SSRG International Journal of Mechanical Engineering
ISSN: 2348-8360/ https://doi.org/10.14445/23488360/IJME-V12I11P104

Volume 12 Issue 11, 33-47, November 2025

Original Article

Design and Comparative Analysis of a Modular Orthosis for Pediatric Lower Limb Rehabilitation

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Received: 05 September 2025 Revised: 06 October 2025 Accepted: 07 November 2025 Published: 28 November 2025

Abstract - *This paper addresses the design of pediatric orthoses for children with cerebral palsy, considering that most current solutions are adaptations of adult models that do not address the anatomical and biomechanical particularities of children. A modular knee orthosis is proposed, ergonomic, lightweight, and primarily active, manufacturable through additive manufacturing, aimed at children aged 4 to 11 years. The design includes the option of integrating a proportional control system to assist or limit flexion-extension movement, adaptable to sensor signals based on the user's gait pattern. The CAD model was validated through structural analysis simulations, which recorded a maximum stress of 452.3 MPa and a safety factor of 15, indicating that the structure could withstand a stress of up to 6,784 MPa without compromising its integrity. Displacement was practically zero, demonstrating high rigidity and stability. The control system exhibited stable behavior, with minimal oscillations, ensuring smooth and comfortable movements. The results confirm that the proposed orthosis is safe, functionally stable, and economically viable, with the potential to improve quality of life and enhance pediatric rehabilitation.*

Keywords *- Pediatric Orthoses, Cerebral Palsy, Pediatric Rehabilitation.*

1. Introduction

In the last decade, rehabilitation and assistance for people with motor disabilities have received growing attention within clinical and engineering research, driven by the global increase in neurological and musculoskeletal disorders. Among these, Cerebral Palsy (CP) stands out as one of the most prevalent causes of permanent motor disability in children, characterized by spasticity, poor muscle coordination, and gait irregularities that directly affect mobility and autonomy. This condition not only limits independence but also demands continuous physical therapy and long-term orthotic support.

Among these devices, orthoses have proven to be fundamental tools in the treatment of motor disorders, especially in conditions such as Cerebral Palsy (CP). Their clinical use has been consolidated thanks to their ability to improve postural stability, control musculoskeletal deformities, and facilitate more functional gait patterns, which is essential for increasing patient autonomy [2, 3].

Conventional orthopedic solutions for children with CP are often scaled-down versions of adult models, designed without consideration for pediatric anatomy, body proportions, or comfort requirements. As a result, many of these devices have a poor fit, limited range of motion, and low user tolerance, leading to lower adherence during rehabilitation. Despite advances in adult-oriented orthopedic systems, current pediatric designs still face significant challenges in terms of ergonomics, adaptability, and comfort.

This situation reveals a clear research gap: while numerous studies have improved control strategies and mechanical efficiency for adult orthoses [2, 3], few have addressed the ergonomic and structural needs of pediatric users, whose growth and biomechanical dynamics require constant adaptability. Therefore, the main problem addressed in this study is the lack of a modular, lightweight, and ergonomically optimized knee orthosis specifically developed for children with cerebral palsy - one that can adapt to growth while maintaining structural safety and comfort during rehabilitation.

In this context, this research proposes the development and computational validation of a modular pediatric knee orthosis, designed to be adjustable, safe, and compatible with additive manufacturing processes. The proposal seeks to fill the gap between current clinical needs and available

orthopedic technology, combining ergonomic design, modular adaptability, and the optional integration of low-complexity active control components.

Orthoses prescribed under the biomechanical paradigm focus on preventing inappropriate joint movements and passively or actively correcting misalignments that compromise gait biomechanics. Instrumented gait analysis has shown that rigid AFOs (Ankle-Foot Orthoses) directly influence the reaction forces acting on the body during standing and the gait cycle, modifying both the kinematics and kinetics of the lower extremities [4]. This modulation of force not only has immediate corrective effects but also helps prevent the development of contractures and long-term structural deformities.

In the specific context of functional rehabilitation for children with cerebral palsy, the use of orthoses has been widely recognized as an integral part of various therapeutic programs [5, 6]. Numerous studies highlight the value of sustained use of orthoses in combination with intensive physical therapy as a means of maintaining and enhancing motor gains throughout growth, allowing interventions on gait biomechanics at critical stages of neuromotor development.

This not only contributes to improving the child's functional independence but also facilitates their integration into school, recreational, and social activities, essential factors for their quality of life. However, available evidence regarding the effectiveness of these interventions, especially in terms of long-term outcomes and dynamic adaptation to the needs of the growing user, remains limited [7].

One of the main problems identified is that many of the solutions available on the market were originally developed for adults and then scaled up for pediatric patients [8]. This approach fails to adequately consider the anatomical, cognitive, and biomechanical differences inherent in childhood, as well as the particular emotional and psychosocial needs of this age group [2, 7].

As a result, poorly tolerated devices have been introduced into the clinical setting, with low user adherence and limited functional effectiveness in real-life settings, significantly limiting the positive impact they could offer on the daily lives of pediatric patients.

Adding to this situation are significant methodological limitations in existing studies. Much of the available scientific literature features small sample sizes, a lack of longitudinal follow-up to assess the sustained impact of the intervention, a lack of standardized biomechanical criteria, and, in particular, a low representation of children in early stages of motor development. [4] These shortcomings hinder the generation of solid evidence to guide the design of new orthotic solutions and the development of clinical guidelines based on robust evidence. On the other hand, direct evaluations of users and caregivers have highlighted the urgent need for more ergonomic, modular, and adaptable solutions.

For example, it has been identified that traditional rigid knee locking systems, although biomechanically effective, limit essential daily activities such as sitting, kneeling, or walking on uneven terrain, also generating thermal and mechanical discomfort during prolonged use.

These practical limitations, coupled with cultural and environmental factors specific to specific contexts, for example, in developing countries where uneven surfaces and high temperatures are common, underscore the importance of adopting a user-centered approach, where the active participation of patients and therapists in orthotic design is a key element.

The literature reviewed shows that, despite the clinical and technological relevance of this issue, studies focused exclusively on pediatric orthoses remain limited in both number and methodological depth. Most current research prioritizes adult exoskeletons and lower-limb assistive systems, often overlooking the needs of the pediatric population, whose needs differ substantially in terms of scale, growth adaptability, and long-term usability. Consequently, the available evidence still fails to provide sufficient background on pediatric-specific mechanical design, user comfort, and modular adaptability.

Most of the devices currently in use have been designed with adult requirements in mind and secondarily adapted for pediatric patients, as seen in the works of Kyung Kim, who analyzed the assistive characteristics of a knee orthosis designed for extension movement, controlled by Muscle Stiffness Force feedback (MSF) [9]; and Gregory S. Sawicki and Daniel P. Ferris, who evaluated the performance of a prototype KAFO (Knee-Ankle-Foot Orthosis) powered by artificial pneumatic muscles during human gait [10]. Similarly, A.J. Young, T.A. Kuiken, and L.J. Hargrove integrated EMG (Electromyography) signals with mechanical sensors using a DBN approach to improve movement intent detection in powered prostheses [11].

