Application of the DfT Methodology for the Design and Validation of Exoskeletons Used in Hand Rehabilitation for Patients with Cerebral Vascular Accident

Erick Chuquimamani [1], Edwin C. Calcina [1,*], Yuri L. Silva [1], Daniela Ponte [2], and Erick Valdeiglesias Flores [1]

[1] Mechanical Engineering Professional School, Production and Services Faculty, Universidad Nacional de San Agustin de Arequipa, Arequipa, Peru
[2] Nursing Professional School, Nursing Faculty, Universidad Nacional de San Agustin de Arequipa, Arequipa, Peru
Email: echuquimamani@unsa.edu.pe (E.C.); ecalcinac@unsa.edu.pe (E.C.C.); ysilvav@unsa.edu.pe (Y.L.S.); dponte@unsa.edu.pe (D.P.); evaldeiglesias@unsa.edu.pe (E.V.F.)
*Corresponding author

***Abstract*—Currently, exoskeletons have been developed for the rehabilitation of patients with paralysis or loss of function in the hands and upper limbs, a condition that mainly result from Cerebral Vascular Accident (CVA). Although significant advances have been made in rehabilitation devices, technical limitations related to mechanical and functional characteristics remain. This article studies the application of the Design for Testability (DfT) methodology to define mechanical and functional evaluation criteria in the design of exoskeletons with potential applications in hand rehabilitation. To this end, recent studies presenting methodologies for evaluating the development of exoskeletons for the rehabilitation of patients with CVA, using mechanical and/or functional criteria, were first reviewed. Based on this and the Design for eXcellence (DfX) concepts, a DfT methodology for exoskeletons was developed and verified, with the potential for implementation in hand rehabilitation for CVA patients at the 50th percentile. The prototype was designed in 3D modeling software, manufactured, and verified using the proposed methodology. The results show that the DfT methodology enabled the design and validation of exoskeletons with the potential to be implemented in hand rehabilitation procedures in CVA patients, covering everything from the design stage to manufacturing, resulting in better mechanical and functional characteristics and low cost in line with the needs of CVA patients.**

***Keywords*—methodology, design, Design for Testability (DfT), hand exoskeleton, Cerebral Vascular Accidents (CVA), Design for eXcellence (DfX), mechanics**

I. Introduction

The World Health Organization (WHO) indicates that heart attacks and Cerebral Vascular Accidents (CVA) account for more than 27.2% of deaths worldwide [1]. In the last decade, the risk of developing CVA has increased by up to 50%. Currently, 1 in 4 people are at risk of suffering a CVA, and 86% of CVA deaths occur in low-income countries [2]. In Peru, CVA cases increased by 6.7 cases per 100,000 people in a single year, with men over 35 years of age the most affected group [3]. The CVA is caused by the interruption of blood flow to part of the brain, which consequently reduces the supply of nutrients and oxygen to the brain, leading to deterioration and damage to motor and cognitive functions [4]. These sequelae are usually paralysis or loss of function in the hands or upper extremities, representing between 85% and 87% of patients suffering from CVA [5, 6].

In response to this, exoskeletons have been developed in recent years for the rehabilitation of the upper and lower limbs. In hand rehabilitation, exoskeletons have become an essential tool for therapeutic procedures [7, 8]. Plessis *et al.* [9] review 43 active hand exoskeletons from the last decade. Huamanchahua *et al.* [10] conducted a systematic review of 33 research articles addressing the assistance and rehabilitation of patients using hand exoskeletons. Kabir *et al.* [11] reviewed 35 Hand Rehabilitation Devices (HRDs) and evaluated their design, actuation, control systems, and therapeutic strategies. Achilli *et al.* [12] presented a classification of hand exoskeletons, dividing them into three categories: rigid, soft, and hybrid.

- Rigid; these are the oldest models and among the first to be developed for hand rehabilitation. They have rigid links and are composed of complex articulated mechanical systems that provide greater load capacity and precision.
- Soft; these work with a mechanical tendon system and resemble soft gloves. They are an alternative

Manuscript received October 28, 2025; revised November 27, 2025; accepted January 26, 2026; published May 13, 2026.

to rigid exoskeletons because they offer greater flexibility, are lightweight, and comfortable.

- Hybrid; their design combines rigid and flexible elements, providing intermediate load-bearing and precision characteristics between rigid and soft exoskeletons. They are also commonly combined with additive technology to create flexible structures and better adapt the device to human movements.

The use of motorized hand exoskeletons showed better results in chronic CVA patients [13]. Haarman *et al.* [14] designed an exoskeleton with mechanical indicators, improving the functionality of the Metacarpophalangeal (MCP) joints, achieving opening and closing ranges of up to 46º. Although these hand exoskeleton options offer optimal results for CVA patients compared to conventional therapies [15], their validation systems primarily focus on clinical indicators. However, these studies do not explore mechanical and functional criteria during exoskeleton development, which is why technical failures persist.

On the other hand, the Design for eXcellence (DfX) approach has evolved in recent years and has been integrated across various areas of device development, optimizing aspects such as reliability, usability, and validation [16–18]. Thompson *et al.* [19] evaluate the incorporation of DfX concepts, such as Design for Additive Manufacture (DfAM), into the design and manufacture of industrial devices. In the medical field, Tsiokou *et al.* [20] implemented DfAM and Design for Recycling (DfR) in orthoses design. In addition, among the DfX concepts, Design for Testability (DfT) stands out, as it enables devices to be developed from conceptualization through manufacturing while accounting for guidelines for subsequent validation. Zhang *et al.* [21] developed an inspired-by DfT model for developing safe systems. Similarly, Acevedo *et al.* [22] affirm the importance of using an approach inspired by DfT methodologies for the design and manufacture of quality products in the medical field. These studies demonstrate that the use of DfX concepts, specifically DfT, is useful for the development and validation of exoskeletons with the potential to be applied in hand rehabilitation for CVA patients, based on mechanical and functional criteria.

In this article, we present a DfT methodology based on DfX, which defines the mechanical-functional evaluation criteria and subsequent validation of mechanical characteristics during the development of a hand exoskeleton for CVA patients. To this end, we analyze several recent studies on hand exoskeletons and their mechanical and functional validation methods. Then, taking into account DfX concepts, we develop a DfT validation methodology tailored to evaluate hand exoskeletons. The methodology is evaluated in a case study of an exoskeleton with the capacity to be implemented in hand rehabilitation for CVA patients at the 50th percentile, from the design phase through its construction and laboratory testing.

II. Literature Review

This chapter reviews 23 studies on hand exoskeletons for stroke patients, where the tests are grouped according to mechanical characteristics into two groups: functional tests and mechanical tests, as shown in Table I.

