufacturing and the analysis through finite element software, were all necessary for the elaboration of the system parts and their operation.

2. Experimental procedure

The project was developed with the methodology Top down, network design, and brainstorming [4,5]. The input for the design process came from a survey of requirements, which allowed to obtain the ideal specifications of the prototype to be designed, emphasizing the lumbar support, hand support, fixation mode, grip and suspension for the exoskeletal rehabilitation system.

After the result and analysis of the concept design requirements, the virtual three-dimensional design was performed with a computer-aided design (CAD) software application (using the Rhinoceros, Keyshot computer programs), taking as input elements the geometries and dimensions proposed for the team manufacturing the mechanical structure. The three-dimensionally designed supports were analyzed in a finite element software application (scand and solver), evaluating parameters such as resistance, tolerance of structures, and their components. The adjustment of these factors involved parameterization.
with the Grasshopper software application; which allowed to perform changes in real-time and updates in the geometries in a controlled and fast way.

The development of friendlier equipment for both the patient and the medical staff influenced the proposal for the assembly and integration of the metal structure with the rehab environment. These designs and adjustments were based on the Colombian technical standard NTC-IEC60601-1 [6], which describes the requirements for basic safety and the essential performance of medical electrical equipment, and UNIT ISO-9992011 [7] which deals with the support devices for people with disabilities.

The final stage involved the development of physical models with CAD and computer-aided manufacturing (CAM) software and tools (Rhinoceros, Grasshopper, and RhinoCAM) through additive and computer numerical control (CNC) manufacturing. The support and fixation system was designed with parametric CAD software to generate the forms according to the percentile of the test subject (75 kg of weight and a height of 1.75 m). The physical construction started with the selection of the 75th percentile for the concept tests, which allowed generating a prototype of low cost and fast manufacturing. The pieces were printed with an Ultimaker 2+ 3D printer with acrylonitrile butadiene styrene (ABS) polymeric material.

The process of design and assembly of the prototype included the development of mechanisms and controls, carrying out the assembly of each of the subsystems, the fastening systems to the extremities, and support systems for a bipedal and a seated position. The manufacture of the prototype of the joints and the case of the orthosis encompassed two stages. The first stage for the development of concepts and simulation of components and templates performed jointly in the digital Fabrication Laboratory (FabLav) of UPB and “Tecnoparque Servicio Nacional de Prendizaje (SENA), Nodo Medellín”. The final stage involved refinement of design and manufacture of finished parts.

Based on the prototype, a functional verification protocol was carried out, taking into account the existing lower limb rehabilitation protocols, the NTC-IEC60601-1 [6] standard for use and safety tests regarding the industrial design of biomedical equipment and devices, and the survey of requirements previously elaborated with the interdisciplinary workgroup. Verification involved the concept of experts in physiotherapy and the simulation through 3D virtual models as demanded by the test and the subsequent integration in the structure of Nukawa.

3. Results and discussion

This section details the results obtained in each one of the design stages. Regarding the methodological aspects and the professional criteria of health personnel (physiotherapists, doctors, and bioengineers) from the application of surveys, a design was achieved involving conditions of functionality, safety, and comfort for the patient. The obtained information facilitated the creation of lumbar support systems, hand support, and fixation, grip and suspension modes for the rehabilitation system. With these elements, man-object relationships were established for the design of each of the components of the system. Figure 1 presents the designed support and fixing parts.

Figure 1. designed support and fixing parts.
Development of the holding and fixing elements of the Nukawa equipment included the verification of tolerances and dimensions of the pieces conforming the system, adjusting the geometry of the pieces to the weight of the patients and the load they would bear when performing the exercises. This process facilitated not only the development of the pieces but also a prototype with greater resistance to loads and efforts. The simulations using parametric software eased the creation of a CAD model, which allowed the optimization of the characteristics of the designed parts.

The construction of the prototypes as proof of concept favored the verification of additive manufacturing processes and the selection of suitable materials for the design. Also, the verification of the geometry of the pieces, a necessary aspect to ensure the attributes of the system. Figure 2.