Other important contributions have focused on optimizing performance and feedback, such as the work of Jeanne C. Patzkowski, who compared three different types of orthoses to determine their functional influence on patients with ankle weakness [12], or the brilliant knee brace developed by Wei-Chun Hsu, capable of monitoring muscle activity in real time using EMG sensors [13].

The design by Osman Ulkir et al. introduced Pneumatic Actuation Foot Orthosis (PAFO) modeled through SimMechanics, which demonstrated its effectiveness as a predictive simulation approach prior to manufacturing [14].

However, only a few studies-such as those by Patané et al. [15] and Villa-Parra et al. [16]-directly address pediatric users with cerebral palsy, combining active control and biomechanical adaptation. Even in these cases, the modularity and ergonomic adaptability to growth stages remain insufficiently explored.

Additionally, research by Vucina et al. [17] in the field of kinematics highlights the biomechanical complexity of stair-climbing movements, emphasizing the importance of joint alignment and load distribution, which are essential for future pediatric orthotic designs.

Based on this evidence, it becomes clear that the literature lacks comprehensive analyses that integrate ergonomic design, structural flexibility, and user-centered adaptability for pediatric rehabilitation, justifying the development of a modular, growth-compatible knee orthosis as proposed in this study.

In response to the limitations identified in the design and application of pediatric orthoses, a modular knee orthosis was developed, designed specifically for children between the ages of 4 and 11. The device is designed as an active, lightweight system, compatible with additive manufacturing processes, capable of being functional from its basic version. However, it has been designed to allow for the optional integration of low-complexity active components, such as myoelectric sensors or non-invasive vibration modules. This flexibility offers the possibility of progressively expanding its functionality without compromising the simplicity, ergonomics, or adaptability of the base system [9, 18].

The overall objective of this research is to conceptually design a computationally validated knee orthosis that meets the ergonomic, clinical, and functional requirements of pediatric users. To achieve this, several specific objectives have been defined: (i) to identify and prioritize the technical and clinical needs associated with the use of orthoses in children with cerebral palsy; (ii) to critically analyze the most advanced current proposals, recognizing both their contributions and their limitations; (iii) to structure a functional solution by developing functional and morphological matrices that allow different viable combinations to be evaluated according to predefined criteria; (iv) develop a CAD model of the proposed design, accompanied by finite element structural simulations to verify its mechanical feasibility; and, finally, (v) establish guidelines for the future integration of simple active systems without compromising the structural integrity or ergonomics of the device [1, 15].

Furthermore, the development of pediatric lower limb orthoses is closely related to the advances achieved in the field of human lower limb exoskeletons, whose research has focused on refining control strategies, sensing modalities, perception, hardware design, and actuation systems. Control strategies such as impedance-based, model predictive, and adaptive control have demonstrated high potential for achieving natural and synchronized human–robot interaction, which is essential in pediatric applications where safety and comfort are critical.

Likewise, modern sensing modalities—including Electromyography (EMG), Inertial Measurement Units (IMU), and force sensors—enable precise detection of gait phases and muscular intent, improving the responsiveness of active assistance systems. The perception mechanisms derived from these modalities provide valuable feedback for individualized rehabilitation.

On the hardware side, current trends emphasize lightweight modular structures, energy-efficient actuators (such as brushless DC motors and pneumatic systems), and ergonomic designs adaptable to growth. Integrating these technological approaches into pediatric orthotic systems strengthens the connection between biomechanical rehabilitation and robotic assistive technology, promoting safer, more effective, and user-centered solutions.

2. Materials and Methods

The methodology adopted for the development of the orthosis is based on a systematic approach to conceptual design proposed by Pahl and Beitz [19], widely used in mechanical engineering. This approach facilitates structured decision-making based on real clinical and technical needs, allowing the incorporation of low-complexity active control elements in future stages in a modular way.

The study began with the identification of needs, based on a review of clinical and technical literature on pediatric orthoses for children with spastic cerebral palsy between the ages of 4 and 11 years.

The age of 6 years is selected as the lower limit to ensure sufficient attention span to focus on specific tasks, sufficient communication skills to follow a series of commands, and sufficient motor skills, all of which are important for compromised rehabilitation therapy as well as the effective use of a motorized orthosis.

The upper age limit of 11 years is selected because children around that age are tall enough (about 150 to 155 cm on average [20, 21] to consider using one of the commercially available orthoses for adults [6]. These values were used in conjunction with average weight and height data reported in [22], and verified with biomechanical proportions validated in adults and extrapolated to the pediatric population based on 3D scanning and DEXA studies [22, 23].

Table 1. Weight and height of the target population

Age	Sex	Mass (kg)	Height (cm)	Thigh Mass (kg)	Leg Mass (kg)	Longitude. Thigh (cm)	Leg Length (cm)
4	-	16	102	1.6432	0.6928	23.664	28.152
6	M	24.3	119.3	2.49561	1.05219	27.6776	32.9268
6	F	23.6	119.2	2.42372	1.02188	27.6544	32.8992
8	M	31.3	131.6	3.21451	1.35529	30.5312	36.3216
8	F	31.9	131.3	3.27613	1.38127	30.4616	36.2388
10	M	30	137	3.081	1.299	31.784	37.812
10	F	30	137	3.081	1.299	31.784	37.812
11	M	46.6	149.9	4.78582	2.01778	34.7768	41.3724
11	F	46.6	150.4	7.87825	2.05675	34.8928	41.5104

Note: M = male, F = female; thigh and leg masses estimated as fixed percentages of total body mass; lengths derived from anthropometric data.

This review (Table 1) included scientific articles, anthropometric databases (CDC, WHO), and specific clinical guidelines [2], which allowed the requirements to be classified into five dimensions.

Functional: stabilise the knee joint during walking, allowing a physiological range of motion.

- Mechanical: resistance to bending/torsional loads with rigidity adjusted to the gait cycle.
- Ergonomic: low weight, comfort, and ease of use for caregivers.
- Growth/modularity: longitudinal and circumferential adaptability without requiring total replacement.
- Manufacturing and accessibility: compatibility with locally available technologies and materials

Subsequently, an analysis of the state of the art was carried out to identify the main limitations of the current proposals: excessive use of active systems that are not tolerable in the child population, poor modularity, and designs derived from adaptations of adult orthoses [9, 16]. This analysis served to define the technical objective of the design: an active, lightweight modular orthosis with the ability to functionally integrate active modules without compromising structural simplicity.

