Adult-Size Bio-Mechatronic Exoskeleton with Robotic Underactuated Mechanism for Continuous Passive Motion Therapy on Hemiplegic Lower Limbs

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***Abstract*—Cerebrovascular accidents (CVA) cause hemiplegia in adult patients, limiting their daily activities and reducing their autonomy, which calls for effective rehabilitation systems for the lower limbs. The study aims to design and simulate a subactuated robotic continuous passive motion system for lower-limb therapy in adult patients with post-stroke hemiplegia. Physical rehabilitation protocols were analyzed, and consultations with specialists were conducted to define criteria related to safety, stability, and adaptability. The mechanical subsystem was developed using SolidWorks with an adjustable structure; the electronic subsystem was designed using Autodesk Eagle and KiCad 7 to enable precise control; and the software subsystem was implemented in Wokwi using an ESP-32 microcontroller for parameter configuration and data transmission. Simulations were conducted in CoppeliaSim, modeling a virtual patient undergoing three rehabilitation modes: knee flexion-extension, ankle flexion-extension, and a combined full knee extension cycle. Simulations validated the correct execution of the planned movements, stability of the power supply, precision in displacement control, and the ability to record and transmit therapeutic data. The strength of materials and the effectiveness of the mechanism were also confirmed. The designed subactuated robotic system represents a safe and effective tool for physical rehabilitation, with the potential to improve mobility and quality of life in patients with lower-limb hemiplegia following a CVA.**

***Keywords*—Bio-mechatronics; engineering design; exoskeleton; stroke rehabilitation; rehabilitation robotics**

I. Introduction

In Peru, the Instituto Nacional de Estadística e Informática (National Institute of Statistics and Informatics – INEI) reported in 2017 that the prevalence of individuals with physical disabilities involving some degree of difficulty in upper and lower limb movement was 15.1% of the total population [1]. In 2018, the Consejo Nacional para la Integración de la Persona con Discapacidad (National Council for the Integration of Persons with Disabilities – CONADIS) registered approximately 2,735 Peruvians with musculoskeletal limitations, the vast majority of whom were eligible for physical rehabilitation. However, a range of factors—particularly economic constraints—prevented many from receiving adequate treatment or, in some cases, any treatment at all [2]. According to 2019 data from the National Institute of Statistics and Informatics, 88.6% of the population with some type of disability did not receive rehabilitation therapy or treatment, meaning that only 11.4% had access to such care [3]. This disparity can be attributed, in part, to the limited use of rehabilitation technology in the country, largely due to economic limitations and a lack of awareness regarding the existence of such devices as components of physical rehabilitation therapies.

According to the World Health Organization (WHO), the global incidence of cerebrovascular accidents (CVA) is 200 cases per 100,000 inhabitants per year, with a projected increase of 27% between 2000 and 2025. The Instituto Nacional de Ciencias Neurológicas - INCN (National Institute of Neurological Sciences) notes that CVA can be prevented by maintaining a healthy lifestyle, and if one occurs, immediate attention from a specialist significantly increases the chances of recovery [4].

At the Polytechnic University of Catalonia, Spain, an active knee-ankle orthosis was designed [5]. This proposal seeks to assist and contribute to the recovery of patients with spinal cord injuries, who present up to 80% of the body without the capacity to perform movements. In Latin America, there are exoskeleton projects designed to contribute to rehabilitation therapies for upper and lower limbs. Regarding upper limb rehabilitation, exoskeletons have been developed that present up to four degrees of freedom, adapted to the anthropometry of Mexican patients through optimal conceptual design [6]. These exoskeletons are focused on humerus rotation movement, elbow flexion and extension [7], and hand pronation and supination [8]. Regarding lower limb rehabilitation, two-degree-of-freedom systems have been designed for ankle and knee therapies, which include force, velocity, and position sensors [9], as well as designs for knee flexion-extension [10]. Based on the aforementioned, improving patient independence is possible with the application of technology in physical rehabilitation.

Patients who suffer a CVA often experience paralysis on one side of the body, a condition known as hemiplegia. As part of their rehabilitation, they must perform passive and repetitive exercises to activate neuroplasticity, a process that facilitates the formation of new neural connections in the brain. According to Perrier, gait disturbances, musculoskeletal deformities, and postural abnormalities are among the motor sequelae commonly resulting from CVA [11]. Mourey notes that the ability to maintain balance is affected by the functional condition of the lower limbs, as the muscles responsible for stabilizing the ankle and foot progressively weaken, impairing postural and movement control [12].

The Instituto de Evaluación de Tecnologías en Salud e Investigación (Institute for Health Technology Assessment and Research – IETSI) of EsSalud states in its "Clinical Practice Guideline for the Diagnosis and Treatment of the Acute Phase of Ischemic Stroke" that patients with CVA who present any level of disability should be included in physical rehabilitation programs. Moreover, it recommends that physical rehabilitation should begin within 72 hours and that patient mobilization commence within 24 hours, considering the patient's condition and hemodynamic status. Rehabilitation involves techniques that are typically administered in hospital settings, which increases the cost of ensuring timely access to treatment. However, early rehabilitation may result in cost savings by reducing long-term disability, in contrast to delayed intervention, which is associated with established disability and the potential for complications due to lack of timely treatment [13].

From the literature review, in recent years, research has been conducted on the design of prototypes and robotic rehabilitation systems for the lower limbs, aimed at assisting patients who have suffered CVA or with mobility impairments. These systems work by replacing lost muscular function with artificial mechanisms to restore walking ability, demonstrating the effectiveness of robotic devices in improving motor function. The following paragraphs provide a brief overview of previous studies related to this line of research.

