Design and Validation of an Exoskeleton for Hand Rehabilitation in Adult Patients with Rheumatoid Arthritis

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Abstract. For the outcomes achieved in this study, it was considered the previous research carried out for the design and creation of a functional prototype of a hand exoskeleton for the rehabilitation of older adults with Rheumatoid Arthritis (RA) using Rapid Prototyping (RP) technologies. The results of each research allowed continuing a line of development until reaching the creation of a portable hand exoskeleton based on an adapted exo-glove that allows the self-supported flexion-extension of the fingers with some opposing tension and facilitates the management of the rehabilitation processes through medical/therapeutic exercises that contribute to reduce the pain caused by the disease. The degree of usability of the system presented considers a user-centered approach, therefore a methodology was designed for the validation of the ARTH-aid System ExoGlove, involving a generic group of 30 patients and an expert group of physiotherapists from an elderly care home in Quito, Ecuador.

Keywords: Rheumatoid arthritis of hand · Exoskeleton · Physical rehabilitation · Rapid prototyping · Computer aided design

1 Introduction

The interest in exoskeletons for healthcare has been increasing, and particularly the interest of satisfying the concerns of the growing aging society [3, 13]. A deeper understanding of the hand as a life tool has been the trigger to carry out an intensive investigation into this field and has evidenced the need to reliably manage the symptoms presented in older adults with RA, using a methodology center in the patients [6, 11, 12].

The existing projects and prototypes of hand exoskeletons on the market have been exhaustively reviewed in previous researches [10]. Of the 36 exoskeletons reviewed, there were alternatives discussed that are conformed with rigid modules or joints, but also flexible gloves that are introduced in the early stages of RA where the patient has not yet been invasively compromised. Indeed, in this phase, rehabilitation exercises can be monitored frequently to reduce the accelerated progression of the disease [9].

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Additionally, in more recent reviews [4], there has been a considerable focus on glove-based devices, as they have been extensively investigated in medical practice. However, in the lack of evidence from well-controlled projects with conclusive results regarding the effectiveness of the proposed interventions [6], it is imperative to focus rehabilitation techniques on training adapted to the patient's needs in terms of the exercises they perform to reduce the symptoms of the disease [10, 11]. All this requires that from the beginning, the exoskeleton must be designed with the user's real requirements in mind.

Many researchers have focused their efforts on static testing, limiting the validation of gloves and ignoring the user's assessment. This hinders the resulting conclusions because without patient contact there may be higher rates of error [8]. Real monitoring of finger joint motion is necessary for the diagnostic process and for obtaining measurements that represent an improvement in the mobility of the hand [5].

In this regard, it is pointed out that, in current hand rehabilitation therapies, there are external factors that are not so favorable for this process. These include the low number of available specialists, assistants and equipment [11, 14], which makes the recovery process more difficult for patients; however, with the use of different RP technologies, it is possible to get closer to a model that can be scaled up to self-fabrication.

Against this background, the previous research was intensified in order to create a functional prototype that aligns with the expectations of improvement in the quality life of patients and that allows to evaluate the improvement of joint movement in a dynamic and systematic way. Taking in consideration the last results with some prototypes made, it is possible to say that the application of the methodology used next to the RP technologies for hand rehabilitation [2, 7, 11] improves the joint arc of movement considerably, increases the muscle stretching, and shows a reduction in pain during finger movement. Figure 1 shows three functional prototypes that have been tested in patients with early RA, all of them were designed using the same methodology that is going to be described in this article.

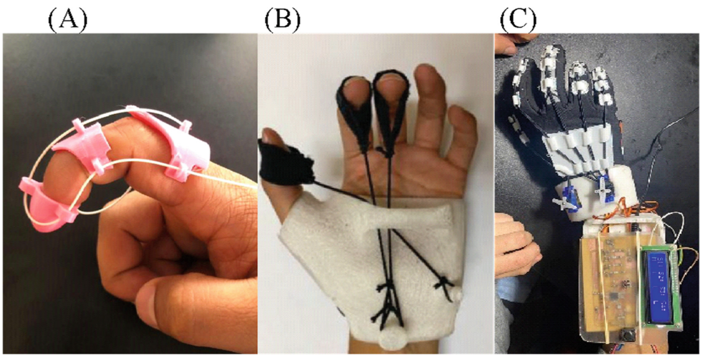

Fig. 1. (A) Finger module [10]; (B) Prototype with tensile threads [12]; (C) Exo-Glove prototype [13].

