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Design of a Standing Device for Children with Spinal Dysraphism

Aydeé Robayo-Torres and Katherine Quiñones-Argote

Abstract

The standing posture is one of the most important factors in the maturation of the neuromotor system, and it is an evolutionary necessity that phylogenetically makes possible the differentiation of functions between the upper and lower limbs, influencing a greater development of the latter; with a fundamental change in the shape of the foot: it increases the importance of the tarsus and metatarsus and reduces the work of the fingers, which facilitates the movement, transfer and independence of the individual in their activities of daily life. The design and production of the prototype of the device, the judgment of the experts, as well as the results of the physiotherapeutic evaluation before and after the standing program, are the threads that are woven in this research proposal. This study seeks to propose a prototype of a standing frame for pediatric patients with spina bifida. The design of a device for standing is proposed based on the individual characteristics of the users, which was evaluated by experts to later perform a case study on a standing program with this type of device in pediatric patients with spine bifida. The designed prototype seems to offer adequate conditions for maintaining standing and on some musculoskeletal conditions of the patient studied. The study concludes that assisted standing should be promoted through inexpensive, functional and continuous monitoring devices. A user-applied design is proposed and not a generic device model.

Keywords: standing, device, children, spinal dysraphism, stander, Congenital abnormalities

1. Introduction

Children and adults who due to their motor disability situation, who cannot adopt the bipedal position, have a greater propensity to complications related to the decrease in bone mineral density, development of myo-tendon contractures, greater risk of gastrointestinal problems, less support of the diaphragm by the effect of gravity; increasing the risk of pressure ulcers because by not having the adequate redistribution of pressure in the ischial tuberosity, sacrum, spinous processes, scapulae and other bony prominences, blood perfusion that the tissues need is not allowed, thus increasing the risk of rupture of the skin in a seated individual. In addition, the possibility of presenting problems in the functioning of the bladder and greater predisposition to urinary tract infections [1].

One of the causes of disability is neural tube defects, which are the most serious congenital malformations of the central nervous system and the spine. They are the second major congenital anomaly after cardiac malformations, with a frequency that ranges between 0.5 and 2 per 1000 pregnancies, although in some geographical regions, for example, in northern China, frequencies of up to 10 per 1000 births. Furthermore, they account for up to 29% of neonatal deaths associated with congenital anomalies in low-income settings. Both the clinical manifestations and the resulting disabilities and mortality depend on its level and extent [2]. The structural defect occurs at any level of the neuraxis, from the brain to the sacrum; These neural tube defects located in the spine are classified as occult spina bifida and open or cystic spina bifida, in the latter, spina bifida is present, but accompanied by a protrusion of a meningeal sac with cerebrospinal fluid with neural tissue inside or without it and are classified as Meningocele, Myelomeningocele and Rachischisis with Mieloschisis. Myelomeningocele is the most serious form of spina bifida cystica that presents as a chronic disease, it produces a strong psychosocial impact on the child and their family since the child may present motor, urological, orthopedic and sometimes cognitive impairment [3, 4]. This can be done damaging effects on a child's well-being, education, and social engagement [5, 6].

Failure to adopt bipedal position implies the limitation of voluntary motor skills such as locomotion, transfers and self-care, sphincter involvement, restricting social and school participation. This is the reason why orthotic attachments or devices to achieve the maintenance of the bipedal position, have been proposed since time immemorial [7].

Recent research even recommends a "24-hour postural management program that you should consider including both a passive standing component and an active component using a stander that steps, vibrates, oscillates, sways, turns, bounces, moves from sit-to-stand under users' own power, allows users to self-propel, and so on, or other devices that combine weight-bearing and movement such as a gait trainer/support walker" [8].

Assisted standing involves using a device to help place load through a person's feet. Standing devices and orthoses provide a stable mechanical support for weight bearing in the supine, prone or upright positions, depending on the device chosen; however, a precise and timely evaluation of individual needs must select the most appropriate design of standing device, orthoses, or both. These benefits include preservation of muscle length and range of joint movement via the stretch that occurs during standing (predominantly of the hip and lower-limb muscles), delayed onset of scoliosis, increased bone density (thereby reducing the risk of fractures), fewer muscle spasms and better respiratory function (including voice control). Research on standing for other conditions has also suggested improved circulation, digestion, and bowel and bladder function. Clinical opinion on standing indicates other benefits, including pressure relief (which improves skin integrity), improvement of well-being and better sleep [9, 10].