Aguirre, J. et al., in their research article titled "Ergonomic Bio-Design and Motion Simulation of a Mechatronic Orthosis System for Knee Rehabilitation," published in IEEE Xplore, present the design of an exoskeleton and its joint structure using SolidWorks, with Aluminum 1060 selected as the material based on anthropometric analysis. The system includes an actuator based on a servomotor rated at 0.4 N·m, considering a leg-foot assembly mass of 7.32 kg and a gear transmission layout to achieve the 40 N·m required to move the lower limb. The Spyder environment and Python were used to develop a graphical interface that enables configuration of movement speed and the number of repetitions. A Von Mises stress analysis was conducted on the joint area by applying a torque of 200 N·m to the power mechanism's coupling section. Additionally, a realistic simulation was conducted in CoppeliaSim, involving a rotational range from 0° to 20°, under real-world conditions such as gravity and the physical properties of the leg and foot. The results verified that the design torque and movement speeds fell within the acceptable range of commercially available products [14].

Jie, H. et al., in their research article titled "Structure Design of Ankle-Knee Rehabilitation Training Robot," published in the IEEE Xplore Digital Library, report that rehabilitation training robots have been widely adopted in the Asian market—particularly lower-limb rehabilitation training robots, which play a significant role in human mobility. Based on current characteristics of existing lower-limb rehabilitation robots, the authors propose an independently developed ankle-knee rehabilitation training robot. The article presents the structural design of the ankle and knee rehabilitation robot, describes key mechanisms and performance features, and briefly introduces the connection mode between robots [15].

Similarly, robotic rehabilitation systems have proven to be essential for delivering passive and consistent therapy over extended periods, enabling the treatment of patients without the continuous presence of a therapist, as compared to traditional manual therapy [16], [17], [18], [19]. This approach facilitates more frequent treatment sessions, significantly reducing associated costs and improving accessibility to rehabilitation therapies [20], [21], [22]. In the context of lower-limb rehabilitation, robotic exoskeletons offer specific advantages by automating repetitive and controlled movements, thereby optimizing functional recovery in patients with neurological impairments [23]. The integration of such systems into rehabilitation protocols represents a significant advancement toward personalized medicine and improved patient quality of life.

On the other hand, Bin He et al. (2019) note that subactuated robotics represents a continuously expanding area of research, characterized by systems in which the number of actuators is lower than the number of degrees of freedom. Although this feature increases the complexity of design and control, it enables the development of lighter, more efficient, and lower-cost robotic systems. The authors also provide a detailed classification of such robots based on non-holonomic constraints, allowing for the organization of various configurations and dynamic behaviors. In addition, they describe commonly used mechanisms in this type of system—such as robotic arms, hands, wrists, and locomotion structures—which have been developed according to principles of mechanical simplicity and energy efficiency. Regarding control strategies, both open-loop and closed-loop approaches are presented, with the latter being particularly relevant due to the incorporation of methods such as fuzzy control and partial feedback linearization. Finally, the article identifies key technical challenges currently faced by the field and proposes a clear direction for future research, focused on refining modeling approaches, control techniques, and practical applications [24].

Despite these advances, existing robotic rehabilitation systems face critical limitations that restrict their accessibility in resource-constrained settings: they predominantly target single joints, rely on high-cost proprietary technologies, and lack integrated validation across mechanical, electronic, and software domains. This gap is particularly acute in Peru, where 88.6% of individuals with disabilities lack rehabilitation access, and early post-CVA intervention remains unattainable for most patients. This study addresses these limitations by presenting a multi-modal robotic lower-limb rehabilitation system (knee, ankle, and combined therapies) designed with low-cost hardware and open-source tools, validated through comprehensive finite element, kinematic, electronic, and clinical expert assessment, establishing a replicable framework for accessible post-CVA rehabilitation.

The structure of this study is organized as follows: Section I introduces the research, presenting the problem statement, its motivation, and the proposed approach to address it. Section II describes the materials and methods, including the design methodology, engineering standards applied, and the tools used for modeling and simulation of the system. Section III reports the main results, focusing on the mechanical, electronic, and software validation, as well as the performance of the robotic system in simulated rehabilitation scenarios. Section IV presents the experimental study approach. Section V outlines the discussion of results. Finally, Section VI summarizes the conclusions of the study and outlines directions for future work, particularly the implementation and clinical validation of the proposed device.

II. Materials and Methods

A. Hemiplegia caused by CVA

CVA are among the leading causes of permanent disability, resulting in severe brain injuries that produce physical sequelae and limit daily activities. According to the Mayo Clinic, an ischemic stroke occurs when the brain's blood supply is obstructed, depriving brain tissue of oxygen and nutrients, whereas a hemorrhagic stroke is caused by bleeding or rupture of cerebral blood vessels, which increases intracranial pressure and damages neurons [25]. Complications include loss of muscle movement or paralysis, which may affect one side of the body or specific muscle groups such as those in the face or arm. According to Rosenbaum, hemiplegia is a condition that partially or completely paralyzes one half of the body, with the term derived from "plegia" (weakness) and "hemi" (half of the body). The Centers for Disease Control and Prevention (CDC) classify it as a type of spastic cerebral palsy affecting 80% of individuals with cerebral palsy, describing it as a condition that impacts one side of the body—typically with greater involvement of the arm than the leg [26].

B. Exoskeletons

According to Azorín et al. (2017), an exoskeleton is a device that provides motor capabilities either passively or actively. Passive devices rely on the energy generated by the user to operate. In such cases, exoskeletons enhance the user's capabilities and are commonly used in military applications and physical rehabilitation. The classification of exoskeletons depends on several factors, including human anthropometric characteristics and, ultimately, the specific pathologies targeted for treatment. Additionally, there are exoskeletons inspired by human movement, typically designed for upper and lower limb mobility, which replicate the human gait cycle through different control strategies [27].