From a biomechanical perspective, the infant's leg was modeled as a rotational mass-inertia system, where the knee joint acts as a spinning axis. When the orthosis is attached, the whole behaves as a physical system with parameters such as total mass, moment of inertia, joint stiffness (K), viscous friction (B), and possible external torques (τ).

$$J\ddot{\theta} = -\tau_g \cos\theta - K(\theta - \theta_r) - A\text{sign}(\dot{\theta}) - B\dot{\theta} + \tau \qquad (1)$$

Where: J – moment of inertia of the leg–orthosis system; θ – knee joint angle; $\dot{\theta}$– angular velocity; $\ddot{\theta}$ – angular acceleration; τ_g – gravitational torque amplitude; K – elastic stiffness constant; θ_r – rest/equilibrium angle; A – dry friction coefficient; $sign(\dot{\theta})$– sign function of angular velocity; B – viscous damping coefficient; τ – external applied torque.

This dynamic equation accounts for gravitational torque, elastic stiffness, dry and viscous friction, and potential external actuation.

To identify the parameters of the dynamic equation that models the leg-orthosis interaction, previous studies were used to validate the estimation of moment of inertia, center of mass, and friction by experimental or segmental methods [9, 22, 23].

Elastic stiffness, viscous friction, and dry friction were taken as a reference from tests with active pediatric orthoses that replicate similar conditions of use [20]. These values allow a precise approximation of the dynamic behavior of the infant leg with and without orthotic assistance.

2.1. Evaluation of Orthotic Alternatives

In order to analyze in a structured way the different orthosis proposals found in the literature, a series of comparative matrices was developed that allowed for classifying, weighing, and evaluating the functional, technical, and economic characteristics of each design. This methodological approach made it possible to transform qualitative observations into quantifiable data, thus facilitating cross-sectional analysis and the extraction of common patterns between models [19].

A set of 10 proposals for active and passive orthoses extracted from the specialized literature was comparatively analyzed [1, 13]. Each orthotic alternative (V1 to V10) was analyzed based on the characteristics described in their respective proposal, allowing them to reconstruct their functional architecture and compare the technical solutions adopted for each function.

Table 2. Design function comparison matrix

Key Function	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10
Load-bearing structure	PP foot	CF leg-thigh	Split frame	CF strut	3D hip-thigh-leg	Alu + pulleys	SS + PP	Thermo boot	Webbing	Modular 3D child
Mechanical joint	Free hinge A-K	Hinge + pneumatic	Hingeless + elastic	Elec hip-knee	Pulleys + stepper	3DOF motors	Servo + VCA	Bellows tire	1DOF knee	RSEA knee-ankle
Subjection	Shoe + lace	Adj. straps	PTB cuff + distal	Anatomical	Belts + pulleys	Adj. straps	Velcro + sensors	Velcro adj.	Straps	Straps + insoles
Active control	Myoelectric	MSF feedback	None	PD + sensors	Step + Arduino	EC-45 + Harmonic	EEG + sEMG + FSR	Manual pneumatic	DC + PD motor	Master-slave
Growth adaptability	No	No	No	Parametric 3D	Modulate	Telescopic sizes	No	No	No	Configurable
Aesthetics /comfort	No	No	Attractive	Compact + light	Portable	Light 7–17 yrs	Portable + secure	No	No	Light + ergonomic

Note: Abbreviations refer to the primary material, mechanism, or control type used in each variant. This matrix summarizes the structural, mechanical, and functional characteristics of ten orthotic designs to facilitate direct comparison. Terms such as "CF" (carbon fiber), "PP" (polypropylene), and "3DOF" (three degrees of freedom) are used for brevity.

A morphological matrix was developed that allowed the identification and classification of the key components present in each of the ten orthosis proposals analyzed. This matrix was organized around six fundamental functions of the biomechanical design of lower limb orthoses:

- Load-bearing structure: defines the material and configuration of the main frame that supports the user's load.
- Mechanical joint: specifies the type of joint used between segments, whether passive, active, or elastic.
- Fastening: mechanism by which the device is anatomically adjusted to the user (straps, clips, laces, etc.).
- Active Control (Optional): Type of assistance used, which may include sensors, actuators, and control strategies.
- Adaptability to growth: the degree to which the design allows it to adjust to the anthropometric changes of the pediatric user.
- Aesthetics and visual comfort: visual perception, weight, shapes, and emotional acceptance, especially relevant in children.

As part of the conceptual evaluation process of the orthosis proposals (Table 2), a methodology based on the VDI 2225 standard, widely used in design engineering for structured decision making during the early stages of product development, was implemented.

This methodology allows technical solutions to be compared using weighted criteria and multi-criteria evaluations, transforming qualitative information into quantifiable and justified decisions [19]. In this study, five technical criteria were defined, which were selected based on the most relevant clinical, ergonomic, and manufacturing requirements in the design of modular orthoses for child rehabilitation. Each criterion was evaluated on a qualitative scale from 0 to 4, where 0 represents non-compliance with the criterion and 4 represents outstanding compliance. In addition, each one was assigned a weight "g" that reflects its relative impact on the functional and technical quality of the final product.

Following the proposed systematic methodology, the study also considers its practical and economic feasibility, particularly when it comes to biomedical devices intended for the pediatric population in real clinical contexts. An economic evaluation matrix was built that allowed identifying the strengths and limitations of each proposal from the perspective of the resources necessary for its production, maintenance, and scalability.

2.2. Selection of the Load-Bearing Structure and Mechanical Components

Based on the values obtained in the technical (Table 3) and economic (Table 4) matrices, a cross-analysis was carried out aimed at selecting a final design and critically evaluating the key functions that make up each orthosis.

Among the most relevant findings, it is highlighted that the models that integrate functions such as light and modular structure, open control, and simple active articulation demonstrated a superior balance between performance and cost [24]. With this, it is proposed that the final design of the pediatric modular orthosis considers the following combination of key functions.

Table 3. Technical criteria evaluation matrix

Technical Criteria	Weight (g)	V1	V2	V3	V4	V5	V6	V7	V8	V9
Simplicity of design	4	1	3	4	3	2	3	1	4	2
Structural strength	5	4	3	4	3	3	3	4	3	3
Ergonomics and comfort of use	4	2	3	3	4	3	3	2	2	2
Modularity/adaptability to growth	5	1	0	0	4	4	4	0	0	0
Ease of assembly and maintenance	3	2	3	4	3	5	5	1	4	2
Weighted sum (Σ p·g)		43	48	60	72	64	68	35	51	37
Ideal sum (p max = 4)	84	=	=	=	=	=	=	=	=	=
Technical Value Xi	1	0.512	0.571	0.714	0.857	0.762	0.810	0.417	0.607	0.440

Note: Evaluation based on weighted scores for each criterion; Xi = technical value.