In addition, for these people, there is the social stigma of depending on others for functional mobility, which is why an assistive device is necessary that facilitates the bipedal position, ambulation in the environment and development of activities typical of age, without assistance from another person and who contribute positively to society as a whole [11, 12].

One of the fields of the human body movement professional is precisely the design, prescription and evaluation of the use of this type of device for standing,

known as Standing Stands. However, the limited and timid research that researchers have found in this field is surprising [13].

2. Material and methods

The approach to the design of machinery that was proposed in this project considered for its realization the steps of the engineering design flow [14], that is to say:

1. Recognition of a need.
2. Specifications and requirements that the machine must meet to solve the need.
3. Study of the possibilities.

The purpose of the probability study is to verify the possible success or failure of a proposal, both from a technical and economic perspective.

4. Synthesis of creative design.

In this phase of design, researchers must act as physiotherapists, “empirical engineers,” inventors, and artists, to create the machine.

5. Preliminary design and development.

Drawings of the machine as a whole and of the specific parts of it, the dimensions and important notations, as well as auxiliary sectional views, that fully explain the proposed design. In addition, kinematic studies are conducted, which include the design of the machine and the possible movements that it should conduct.

6. Detailed design.

Detailed design refers to the actual rigging and sizing of all individual components, both purchased and manufactured, that make up the total product, device, or system. The assistance of experts in the different areas was necessary in order to carry out the stander on the right track.

7. Prototype construction and testing.

At this stage, the parts were manufactured, the commercial components were purchased and the machine or system, after the assembly, is ready for evaluation and testing. After the necessary changes and/or modifications have been made, the new components are incorporated into the prototype assembly to continue with the tests and evaluations. This process was performed until the designer, in this case the researchers, were satisfied with the stipulated specifications.

8. Production design, this stage is not part of this project as it is a pilot test.

This was the prototype of the standing frame that was used in the case, which was subjected to evaluation in the prototype workshop of the Faculty of Engineering of the National University, and to an expert judgment (**Figure 1**).

Figure 1.
Graphic design of the prototype.

Based on the prototype, a case study was designed with a 10-year-old patient with myelomeningocele type spina bifida level T12 - L4, the most relevant sequelae of which were bilateral-grade IV/V vesicourethral reflux, flaccid neurogenic bladder in catheterization intermittent from the age of 4 years old, bilateral hydronephrosis, bilateral dysplasia of the hips and coxa varas, flaccid paraplegia, among others.

The researchers understood, assumed and classified this research project as minimal risk, given that other stanchions have been created in the world, which have facilitated the study and description of the risks derived from its use in the adult population [15], and to a lesser extent in the pediatric population, with an inability to acquire the bipedal position. The possible risks, their handling and control are known and foreseen by the researchers. These risks include signs of orthostatism, diaphoresis, emesis, pressure zones, allergy to materials, tinnitus, paresthesia, fall, tachycardia, bradypnea or polypnea [16].

The benefit derived from the use of the stander was based on the care of the conditions that generally affect people unable to adopt the bipedal position [1]. Therefore, in the cost-benefit ratio, the risks inherent to the research were widely outweighed by the benefits provided by assisted standing in this type of population, being a novel and reasonable orthosis, insofar as it was intended to attend a sequel and a need that the Colombian health system is not prepared to meet and has completely neglected in the research study subject.

Confidentiality was guaranteed by the researchers for both the study subject and his family.

According to Title III of the current regulations, in this study an informed consent was obtained for the research subject, with prior evaluation by the psychology service of the Faculty of Medicine of the National University in which it was certified that the subject of study, can understand, reason and logic, which allows

you to understand the importance and role of your participation in this research. In the same way, they proceeded to obtain informed consent from their parents.