Following and extending the scope of this line of research, the objective is to design and create a new and improved prototype that responds to the essential requirements for hand rehabilitation. The development of the user-centered methodology will describe, on the one hand, the evaluation of the factors related to the patient-device interaction and, on the other hand, the efficiency and feasibility of the prototype, which must be accepted by the end user and the physiotherapist to guarantee the degree of usability in a selected group of users.

This article describes the design and development of the ARTH-aid System ExoGlove, an exoglove that suits the reality of patients from a specific niche and that attends to the requirements established by the patients involved. Thanks to the methodology used, the prototype was accepted by patients and by the experts who supported the validation and testing process.

2 Methodology

An experimental methodology that collects information from the direct user was used in this study, and the work was carried out with the express permission of the medical management of the "Santa Catalina Labouré" Elderly Home located in Quito, Ecuador. The home has 70 patients and the organization is dedicated to the care of the elderly.

The home also has a population of expert physiotherapists and a rehabilitation area that includes a specific place for the treatment of patients with RA. Based on a clinical history, a sample of 30 patients (10 men and 20 women) was determined, their ages are between 65 and 104 years, and they all have minor or severe joint pain due to the disease.

Although the intervention group is not copious, a 95% confidence level (based on the total population of the residence) is enough to detect most of the usability issues. With this generic group, the main reason of the intentional sample is the generation of estimations or deductions towards this specific population, but it is not related to a totally probabilistic character in which a population is represented. This decision has been taken considering the particularities and characteristics of the case study.

For the first phase of the validation methodology, the validation experience from previous research was taken as a starting point and the following recommended principles for validation with users were taken into account [11]:

- Make an early diagnosis and provide appropriate treatment.
- Instruct the physiotherapist on the appropriate management of the system.
- Individualized management
- Regular monitoring of the process
- Taking comorbidity into account
- Adapt to the reality of medical/therapeutic practice

To provide treatment at the right time, it is considered that functional disability limits the activities of daily living of the older adult, who often requires the assistance of other people [9]. Therefore, a questionnaire adapted from the HAQ (Health Assessment Questionnaire) with 17 items grouped into 6 areas containing daily activities was applied to the patient-group to evaluate the patient's dependence (or independence) to perform the activities. The questionnaire (see Table 1) also includes corrective questions that can modify (correct) the score of the areas they affect.

Table 1. Questionnaire adapted from the HAQ. Source: Own elaboration (2021).

Dressing and grooming	Over the past week, have you been able to…							
	1	Self-dressing, including fastening buttons and tying shoelaces?						
		Unable to do so	0	1	2	3	No difficulty
	2	Shower and wash your hair/head?						
		Unable to do so	0	1	2	3	No difficulty
	3	Wash and dry your entire body?						
		Unable to do so	0	1	2	3	No difficulty
	4	Use rings?						
		Unable to do so	0	1	2	3	No difficulty
Get up								
	5	Getting up from a chair without arms?						
		Unable to do so	0	1	2	3	No difficulty
	6	Lie down and get out of bed?						
		Unable to do so	0	1	2	3	No difficulty
Eat								
	7	Cut a steak of meat?						
		Unable to do so	0	1	2	3	No difficulty
	8	Open a box of cardboard or a package of foodstuffs?						
		Unable to do so	0	1	2	3	No difficulty
	9	Grab a cup or pour yourself the drink?						
		Unable to do so	0	1	2	3	No difficulty
Reach								
	10	Reaching a heavy object from an elevated shelf?						
		Unable to do so	0	1	2	3	No difficulty
	11	Bending down and picking up clothes from the floor?						
		Unable to do so	0	1	2	3	No difficulty
Grip								
	12	Open jars?						
		Unable to do so	0	1	2	3	No difficulty
	13	Open and close the taps?						
		Unable to do so	0	1	2	3	No difficulty
	14	Hold lock keys?						
		Unable to do so	0	1	2	3	No difficulty
	15	Squeeze a towel?						
		Unable to do so	0	1	2	3	No difficulty
Others								
	16	Do housework like sweeping or washing dishes?						
		Unable to do so	0	1	2	3	No difficulty
	17	Press buttons on the remote control or other device?						
		Unable to do so	0	1	2	3	No difficulty

