Journal of Mechanics Engineering and Automation 11 (2021) 97-104
doi: 10.17265/2159-5275/2021.04.002

Design and Construction of Adjustable Mini-standing for Children from 4 to 9 Years Old with Diplegic, Triplegic or Hemiplegic Cerebral Palsy

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Abstract: The present paper sought to redesign, technify and adjust to different sizes of a mini-standing to improve the physical therapy of children from 4 to 9 years old with mild cerebral palsy or in medical conditions that moderately affect their lower body. This orthopedic attachment provides support to the calf of the patient, resembling its body to a cantilevered element. This allows the patient to improve their posture and safety and prevent bone deformations. To achieve this attachment, simplified design techniques were complemented with Autodesk Inventor finite elements, also additive manufacturing in Polylactic Acid polymer PLA was used for structural parts like the calf support; Likewise, Computerized Numerical Control (CNC) was carried out on Nylon 6/6, a material used due to hygiene and lubrication between parts. A functional and safe prototype is obtained that meets the required age range, whose limitations are children of 120 cm or 30 kg. These were determined in the design requirements and verified with own replicable tests, as well with ASTM (American Society of Testing Materials) standards.

Key words: Orthopedic attachment, cerebral palsy, additive manufacturing, physiotherapy, adjustability.

1. Introduction

Cerebral palsy is a hereditary or acquired neuronal condition that is not progressive [1], this together with other conditions such as West syndrome directly affects the responses of different muscular systems and this translates into loss of fine and gross motor skills in the individuals suffering from it [2]. These are delicate when found in children, since the muscles grow at a different rate from their bone system, which leads to painful deformations, especially in cases of spasticity or stiff muscle tone [2].

When the condition is diplegic, triplegic or hemiplegic, it manifests itself mainly in the middle and lower train and can be mild with control of the neck and trunk, moderate, severe, and deep, where there is no control of the neck or trunk and there is even no speech. In summary, these conditions are described by muscle stiffness, the area of the body affected and its severity [2].

For the purposes of this design, the Aconiño association in Bogotá is used, where these conditions are treated in children from 0 to 18 years old [3]; An observation is made understanding the differences in technical language between an engineer and a physiotherapist, for which object-centered industrial design techniques presented by Natalia Agudelo [4] are adapted to access the information and reinterpret it in engineering terms.

A possibility of improvement and technification is observed in a mini-standing made of artisanal materials (see Fig. 1), this allows the patient to act as a cantilever element and exercise their lower and central train, to maintain balance and achieve a posture upright and aligned bipedal. The existing mini-standing is not ideal; it lacked adjustability to adapt to the size range of patients. For this reason, this type of therapy was carried out by the physiotherapist stepping on the patient's feet, implying effort and time for her and

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Fig. 1 (a) Mini-standing Artisan [5], (b) Therapy without mini-standing using therapist feet [5].

individualized the therapy so that she could not attend more patients simultaneously (see Fig. 1).

A solution composed of various materials with non-permanent joints was proposed for greater precision and better maintenance [5] and it was considered additive manufacturing in PLA for structural parts, considering the complex geometry of the calf and the need for the use of splints and shoes during therapy, in addition to the design to withstand the bending stress to which it is subjected [5]. It should be noted that this manufacture is not commonly used to withstand this type of effort, so the design of the piece and the arrangement of the material was vital for its success.

To apply engineering to the mini-standing, it was necessary to model with simplifications and apply the Von Mises theory of failure since it is the most conservative.

$$\sigma_{VM} = \frac{Sy}{n} \quad (1)\ [6]$$

where σ_{VM} is the Von Mises stress, Sy the yield stress and n the factor of safety.

Now to apply this theory, a safety factor is required, in this case it is given thanks to the Ullmann method [7], considering the few design restrictions.

$$n = FS = FS_{mat} * FS_{Stress} * FS_{Geo} * FS_f * FS_{cof} \quad (2)$$

where FS is the safety factor n, FS_{mat} is associated with the material, FS_{Stress} is associated with how well the load is known, FS_{Geo} refers to the knowledge of the tolerances of the parts, FS_f contribution of the failure analysis and FS_{cof} the required reliability. These coefficients vary between 1 and 1.7 depending on the degree of knowledge about materials and design [7].