C. Previous Research

The initial study established the conceptual and methodological framework for the design of a subactuated robotic continuous passive motion system aimed at lower-limb rehabilitation in adult patients who have suffered a CVA. The research was based on the recognition that stroke is one of the leading causes of permanent disability, resulting in severe brain damage with physical consequences that significantly limit autonomy in daily activities. Through modeling and simulation using Computer-Aided Design (CAD) tools in Autodesk Inventor Professional 2023, the initial and final positions of the robotic system were defined, along with a full simulation of continuous passive motion. The results showed that accurate patient measurements significantly increase the feasibility of constructing a functional prototype, thereby contributing effectively to the rehabilitation process and enhancing the chances of recovering gait mobility [28].

Subsequently, a more specific and technically refined design of the subactuated robotic system for continuous passive motion therapy was developed, applying the VDI 2206 and VDI 2225 engineering standards to rigorously structure the design process. In this phase, system requirements were defined based on specific anthropometric and biomechanical data. Functional structuring was implemented, and a morphological matrix was used to explore various solution alternatives. Weighted matrices were applied to evaluate criteria such as ergonomics, control precision, and safety, allowing for the selection of an optimal design for knee and ankle rehabilitation. As a result, a system was obtained that provides controlled passive motion with a load-bearing capacity of up to 80 kg, featuring adjustable speed and variable load resistance to ensure smooth actuation and effective biomechanical alignment for motor recovery. Structural validation through Von Mises stress analysis of the structure-to-rail connector—using 304 stainless steel under a vertical load of 784 N—revealed a maximum stress of 29.58 MPa and a strain of 1.12×10^{-4}, remaining within the elastic limit of the material and confirming the structural integrity of the design [29].

D. Mechatronic Systems Design Standard VDI 2206 and VDI 2225

The VDI 2206:2021 model consists of three bands: The inner yellow band describes work management according to requirements, the central orange band comprises the main activities and tasks, and the outer blue band represents modeling and analysis activities [30]. Likewise, the model is supported by a structure of six control points, which contain orientation questions and support the user in tracking project progress [31].

According to Gräßler et al., the VDI 2206 design model comprises seven interrelated stages: requirements identification (recognition and schematization of needs in a detailed list), system architecture and design (decomposition into mechanical, electronic, and software units), element implementation (selection, dimensioning, and detailing of components), integration and verification (combination of mechanical, hardware, and software aspects with examination of interactions), validation and transition (demonstration of usability and delivery of the integrated system), modeling and analysis (digital representation and simulation of the global system), and requirements management (structuring and change control during development) [31]. Complementarily, the VDI 2225 standard provides design methodology based on optimal cost and simplification, including calculation methods to estimate material and manufacturing costs through graphical analysis.

Fig. 1 shows a concept map illustrating the systematic methodology employed in the development of a subactuated robotic rehabilitation system for the lower limbs, designed for patients with hemiplegia caused by CVA. The methodology is structured into sequential phases, ranging from the identification of the research problem—based on the lack of rehabilitation technology in Peru and the specific need to address post-stroke hemiplegia—to the proposal of future work. The methodological process integrated project evaluation based on virtual patient criteria, modularity, mechatronic aspects, and material selection, followed by the conceptual design, which incorporates technical standards and components of the robotic system. Finally, the methodology concludes with an analysis using CAD and simulation of the mechatronic system, establishing the foundation for future implementation and clinical validation of the device.

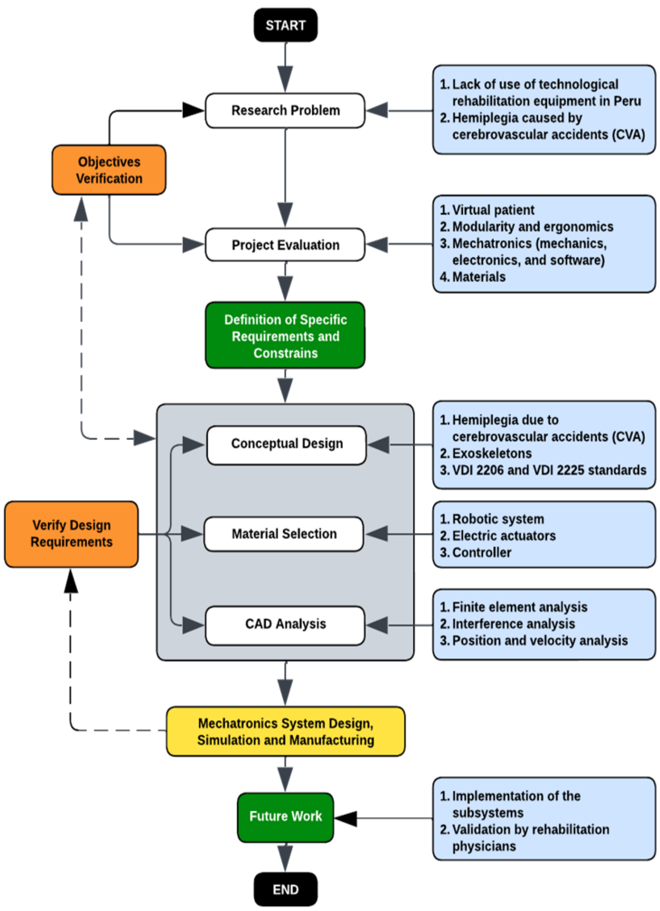

Fig. 1. Methodology for the design and simulation of the underactuated robotic system with passive-continuous movement for lower limb rehabilitation.