It is important to point out that the approach to the participants has been only for research purposes and the work has been carried out with the consent of the home that looks after them, maintaining the anonymity of each patient. In the following corollary has been obtained after data analysis in the Statistical Program Excel:

1. 50% of women have +6.66% difficulty dressing and grooming, and most of these women range from 70 to 85 years old.
2. More than 60% of patients (between men and women) do not have problems getting up from chairs or bed.
3. At lunchtime, those who present the greatest difficulties are men (3% more than women). In the same way, this percentage occurs in 30% of men to reach objects.
4. Only 40% of patients (between men and women) indicate a high level of difficulty in grasping objects
5. To perform other activities, such as housework, men have a −3% difficulty.

This questionnaire ends up in the reflection and understanding of the answers, therefore a correct measurement of the maximum degrees of flexion and extension, as well as of the pressure exerted, is required. This is detailed below in Table 2, considering that the movement of the fingers is measured as a function of the maximum degrees of flexion-extension and that standardization is required to ensure the correct functioning of the prototype by all physiotherapists.

Table 2. General technique for measuring MCP flexion-extension of the fingers. Source: Own elaboration (2021).

Articulation	Description of the technique	Type of flexion and/or movement
All fingers of the hand - metacarpophalangeal joint	Position: patient seated, elbow at 90°, with hand and forearm resting on a table, with wrist in position 0 and thumb in position 0	– Normal values: MCP flexion of the fingers of the hand: 0–90° – Normal values: MCP extension of the fingers of the hand: 0–30°
Thumb – Articulation metacarpophalangeal		– Normal values: MCF flexion of the thumb: 0–50°

Incoming phase two, which corresponds to therapy and measurements, the first step is to establish an organized routine with weekly exercises (two or three days per week) to be performed with the exoskeleton, here is essential to record the degrees of flexion with the device, with a frequency of one or two times per week. At this point it should be mentioned that measuring instruments such as goniometers have a significant margin of error in data collection [8] and the prototype must solve the measurement factor to obtain accurate data to ensure the validation of the prototype.

Focussing on hand movement recovery and passive/active hand training, some activities were assigned according to the recommendations of the American Physical Therapy

Association (APTA) [1] and approved by the physiotherapist. The exercises are simple to execute by the users, and efficient according to the prescription of the expert who recommends mainly those low-impact exercises that promote muscle tone and flexibility.

Therapies are set at a time interval (between 5 and 10 min) that safeguards the patient's integrity and avoids exposing him/her to overexertion and/or fatigue. In terms of rehabilitation, it is required that the treatment sessions include an appropriate control of the posture of the patient, as well as a periodic measurement of the flexion-extension angles, as indicated in Table 3.

After 15 weeks of therapy, a third and final phase is dedicated to evaluate satisfaction, focusing on identifying improvements (if necessary) of the prototype and determining how it contributes to the early improvement of mobility and reduction of joint pain in patients. It is necessary to get feedback from either patients or experts due to: (1) the senility of the patients and (2) to avoid locating technical errors. The satisfaction questionnaire consists of two parts: (1) the evaluation of the user experience with respect to ease of use, end-user satisfaction & system safety; (2) the evaluation of the impact of the device on rehabilitation and on the improvement of daily activities performed by the patients.

3 Results

In the innovative technologies that were investigated for this purpose [12], it was identified that for an exoskeleton specifically designed for hand rehabilitation, it is necessary to consider ergonomic, functional and therapeutic aspects in the treatment of RA. Table 3 shows each of the requirements that are needed for the construction of the prototype.

Table 3. Feedback based on the requirements. Source: Own elaboration (2021).