On the other hand, complex designs must be corroborated with the finite element software Autodesk Inventor so that tensor equations and the assignment of materials and their properties, can be calculated at each point of the mesh: the displacement and the different types of forces complete and by components.

Finally, the scope of this design was limited to making a functional prototype that meets the requirements of the actors involved, which will still require interactions to become a product [5].

2. Method

2.1 Requirements and Restrictions

The requirements and restrictions were initially determined using Agudelo's techniques [4].

2.1.1 Anthropometry

Measurements of certain parts of the patient's body are necessary considering the nature of the mini-standing, such as: shoulder width (equivalent to hip width), length from floor to knee, calf diameter, femur/height ratio, stature, and mass, in addition to other measurements such as shoe size and the width of the shoe at the heel.

Due to limitations, anthropometric measurements were obtained through specific growth curves for patients with the mentioned conditions. For design purposes, the maximum measurements were chosen.

2.2 Conceptual Design

To reconcile with the project stakeholders: patients, parents of patients, physiotherapists and researchers, a model was made in which a preliminary design was captured and based on this, the desired measures and requirements were proposed for the final design; In this model, the conceptual design could be iteratively refined. As a result, a product diagram is obtained in which the system and the subsystems of the design are broken down, in addition to a first approach to the parts and the assembly, from then on, the design is improved in Inventor's CAD. The last step of this stage focuses on choosing the materials based on the requirements.

2.3 Detailed Design

The conceptual design is dimensioned, this detail has two components: first, a simplification of components and manual calculation with material mechanics equations from the mechanical properties of the materials chosen for the design.

Second, the initial dimensions obtained by the simplification in the CAD of the conceptual design are used and it is simulated with the loads of the maximum requirements defined in the introduction. This detailed design is repeated iteratively until obtaining the minimum dimensions with which the Ullmann safety factors are met, a displacement criterion of 1 mm is also established for parts that require an extra sense of security in the one that cannot allow an elastic deformation. However, apart from the mechanics of the materials, the manufacture of said materials and how it alters their physical and mechanical properties must be considered. Finally, the CAD drawings in inventor are obtained.

2.4 Manufacture

The CNC lathe was used for the Nylon 6/6 parts, the conventional lathe for the bushings and facing of the rails, the milling cutter for the racks and pinions, and the 3D printer was used for the calf part. These techniques, together with the expertise of the laboratory technicians, made it possible to manufacture and assemble the pieces of the adjustable mini-standing. Then the design enters an adjustment stage in which the ideal mechanism in the CAD is aligned with the real parts, the assembly is simulated again to verify the calculations and it is verified that the mini-standing works properly.

2.5 Qualitative and Quantitative Tests

Considering that it will be used in a delicate population. Three quantitative tests were proposed; In 2 of them, the structural resistance in 2 of the device axes is sought and in the third it is verified that the device does not slide on the ground: The maximum flexural or overturning load with its own device that emulates the most critical position of eccentricity with respect to the recessed end of the test subject and the 30 kg of mass is held, the acceptance criterion is that it does not turn over or that the Velcro detaches.

The resistance to the brake mechanism was also measured with an Instron 5585 machine. It is progressively loaded up to 80 N or 1/3 of the design load. It is emphasized that this mechanism should not resist load, however it is important to guarantee the integrity of the parts in a possible load not contemplated.

The standard test for static and kinetic coefficients of friction of plastic film and sheets ASTM-D1984 was also performed with an Instron 3367 to ensure safety and adherence to the device floor during therapy.

Finally, after testing the device, the final prototype is shown to the actors involved so that they can make a qualitative test of it, this test consisted of a survey.

This included the following items:

(1) Security
(2) Postural alignment
(3) Correct support on the calf
(4) Malleability in the fastening ropes
(5) Safety in restraint ropes
(6) Amount of clamping reacts
(7) Robustness and weight of the device
(8) Maneuverability of the device in space
(9) Smooth sliding of the mechanism on the guides
(10) Installing patient settings
(11) Finishing
(12) Material
(13) Color
(14) Total fulfillment of the mini-standing function

This qualitative problem is summarized in the results of the mechanical problems that received authorization to test patients.

3. Results

3.1 Requirements

During several rounds of discussion, it was possible to reconcile with the actors on the following requirements [5]:

(1) The age range of 4 to 9 years.