TABLE I. Functional and Mechanical Tests in Current Research

Reference	Functional Test	Mechanical Test	Test Details
[23]	Yes	Yes	Mobility tests, mechanical simulations.
[24]	Yes	No	Mobility tests with CVA patients.
[25]	Yes	No	Functional testing with video game interface.
[26]	Yes	Yes	Assessment of performance, strength, and mobility.
[27]	No	No	Design and manufacturing, without testing.
[28]	No	No	Conceptual design, untested.
[29]	No	No	CAD design, without experimental validation.
[30]	Yes	Yes	Motor control and strength tests on prototype.
[31]	Yes	No	Preliminary clinical trials considering mobility.
[32]	Yes	No	Evaluation of aptica experience with users.
[33]	Yes	No	Grip and mobility assistance tests.
[34]	Yes	No	Clinical trials in patients undergoing assisted therapy.
[35]	Yes	No	Functional evaluation with neural networks.
[36]	Yes	Yes	Mechanical and functional tests.
[37]	No	No	Architectural proposal, without evidence.
[38]	Yes	Yes	Electromyographic control and resistance tests
[39]	Yes	No	Basic functionality tests.
[40]	Yes	Yes	Finger movement and strength tests.
[41]	Yes	No	Functional assessment with CVA patients.
[42]	Yes	Yes	Control and mechanical response tests.
[43]	Yes	No	Mobility tests with post-CVA patients.
[44]	Yes	No	Functional tests in CVA patients.
[45]	Yes	Yes	Functional testing and evaluation with CAD design

First, a systematic review was conducted in Scopus, IEEE Xplore, and Google Scholar, covering the period from 2014 to 2025 and using the following combination of keywords: “hand rehabilitation exoskeleton”, “limb exoskeleton”, “low cost”, “testing methodology”, “evaluation protocol”, “clinical testing”, and “rehabilitation post CVA patients”. Next, studies were included that evaluated mechanical, functional, or combined hand exoskeletons, either with real tests or software validation. Studies that mentioned exoskeletons

for rehabilitation of limbs other than the hand were excluded, as were studies with a control focus, electrical and electronic design, and duplicate studies. Consequently, this systematic review identified 23 studies that met the above criteria.

It was found that 19 studies incorporated functional tests, as shown in Fig. 1, evaluating mobility, control, and functionality with patients. It was also found that 8 studies incorporated mechanical tests, evaluating resistance and rigidity with software simulations, as well as load capacity and grip. In addition, other 8 studies integrated mechanical and functional validation, resulting in a hybrid evaluation. This grouping of tests allowed us to identify that, according to the mechanical characteristics, the functional type test is the most used, and mechanical validation has not been explored in the same way, showing inequality and low reliability in current validation protocols.

On the other hand, there are IEC/ISO validation standards such as IEC 60601, ISO 14971, and IEC 62366 that provide validation protocols for medical devices regarding electrical safety, risk management, and usability, respectively [46–48]. However, these procedures do not focus on the mechanical and functional aspects applicable to hand rehabilitation exoskeletons. The IEC 80601 standard described a functionality assessment procedure for rehabilitation devices [49], while ISO 5363 presented a testing methodology for robots and walking exoskeletons [50]. However, although these standards provide a partial functionality assessment methodology, they do not integrate specific mechanical assessment aspects for hand exoskeletons applied to hand rehabilitation in CVA patients.

This suggests the need to implement a standardized testing methodology that includes more mechanical aspects and seeks to optimize the designs of hand exoskeletons for CVA.

III. Design for Execellence and Design for Testability

This chapter explains the concepts of DfX and DfT, as well as the components of the validation methodology inspired by DfT.

The concept of DfX refers to a design methodology for obtaining products according to specific criteria, such as manufacturing, assembly, quality, ergonomics, among others.

Among the DfX criteria, this work focuses on DfT. Since it focuses on designing a product with efficient validation protocols, it allows technical problems to be detected during the design phase and ensures it is optimally adapted for validation testing. The importance of DfT in this research lies in the fact that it will increase the reliability of hand exoskeleton designs with the potential to be applied in the rehabilitation of stroke patients, as well as in the development of comprehensive validation protocols that focus on functional and mechanical protocols.

Based on DfT concepts, a methodology for developing and evaluating hand exoskeletons has been developed. This methodology is divided into three components, as shown in Fig. 1: design requirements; design and construction; and validation with DfT protocols.

(1) Design requirements: User requirements are collected, then design requirements are generated based on the functional and mechanical tests explained in the previous chapter, seeking to integrate a comprehensive testing protocol for DfT.
(2) Design and construction: CAD mechanical design is developed in this case study, the mechanical characteristics are verified for strength and deformation using software and the Finite Element Analysis (FEA) method, then the prototype is manufactured and assembled, also evaluating manufacturing costs.
(3) Validation with DfT protocol: Six types of tests (anthropometric; mobility; weight; assembly/disassembly; ergonomic, comfort, and usability; grip strength) are incorporated based on the validation methods used in various hand exoskeleton development studies. These are integrated, and the DfT validation protocol is generated for our case study.

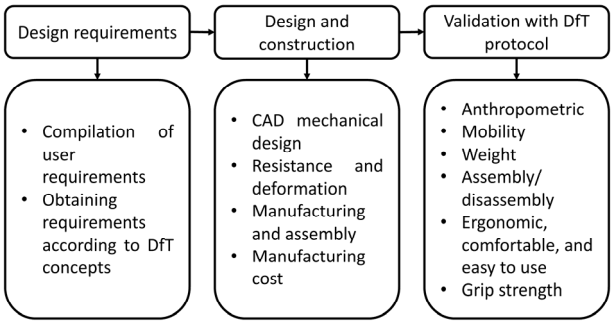


Fig. 1. DfV methodology applied to hand exoskeletons.

This methodology allows for the establishment of test methods and measurable acceptance criteria for each design requirement from the earliest stages, focusing on evaluating the mechanical and functional performance of the exoskeleton for hand rehabilitation during the design, construction, and validation stages.

IV. Case Study: Design of an Exoskeleton with Potential for Implementation in Hand Rehabilitation for CVA Patients

This chapter presents a case study of hand exoskeletons with characteristics that could potentially be implemented in stroke rehabilitation procedures and how the DfT methodology proposed in the previous chapter is applied during their development.

Following the DfT methodology outlined in the previous chapter and after exploring the research in Table I, the 11 characteristics that a hand exoskeleton should have were identified, and the specific requirements, validation methods, and acceptance criteria were adjusted with a mechanical and functional evaluation approach for each characteristic, as shown in Table II. This shows how the design decisions that will be developed during this case

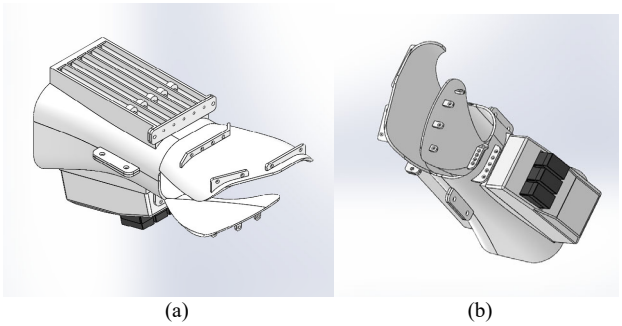
study are related to a validation method and acceptance criteria.