Requirements		Description
Of use	A. Versatility	Must be used in different user's hands
	B. Minimum weight	The structure complies with an indicated weight limit
	C. Maintenance	Modules requiring care are independent and can be separated from each other
	D. Easy control interface	Proper fitting and removal procedure
Of therapy	E. Strength control	Must activate resistance in both flexion and extension of the fingers
	F. Flexibility	It must provide the necessary number of GDLs (3)
	G. Gripping capacity	It is necessary to provide the possibility to perform different types of gripping (the most common)
	H. Open palm	Since some grasping skills are anticipated, the user's palm and fingertips should be left as free as possible

(*continued*)

Table 3. (*continued*)

Requirements		Description
	I. Simplified activation	Activation of the flexion-extension opposition is regulated
	J. Response time	Movements are immediately captured by the electronic system
	K. Materialization	Manufacturing allows customization of the device using rapid prototyping tools
	L. Robustness	It is constructed based on an alloy of 3D printing technology and textile materials

The development started with an innovation combining Computer Aided Design (CAD) tools and mainly using 3D printing in PLA material. The ARTH-aid System Exo Glove consists of an exo-glove designed with 3 Degrees of Freedom (DOF), the same that were verified in previous studies [11–13] allowing polyarticular movement of the fingers. The system is complemented with the "BlueTerm" software application linked to an electronic architecture. The design process is summarized in the schematic presented in Fig. 2.

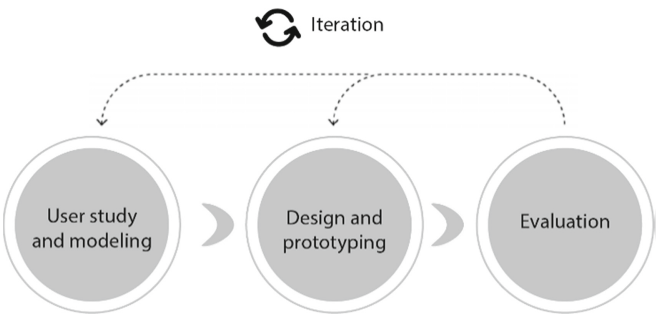

Fig. 2. Design process. Source: Own elaboration (2021)

3.1 System Modules

According to the main objective of the mechanical design, which is to achieve the independent and organic movement of the finger, modules were designed to allow the patient to adapt to the opposition of force generated by the tension wires that are attached along each finger.

- 3D modules: these are attached to the glove and make it possible to place the tensioning thread along each finger. Knob: this module is based on "boa Technology inc" to generate the necessary tension during the finger flexion. This option was chosen instead of servomotors for its simplicity of control and to save space. The CAD design of each module is shown in Fig. 3.

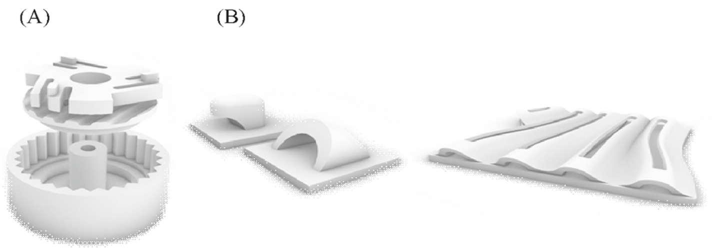

Fig. 3. Glove components: (A) Control knob; (B) Tension wire modules. Source: Own elaboration (2021)

- Sensors: there are four flex sensors and a force sensor located in the palmar area to measure the degrees of the flexion arc and the pressure generated by the patient's thumb. These elements work as a resistance therefore, the higher the flexion, the higher their value increases. Thanks to a voltage divider, it is possible to read the sensor and convert it into an equivalent value in percentage for data analysis. The most popularly available sensors [9] were used, making the model accessible and not compromising the aesthetics and robustness of the glove, as well as facilitating its use in different contexts.