(2) Safety: robustness, without deformation and without movement of the patient.

(3) The back should be free due to the important nerves and blood vessels there.

(4) Postural alignment: small adjustment distances between the patient's feet.

(5) Melt strips of at least 3 cm on the calf and spine. The configuration must be cut with Velcro.

(6) Low addition weight.

(7) Neutral color with rounded and smooth finishes.

(8) Easy cleaning and non-oxidizing.

(9) Low cost.

3.1.1 Anthropometry

In Table 1 there are anthropometric measurements obtained from the curves and indexed information [5, 8-10].

Table 1 Anthropometric dimensions.

Anthropometric dimensions		
Measure	Dimension	Units
Hip width	30	[cm]
Floor knee length	30	[cm]
Femur/height	0.27	[-]
Height	120	[cm]
Mass	30	[kg]
Calf diameter	8	[cm]
Shoe size	26	[Colombian]
Shoe heel width	7	[cm]

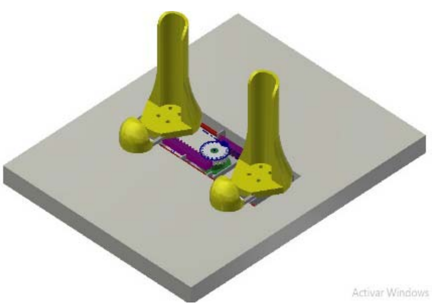

Fig. 2 Preliminary CAD [5].

3.2 Conceptual Design

From the requirements obtained, the anthropometric dimensions, the mini-standing of Fig. 1 and the aforementioned model are proposed: a preliminary CAD, estimated dimensions of the pieces and the materials to be used, this is observed in Fig. 2.

The materials for the parts and subsystems according to requirements were [5]:

Nylon 6/6: meets hygiene, lubrication between parts, low noise, low weight of parts.

AISI 304 (stainless steel): complies with hygiene and non-corrosion, provides the resistance required for reinforcement elements and slide rails.

PLA: has sufficient thermal stability not to deform when 3D printing large pieces (15 cm or 20 cm onwards), and is available in yellow color.

Laminate Pine: 18 mm thick gives the design a stable base at a low cost. It was varnished and milled to a good finish.

3.3 Detailed design

Considering the requirements of height and mass, the equivalent force is calculated assuming the center of gravity at the hip [10] and the cantilever model with an inclination angle of 15°. The equivalent force is 217.14 N [5]

3.3.1 Parts and Mechanisms

The brake subsystems, the calf or foot support and the width adjustment mechanism between the supports are shown in Figs. 3 and 4. In these the reengineering work is reflected; their design is briefly emphasized.

Foot: Due to the complexity of the piece, it is manufactured with 3D printing, orienting the layers vertically to withstand flexural stresses. It also has a conical interior that ergonomically adjusts to the patient's calf. It is complemented by a stainless-steel reinforcement.

Brake: The arrangement of the pieces allows a vertical movement without torsional restriction, to be able to cross the pinion and the recessed base with a long pin.

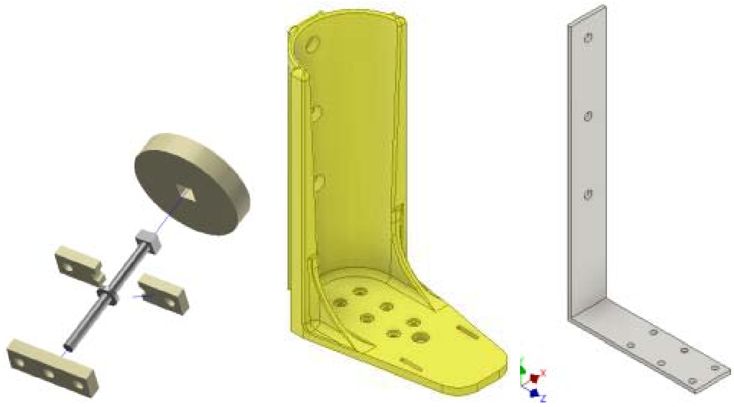

Fig. 3 Brake mechanism exploded (left) [5]; Refined foot support and reinforcement (right) [5].