III. RESULTS

An underactuated robotic system with passive-continuous movement was designed for the physical rehabilitation of lower limbs for adult patients with hemiplegia due to CVA. This system provides a comprehensive tool that contributes to physical recovery through safe and effective planning of rehabilitation exercises, using robotic technology, and with the objective of providing greater probabilities of improvement in patients' quality of life. To define the requirements of the robotic system, it was necessary to establish the functional tasks, focused on knee flexion movements, dorsiflexion, and plantar flexion of the ankle [32]. In addition, it was important to consider the natural range of motion of each joint and the mechanical constraints required to reproduce these movements accurately and safely. The design process also included a review of rehabilitation protocols to ensure that the system could adapt to different stages of patient recovery, from early passive mobilization to more advanced therapeutic exercises. Table I presents the anthropometric parameters of the lower limb. The correct implementation of these measurements guaranteed adequate biomechanical alignment and balanced load distribution during the rehabilitation process, essential aspects for maximizing treatment efficacy and safety, ensuring proper interaction between the device and the user throughout the therapy sessions.

TABLE I. ANTHROPOMETRIC PARAMETERS OF THE LOWER LIMB

Anthropometric parameters	
Lower extremity segment	***Male average (cm)***
Hip width	32.852
Femur length	40.303
Knee to ankle length	42.312
Foot length	26.144
Foot width	9.900

According to Table II, the ranges of motion for flexion, dorsiflexion, and plantar flexion in the knee and ankle joints [33] allow for the design of robotic rehabilitation systems that provide personalized therapies for each patient. The possibility of modifying resistance and movement velocity according to each patient's requirements [34] is fundamental for improving rehabilitation outcomes and effectively recovering motor function in the lower limbs.

TABLE II. CLINICAL PARAMETERS OF THE LOWER LIMB

Clinical parameters		
Joint	***Motion***	***Range (°)***
Knee	Flexion	0-135
Ankle	Dorsiflexion	0-20
	Plantar flexion	0-40

The process then began with the conceptual design of the robotic system, following the German standards for mechatronic design (VDI 2206) and solution concept validation (VDI 2225). This was followed by the design of the mechanical subsystem, which includes the structure and supports for the lower limb. Transmission components were integrated to manage joint movements via two motors: one for the knee and one for the ankle. The next step was the design of the electrical subsystem responsible for supplying power to the robotic system. The next phase involved selecting the electrical and electronic components and programming the microcontroller to synchronize the selected motors. The functionality of the designed subsystems that comprise the robotic system was validated using specialized engineering software such as Proteus and MATLAB. Finally, the robotic system was simulated using engineering software tools such as MATLAB and CoppeliaSim to replicate the execution of physical rehabilitation therapies on a virtual patient.

A. Mechanical Prototyping

The mechanical subsystem was entirely designed using SolidWorks 2023 software due to its integrated finite element analysis tools and parametric design, with a specific focus on assisting joint movements of the lower limb. The mechanical configuration includes adjustable thigh and leg supports, implemented with longitudinal extension systems to ensure anthropometric adaptability. Specifically, the thigh support accommodates femur lengths ranging from 35 to 45 cm, while the leg support adjusts to knee-to-ankle distances between 40 and 50 cm, covering the anthropometric range of the target patient population. These supports incorporate securing mechanisms that provide stabilization and alignment of the limbs during rehabilitation. The ankle joint integrates a gear motor coupled to the foot support, enabling flexion-extension movements. The knee joint operates through a U-shaped structure connected to the main support and a linear guide rail, allowing for displacement with minimal deviation tolerances. The transmission system ensures a biomechanical trajectory that simulates the natural movement vectors of the joint. Additionally, the system features a subactuated configuration, as it includes only two active actuators: a DC motor for foot movement and a linear spindle for knee articulation. These actuators control a total of four degrees of freedom distributed across both joints, meaning not all movements are generated directly by motor action. In this type of design, some displacements occur passively through mechanical interaction between components, allowing for a reduced number of actuators without compromising system functionality. This strategy also contributes to lower weight, energy consumption, and control complexity, which is especially advantageous in rehabilitation applications. All components are shown in Fig. 2.

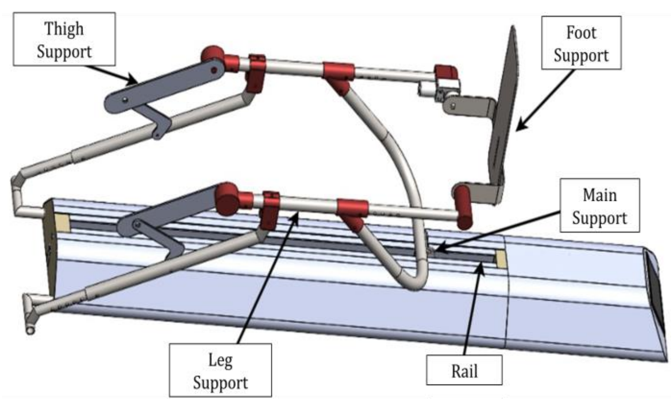

Fig. 2. Rehabilitation equipment components.

The device is designed to perform three therapy modes. In the first mode, only knee movements are executed: a) flexion and b) extension, as shown in Fig. 3. In this mode, the mechanism operates with five rotational passive joints, indicated by purple arrows, and one linear DOF, indicated by the orange arrow. The second mode enables ankle movements: a) plantar flexion and b) dorsiflexion, as illustrated in Fig. 4, which involves a single rotational DOF, also represented by purple arrows. Finally, the third mode combines both knee and ankle movements, allowing for consecutive and coordinated actions that mimic functional lower limb motion. In this mode, the device first performs full knee extension, followed by ankle movement, flexion and then extension, and concludes with knee flexion. This sequential control enables a more comprehensive rehabilitation pattern, enhancing neuromuscular coordination and facilitating a more natural gait-like exercise.