The software application was not originally planned, but given the possibilities of adapting the system to the physiotherapist's needs, it was decided to use the Bluetooth option with the "BlueTerm" mobile application. The sensor reading indicates the pressure exerted by the thumb and is transformed into a value in kg/f dimensions while the remaining four sensors (1 to 4) indicate the percentage of flexion. Figure 4 shows the sensor number for each finger and the data collected by the application and the data obtained by the application.

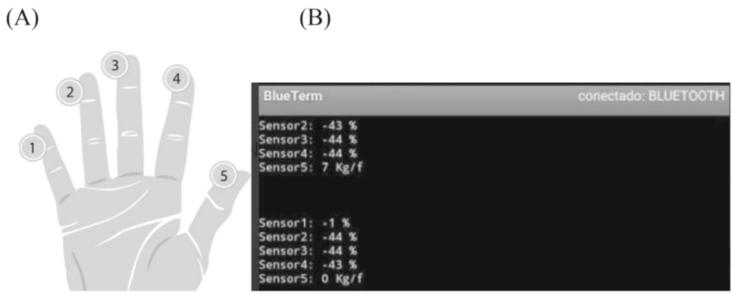

Fig. 4. (A) Finger numbering for each sensor. (b) Screenshot of the serialized reading in the mobile application. Source: Own elaboration (2021)

3.2 Construction del ARTH-aid System Exo Glove

The formal design of the system is based on the verification of the effectiveness of several previous prototypes, taking into account the mechanical analysis of the loads, the main stresses applied, the resistance according to the shape and the construction material.

The first step was the manufacture of the glove, with a fabric that presents a certain stiffness in order to protect the sensors and guarantee their correct operation. The plain glove is fitted with internal pockets for placing the sensors so that they can be changed. In addition, the 3D modules that are part of the mechanical system are attached to the counter palm.

For the assembly of the electronic components, they were all soldered on a 22 × 28 cm board. Giving a total weight of approximately 100 g, including the weight of the glove. Low power consumption is provided by a 3.7-V rechargeable battery used to operate the system. With the board complete, and the coding ready, a protection case was built to contain the components and keep them safe from bumps or drops. This case is the heaviest part of the prototype, but it is not very sturdy. Figure 5 shows the complete system.

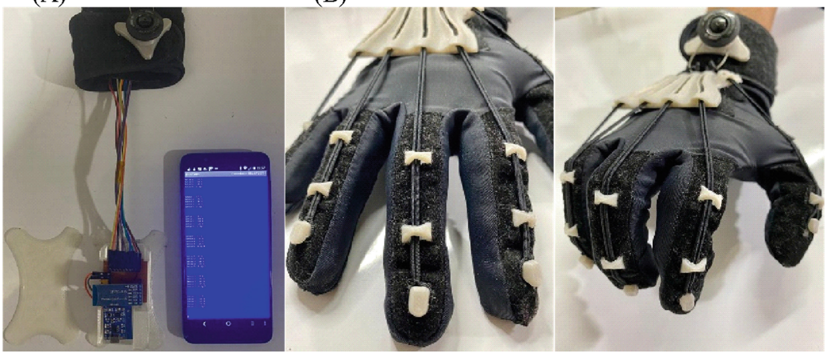

Fig. 5. (A) Connections, case and mobile application with data reading; (B) Assembly and physical tests of the prototype. Source: Own elaboration (2021)

In general, the design is designed to avoid discomfort to patients during the use of the exo-glove and to integrate all the components without further complication, which also benefits the manufacture and installation of the system and contributes to the regular use of the glove, which will consequently have a positive impact on the rehabilitation of the elderly.

The functionality of the ARTH-aid System Exo Glove is oriented to the patient and the physiotherapist so that both can understand it and does not demand a considerable amount of time to set it up and put it on. In the mobile application, the data obtained in each of the sessions was collected and this allowed to import all the data in Excel and to analyze each patient's information.

With the rehabilitation exercises and the use of the exoskeleton, in 62% of the patients a maximum of 57° of range of motion was achieved in the MCP of the index and middle finger; and an approximate angle of 59° of the thumb. Then, focusing the analysis on the pinky finger, it has a smaller range of motion and a CCM flexion of 24° was achieved in 40% of the patients. With the week-to-week mobility data it is concluded that there was a 1,315% improvement in MCP flexion-extension of the analyzed fingers.