Table 4. Economic criteria evaluation matrix

Economic Criterion	Weight (g)	V1	V2	V3	V4	V5	V6	V7	V8	V9
Material Cost	5	1	3	1	2	3	2	1	4	1
Fabrication/Assembly Cost	4	1	3	2	2	2	2	1	4	1
Maintenance Cost	3	1	3	4	3	3	3	1	4	2
Possibility of partial replacement	3	0	2	1	4	4	4	1	2	1
External technological dependence	2	0	3	4	2	3	2	0	4	0
Weighted sum (Σ p·g)		12	48	36	43	50	43	15	62	18
Ideal sum (p max = 4)	68	=	=	=	=	=	=	=	=	=
Yi Economic Value	1	0.176	0.706	0.529	0.632	0.735	0.632	0.221	0.912	0.265

Note: Scores weighted by economic criterion importance; Yi = economic value.

The selected load-bearing structure is based on a modular, segmented, and lightweight design, taking as a reference the V4, V6, and V10 proposals, which stand out for their anatomical and clinical orientation. This type of configuration facilitates assembly, reduces pressure points, and improves ergonomics, key aspects for pediatric orthoses where comfort is decisive for prolonged use. Although these proposals do not specify the materials, the functional approach suggests the use of medium-rigidity structural plastics or lightweight composites, suitable for supporting moderate loads without compromising comfort. This configuration also allows for easy assembly and maintenance, which is important in clinical settings. As for the mechanical articulation, a motorized system with a stepper motor and mechanical reducer (V5 proposal) is adopted, which stands out for its simplicity, low energy consumption, and ease of integration with open platforms, in addition to offering stable control and a precise functional response in assisted movements. For fastening, adjustable Velcro straps combined with soft support insoles (V2, V4, V6, and V10) are chosen, as they provide a secure anatomical fit, are economical, easy to put on, and compatible with different sizes, which is crucial in pediatric patients in the growth phase.

In terms of active control, an open control system based on FSR (force-sensitive resistors) foot sensors has been chosen (proposals V4, V5, V6, and V10). This system stands out for being accessible, flexible, and having a large support community, which facilitates future modifications or custom adaptations.

The foot sensors provide information on pressure distribution during walking, allowing for the implementation of progressive assistance strategies, adjusting support levels according to the patient's progress. This feature is handy in pediatric rehabilitation programs, where muscle response varies significantly with growth.

To ensure adaptability to growth, priority is given to a modular design with telescopic or resizable segments using parametric CAD (V4, V6, and V10). This solution allows the segments to be lengthened or adjusted as the child grows, avoiding frequent replacements and prolonging the clinical life of the device. In addition, this modularity facilitates quick repairs and replacement of specific components, reducing maintenance costs and promoting availability in healthcare centers.

Finally, aesthetics and visual acceptance are considered strategic factors in increasing treatment adherence in pediatric patients. Based on proposal V10, a case with soft shapes, a lightweight design, and a friendly appearance is proposed, with the aim of building trust and reducing psychological rejection of the device. While functionality is a priority, an attractive visual design, with striking or personalized colors, can encourage the child to wear the device consistently, which is essential for progress in rehabilitation.

Weight reduction and ergonomics also contribute to this acceptance, as a device that is more comfortable and easier to integrate into daily activities improves the perception of functional independence. Taken together, these technical decisions seek not only to optimize the mechanical and clinical performance of the device but also to ensure its practical, economic, and psychological viability in a pediatric context.

2.3. Development of the 3D Three-Dimensional Model

A three-dimensional model of the pediatric knee orthosis was developed using CAD software, based on the results obtained through morphological analysis and the technical and economic evaluation of the different proposals. The final design corresponds to an adjustable modular solution, aimed at facilitating both adaptation to the patient's growth and manufacturing by conventional or assisted means [1, 2].

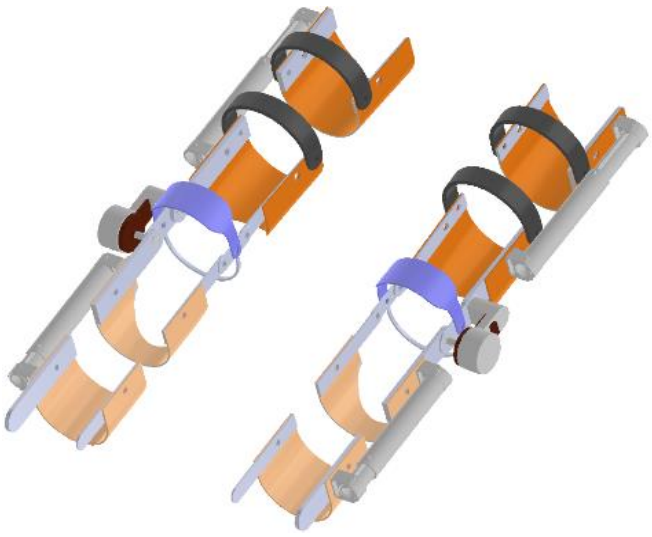

Fig. 1 Model of the proposed orthosis structure

Figure 1 shows the three-dimensional model generated. The design incorporates the following key elements:

- Modular load-bearing structure: Composed of height-adjustable segments, with mechanical couplings that allow it to adapt to different thigh and leg lengths. This approach has been supported in previous research for its ability to adapt to child growth without compromising stability [6, 25].
- Anatomical shells: The orange and peach sections represent the thigh and leg supports. They are designed to properly distribute the load and offer comfort to the user, integrating padded fastening straps (in black). The ergonomic approach is influenced by previous recommendations on pediatric orthopedic devices [1].
- Articulated hinge with actuator: A motorized mechanical joint is integrated, located at knee height, which allows controlled flexion and extension movements. This joint is designed to incorporate a Maxon EC-45 motor with a reducer, a choice validated for its efficiency and use in active orthoses [3, 25].
- Sensor mounts: The design geometry considers mounting zones for FSR sensors on the sole or under the orthosis, and for EMG sensors at the interface with the thigh. This approach seeks to emulate modern implementations of myoelectric and pressure control [9, 11].
- Compatibility with biomechanical tests: The model accommodates spaces for future instrumentation or adjustments, enabling kinematic or torque studies to be carried out, which are instrumental in clinical or research applications.

The three-dimensional model was dimensioned using pediatric anthropometric data from children aged 4 to 11 years, establishing an adjustable total length of 20 to 40 cm that allows for adaptation to the patient's growth through modular segments. The anatomical supports, designed to adapt to the shape of the thigh and leg, were optimized to improve load distribution and provide greater comfort to the wearer. The load-bearing structure was designed to maintain a balance between rigidity and lightness, reaching a total mass of 2,234 kg, with the aim of minimizing fatigue during prolonged use.