3.1. Security of the funcionation

An emergency stop safety system was implemented with commercial elements, with controllers for commanding actions from both patient and medical personnel, as shown in Figure 3. Both systems seek to ensure adequate equipment semiotics and improve the intuitive manipulation of the machine. Nukawa has a series of inductive sensors to control the stretcher that makes up the mechanical structure, avoiding dangerous positions that threaten the integrity of the patient and the machine. The complete Nukawa system was tested at low motor speeds, governed by a Siemens drive with a frequency of 6 Hz, to which the inductive sensors are connected. The tests showed a correct operation of both the engine and the sensors, achieving a stop in less than two seconds. The equipment remained stopped even if the operator kept pressing the activation button.

Figure 2. Geometry of the pieces.

Figure 3. Emergency stop safety system.

Figure 4. Emergency stop safety system.
To improve the settlement of the machine on the ground, to avoid part damage, and to delimit the personnel circulation area, we used neoprene of a caliber of 5 mm. In order to ensure patient safety, a series of protection elements were implanted in most of the mobile segments of the robot. The spaces for the ubication of the reduction systems between engines and gears were identified as the main risk sources, which can be easily reached by those involved in the rehabilitation. Polyethylene cases were manufactured to easily cover the mentioned parts, as shown in Figure 4.

3.2. Security of the patient
Safety conditions considered the surpass of limits in patient joints and ligaments in the event of a faulty rehab sequence or machine failure. So, in addition to the software limits already in place, two mechanical stops and two electric stops are used in each articulation to avoid exceeding joint limits. Therefore, to improve safety in each joint, 10° of the total joint range is decreased both in flexion and extension. This reduction is employed for the location of the inductive sensors, as the first safety measure, and then the mechanical stops.

3.3. Equipment semiotic
On the other hand, a semiotic proposal was formulated for the quick and easy identification of the machine characteristics by the patient. A signaling scheme indicates the direction of the movements of the segments and the main moving parts involved in the rehabilitation. The most relevant characteristics of the semiotic proposal rely on the manipulation of the telescopic systems to adapt the distance of the equipment with the body segments of the lower limb, improving the adaptation to the different patient biotypes. In addition to indicating joint angles as the first level of safety in Nukawa system adjustment, the signaling scheme allows the operator to have visual feedback of the position angle at each articulation of the patient, in order to monitor the process effectivity. In the semiotic proposal, the color was taken into account as a fundamental factor to transmit an environment of tranquility to the patient. In this way, Nukawa structure is white, and the supports and fastening systems are in light colors. Other colors were also used to denote certain limits and parts concerning machine operation, and that should be out of the contact of the patient.

The semiotic proposal also contemplated the future use of the equipment in a rehabilitation area, considering the measures and distribution of the Nukawa equipment in such a space.

In Colombia, biomedical devices are considered a fundamental component for the provision of health services, ranging from the most basic medical instruments to the high-tech equipment used in the field of rehabilitation and clinical diagnosis [8-11]. Elements such as support systems and fixation of body segments are necessary when using this equipment, as these systems will be responsible for ensuring perfect patient accommodation, alignment, and stability. At the same time, factors such as the morphological study and the security and ease-of-access systems developed for Nukawa, contribute to the implementation of similar elements in other robotic rehabilitation systems or even in equipment for the sports area [12].

4. Conclusions
This academic exercise describes the morphological and semiotic proposal to transform a robotic system into a rehabilitation system for the treatment of different hip, knee and ankle injuries, providing comfort, safety, and functionality to the patients.

The proposal considered different factors from the conception of biomedical devices, being consistent with the results observed in other investigations and prototypes. However, the developed prototype covered broader aspects such as using morphemes and systems to make the device useful for a specific population segment. The applied methodology falls in line with the design of machines requiring constant interaction with the patient, and the development of human-machine interfaces that allow the patient to know the general functioning of the equipment with simplicity. The generated prototype is a system intuitive enough, where each of its parts interacts with each other to execute the rehabilitation process, with the least possible risk for the patient.
Moreover, the implementation of parametric software, specifically Rhino and Grasshopper, allowed for a simple way to modify the morphologies in the different design stages. Likewise, the use of 3D printing facilitated a quick and easy way to test the used concepts and forms.

Despite the high degree of reliability in the criteria of the experts surveyed (20 experts in the area of health and rehabilitation) and of the results obtained, more work is still pending. Further stages intend to perform tests on patients with the supervision of the physiotherapist and the inclusion of technologies such as surface electromyography. The latter technology will allow experimental validation of the activation of the correct muscle groups by Nukawa and the effects of muscle compensation when performing the rehab exercises.

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