Both experts and end-users contributed with feedback and some comments on the efficacy and feasibility of using the ARTH-aid System Exo Glove were obtained. Patients scored the glove positively, but also mentioned that one of their greatest expectations was to be able to wear the glove for a longer period of time without fatigue.

Among the results obtained, first there is the level of satisfaction of the users (patients) after having used the exoskeleton during the rehabilitation time. The graphs below (Fig. 6, 7 and 8) show a level of satisfaction above 50% in most of the specified requirements.

In the first diagram, the versatility and the easy control of the interface, does not really matter to patients. Instead, they're more focused on the maintenance of the product and the light weight, which is a positive aspect of the system.

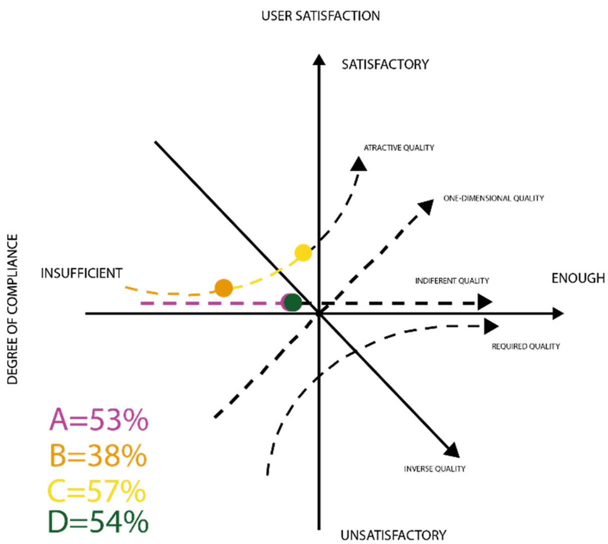

Fig. 6. User satisfaction results from requirements A to D. Source: Own elaboration (2021)

The following graphic indicates the more attractive aspects for the patients, these are the flexibility and the strength control. This last requirement is the most attractive (with 74%) because the patients feel free to ask to raise or lower the tension, according to their physical or emotional state. And there is a 72% for the grip capacity in the one-dimensional quality, which means that this requirement is necessary to implement on the exo-glove but it is not really an important or attractive characteristic of it.

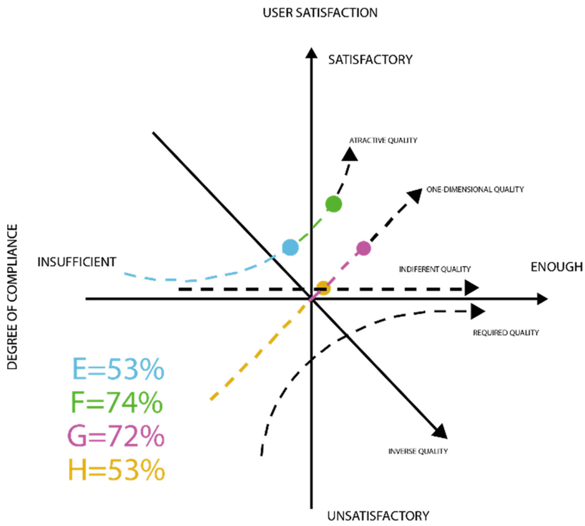

Fig. 7. User satisfaction results from requirements E to H. Source: Own elaboration (2021)

And Fig. 8 shows that is really attractive (with 78%) the fact that that glove is comfortable in the user's palm because it allows to open and close the hand, also to make activities like holding things. However, here are two other indifferent qualities: the time that the measurements take to be showed in the app and the robustness.