The load-bearing structure of the orthosis, as well as the telescopic tubes that allow adaptability to the patient's growth, were manufactured in 6061 aluminum, a material widely used in medical devices for its combination of lightness and resistance, which allowed the overall weight of the system to be reduced without compromising structural stability. The choice of this material also responded to its commercial availability and the ease of manufacture through conventional processes such as machining or assisted cutting. On the other hand, the fastening bracelets and straps were made of rubber, silicone, and polypropylene, prioritizing in their selection the comfort of the user during prolonged use, safety in direct contact with the pediatric skin, and the possibility of making

quick and progressive adjustments. These materials, due to their flexibility and ease of handling, adapt to the anatomical shapes of the thigh and leg, thereby improving pressure distribution and reducing excessive friction points. Finally, the definition of these materials enabled the development of structural analysis simulations with greater precision, ensuring that the model meets the functional requirements and supports the expected loads under normal operating conditions.

2.4. Control System and Sensors

The control system designed for the paediatric orthosis is based on a hybrid scheme based on the processing of signals from FSR (Force Sensing Resistor) and EMG (Surface Electromyography) sensors, with the aim of activating the motorised joint in a coordinated and safe manner. This design seeks to simulate a natural assisted gait pattern, instrumental in pediatric rehabilitation contexts [13, 15].

2.5. Sensory Input and Logic Activation

The system begins with the acquisition of two signals: The FSR signal represents plantar pressure. A logical comparison (>0.5) is used to identify the stance phase in the gait. This threshold has been taken as a reference value for activation during foot contact with the ground, in line with previous proposals for orthopaedic activation systems.

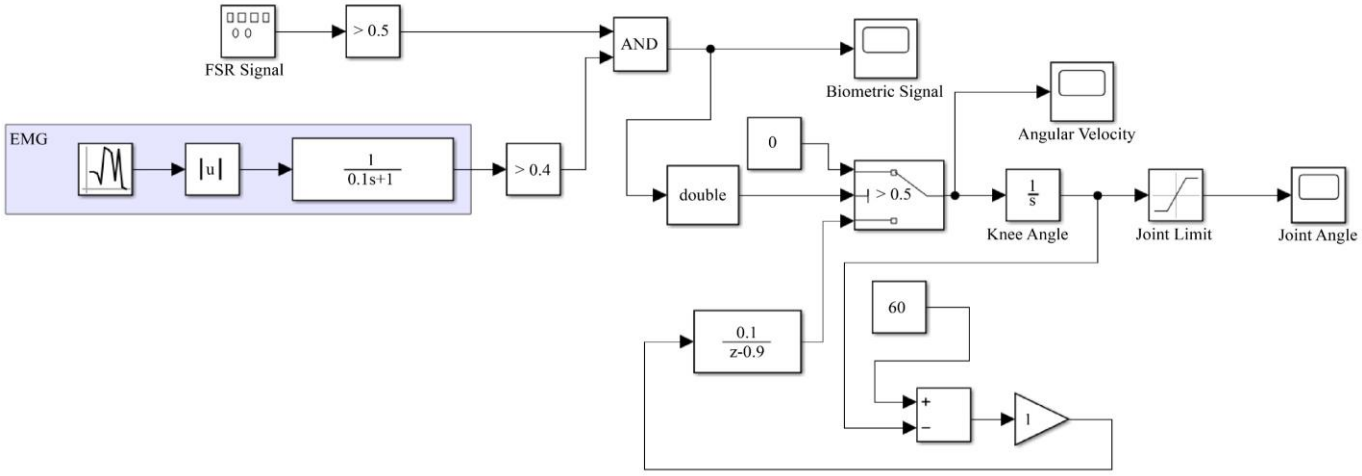

Fig. 2 Simulated control system for the proposed model

The EMG signal, which is captured from the quadriceps or related muscles, is rectified and filtered by a discrete low-pass transfer function. Then, it is compared to a threshold (>0.4) to detect muscle intention. This approach is common in myoelectric orthotic systems.

Both signals are evaluated by means of an and (Figure 2) block, so that the joint is only activated when there is plantar contact and a muscle signal, guaranteeing safe and contextualized behavior.

2.6. Motion Generation

When the activation conditions are met, the system generates a joint velocity profile. A constant base speed value (60 °/s) is used if the system is activated, and 0 if it is not, by means of a Switch block. The velocity signal is integrated to obtain the gross joint angle, which then passes through a saturation block that limits the range of 0° (total extension) and 140° (maximum permissible flexion) according to physiological values [17].

2.7. Adaptive Cruise Control

In addition, a logic has been integrated to allow dynamic modulation of the speed as a function of error with respect to the desired angle (usually 90° for controlled partial bending). The filtered EMG signal is fed into a proportional control branch that calculates the difference with the desired value. The result is used as a scale factor of angular velocity, allowing adaptive accelerations and decelerations, useful for dynamic adjustments according to the user's level of effort.

3. Results and Discussion

The analysis of results has been divided into two main sections: the first related to the mechanical and structural evaluation of the orthosis under different load conditions, and the second linked to functional and control behavior. Finally, technical-economic considerations are incorporated that validate the viability of the design.

3.1. Structural Analysis.

3.1.1. Evaluation under Gravitational Load

The first simulation focused exclusively on the action of gravity on the weight of the device itself, without yet considering body weight or active movements. This preliminary analysis was essential to determine the intrinsic rigidity of the structure and validate that, under resting conditions, there would be no deformations that would affect the anatomical fit.

The results obtained, illustrated in Figure 3a (stresses) and Figure 3b (displacements), showed that the maximum stresses are considerably lower compared to the permissible limits of the material, which is indicative of an efficient design with intentional structural oversizing to increase safety. The displacements recorded are practically negligible, which ensures that the orthosis will maintain stable joint alignment even during long periods of use.

An important point is that the low magnitude of the stresses implies that the structure will not be exposed to premature fatigue processes or cyclical stresses relevant to its own weight. This is critical in pediatric orthotic devices, as they are expected to be worn for extended periods and subjected to repetitive cycles of donning and doffing. In summary, this analysis confirms that the structure, even under passive conditions, offers high reliability and a long service life.

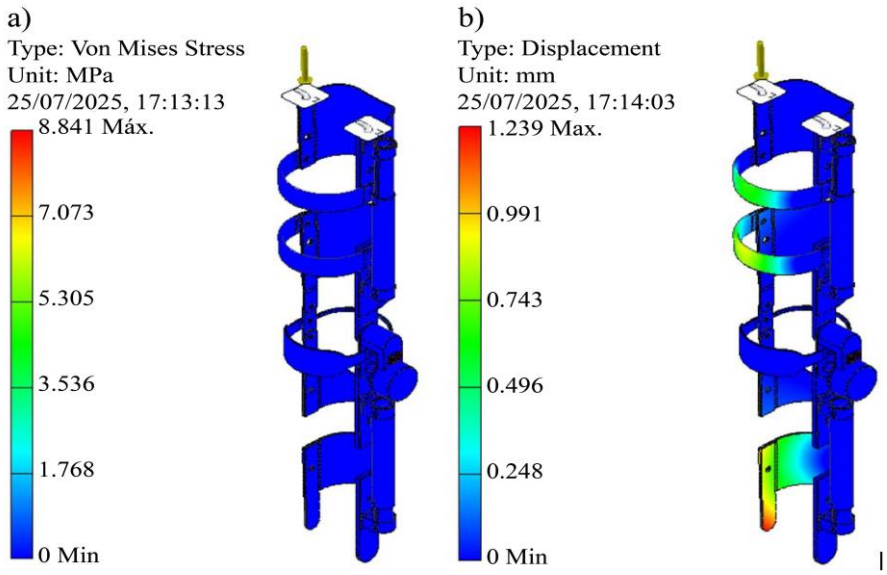

Fig. 3 Structural analysis without user load (a) Von Mises, and (b) Displa.