The acceptance criteria determined in Table II were based on actual biomechanical and clinical rehabilitation values. The 50th-percentile dimensions and angles of each joint, based on the DIN 33402 standard, ensure a design that fits the average adult hand. The weight recorded in other studies of 415 g indicates that the 500-gram limit is in line with low-cost exoskeletons. The proposed 10DoF is a limit that coincides with the common range of commercial exoskeletons, which range from 5 to 15 DoF. Five minutes for assembly and maintenance corresponds to an adequate time for clinical devices. The Likert scale rating of 4 or higher for safety, comfort, ergonomics, and usability was established according to the Likert scale with questions appropriate to clinical criteria. The cost of 100 USD aligns with the trend toward low-cost prototypes, falling below the recommended values for exoskeletons of 200 USD. The safety factor was determined to ensure the structural integrity of the device. Likewise, the load capacity was defined as a minimum of 10N so that the exoskeleton can provide day-to-day rehabilitation operations with objects such as bottles, plates, cutlery, and tools mentioned in the Yale-CMU-Berkeley list of objects.

TABLE II. DESIGN REQUIREMENTS ALIGNED WITH DFT

Feature	Specific Requirement	Validation Method	Acceptance Criteria
Anatomical adaptability	Adjustable to size M (50th percentile)	Anthropometric	Complies with the hand size range of adults above the 50th percentile according to DIN 33402 [51].
Range of joint motion	60º–70º (MCP) 80º–90º (PIP) 60º (DIP)	Mobility	The movement complies with the range of motion of joints in standard DIN 33402 [51].
Weight	Lightweight	Weight	Less than 500 g, considering that existing hand exoskeletons weigh 415 g [52].
Degrees of freedom	Flexible mobility in every finger	Mobility	10 Degrees of Freedom (DoF), above average value of existing designs ranging from 5 to 15 DoF [9].
Assembly and maintenance	Assembly/disassembly time less than 5 minutes	Assembly/Disassembly	Less than 5 minutes without complex tools and in low-resource environments [53].
Safety	No risk of entrapment or cuts	Ergonomic, comfortable, and simple to operate	Ergonomics and safety report according to the Likert scale with values equal to or greater than 4 [54].
User comfort	Prolonged use without discomfort	Ergonomic, comfortable, and simple to operate	Comfort rating according to the Likert scale with values equal to or greater than 4 [54].
User-device interface	Simple on/off switch	Ergonomic, comfortable, and simple to operate	Usability rating according to the Likert scale with values equal to or greater than 4 [54].
Cost	Low cost, less than 100 USD	Manufacturing costs	Less than 100 USD, according to the low-cost recommendation indicating values below 200 USD [34].
Basic durability	Resistant and rigid under stress	Strength and rigidity	Safety factor greater than 2.0. This value aligns with standard recommendations in mechanical design to prevent structural failure.
Grip strength	Lift light objects with a load of up to 10N	Grip strength	Over 10 N of force in the fingers, aligned with the maximum recorded weight of 1.131 kg, on standard Yale-CMU-Berkeley objects [55]

Next, the 3D model of the exoskeleton is designed, taking into account the validation criteria and requirements seen above. The modeling is done in SolidWorks software, as shown in Fig. 2. The design takes into account the dimensions of a 50th-percentile hand. The traction rings are designed to fit between the phalanges of the fingers, and their upper and lower holes, through which the traction cord passes, are aligned at the midpoint of the Metacarpophalangeal (MCP), Proximal Interphalangeal (PIP), and Distal Interphalangeal (DIP) joint phalanges. The traction couplings were designed with holes to allow the springs and cords to be exchanged during testing, and their location behind the exoskeleton prevents jamming between the glove fabric and the springs. Both the lower and upper casing designs were designed to accommodate a 50th-percentile hand, with a foam coating, considering the variation in dimensions among patients of the same percentile. The design has external rails for the cords and springs so that any type of failure can be detected during testing. Both the box and the electronic component support have side and top cavities, as well as screw connections for easy disassembly and visualization of the electronic components during testing.



(a) (b)

Fig. 2. 3D modeling of exoskeleton with the ability to be applied to hand rehabilitation: (a) top view of the model in left image; (b) bottom view of the model in right image.

The mechanical characteristics of both strength and stiffness are then evaluated using FEA, as shown in Figs. 3 and 4, respectively. A load of 10 N was applied, representing the minimum force clinically required

according to the critical weight of objects in the Yale-CMU-Berkeley standard. The outer face of the upper housing was restricted to simulate fixation. PETG material with a Young's modulus of 2.96 GPa, Poisson's ratio of 0.37, and elastic limit of 57.3 MPa was applied. The mesh is based on curvature with an average mesh size of 4.95 mm. Design iterations were performed using FEA to minimize the risk of structural failure and deformation. The maximum stress was recorded at 7.065 MPa, located in the upper shell of the thumb cavity, and the maximum deformation recorded was 1.39 mm, occurring in the same shell, at the point furthest from its structure, approximately above the index finger. To calculate the safety factor, the values obtained from the FEA analysis are substituted into Eq. (1), where "*FS*" is the safety factor, "σ_y" is the elastic limit of PETG, and "σ_{max}" is the maximum Von Mises stress obtained from the FEA simulation:

$$FS = \sigma_y / \sigma_{max} \quad (1)$$

The critical safety factor value was calculated at 8.1. This indicates that the proposed design guarantees structural strength and rigidity, and would even allow for further optimization of its design to reduce the weight of the device for future work. This analysis also allows us to identify critical areas to pay attention to during testing.

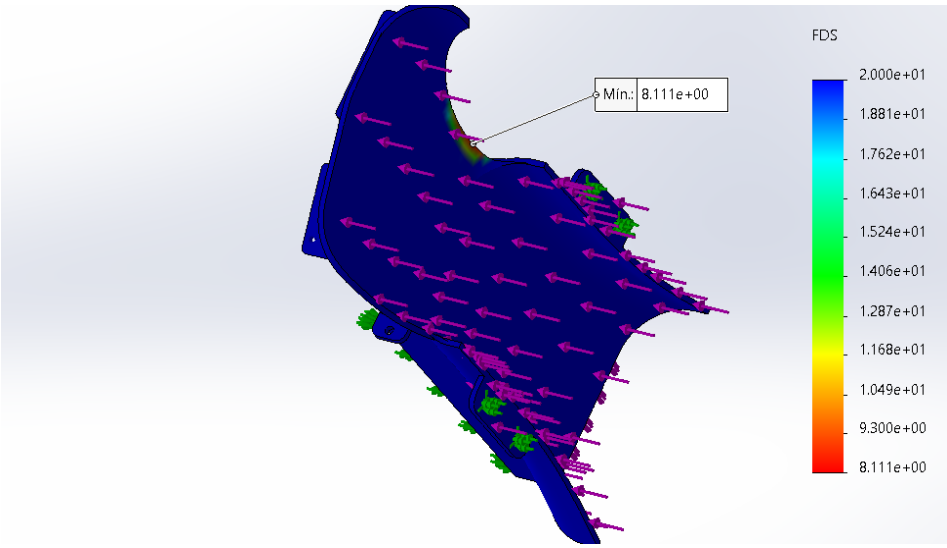


Fig. 3. FEA simulation to validate strength.