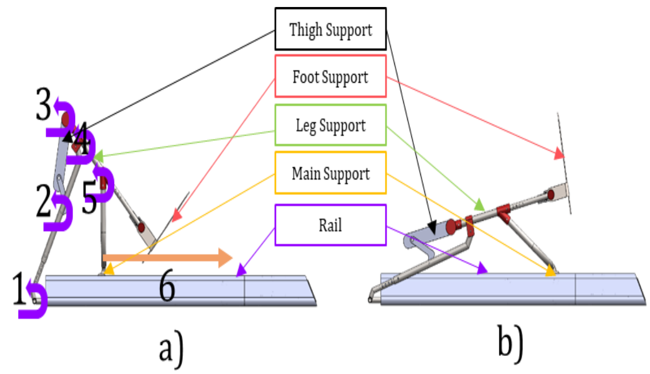

Fig. 3. Knee: a) flexion and b) extension.

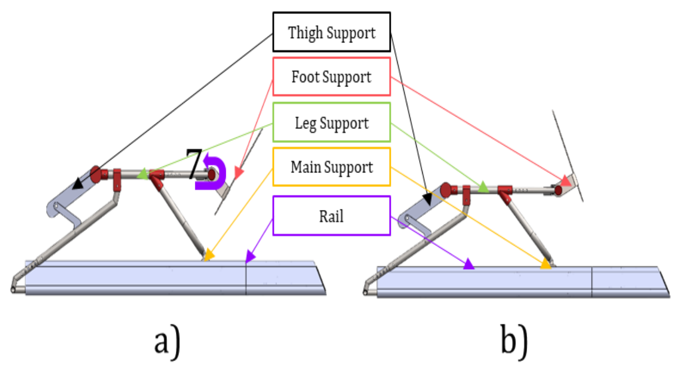

Fig. 4. Ankle: a) plantar flexion and b) dorsiflexion.

B. Finite Element Analysis of the Mechanical Structure

Finite element Von Mises stress analyses were conducted on both the U-shaped support component and the main spindle-type support, using AISI 304 stainless steel as the material and applying a load equivalent to the patient's weight (784 N) to validate the mechanical behavior of the selected material (Fig. 5). The results showed that the U-shaped support experienced a minimum stress of 0.527 MPa and a maximum stress of 0.183 MPa [Fig. 5(a)], with a maximum displacement of 1.0361 mm [Fig. 5(b)]. The main spindle-type support registered a minimum stress of 37.91 MPa and a maximum stress of 30.33 MPa [Fig. 5(c)], with a maximum displacement of 1.603×10^{-3} mm [Fig. 5(d)]. Both components exhibited maximum stress values significantly below the yield strength of AISI 304 stainless steel (206.8 MPa), thereby ensuring efficient and safe mechanical performance of the supports under the evaluated loading conditions.

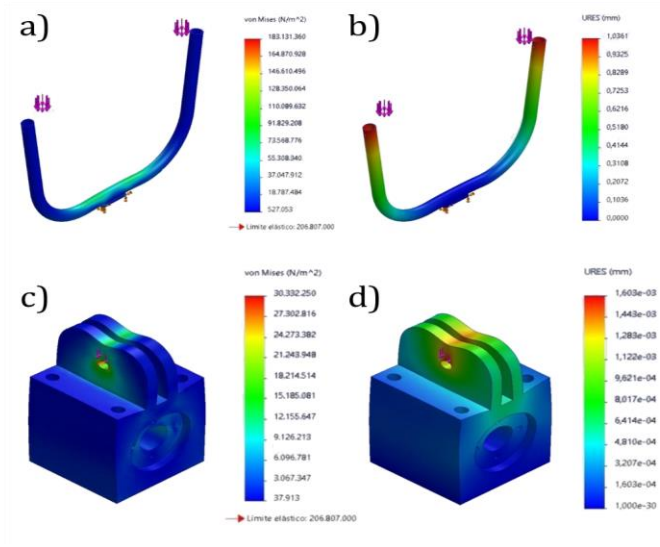

Fig. 5. Finite element analysis of structural components: a) Von mises stress distribution in U-bracket. b) Displacement analysis in U-bracket. c) Von mises stress distribution in main spindle-type support. d) Displacement analysis in main spindle-type support.

C. Electrical and Electronic Prototyping

The main components of the electronic subsystem include: a 5-inch NEXTION NX8048T050 TFT display with a resolution of 800×480 pixels for the HMI interface, powered at 5V with a current consumption of 410 mA and 16MB of FLASH memory; two optical incremental encoders for measuring position and speed through infrared light interruptions; A4988 stepper motor drivers with microstepping capability (1/16) and a current rating of ±2A up to 35V; an SD module compatible with micro SDHC cards up to 32GB via SPI interface with 5V/3.3V level conversion; NEMA 23 bipolar hybrid stepper motors, 56×56 mm in size, with a 1.8° step angle, ±5% accuracy, and an operating temperature range from –20°C to +50°C; and 40 cm T8 trapezoidal lead screws made of AISI 304 stainless steel, with an 8 mm/rev pitch, designed for high-precision linear transmission in automation systems. The electrical subsystem was designed to ensure the safe operation of the robotic system during rehabilitation therapy sessions. For this purpose, it included a power switch, a switching power supply, and an emergency stop button. The electronic and electrical design was carried out using KiCad 7.0, as shown in Fig. 6.

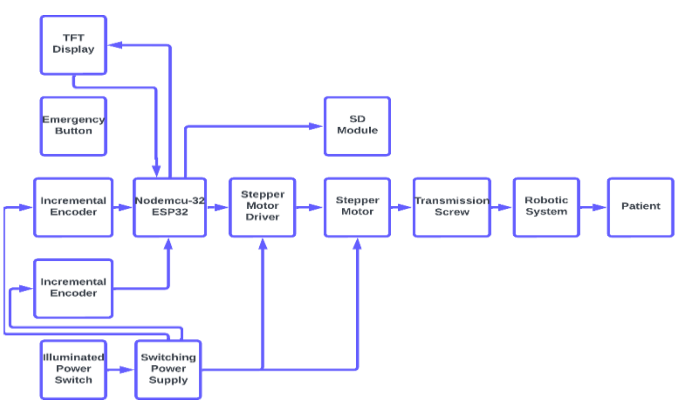

Fig. 6. Electronic circuit design in KiCad 7.0.