3.1.2. Evaluation under Axial Load Simulating Body Weight

Once the basic stiffness was validated, simulations were carried out considering the axial load generated by body weight, evaluating the adaptability of the orthosis to different stages of growth. To this end, two case studies were defined:

Case B1: Lower weight children (Figure 4a – stresses, Figure 4b – displacements).
Case B2: Heavier children (Figure 4c – tensions, Figure 4d – displacements).

In both cases, the Von Mises stresses remained below the yield strength of the material (Table 5), confirming that the structure maintains its integrity under the actual loads of use.

However, in Case B2, a notable increase in tensions was observed in the joint area, which was foreseeable due to the concentration of stresses in the contact area between the lateral support and the joint. Even so, these values still do not compromise the security of the device.

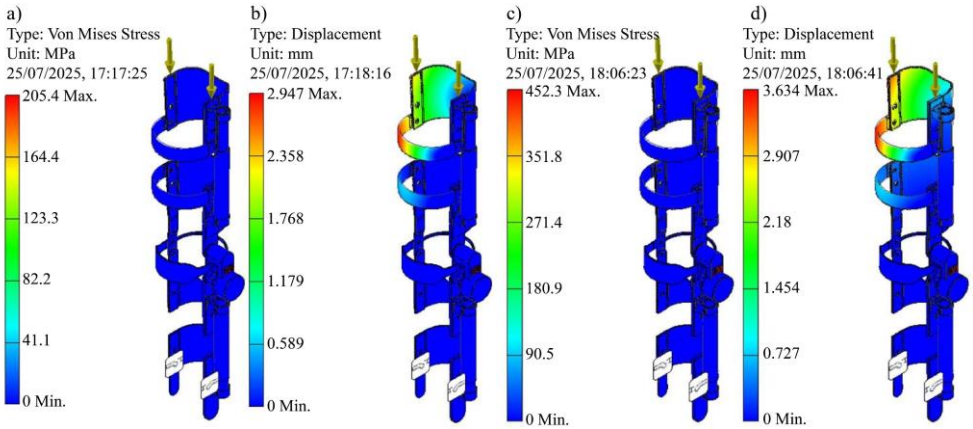

Fig. 4 Structural analysis with body weight (a) Von Mises (4-7 years), (b) Displacement (4-7 years), (c) Von Mises (8-11 years), and (d) Displacement (8-11 years).

Table 5. Weight and height of the target population

Age	Máximo von Mises (MPa)	Maximum Displacement (mm)
4-7	205.4	2.947
8-11	452.3	3.634

Note: Von Mises stress and displacement values correspond to maximum loads for each age group.

The behavior of the displacements was also acceptable in both simulations, staying within clinically tolerable margins so as not to alter the alignment of the limbs during use. This result is especially relevant in pediatric orthotics, as small variations in fit can affect comfort or therapeutic effectiveness. The ability of the orthosis to support body weight at different stages of growth confirms its viability as an adjustable and reusable device, prolonging its clinical lifespan.

Assessment with Joint Flexion and Motor Moment

Finally, structural performance under dynamic conditions was evaluated, considering active joint flexions generated by the combined action of gravity and momentum provided by the motorized actuator. Three configurations representing different degrees of bending were simulated:
Case C1: 45° bending (Figure 5a – stresses, Figure 5b – displacements).
Case C2: 90° bending (Figure 5c – stresses, Figure 5d – displacements).
Case C3: 110° bending (Figure 5e – stresses, Figure 5f – displacements).

The results showed a progressive increase in stresses and displacements as the flexion angle increases, concentrating mainly on the junction region between the lateral plate and the joint support. As expected, Case C3 was the most demanding, as shown in Table 6, presenting the maximum values of stresses and displacements. However, all cases were kept within acceptable safety margins, confirming that the design reliably supports dynamic requests.

Table 6. Results matrix with joint flexion and motor moment

Position Angle (°)	Maximo Von Mises (MPa)	Maximum Displacement (mm)
45	78.37	1.572
90	78.70	1.050
110	88.67	1.265

Note: Values obtained from finite element analysis under specified joint flexion angles.

The minimum safety coefficient obtained was 15, corresponding to the case of evaluation under axial load that simulates the body weight of children with greater mass, considered as the most critical operating scenario. Figure 6 shows this case, in which the highest von Mises stress values were recorded and, consequently, the lowest safety coefficient.

The other components have higher values, which confirms that the orthosis offers a wide margin of resistance against the loads expected in practice. This level of oversizing ensures the durability of the device and allows future adaptations to be contemplated, such as increasing the torque of the actuator or its use in patients with greater weight, maintaining an optimal balance between rigidity, flexibility, and resistance, essential aspects for its therapeutic function and its adaptability to pediatric growth.

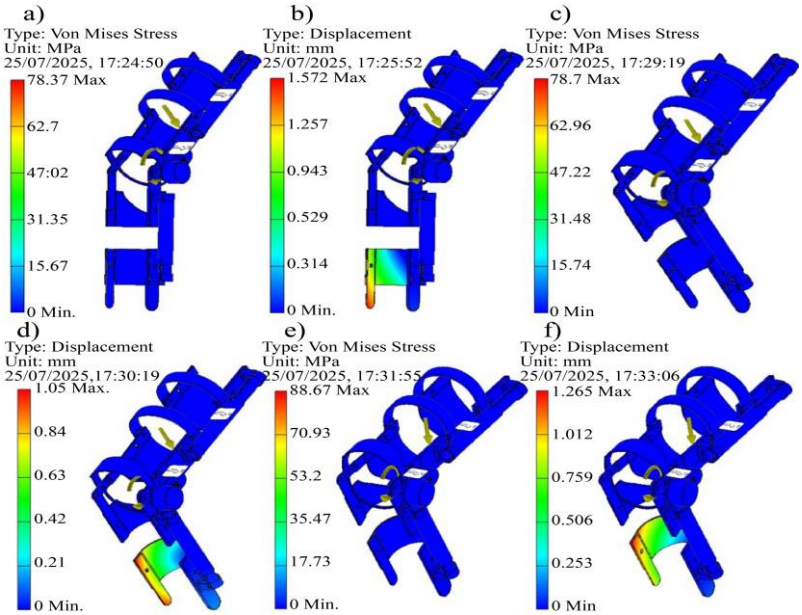

Fig. 5 Structural analysis in flexion condition (a) Von Mises (45°), (b) Displacement (45°), (c) Von Mises (90°), (d) Displacement (90°), (e) Von Mises (110°), and (f) Displacement (110°).