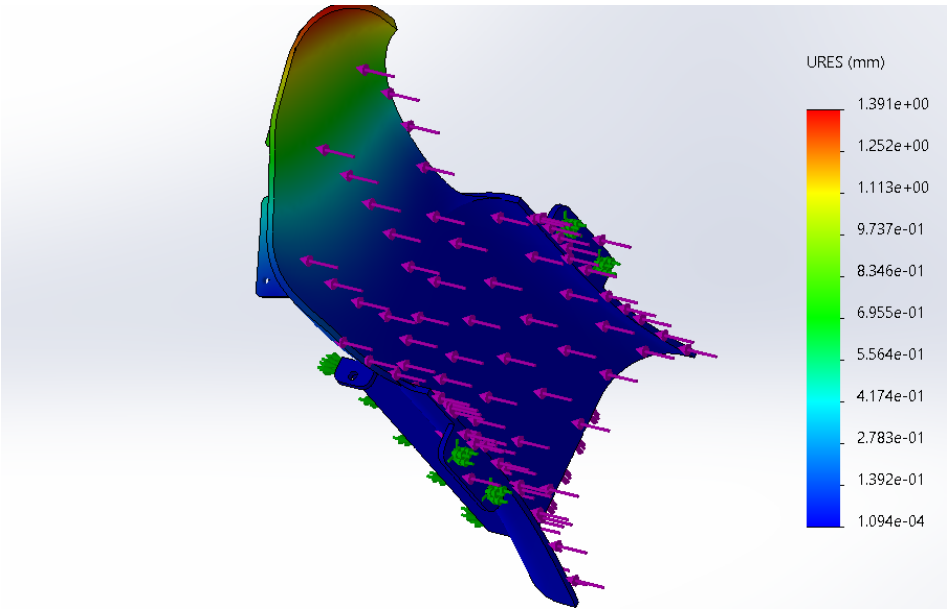


Fig. 4. FEA simulation to validate stiffness.

Finally, the prototype was manufactured using additive printing technology with PETG material and assembled as shown in Fig. 5. There are 20 parts divided into three groups: traction structures, main structure, and secondary structures. The main structure consists of two parts, one being the upper casing and the other being the lower casing. These two pieces are attached to the hands of users in the 50th percentile. The rail where the traction springs

are located is installed on the upper casing, and the secondary structures, which refer to the structures of the electronic components, are attached to the lower casing. The secondary structure consists of three parts: two parts are the frames to which the electronic components and motors are screwed, and one part is the electronic box, which covers and protects the entire set of electronic components and attaches them to the lower casing of the exoskeleton. Then, in the traction structures, it refers to the mechanisms that interact with each other to generate the movement of the MCP, DIP, and PIP joints, as well as the opening and closing movement of the exoskeleton. It is composed of 15 pieces, 10 of which are traction rings that are installed on each finger (2 rings per finger). Each ring has two opposite holes through which the traction cord passes. On one side, the cords are connected to three servomotors, distributed as follows: the cord for the thumb mechanism goes to one servomotor, and the other four sets of mechanisms are connected to two servomotors. On the opposite side of the cords, there are five pieces that are the traction couplings for each cord. These couple the cords coming from the fingers to a traction spring each. The drive is powered by a spring-cord traction system, where the mechanisms of each finger are pulled by servomotors. The servomotors wind the cords onto a pulley, generating the flexing movement of each finger's phalanges. The fingers are extended by the force of the traction springs, which generate passive movement, reducing the energy consumption of the motors. As seen above, the structural configuration of the exoskeleton and the selection of a rope-spring traction system reduce the mass and number of components, making the exoskeleton design a simplified structure that is easy to assemble/disassemble. The drive system with three servomotors is a configuration that also simplifies the design and reduces the number of actuators without the exoskeleton losing its basic flexion/extension functions. From a DfT perspective, the exoskeleton's design facilitates the evaluation and detection of mechanical failures in each component during the different stages of the DfT evaluation.

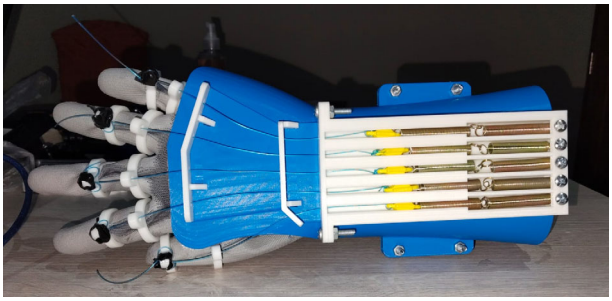


Fig. 5. Construction and assembly.

Next, a manufacturing cost analysis was performed for the proposed exoskeleton, considering mechanical materials (screws, springs, traction cables), electronic components (servomotors, batteries, microcontroller board, resistors, buttons, and cables), PETG 3D printing material, assembly labor, and 3D printing operator labor, which can be seen in Table III.

TABLE III. MANUFACTURING COSTS

Description	Cost (USD)
Mechanical materials	8
Electronic components	12
PETG 3D printing material	30
Assembly labor	20
3D printing operator labor	14

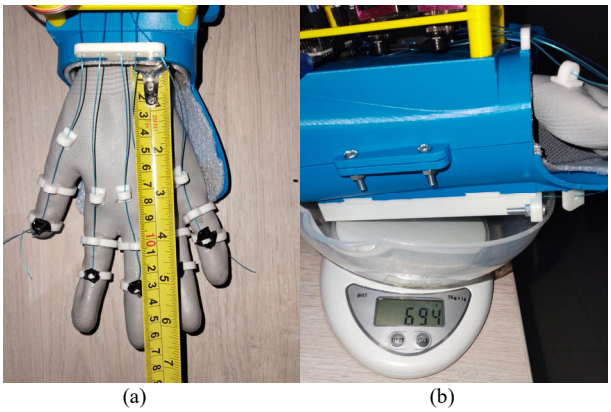
The total manufacturing cost is USD 84, which is in line with the DfT approach, as it contributes to the goal of developing a low-cost exoskeleton for clinical environments with limited resources. In addition, this facilitates maintenance and sustainability operations, due to the easy replacement of parts and the low cost provided by the additive manufacturing process.

V. APPLICATION OF DFT METHODOLOGY IN CASE STUDY

This chapter presents the tests from the DfT methodology testing protocol, as well as their application for evaluating the hand exoskeleton. The tests are divided into six types: anthropometric; mobility; weight; assembly/disassembly; ergonomic, comfort, and usability; grip strength.