3. Results from the expert judgment

A search was carried out for experts in various areas such as pediatric neurology, biomedical engineering, biomechanics and medical technology; who could evaluate the different characteristics of the stander. For this, five expert professionals were contacted, of which 80% were physiotherapists and 20% belonged to mechanical engineering.

4. Criteria for the evaluation of the stander

The characteristics of both the shape (design, safety, resistance, weight, mobility, esthetics, among others) and the bottom of the standing frame were evaluated with a view to incorporate the changes, modifications and suggestions received by the judges into the final prototype. At the request of one of the evaluators, the researchers made a technical specification sheet, which could unify a technical language that is understandable to the reader. The evaluation was conducted using the following qualification criteria:

1. Excellent
2. Very good
3. Good
4. Regular
5. Bad
6. Very bad

4.1 Design creativity

The grade point average for this criterion was excellent.

One aspect highlighted by one of the experts was the fact of considering standard measures of Colombian architecture, such as the width of the doors, and the standardized measures of wheelchairs, to provide better accessibility to various spaces.

4.2 Security provided by the patient standard

In this criterion, the experts argued that some improvements must increase safety, such as lateral supports on the back and seat. Another evaluator expressed concern about how safe an obese patient might be. The average grade for this criterion was very good.

4.3 Design of supports to avoid pressure zones in the body segments

The average qualification for this criterion was very good, although we insist on reviewing any pressure zones.

4.4 Materials used for creation the stander

The testers expressed that they look tough and that they are suitable for durability and strength. Another evaluator requested a technical sheet of the stander and the value of the resistance of the materials. The grade point average for this criterion was very good. One of the elements highlighted in the structure was the use of a special weld, which guarantee safety in the different joints of the standing frame.

4.5 Structural strength of the staircase

In this item, the evaluators stated that the design and manufacture guaranties the resistance of the stanchion and suggested performing load-bearing tests for a more generalized use. The grade point average for this criterion was very good.

Considering that the structural resistance of the prototype is fundamental, the researchers consulted with a mechanical engineer to make a 3D modeling, in which a simulation was intended to find resistance values and critical points in the structure. Regarding the load-bearing test, when manufacturing the prototype, a static test with a weight of 100 kg was performed for 24 hours, finding that the structures did not suffer any damage. However, to conduct other types of tests, it must have another manufactured stanchion, which is available only to measure with what applied force it could suffer some damage.

4.6 Weight of the staircase

The evaluators stated that it is a bit heavy, however it is much lighter than other types of stanchions that do not have an electric motorization system; They also expressed that another type of material such as aluminum could reduce the weight. The grade point average for this criterion was very good.

4.7 Ease of handling

In this evaluation criterion, the evaluators stated that they are concerned about children with spina bifida who have attention and coordination difficulties, they stated that the regulatory system could be improved to make it easier for the family to manipulate, modifying it to a system of pin commonly used on crutches and canes; it is also required to improve transportability. The grade point average for this criterion was very good.

4.8 Expansion capacity in the different segments whereas loads is produced

The experts expressed that the stander offers wide possibilities to adjust the size in different parts of it, although some adjustments are required to improve the expansion capacity in the seat. The grade point average for this criterion was excellent.

4.9 Stander dimensions

The experts stated that they were adequate to achieve difficult accesses, although, if it does not risk stability, it would be preferable to shorten it a bit; another expert said he finds it a bit cumbersome to fit into an average car. The rating for this criterion was very good.

4.10 Esthetic appearance in shape, textures, accessories, colors, among others

The evaluators stated that the colors were very striking, had very special details and colors with a specific objective. The grade point average for this criterion was very good.

4.11 Ease off cleaning the staircase

The stander met the hygiene requirements set by the researchers and evaluators. The grade point average for this criterion was very good.