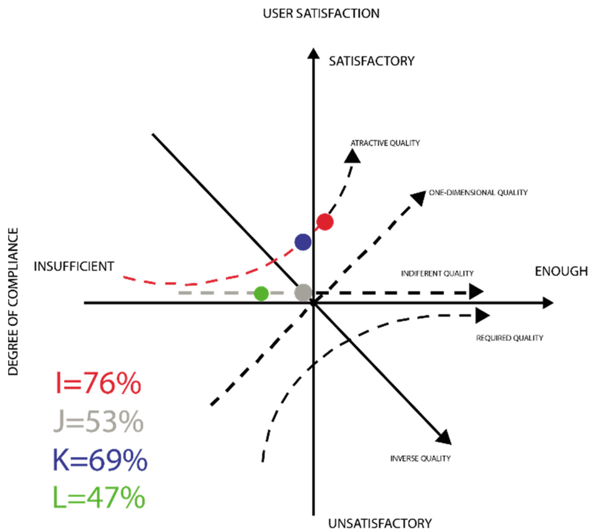

Fig. 8. User satisfaction results from requirements I to L. Source: Own elaboration (2021)

The expert group mentioned that the tension generated by the wires was correct and that the methodology designed for the rehabilitation process was easy to follow and to accompany with the exoskeleton. Table 4 summarizes the impact on the users.

Table 4. Feedback based on the requirements. Source: Own elaboration (2021).

Requirement		Scoring/Feedback
Of use	A) Versatility	4 (Partially addressed) The exoglove should fit the hand better
	B) Minimum weight	5 (Boarded) Feel comfortable using the exoglove
	C) Maintenance	4 (Boarded) Correct choice of materials
	D) Interface easy control	3 (Pending) The placement and removal procedure should be more practical
Of therapy	E) Force control	5 (Addressed) The knob system is useful
	F) Flexibility	5 (Addressed) There are no limitations for polyarticular movement
	G) Grip capacity	5 (Addressed) The quality of the movements is good
	H) Open palm	5 (Addressed) Allows exercises with reinforcement objects
	I) Simplified activation	5 (Addressed) The application takes care of the measurement
	J) Response time	4 (Partially addressed) The value of the pressure sensor should be reflected faster
	K) Robustness	5 (Addressed) Combines several prototyping technologies

In terms of rehabilitation, as in previous prototypes, an improvement in the joint arc of movement was evidenced, increasing the muscle stretching. However, a reduction in joint pain could not be verified because these patients did not present intense pain as in previous cases. The next steps will focus on extend this methodology to a bigger group of patients; this will be useful to increase the feasibility of the exo-glove. So, it is imperative to improve the electronic elements like the sensors, in order to have a better response time during the register of the movement. Other requirement that will be taken into account is the versatility of the globe, in this study it became evident that the hands of the patients are a particular case at the time of dressing thus, to avoid making this experience uncomfortable it's necessary to pain attention to some details of the confection of the glove. At this point, with the results obtained, it is not yet possible to talk about producing ultra-customized or mass-produced gloves, but it is possible to think about standardizing them for different ages and patient groups.

4 Conclusions

Thanks to the validation methodology designed, it was possible to evaluate properly the exoskeleton with each patient and with the expert involved. On the one side, at the end of the rehabilitation period it was determined that the articular arc of movement of the phalanges improved, which indicates that the longer the period of use, the greater the range of movement. And on the other side, the satisfaction Questionnaire results were favorable in terms of having achieved the objective of the system and having fulfilled most of the requirements.

The ARTH-aid System Exo Glove is the result of several investigations focused on improving the quality of life of the older adult with RA and this prototype allowed the therapist to control the efforts according to the patient's needs. The monitoring and data management through the application was ideal for creating a reference history of the patient's evolution. The system is portable, comfortable, flexible and safe, which is an achievement compared to previous prototypes.

More researchers who wish to venture into the field of re-habilitation of RA patients are encouraged to employ the methodology with an expert group to guide the process. There are several factors that can support or inhibit hand rehabilitation in patients with RA and therefore expert guidance in the use of rehabilitation technologies is essential.

The approach to patients and experts has been satisfactory and has raised a wide interest to extend the scope of this line of research and of the prototype in terms of user satisfaction. It is intended to extend this line of research in terms of software design, creating greater patient participation and thus improving the patient's rehabilitation experience so that the use of the exoskeleton is more prolonged. The search for new motivational techniques to involve users in the performance of medical/therapeutic exercises is one of the factors to be considered in future work.

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