A. Anthropometric Test

This test allows the dimensions of the prototype manufactured using additive printing technology to be evaluated in comparison with the design, as shown in Fig. 6. To do this, 10 anthropometric measurements are considered, and up to 5 measurements were taken for each item, as shown in Table IV. Measurements such as the length of the support for the little finger and the height/thickness of the palm space were made with precision. However, other measurements, such as the distance of the index finger support and the distance from the base of the wrist to the start of the fingers, vary from the designed measurement by 0.39% and 0.4%, respectively. These variations are due to manufacturing parameters, as well as thermal expansion that occurs during 3D printing. Despite the variations, these did not cause any complications during the assembly of the prototype.



(a) (b)

Fig. 6. Anthropometric and weight validation of the exoskeleton: (a) Left: anthropometric validation; (b) Right: weight validation.

TABLE IV. VALIDATION RESULTS OF ANTHROPOMETRIC DIMENSIONS

Item	Description	Design Value (mm)	Measured Value (mm)	Diff. %
1	Total length from wrist to middle finger tip	183	182.9 ± 0.2	0.05
2	Maximum width of the palm	97	97.2 ± 0.3	0.21
3	Thumb rest length	71	71.1 ± 0.1	0.14
4	Index support length	87	87.0 ± 0.1	0.00
5	Length of the support for the medium	103	103.4 ± 0.4	0.39
6	Length of the ring finger support	88	88.2 ±0.2	0.23
7	Length of the little finger support	72	72.0 ± 0.1	0.00
8	Index-middle interdigital space	28	28.1 ± 0.1	0.10
9	Height/thickness of palm space	45	45.0 ± 0.1	0.00
10	Length of the base from the wrist to the start of the fingers	95	95.4 ± 0.3	0.40

TABLE V. REFERENCE VALUES FOR MECHANICAL AND FUNCTIONAL ANGLES

Finger	Joint	Mechanical Reference Angle	Functional Reference Angle
Index, Middle, Ring, Little	MCP	80°–90°	60°–70°
	PIP	100°–110°	80°–90°
Thumb	MCP	61°	60°–70°
	IP	81°	80°–90°

TABLE VI. VALIDATION RESULTS OF JOINT MOTION RANGE

Finger	DoF	Joint	Mechanical Angle	Functional Angle
Index	2	MCP	84.6 ± 0.5	69.4 ± 3.7
		PIP	105.4 ± 1.3	85.6 ± 1.3
Medium	2	MCP	84.6 ± 0.9	68.2 ± 2.2
		PIP	106.8 ± 1.5	82.0 ± 2.1
Ring	2	MCP	87.4 ± 0.5	69.8 ± 1.3
		PIP	106.4 ± 1.5	80.8 ± 2.5
Little	2	MCP	86.6 ± 0.9	70.0 ± 2.7
		PIP	105.0 ± 1.4	77.6 ± 0.9
Thumb	2	MCP	62.8 ± 1.3	41.4 ± 2.5
		IP	80.8 ± 0.4	70.4 ± 1.5

B. Mobility Test

This test evaluates the mobility of the phalanges and joints of the hand exoskeleton. Table V shows the reference angles for the Interphalangeal (IP), MCP, and PIP joints, according to the studies by Tavakoli *et al.* [56] and Lee and Jung [57]. Table VI shows the results obtained from the mobility tests, with 2 DoF per finger, 10 degrees of freedom for the entire exoskeleton, and up to 5 measurements per item for mechanical and functional angles. In terms of the mechanical angle assessment, only the thumb had a variation of 1.8° with the reference measurement in the MCP and 0.2° from the reference measurement in the IP. On the other hand, the functional angle evaluation shows greater variations. Initially, most fingers did not reach the reference angular measurement. In response to this, the servomotor was adjusted by modifying the stop on its mechanism, achieving an angle greater than 180°. This modification allowed the angular values of the fingers to be increased. However, in the little finger, the PIP angle of 77.6 ± 0.9° did not reach the reference measurement, as was the case with the thumb, with MCP and IP with values of 41.4 ± 2.5° and 70.4 ± 1.5°, respectively. This is due to the anatomical complexity of the thumb, which causes deviations in its functional angles, and to limitations in the drive system that moves the traction cords for the little finger and thumb. Even so, these deviations are acceptable for rehabilitation tasks, as they do not require a high degree of precision. However, for tasks that require grasping objects, the servomotors for the thumb and little finger would need to be redesigned. In the case of the thumb, the position of the servomotor would need to be redesigned to compensate for the displacement of the traction cord and achieve the desired angles. For the little finger, an independent motor would need to be added and its position redesigned in a similar way to the thumb.

C. Weight Test

The weight test evaluates the weights of each component and the total weight of an exoskeleton with potential for implementation in hand rehabilitation.

Fig. 6(b) shows the total weight of the device, which is 694 g. the specific weights of each component are shown in Table VII. The heaviest components are the lower and upper shells, weighing 121 g and 117 g, respectively. The lightest components, weighing less than 10 g, are the rail guides, protective foam, and the Arduino Nano. The structural components account for 71% of the weight, while the electronic components account for 29%. This increase in weight is mainly due to the inaccuracy of the weight of mechanical components (screws, springs, foam) and electronic components (Arduino Nano, cables) available on the local market.

D. Assembly and Disassembly Test

This test allows the assembly and disassembly time for device maintenance to be evaluated. The results are shown in Table VIII, with similar, short times for easy maintenance.

TABLE VII. WEIGHT VALIDATION RESULTS

Component	Recorded Weight (Grams)
Electronics box	62
Lower casing	121
Upper casing	117
Electronic component mounts	44
Traction spring rail	65
Rail guides	5
Protective foam	4
Servomotors	39
6V batteries	85
Arduino Nano	7
Electrical connections	70
Screws	75

TABLE VIII. ASSEMBLY AND DISASSEMBLY VALIDATION RESULTS

Activity	Time
Assembly	5 min 38 s
Disassembly/Maintenance	4 min 10 s

TABLE IX. RESULTS OF ERGONOMIC VALIDATION, COMFORT AND USABILITY USING THE LIKERT SCALE

Description	1	2	3	4	5
The exoskeleton fits comfortably on the user's hand.	-	-	-	×	-
No pressure points or discomfort are felt during use.	-	-	×	-	-
The movements made with the exoskeleton were natural and fluid.	-	-	-	×	-
It is safe and there is no risk of entrapment that could cause injury.	-	-	×	-	-
You can wear the exoskeleton for more than 30 min without feeling discomfort.	-	-	×	-	-
Turning the device on and off is simple and easy to use.	-	-	-	-	×
The basic manual adjustment of the exoskeleton is easy to perform.	-	-	-	-	×
The user-device interface is intuitive and accessible without specialized guidance.	-	-	-	×	-

E. Ergonomic, Comfort and Usability Testing

This test allows an exoskeleton to be evaluated based on the opinions of six healthy users, under the supervision of two rehabilitation specialists, regarding comfort, ergonomics, and usability, applying the Likert scale. According to Koo and Yang [54], the Likert scale evaluation method has a numerical rating range from 1 to 5, with 1 being the lowest and equivalent to a strong disagreement, and 5 being the highest, equivalent to a strong agreement. The results are shown in Table IX. An optimal result according to the Likert scale should be greater than or equal to 4 in at least 3 or 4 items, resulting in 5 items for our case study, with results above 4. On the other hand, it can be seen that aspects such as the presence of pressure points, the feeling of entrapment risks, and prolonged use without discomfort have an average score of 3. These aspects are more sensitive in actual stroke patients, which could affect the usability of the device in actual clinical rehabilitation. Therefore, in terms of device safety, design improvements should still be proposed to increase confidence and incorporate the device in rehabilitation protocols with patients in the future.