D. Simulation of the Electronic-Electrical Subsystem

Fig. 7 illustrates the user interface workflow of the robotic rehabilitation system, implemented using the Wokwi simulator for the ESP-32 microcontroller. The process is divided into three main stages: a) Initial parameter configuration, where the user sets the initial and final joint angles as well as the movement speed (Screens 1–4); b) Therapy type and repetition selection, allowing the user to choose between knee, ankle, or combined therapy modes, along with the desired number of repetitions (Screens 5–8); c) Therapy initiation with real-time monitoring, during which the system displays the progress of repetitions, movement direction, and provides visual feedback through servomotors that simulate joint behavior (Screens 9–10). Safety features include angular limit checks and emergency stops activated by user. This intuitive interface facilitates the customization of therapy according to the specific needs of the patient, while the monitoring system enables continuous tracking of progress throughout the rehabilitation session.

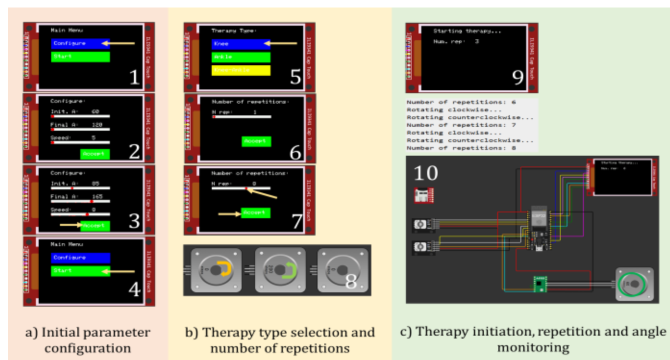

Fig. 7. User interface workflow of the robotic rehabilitation system.

E. Functional Simulation with a Virtual Patient

The model was transferred to the CoppeliaSim environment to simulate the use of the prototype with a virtual patient. For this purpose, a bed was designed and the system was integrated with the virtual patient in a fully supine position. Three rehabilitation modes were implemented: i) full knee extension and flexion, ii) full ankle extension and flexion, and iii) a combined sequence consisting of full knee extension, a three-second pause, full ankle extension and flexion, another three-second pause, and full knee flexion. These movements are illustrated in Fig. 8.

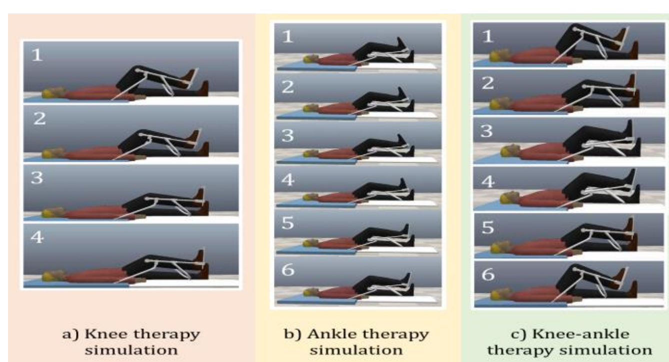

Fig. 8. Rehabilitation modes: a) Only knee therapy simulation. b) Only ankle therapy simulation. c) Knee and ankle therapy simulation.

Fig. 9 display the temporal evolution of joint angles during the rehabilitation therapy simulations in CoppeliaSim, using sinusoidal functions to model the movement of each joint according to the equation $\theta_i(t) = \theta_0 + A_i \sin(2\pi f t + \varphi)$, where $\theta_i(t)$ represents the joint angle, θ_0 the initial position, A_i the amplitude, f the frequency, and φ the phase. In the knee therapy [Fig. 9(a)], the hip oscillates between –50° and 0°, while the knee exhibits an inverse pattern ranging from 0° to 60°, reflecting the natural gait dynamics, and the ankle shows smaller variations between –10° and 0°. The ankle therapy [Fig. 9(b)] follows the equation $\theta_{ankle}(t) = \theta_{ankle,0} - A_{ankle} \sin(2\pi f t + \varphi)$, where the negative sign inverts the oscillation, reaching a minimum of –35° at 20 seconds and increasing to 5° at 70 seconds. The combined knee-ankle therapy (Fig. 10) implements a structured sequence that integrates both models with symmetry around the 150-second mark, beginning with knee therapy, transitioning to ankle therapy, and returning to the knee pattern. This sequencing allows for the distribution of effort across joints, reducing fatigue and optimizing treatment effectiveness through personalized protocols tailored to specific clinical needs.

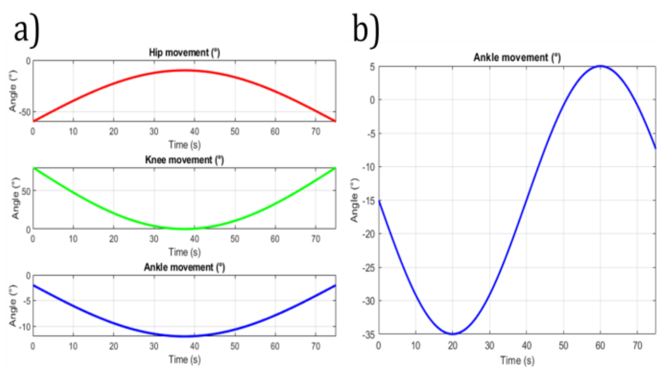

Fig. 9. Joint angles: a) Angles obtained for knee therapy. b) Angles obtained for ankle therapy.