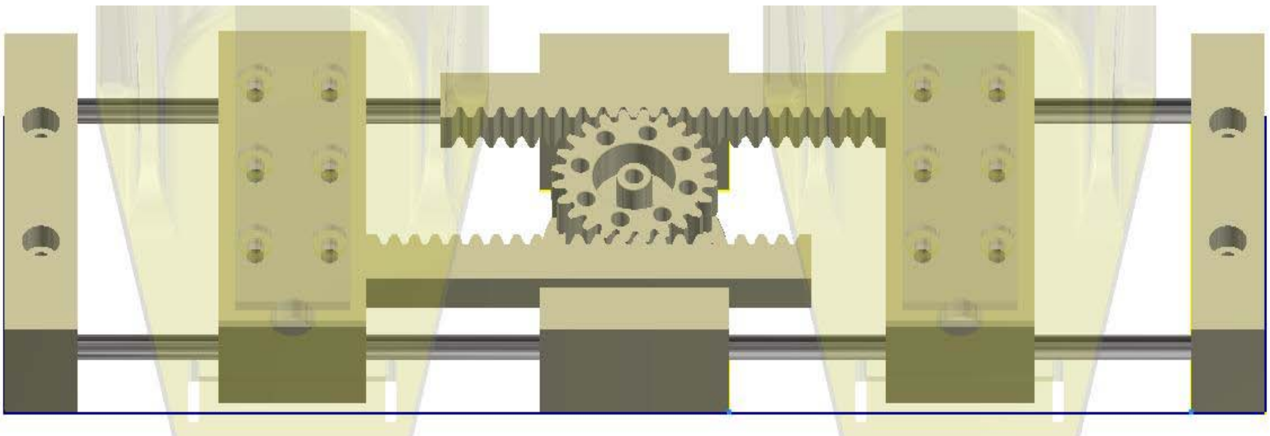

Fig. 4 Foot width adjustment mechanism with pin brake and holes between pinion and axle.

Adjustment mechanism: It has two zippers and a pinion that allows the movement of the footrests in an equidistant way. The holes in this pinion and base shaft align with the brake pins to meet the requirement for adjustability and safety.

3.3.2 Finite Element Simulation

In Fig. 4, it shows the worst-case scenario for guides or rails that are 30 kg in mass multiplied by the safety factor n. In Fig. 5 the same scenario is presented for the foot that corresponds to a 15° deviation of the hip on the embedded support, this corresponds to 48.8 Nm or 217.14 N of force equivalent to ¾ of the length from the floor to the knee, complying with the requirements.

There were 2 design criteria depending on whether a subassembly or a single piece was calculated. In the case of Fig. 5, the Von Mises stress was considered because the creep is what determines the failure of the rail.

$$n = \frac{Sy}{\sigma_{VM}} = \frac{245\ MPa}{67.32\ MPa} = 3.64$$

A safety factor greater than that determined by the Ullmann method was obtained.

On the other hand, in Fig. 6, a different criterion was established, one of displacements, because the feeling of security for the patient does not depend on the fluency of the piece, but on its minimal elastic deformation, which is why it was associated with a displacement of less than 1 mm. It is observed that this was 0.8 mm in the sub-assembly of the foot [5].

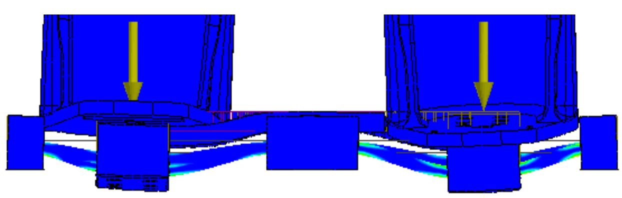

Fig. 5 Von Mises Stress. Finite elements [5].

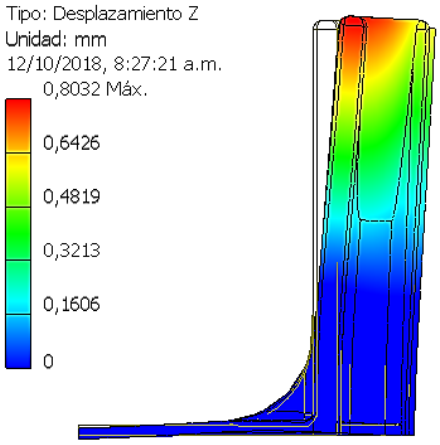

Fig. 6 Stainless steel reinforcement foot sub-assembly (1 mm criterion) [5].