F. Grip Strength Test

This test allows the load capacity of the hand exoskeleton to be evaluated against different weights, as shown in Fig. 7. The test protocol has the following sequence:

- First, start with a weight of 5 N. Place the weight on the exoskeleton's fingers as shown in Fig. 8.
- The device is then activated using the buttons until it reaches its maximum joint angle, at which point the buttons are released. If the fingers remain in that position, the test is passed.
- This procedure is repeated, increasing by 5 N.

Fig. 7. Standardized weights for grip strength testing.

Fig. 8. Grip strength validation.

The test results are shown in Table X. It was determined that the prototype reaches a maximum load of 25 N with stress samples in the servomotors. At the next weight of 30 N, the servomotors were unable to lift the weight, stopping the test. The 25 N load achieved by the device is acceptable for lifting everyday objects such as cups (0.147 kg/1.44 N), bottles (1.131 kg/11.09 N), utensils (0.950 kg/9.32 N), or tools (0.895 kg/8.78 N) [55].

TABLE X. GRIP FORCE VALIDATION RESULTS

N°	Strength (N)	Does it comply? YES/NO	Comments
1	5	YES	Normal operation
2	10	YES	Normal operation
3	15	YES	Normal operation
4	20	YES	Normal operation
5	25	YES	Effort in servomotors
6	30	NO	Servomotors stop

VI. DISCUSSION

The application of a DfT methodology based on the case study of the design and validation of an exoskeleton with potential for hand rehabilitation in CVA patients made it possible to establish a methodology that integrates mechanical and functional aspects from the initial stages of requirements, minimizing technical failures in the manufacture of the product and improving the performance of the exoskeletons in validation tests.

The application of the DfT methodology in mechanical design software was also taken into account, where 3D models were generated with geometries that facilitated the validation of the CVA hand exoskeleton.

The first validation of the DfT methodology begins with a finite element analysis of the design. This allowed us to identify potential structural failures in terms of strength

and rigidity, enabling us to correct the model in software before manufacturing. This analysis also shows critical areas, allowing us to pay attention to these areas during subsequent validation tests.

The manufacture of the hand exoskeleton cost 84 USD, which is quite affordable and was achieved by applying the DfT methodology from the initial phase of the device design.

The DfT methodology allowed for the establishment of a validation protocol during the empirical validation stage that incorporates both mechanical and functional aspects, which in turn improved the way hand exoskeletons for CVA patients are validated. First, in the anthropometric test, dimensional deviations are less than 0.4%, indicating that software design and additive manufacturing methods achieve a level of precision suitable for hand exoskeletons. In addition, additive technology allows precision to be adjusted with tolerances between 0.1 mm and 0.2 mm for each part. In the mobility tests, it is possible to achieve the reference mechanical angles DIP, PIP, and IP for the exoskeleton fingers, indicating that the parts are adequately designed. However, the reference values for the functional angles remain at the lower limit of that reference value, suggesting the use of servomotors with a greater range of rotational movement. In weight tests, the reference weight was estimated at 500 g. However, a weight of 694 g was achieved. Structural components account for 71% of the total weight. To achieve the reference weight, topological optimization of the structure is suggested to reduce weight. On the other hand, among the electronic components, the heaviest is the battery, so it is suggested to replace it with lighter batteries, such as lithium batteries. In the assembly and disassembly validation test, the operation was performed in 5 min 38 s and 4 min 10 s, respectively. These times are acceptable since the reference time required is 5 min. The time can be improved with longer use by the user. To validate ergonomics, comfort, and usability, the Likert scale was applied, which suggests improvements in the comfort of the exoskeleton, such as the addition of padding in areas where greater pressure points are perceived to improve the comfort of the device, as well as the implementation of safety aspects based on Design for Safety (DfS). Finally, in the grip strength test, the exoskeleton was able to support a maximum load of up to 25 N with the fingers extended. This value exceeded the required 20 N and makes the proposed exoskeleton superior to several models available on the market. However, above 25 N, motor failures occur, so it is suggested that a locking system be implemented for loads above the limit.

Although the design of the proposed exoskeleton has a similar architecture and actuation system to several designs created by other research groups and devices available on the market, the main contribution of this work is the integration of a replicable DfT methodology in the different phases of exoskeleton development. This differs from other studies that focus on evaluating strength, endurance, movement, grip, CAD design, or move directly to clinical evaluations. This study seeks to integrate a validation methodology that addresses the exoskeleton design process from a mechanical and functional point of view, allowing technical failures to be identified early and corrected in a timely manner, thus reducing the probability of technical failures in exoskeletons and offering the possibility of improving performance in future clinical trials.

VII. Conclusion

The implementation of a methodology inspired by DfT concepts allowed for the integration of mechanical and functional evaluation into the development of hand exoskeletons with potential for hand rehabilitation in stroke patients, from the initial requirements and design phase to construction and testing. This minimized technical failures and resulted in a functional, low-cost product.

In the CAD design, the use of finite element analysis software with DfT criteria made it possible to correct potential mechanical failures and identify critical areas to be considered in testing and commissioning. In the manufacture of the exoskeleton, the use of additive technology demonstrated dimensional tolerances of less than 0.4%, and it was also possible to manufacture an affordable product at a cost of USD 84. Tests using the DfT methodology show that the prototype developed achieves the mechanical angles of the DIP, PIP, and IP fingers. However, the results of the functional angles are lower than required, which could mean the implementation of servomotors with a higher degree of rotation. The value of 694 g represents the total weight of the designed device, which exceeds the required weight of 500 g. This suggests that the structure needs optimization to reduce the weight below the required level. Switching to a lighter lithium battery is also suggested. Assembly and disassembly times are satisfactory. The evaluation of ergonomics, comfort, and usability was carried out using the Likert scale, which allowed us to identify characteristics to be improved in the exoskeleton, such as design improvements for greater comfort and safety recommendations. Finally, in the grip strength test, the exoskeleton has a maximum load capacity of 25 N, which is higher than various similar devices on the market.

For future work, the following aspects are considered. The CAD design will by adjusted by applying topological optimization techniques to reduce structural weight, as well as switching to lighter batteries such as lithium batteries. Servomotors with a greater range of rotation will be implemented to achieve the functional angle values of the exoskeleton. To achieve better results from the DfT methodology, it is recommended to implement safety criteria through DfS for greater exoskeleton reliability. The strength testing protocol will be supplemented by measurements of electrical and thermal characteristics, as well as repetitive load testing to assess long-term reliability. The exoskeleton developed using the DfT methodology did not include clinical validation with real patients; therefore, in future work, the device will be evaluated in groups of 10 to 30 stroke patients to validate its use at the hospital level, evaluating grip strength and movement. Clinical scales such as the Fugl-Meyer and

Barthel index will also be implemented, ensuring ethical aspects and consents.