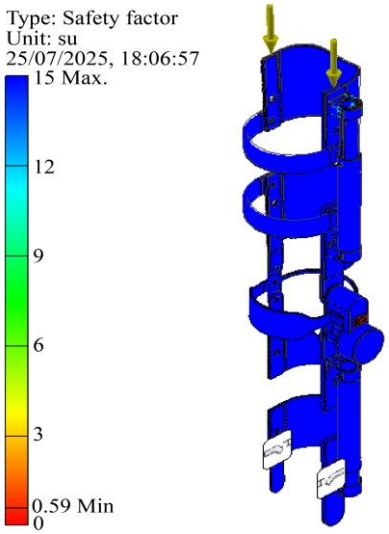

Fig. 6 Critical case-minimum safety factor under axial load

3.2. Analysis of Control Behavior

The analysis of the control system implemented shows a stable and safe behavior, complying with the criteria set for the activation of the orthosis. The logic based on the combination of FSR and EMG signals, processed by pre-established thresholds, ensures that the joint is only activated under biomechanically appropriate conditions, avoiding out-of-context movements.

Figure 7 shows the binary signal resulting from the AND block, where the value "1" indicates the instants in which the system is enabled, that is, when the plantar contact (FSR > 0.5) and the muscle intention detected by the EMG (EMG > 0.4) coincide. The values "0" correspond to periods without activation, ensuring that there are no movements out of context.

Figure 8 shows the angular velocity profile during the activation periods. It can be seen that the increase in speed is progressive and remains stable in the active intervals, evidencing that the system responds in a smooth and controlled way. The absence of abrupt oscillations indicates that proportional adaptive control adequately handles changes in the EMG signal.

Figure 9 shows the evolution of the joint angle in response to activation. The movement is kept within the permitted physiological range (0° to 140°), with a progressive and controlled flexion, synchronized with the user's intention. This suggests that the system is suitable not only for gait assistance but also for rehabilitation processes where the gradual modulation of muscle effort is essential. The proportional adaptive control, incorporated in the third stage, allowed the angular velocity to be dynamically adjusted based on the detected muscle effort, resulting in better synchronization with the user's intention. This behavior suggests that the system is not only suitable for assisting gait under normal conditions but also potentially useful in rehabilitation scenarios where gradual modulation of effort is critical.

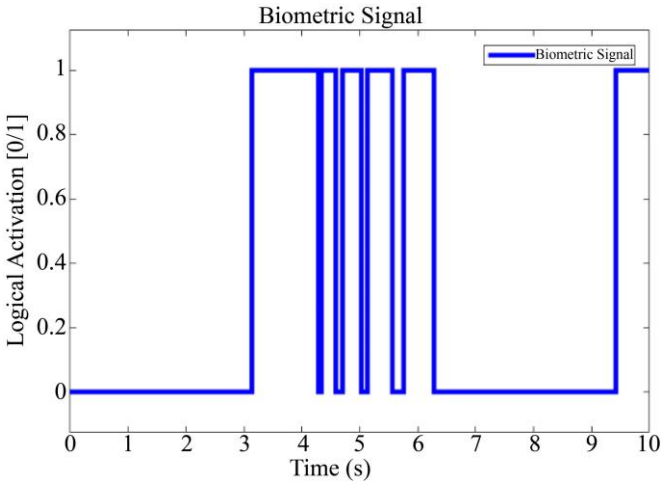

Fig. 7 Logic activation signal generated by the AND block

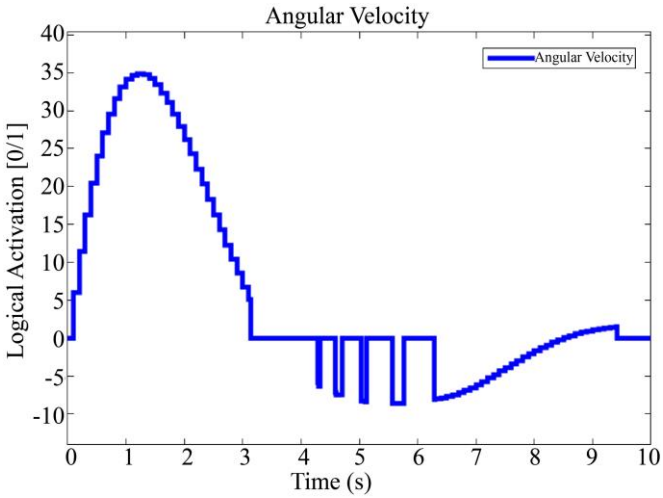

Fig. 8 Angular velocity during activation

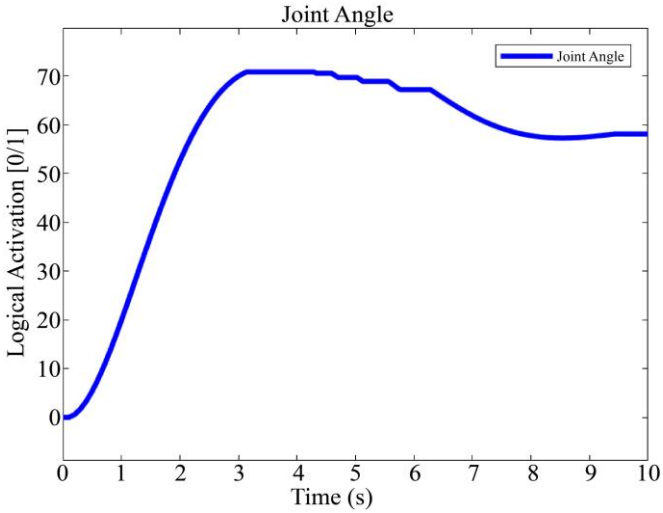

Fig. 9 Joint angle obtained in the simulation

3.3. Technical and Economic Analysis

The joint analysis of the technical and economic aspects showed that both criteria are closely related and complement each other in the viability of the orthotic system. From a technical perspective, the design showed safe and stable structural behavior during the simulations carried out. Under the most demanding conditions, the maximum voltage recorded was 452.3 MPa (Figure 4c), remaining within the permissible range of the selected material. This result confirms that the acting stresses do not compromise the structural integrity of the device and that the critical areas operate under safe conditions. Likewise, displacement was practically non-existent, which demonstrates adequate structural rigidity and minimal deformation under load, guaranteeing stability and comfort during prolonged use.

In order to quantify the technical performance, the design was evaluated using a weighting matrix that considered fundamental criteria for its pediatric application. Each criterion was weighted according to its relevance and qualified according to the results of simulation and structural analysis. Table 7 presents the values obtained.