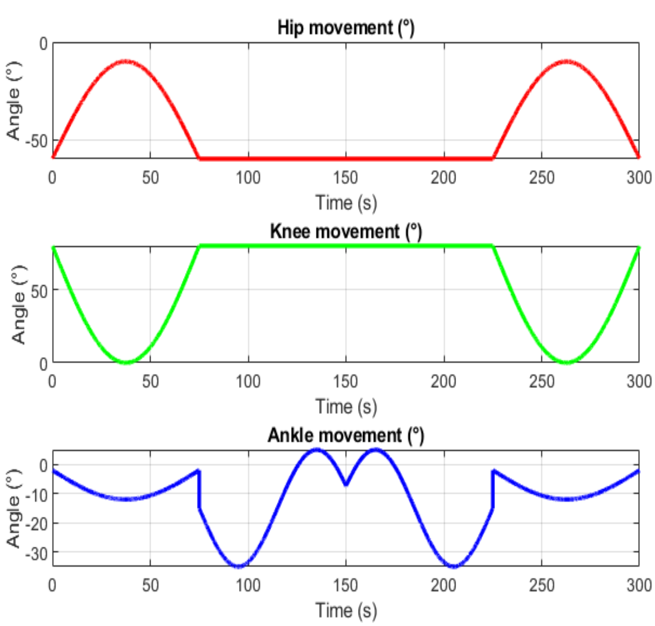

Fig. 10. Angles obtained for knee-ankle therapy.

IV. Experimental Study Approach

A. Data Collection Instruments

To ensure a comprehensive validation of the robotic rehabilitation system, three data collection instruments were implemented at the beginning of the research project. These instruments were specifically designed to assess both the technical requirements and clinical aspects of the lower-limb physical rehabilitation process. The primary data collection tool consisted of a checklist designed to record and monitor the technical and clinical requirements involved in lower-limb physical rehabilitation. This systematic approach ensured that all critical parameters were consistently tracked throughout the entire evaluation phase. Additionally, two specialized observation forms were developed to capture specific system parameters. The first observation form was designed to record the dimensions and maximum weight of the lower limb, as well as the maximum movement speed and torque, along with the response time of the user interface during system simulation. The second observation form focused on evaluating the functional capacity of the robotic system, with the aim of refining its technical specifications and the clinical parameters relevant to physical rehabilitation.

B. Pre-Test and Post-Test Validation

The clinical validation process incorporated both pre-test and post-test questionnaires administered to a specialist in physical rehabilitation, aiming to assess the effectiveness of the proposed system in a systematic and unbiased manner. In this regard, the results of the pre-test questionnaire indicated 100% acceptance across all three evaluated indicators. These results validate the requirements established in the project and simultaneously confirm their alignment with the expectations of the proposed design. Subsequently, following the demonstration and evaluation period, a post-test questionnaire was administered to assess the system's performance after direct observation. In this context, the results revealed 100% acceptance across all indicators within the three evaluated dimensions. Moreover, these findings were corroborated by the rehabilitation physician through the real-time observation of the simulation, thereby validating the effectiveness and functionality of the system in accordance with the requirements defined in the project. Finally, the comprehensive evaluation process demonstrates that the robotic rehabilitation system successfully meets both the technical specifications and the clinical expectations.

Limitations: It is important to acknowledge that the current validation was conducted through simulation using the Wokwi platform and expert consultation, rather than clinical trials with actual patients. While the system demonstrated technical feasibility and received positive feedback from rehabilitation specialists, comprehensive clinical validation with real patients is required to fully assess therapeutic efficacy, safety, and usability under real-world conditions. A clinical implementation phase is planned for 2025–2026 to address these aspects and gather empirical data on patient outcomes.

V. Discussion

The design of the robotic system aligns with previous research that highlights the importance of ergonomic and functional design in rehabilitation devices. For example, Aguirre, J. et al. presented an exoskeleton designed in SolidWorks, emphasizing the importance of selecting appropriate materials and using advanced design techniques to ensure system effectiveness [14]. Similarly, Grijalva, C. developed the design and construction of a device based on Continuous Passive Motion (CPM), demonstrating the positive impact of this methodology on knee rehabilitation [35], [36]. Another relevant precedent is the work of Villanueva, J., who developed a device based on a six-bar mechanism with one degree of freedom (DOF). Through dimensional synthesis and the analysis of several conceptual designs, he was able to determine an optimal and detailed configuration that integrates key components for an efficient rehabilitation device [37]. However, unlikely these single-joint or single-modality approaches, the present system introduces a distinctive multi-modal capability through its three independent therapy modes (knee-only, ankle-only, and integrated knee-ankle exercises), enabling progressive rehabilitation protocols within a single device. These studies support the presented design and emphasize the importance of applying mechanical design and analysis methodologies to ensure that rehabilitation devices are functional, safe, and adapted to the user’s specific needs.

With regard to the simulation component, this study validates its findings through the precedent set by Franco, B., who proposed an innovative design for a passive knee rehabilitation device with a focus on portability, targeting adult patients undergoing surgical interventions to restore joint functionality or those affected by CVA impacting the lower limb. Franco’s work included a review of existing rehabilitation techniques and devices available on the market, and defined the geometric and kinematic conditions necessary to deliver effective, repetitive therapies that support recovery [38], [39]. Additionally, the study considers the research of Jie, H. et al., who emphasize the widespread use of rehabilitation training robots in the Asian market, particularly for lower-limb rehabilitation due to its critical role in human mobility. The authors propose an independently developed robot for ankle and knee rehabilitation and introduce a robot-to-robot connection mode, which represents a significant advancement in the customization and effectiveness of rehabilitation therapies [15]. The present system achieves integrated multi-joint coordination through a unified mechanical structure and synchronized control architecture, eliminating the need for robot-to-robot interfaces and reducing system complexity. Both studies underscore the importance of combining innovative design approaches with biomechanical simulation in order to validate functionality and ensure the effectiveness of rehabilitation devices for patients with reduced mobility. The present work extends beyond these precedents by implementing a comprehensive validation framework that integrates mechanical finite element analysis, kinematic simulation in CoppeliaSim, and electronic control verification in Wokwi.