These aspects will be addressed in future research to optimize methodologies and the development of the hand exoskeleton.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

EC and ECC carried out the main designs to obtain the CVA hand exoskeleton, as well as the development of the DfT methodology; EVF built the exoskeleton; DP performed the validation tests; YLS reviewed and corrected the manuscript for submission; all authors approved the final version of the manuscript.

ACKNOWLEDGMENT

The authors would like to thank the National University of San Agustín in Arequipa for its support in the design and manufacture of the ACV hand exoskeleton.

REFERENCES

[1] Cardiovascular diseases (CVDs). (2025). *World Health Organization (WHO)*. Available: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)

[2] World stroke day 2022. (2022). *World Health Organization (WHO)*. Available: https://www.who.int/srilanka/news/detail/29-10-2022-world-stroke-day-2022

[3] B. Ortiz, Antonio, C. Larco *et al.,* "Incidence rate of stroke in Peru," *Peruvian Journal of Experimental Medicine and Public Health*, vol. 38, no. 3, pp. 399–405, 2021.

[4] A. Brami, N. Jarrasse, and R. Parry, "Impairment and compensation in dexterous upper-limb function after stroke. From the direct consequences of pyramidal tract lesions to behavioral involvement of both upper-limbs in daily activities," *Frontiers in Human Neuroscience*, vol. 15, 662006, 2021.

[5] H. Wang, R. Arceo, S. Chen *et al.,* "Effectiveness of interventions to improve hand motor function in individuals with moderate to severe stroke: A systematic review protocol," *BMJ Open*, vol. 9, no. 9, 2019.

[6] J. Knutson, M. Harley, T. Hisel *et al.,* "Improving hand function in stroke survivors: A pilot study of contralaterally controlled functional electric stimulation in chronic hemiplegia," *Archives of Physical Medicine and Rehabilitation*, vol. 88, no. 4, pp. 513–520, 2017.

[7] A. Perez, J. Rumbo, G. Ortiz *et al.,* "Soft exoskeletons: Development, requirements, and challenges of the last decade," *Actuators*, vol. 10, no. 7, 2021.

[8] D. Tang, L. Qi, L. Xiao *et al.,* "Research progress and development trend of flexible hand rehabilitation gloves," in *Proc. the Institution of Mechanical Engineers, Part C: Journal of Mechanical Engineering Science*, vol. 238, no. 14, pp. 7155–7171, 2024.

[9] T. Plessis, K. Djouani, and C. Oosthuizen, "A review of active hand exoskeletons for rehabilitation and assistance," *Robotics*, vol. 10, no. 1, 2021.

[10] D. Huamanchahua, P. Toledo, J. Aguirre *et al.,* "Hand exoskeletons for rehabilitation: A systematic review," in *Proc. 2022 IEEE International IOT, Electronics and Mechatronics Conf. (IEMTRONICS)*, Toronto, 2022, pp. 1–6.

[11] R. Kabir, M. Sunny, H. Ahmed *et al.,* "Hand rehabilitation devices: A comprehensive systematic review," *Micromachines*, vol. 13, no. 7, 2022.

[12] G. Achilli, C. Amici, M. Dragusanu *et al.,* "Soft, rigid, and hybrid robotic exoskeletons for hand rehabilitation: Roadmap with impairment-oriented rationale for devices design and selection," *Applied Sciences*, vol. 13, no. 20, 2023.

[13] S. Yeh, Y. Wang, W. Fang *et al.,* "Effectiveness of powered hand exoskeleton on upper extremity function in people with chronic stroke," *Actuators*, vol. 14, no. 2, 2025.

[14] C. Haarman, E. Hekman, J. Rietman *et al.,* "Mechanical design and feasibility of a finger exoskeleton to facilitate finger extension in patients with severe stroke," *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, vol. 31, pp. 1268–1276, 2023.

[15] N. Singh, M. Saini, N. Kumar *et al.,* "Evidence of neuroplasticity with robotic hand exoskeleton for post-stroke rehabilitation: a randomized controlled trial," *Journal of Neuro Engineering and Rehabilitation*, vol. 18, no. 1, 76, 2021.

[16] C. Sassanelli, A. Urbinati, P. Rosa *et al.,* "Addressing circular economy through design for X approaches: A systematic literature review," *Computers in Industry*, vol. 120, 103245, 2020.

[17] J. Mesa, "Design for circularity and durability: An integrated approach from DFX guidelines," *Research in Engineering Design*, vol. 34, no. 4, pp. 443–460, 2023.

[18] Y. Nurcahyanie and L. Rohmadiani, "Design for longevity and design for X: Concepts, applications, and perspectives," *Tibuana: Journal of Applied Industrial Engineering*, vol. 6, no. 1, pp. 58–64, 2023.

[19] M. Thompson, G. Moroni, T. Vaneker *et al.*, "Design for additive manufacturing: Trends, opportunities, considerations, and constraints," *CIRP Annals*, vol. 65, no. 2, pp. 737–760, 2016.

[20] V. Tsiokou, A. Papatheodorou, D. Ntenekou *et al.,* "An integrative computational design workflow and validation methodology for 3D-printed personalized orthopedic devices: Case study of a Wrist–Hand Orthosis (WHO)," *Processes*, vol. 11, no.7, 2204, 2023.

[21] J. Zhang, D. Chen, P. Gao *et al.,* "Research on modeling method of testability design based on static automatic fault tree," *Processes*, vol. 12, no. 12, 2826, 2024.

[22] J. Acevedo, N. Saldarriaga, J. Orozco *et al.,* "Design of a validation protocol for medical technology according to current standards," in *Proc. VII Latin American Congress on Biomedical Engineering CLAIB 2016*, Bucaramanga, 2016, vol. 60, pp. 634–637.

[23] I. Rojek, M. Kaczmarek, P. Kotlarz *et al.*, "Hand exoskeleton—Development of own concept," *Applied Sciences*, vol. 13, no. 5, 2023.

[24] R. Megalingam, A. Baburaj, A. Mattathil *et al.,* "Low cost hand orthotic device to improve hand function of stroke patients," *Technology and Disability*, vol. 30, no. 4, pp. 185–197, 2019.

[25] Y. Bouteraa, I. Abdallah, and A. Elmogy, "Training of hand rehabilitation using low cost exoskeleton and vision-based game interface," *J Intell Robot Syst*., vol. 96, pp. 31–47, 2019.

[26] M. Norouzi, M. Karimpour, and M. Mahjoob, "A finger rehabilitation exoskeleton: Design, control, and performance evaluation," in *Proc. 2021 9th RSI International Conf. on Robotics and Mechatronics (ICRoM)*, Tehran, 2021, pp. 301–308.