Table 7. Technical criteria evaluation matrix for the proposed orthosis

Technical Criteria	Weight (g)	V1
Simplicity of design	4	4
Structural strength	5	4
Ergonomics and comfort of use	4	3
Modularity/adaptability to growth	5	4
Ease of assembly and maintenance	3	4
Weighted sum (Σ p·g)		80
Ideal sum (p max = 4)	84	=
Technical Value Xi	1	0.952

Note: Evaluation based on weighted technical scores; Xi = technical value.

The technical evaluation showed that the design effectively supports weight in different age ranges, from young children to adults, validating its adaptability to the user's growth. This feature, in addition to allowing prolonged use without the need for frequent replacements, translates into a significant reduction in costs in the long term and greater accessibility of the device for families and rehabilitation centers. The overall technical value (Xi = 0.952) reflects a performance very close to the ideal scenario (Xi = 1), which confirms its structural and functional viability for the conditions of pediatric use, guaranteeing safety, comfort, and reliability during orthotic treatment.

In order to analyze the economic viability, criteria related to the costs of materials, manufacturing, and maintenance processes, the possibility of partial replacement of components, and the degree of external technological dependence were evaluated. This analysis complements the technical evaluation, as it determines not only the feasibility of manufacturing but also the economic sustainability of the device over time. The results obtained are presented in Table 8.

The economic analysis showed that, although it does not reach the ideal value, the design maintains a favorable cost-benefit ratio, standing out in the criteria of maintenance and possibility of partial replacement, with values higher than the weighted average. This confirms that the orthosis can be manufactured and maintained at an affordable cost, which favors its implementation in clinical settings with limited resources and reduces dependence on external imports or technologies.

Overall, the results in Table 7 validate the structural strength and reliability of the system, while those in Table 8 show its economic viability. The correspondence between both analyses reinforces the conclusion that the proposed system not only meets safety and functionality standards but is also within an affordable cost range, which makes it a viable alternative for its future implementation in pediatric rehabilitation.

Table 8. Economic criteria evaluation matrix for the proposed orthosis

Technical Criteria	Weight (g)	V1
Material Cost	5	3
Fabrication/Assembly Cost	4	3
Maintenance Cost	3	4
Possibility of partial replacement	3	4
External technological dependence	2	3
Weighted sum (Σ p·g)		57
Ideal sum (p max = 4)	68	=
Yi Economic Value	1	0.838

Note: Scores weighted by economic criteria; Yi = economic value.

3.4. Comparison with the Best Cases Presented

When contrasting the results obtained with the two best reference cases described at the beginning of the study, significant differences are evident in both technical and economic performance.

In the technical analysis, the proposed design reached a value Xi = 0.952, clearly surpassing the model that, until then, had shown the best structural and functional performance (V10, Xi = 0.896). This result confirms that the orthotic system developed optimizes not only the structural resistance

to maximum stresses, but also other determining aspects such as ergonomics, adaptability to pediatric growth, and simplicity of assembly. The fact that the technical value obtained is much closer to the ideal (Xi = 1) shows that the device guarantees greater safety, stability, and comfort during prolonged use, which reinforces its relevance as a high-performance functional alternative.

Table 9. Technical and economic comparison with the best reference cases

Model	Technical Value (XI)	Economic Value (Yi)
V10 (Best Starting Technician)	0.896	0.706
V8 (Best Initial Economy)	0.607	0.912
Proposed Design	0.952	0.838

Note: Comparison highlights the proposed design's superior balance of technical and economic values relative to the best reference cases.

On the other hand, the economic analysis showed a different picture. The most favorable reference model in terms of cost-benefit (V8) maintains a slight advantage, with a Yi value = 0.912 compared to 0.838 of the proposed design. This difference is mainly explained by the selection of higher-quality materials and by a structural design that prioritizes rigidity and stability, factors that slightly increase the initial manufacturing cost.

However, this relative disadvantage is offset by the possibility of prolonged use without the need for frequent replacements, ease of maintenance, and partial replacement of components, features that reduce long-term operating costs and favor their economic sustainability in clinical settings.

Table 9 summarizes the comparison of the technical and economic values between the two best initial models (V8 and V10) and the proposed design. As can be seen, the new design manages to clearly outperform both in the technical aspect, reaching the highest Xi value recorded, while in the economic aspect, although it does not surpass the V8, it remains within a competitive range that does not compromise its viability or future implementation.

Taken together, these results confirm that the orthotic system developed constitutes a functionally superior and economically acceptable alternative, making it a solid and reliable option for application in pediatric rehabilitation.

4. Conclusion

In the present work, a modular pediatric orthotic system was developed and evaluated for the rehabilitation of lower limbs was developed and evaluated. The design was conceived considering anthropometric parameters of children between 4 and 11 years old, prioritizing adaptability to growth, comfort in prolonged use, and structural reliability. For its validation, structural analysis simulations and performance tests of the control system were carried out, complemented by a technical and economic evaluation that allowed determining its viability for clinical environments.

The results obtained demonstrated safe and reliable structural behavior. The maximum tension reached 452.3 MPa, remaining within the permissible limits of the material, while the minimum safety coefficient recorded was 15 in extreme conditions (axial load simulating the weight of children with higher body mass). Compared with previously reported studies, the proposed design demonstrates improved structural and functional performance.

In contrast to pneumatic or rigid active orthoses developed by Sawicki and Ferris [10] and Young et al. [11], which emphasize actuation efficiency but lack ergonomic adaptability, this orthosis achieved a higher safety factor (15) while maintaining reduced weight and adjustable geometry.

Similarly, compared to systems reported by Patané et al. [15] and Villa-Parra et al. [16], the proposed model integrates a simpler hybrid control using FSR and EMG sensors, ensuring stable operation without oscillations or overshoot.

These results confirm that the modular configuration and ergonomic design directly contribute to better mechanical stability and clinical usability than ¡those previously reported.

This value indicates that the structure could theoretically withstand stresses of up to 6.78 GPa before failure, ensuring a long, useful life and absence of structural risk in operation. The displacement was negligible, evidencing high rigidity and stability during prolonged use.

In the control system, the dynamic response was stable and efficient, achieving adequate monitoring of the established parameters without significant oscillations or delays, which guarantees smooth and predictable movements that favor the comfort of the user.

The overall value of technical performance (Xi = 0.952) confirms the reliability of the design, while its modularity ensures adaptability to different age ranges without the need for frequent replacements.

Finally, from the economic point of view, a viability index (Yi = 0.838) was obtained, which shows a favorable cost-benefit ratio and simple maintenance with partial replacement of components.

Taken together, these results confirm that the proposed orthotic system is a safe, adaptable, and accessible alternative for pediatric rehabilitation, with a high potential to improve the quality of life of users.

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