The quantitative validation of the system performance was achieved through finite element analysis, kinematic simulation, and electronic programming verification. Structural integrity analysis revealed the U-shaped support component withstood 784 N loading with maximum Von Mises stress of 0.183 MPa and displacement of 1.0361 mm, yielding a safety factor of 1,129, while the main spindle-type support demonstrated superior performance with maximum stress of 30.33 MPa and displacement of 1.603×10^{-3} mm, resulting in a safety factor of 6.8. CoppeliaSim kinematic simulations validated the therapeutic motion profiles using sinusoidal functions $\theta_i(t) = \theta_0 + A_i \sin(2\pi ft + \varphi)$, with knee therapy achieving 60° oscillation amplitude (-50° to 0° hip, 0° to 60° knee) and ankle therapy demonstrating -35° to 5° range with position error <0.5°. The electronic subsystem programming, implemented through ESP-32 microcontroller with NEXTION display (800×480 resolution) and A4988 drivers (1/16 microstepping), achieved positioning accuracy of ±0.1125° and user interface response times <0.5 seconds, confirming the integration of mechanical design, motion control algorithms, and human-machine interface for effective rehabilitation therapy execution. Furthermore, the system's use of accessible, open-source simulation tools for validation, combined with low-cost hardware, establishes a replicable development methodology that lowers barriers to entry for resource-constrained rehabilitation research environments.

VI. Conclusion

In the development of this project, the mechanical, electronic, electrical, and software subsystems of the robotic lower-limb rehabilitation system were designed and evaluated. In addition, simulations were conducted to validate the performance of each subsystem, confirming their functionality and compliance with the established requirements. This work presents a comprehensive simulation-based approach to designing an integrated robotic rehabilitation system that addresses the gap between conventional therapy limitations and the need for accessible, patient-center lower-limb rehabilitation. The mechanical subsystem ensured the safe and stable operation of the robotic system, incorporating an adjustable design capable of performing three therapy modes: knee-only movements (flexion and extension), ankle-only movements (plantar flexion and dorsiflexion), and an integrated mode combining knee and ankle exercises. Mechanical simulations confirmed the appropriate material selection and the structural strength of the system under applied rehabilitation loads. The electronic and electrical subsystems were designed in an integrated manner to control the movements of the robotic system and ensure continuous power supply. Simulations conducted in Wokwi validated the precision and stability of the control system, as well as its ability to maintain uninterrupted operation during rehabilitation sessions. The software subsystem provided an intuitive user interface capable of configuring parameters in real-time, storing session data, and transmitting it for clinical analysis. The simulation of this subsystem demonstrated its efficiency in managing information and dynamically modifying therapeutic parameters.

Furthermore, the integration and validation of the system through simulations in MATLAB and CoppeliaSim allowed for the evaluation of its performance in rehabilitation exercises with a virtual patient, demonstrating its feasibility for supporting physical therapy. The primary contribution of this research lies in the holistic design and virtual validation of a multi-modal rehabilitation system that combines mechanical adaptability, precise electronic control, and user-friendly software integration, validated through both engineering simulations and clinical expert evaluation.

It is concluded that the system has the potential to optimize patient recovery through precise, repetitive, and customizable therapies, thereby contributing significantly to quality of life. The clinical evaluation conducted by specialists in physical rehabilitation confirmed the usefulness of the robotic system, particularly for patients with spastic hemiplegia in the subacute and chronic phases of neurological sequelae. Moreover, the design facilitates self-administration in patients who retain cognitive function after a CVA, enhancing their autonomy during treatment. Specialists also highlighted the system's potential to optimize conventional therapy, especially in assisted mobilization, by automating parameters such as time, speed, and torque, thus reducing the physical burden on therapists. Accordingly, the robotic system offers significant advantages in terms of efficiency, reducing the physical strain on healthcare personnel while improving the quality and frequency of rehabilitation sessions. At the same time, it enables home-based therapy, enhancing accessibility and continuity of care. While its positive impact on reducing healthcare costs is evident, further studies are recommended to assess its effectiveness in real-world clinical settings.

However, several constraints must be acknowledged. First, this study relies entirely on simulation-based validation; the system has not yet been physically implemented or tested with real patients. Second, the clinical evaluation was conducted through expert consultation rather than controlled trials, limiting empirical evidence of therapeutic efficacy. Third, long-term durability, user acceptance, and cost-effectiveness in diverse healthcare settings remain to be investigated. Additionally, real-world deployment will face practical challenges including: ensuring regulatory compliance and safety certifications for medical devices, developing training protocols for healthcare personnel and patients, addressing potential technical failures during unsupervised home use, and adapting the system to diverse patient anthropometries and pathological conditions beyond the initially targeted spastic hemiplegia cases.

Despite these limitations, the scientific value of this work resides in its systematic integration of engineering design with clinical needs assessment, providing a validated framework for future physical prototyping. Practically, the system's modular design, home-use capability, and therapist workload reduction position it as a promising solution for scaling rehabilitation access in resource-constrained settings.

As future work, the physical implementation of the subsystems is projected for the 2025–2026 period, incorporating ergonomic, comfort, and safety considerations. Subsequently, the system will be validated in collaboration with physical rehabilitation physicians and an adult volunteer patient.

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