[27] S. Urmode, S. Patil, A. Sayyed *et al.,* "Design and manufacturing of cost-effective hand exoskeleton for paralysis patient," in *Proc. the 2023 International Conf. on the Confluence of Advancements in Robotics, Vision and Interdisciplinary Technology Management (IC-RVITM)*, Bangalore, 2023, pp. 1–8.

[28] P. Baniqued, R. Baldovino, and N. Bugtai, "Design considerations in manufacturing cost-effective robotic exoskeletons for upper extremity rehabilitation," in *Proc. the 8th IEEE International Conf. Humanoid, Nanotechnology, Information Technology, Communication and Control, Environment and Management (HNICEM)*, Cebu, 2015, pp. 1–5.

[29] T. Shahid and U. Khan, "Design of a low cost multi degree of freedom hand exoskeleton," in *Proc. 2014 International Conf. on Robotics and Emerging Allied Technologies in Engineering (iCREATE),* Islamabad, 2014, pp. 312–316.

[30] J. Park, K. Lee, K. Jeon *et al.,* "Low cost and light-weight multi-DOF exoskeleton for comprehensive upper limb rehabilitation," in *Proc. 2014 11th International Conf. on Ubiquitous Robots and Ambient Intelligence (URAI),* Kuala Lumpur, 2014, pp. 138–139.

[31] K. Anam, A. Rosyadi, and B. Sujanarko, "The design of a low-cost therapy robot for hand rehabilitation of a post-stroke patient," in *Proc. 2018 International Conf. on Computer Engineering, Network and Intelligent Multimedia (CENIM),* Surabaya, 2018, pp. 77–80.

[32] T. Götzelmann, "A 3D printable hand exoskeleton for the haptic exploration of virtual 3D scenes," in *Proc. 10th International Conf. on PErvasive Technologies Related to Assistive Environments (PETRA),* Island of Rhodes, 2017, pp. 63–66.

[33] J. Maldonado, M. Múnera, C. Diaz *et al.*, "A fabric-based soft hand exoskeleton for assistance: The ExHand exoskeleton," *Frontiers in Neurorobotics*, vol. 17, 1091827, 2023.
[34] G. Rudd, L. Daly, V. Jovanovic *et al.,* "A low-cost soft robotic hand exoskeleton for use in therapy of limited hand–motor function," *Applied Sciences*, vol. 9, no. 18, 2019.
[35] L. Yang, F. Zhang, J. Zhu *et al.,* "A novel deep learning method for motion assessment in upper limb rehabilitation grasping test," *Industrial Robot*, vol. 51, no. 6, pp. 997–1005, 2024.
[36] M. Haghshenas, R. Patterson, N. Bugnariu *et al.,* "A pilot study on the design and validation of a hybrid exoskeleton robotic device for hand rehabilitation," *Journal of Hand Therapy*, vol. 33, no. 2, pp. 198–208, 2020.
[37] S. Gupta, A. Agrawal, and E. Singla, "Architectural design and development of an upper-limb rehabilitation device: A modular synthesis approach," *Disability and Rehabilitation: Assistive Technology*, vol. 19, no. 1, pp. 139–153, 2024.
[38] I. Abdallah, Y. Bouteraa, and C. Rekik, "Design and development of 3d printed myoelectric robotic exoskeleton for hand rehabilitation," *International Journal on Smart Sensing and Intelligent Systems*, vol. 10, no. 2, pp. 1–26, 2017.
[39] V. Durairajah, S. Gobee, W. Rauf *et al.,* "Design and development of low cost hand exoskeleton for rehabilitation," in *Proc. 2nd International Conf. for Innovation in Biomedical Engineering and Life Sciences*, Singapore, 2017, vol. 67, pp. 107–110.
[40] M. Jiang, L. Cao, Q. Meng *et al.,* "Design and prototyping of a hand exoskeleton for finger rehabilitation by driving distal phalanx," in *Proc. Mechanism Design for Robotics (MEDER 2024)*, 2024, vol. 166, pp. 202–209.
[41] H. Yoo, S. Lee, J. Kim *et al.,* "Development of 3D-printed myoelectric hand orthosis for patients with spinal cord injury," *Journal of Neuroengineering and Rehabilitation*, vol. 16, no. 1, 162, 2019.
[42] R. Araujo, C. Silva, S. Netto *et al.,* "Development of a low-cost EEG-controlled hand exoskeleton 3D printed on textiles," *Front. Neurosci.,* vol. 15, 661569, 2021.
[43] A. Grandi, A. Karthikeyan, E. Junior *et al.,* "Low-cost 3D printed exoskeleton for post-stroke hand rehabilitation," *Computer-Aided Design and Applications*, vol. 19, no. 6, pp. 1207–1215, 2022.
[44] P. Prieto, F. Auat, M. Escobar *et al.*, "Robotic care: A low cost design to assist therapy for brain stroke rehabilitation," in *Proc. the Design Society: International Conf. on Engineering Design*, vol. 1, no. 1, pp. 975–984, 2019.
[45] N. Singh, M. Saini, S. Anand *et al.,* "Robotic exoskeleton for wrist and fingers joint in post-stroke neuro-rehabilitation for low-resource settings," *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, vol. 27, no. 12, pp. 2369–2377, 2019.
[46] Safety Requirements for Electrical Medical Equipment, IEC Standard 60601-1:2005.
[47] Application of Risk Management to Medical Devices, ISO Standard 14971:2019.
[48] Application of Usability Engineering to Medical Devices, IEC Standard 62366-1:2015.
[49] Particular Requirements for Basic Safety and Essential Performance of Medical Robots for Rehabilitation, Assessment, Compensation or Alleviation, UNE Standard EN IEC 80601-2-78:2020.
[50] Robotics Test Methods for Exoskeleton Type Walking RAC Robot, ISO Standard 5363:2024.
[51] Human Body Dimensions, DIN Standard 33402-2:2020-12.
[52] N. Secciani, C. Brogi, M. Pagliai *et al.*, "Wearable robots: An original mechatronic design of a hand exoskeleton for assistive and rehabilitative purposes," *Frontiers in Neurorobotics*, vol. 15, 2021.
[53] J. Cruz, A. Chambi, E. Valdeiglesias *et al.*, "Implementation and evaluation of a hand prosthesis focused on grasping tasks through low-cost additive printing," *International Journal of Mechanical Engineering and Robotics Research (IJMERR)*, vol. 14, no. 1, pp. 59–66, 2025.
[54] M. Koo and S. Yang, "Likert-type scale," *Encyclopedia*, vol. 5, no. 1. 18, 2025.
[55] B. Calli, A. Singh, J. Bruce *et al.*, "Yale-CMU-Berkeley dataset for robotic manipulation research," *The International Journal of Robotics Research*, vol. 36, no. 3, pp. 261–268, 2017.
[56] M. Tavakoli, R. Batista, and L. Sgrigna, "The UC Softhand: Light weight adaptive bionic hand with a compact twisted string actuation system," *Actuators*, vol. 5, no. 1, 1, 2015.
[57] K. Lee and M. Jung, "Ergonomic evaluation of biomechanical hand function," *Safety and Health at Work*, vol. 6, no. 1, pp. 9–17, 2014.