Fig. 7 Finished mini-standing [5].

3.4 Manufacture

Fig. 7 shows the finished mini-standing with all its fastening ropes. Due to the use of the material, spare parts for the rack and pinion could be manufactured. It should be noted that all the bolts were of standard 1/8" and ¼" diameters and with lock nuts. Likewise, the base was sealed and varnished to avoid dirt and gave a good appearance.

The mini-standing had a total cost of $1,656,600 COP, a price at least 5 times lower than any RIFTON device specialized in patients with motor deficiencies [5]. Although it is true that it is more expensive than a mini-standing made of plaster as is traditionally made, the one manufactured by the researchers has mechanical and functional advantages as well as a greater sense of security and confidence.

Fig. 8 Tipping test [5].

3.5 Tests

As mentioned above, 3 tests were performed.

Fig. 8 shows the tipping test in which a galvanized steel and PVC structure that resembles the strength and lengths of the tibia, femur, and hip of a healthy 9-year-old child with a 25° bending angle. Under this configuration, only 23 kg are needed to obtain a required torque of 48.8 Nm. This structure was successfully loaded with 22.7 kg. It is assumed as a safe prototype.

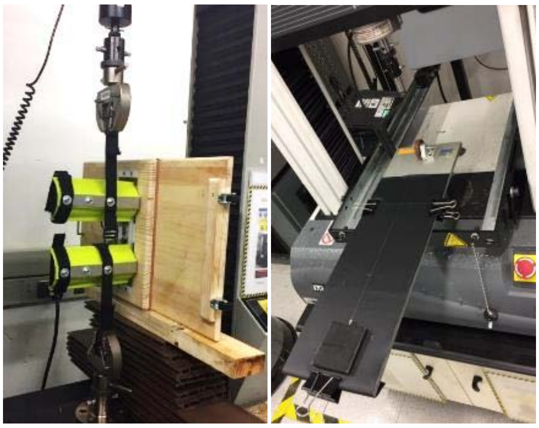

Fig. 9 Brake integrity test (left) [5]; ASTM-D1984 test for non-slip of mini-standing base (right) [5].

The brake integrity test (Fig. 4 mechanism) in Fig. 9 (LEFT) sought to load 1/3 of the initial force or 80 N on the brake system and on the Nylon 6/6 elements. "Although, just as the gear rack in its real function should not be subjected to axial loads, it is better to guarantee a load to avoid bending due to the 20-degree angle at which the force is transmitted due to the pressure angle of the gear teeth and rack" [5].

Fig. 10 From left to right: Mini-standing in use by children of 4, 6 and 9 years old with satisfactory results [5].

It was loaded progressively, no noise was heard and when unloading the functionality of the mechanism was verified, and there was no creep in any part. All pieces remained intact.

On the other hand, in Fig. 9 the standard test for static and kinetic friction coefficients of plastic film ASTM-D1984 yielded a static friction coefficient of $\mu s = 1.195 \pm 0.117$ and a dynamic friction coefficient $\mu k = 1.102 \pm 0.032$ [5]. They are good coefficients, which correspond to rubber on rubber [11] and allow us to infer that the selected material is adequate to be used as non-slip.

Now, the qualitative tests mentioned previously were applied to 5 people: 2 parents, 2 physiotherapists and the executive director of the association, on average a rating of 5 out of 6. It is true that it is not a perfect rating, but to be a first prototype is good enough to be used while a second version is studied and redesigned that fully meets these tests [5].

Finally, after passing the technical and qualitative tests, a test was approved in patients, in Fig. 10 the adaptability of the mini-standing is observed since it performed successfully in the entire age range for which it was designed.

4. Conclusions

The age range for which the mini-standing was designed [5] is satisfied.

An adequate level of satisfaction was obtained for the 4 actors, the mini-standing can be presented as a functional prototype [5].

The choice of materials was adequate, all the mechanical, aesthetic, and functional requirements met with a low weight, which benefits not only the patient but also the physiotherapist.

The safety of the mini-standing was guaranteed by passing the tipping tests with a torque of 49 Nm, brake resistance equal to 80 N and obtaining static and dynamic friction coefficients greater than 1.

The non-permanent joints allowed the attachment to be assembled and disassembled without losing precision and allowing having interchangeable spare parts.

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