4.12 What other evaluation item would you formulate?

The experts proposed the following form evaluation criteria for the stander:

- Durability of materials
- Inquire about costs
- Manipulation by the family

In the same way, the group of experts made the following contributions from the open questions:

- Check the push bar, as safety concerns for the people accompanying the child, their companions or caregivers. Regarding this recommendation, the researchers proceeded to shorten the bar by 30 cm, to avoid accidents in other people.
- Consider foot deformities, specifically the tendency to clubfoot, added to the absence or little sensitivity in relation to the footrest. Here, the patient has an AFO type orthosis, which favors the stabilization of these segments, even more so when acquiring the bipedal position. However, this aspect should be reviewed at the time of series production.
- Pelvic belt and foot safety at 45°, with Velcro: regarding the angulation of the pelvic belt, it would be necessary to do it in the case in which the prototype only offered the possibility of maintaining the sitting position, however, when also assisting the position bipedal, a position must be found that ensures stability in both positions.
- Abductor stop: the population with altered tone requires this help. This modification is intended to be conducted in subsequent prototypes.
- Wider wheels: for the rear wheels, it is possible to carry out this modification, however for the front wheel it would involve a considerable increase in friction, which would not allow the user to easily direct the movement of the stander, consequently a complete change in steering system.
- Modification of the command panel: one of the evaluators considers that it is necessary to change some buttons, so that they are easier for the user to understand. Regarding this, the researchers performed a previous test, with

a child of the same age and schooling as the study subject, finding that after a brief instruction, the child was able to maneuver the standing frame in all directions, so no this modification is considered necessary.

4.13 Results of the implementation of the bipedestation in the subject of study

Making the comparison between the physiotherapeutic evaluation before and after the standing protocol in the study subject, it was found that:

- In the cardiovascular and respiratory dimension it was found:
 - On the scale of perceived exertion (modified Borg), the study subject initially considered standing activity with a rating of hard; after finishing the sessions, the rating decreased to soft.
 - When performing the evaluation of ventilatory mechanics, it was found that there was an increase of 0.5 cm in the thoracic expansion of the study subject.
- Regarding the anthropometric characteristics, the following changes were found:
 - In the initial evaluation, the BMI was in the 65th percentile and in the final evaluation it was in the 30th percentile. Despite this decrease, the BMI was in the normal ranges.
 - Regarding the perimeters, an increase of 1.5 cm was found in shoulders and abdomen; at the hip 2 cm; 1.7 cm for the right upper thigh and 2.7 cm for the left and 0.5 cm for the leg. Likewise, there was a decrease in some perimeters, such as 1 cm in the right middle thigh and 0.8 cm in the lower thigh.
- In the positive internal contextual factors and participation, it was found that the patient improved her mood after the start of standing, has greater initiative to conduct different activities that she did not do before, such as helping to wash the dishes after eating, help serve in the store of their parents.
- Regarding integumentary and vascular integrity, it was found:
 - Regarding the pressure ulcer presented by the study subject, it was found that in the initial evaluation, it had dimensions of 2.4 cm wide x 1.5 cm high; in the final evaluation it was 2.1 cm wide x 1 cm high. This shows a decrease of 0.3 cm in width and 0.5 cm in height in the crater.
- Regarding joint integrity and mobility, the results obtained can be seen in **Table 1:**
- In the muscle evaluation, a slight contraction was found in the hip flexor muscles on both sides in the final evaluation.
- In the evaluation of sensory and neuromotor integrity it was found:
 - Superficial sensitivity: when evaluating touch and pain, it was obtained that the study subject initially reported perceiving the stimuli up to the level of T12 on the left side and T11 on the right side. In the final evaluation, a

Joint	Range of motion
Gain	
Right and left hip flexion	22°
Right hip internal rotation	26°
Left hip internal rotation	16°
Left hip external rotation	7°
Left knee flexion	6°
Knee extension	10°
Right foot neck inversion	5°
Left foot neck inversion	3°
Right foot neck eversion	30°
Left foot neck eversion	25°
Decrease	
Hip adduction	17°
Left foot neck dorsiflexion	15°
Right metatarsophalangeal flexion	18°
Left metatarsophalangeal flexion	30°
Bilateral metatarsophalangeal extension	10°

Table 1.
Comparison of gain and decrease in the ranges of motion obtained in the pre and post physiotherapeutic evaluations.

perception of the stimulation was obtained on the lateral aspect of L2 in the right hemibody and up to L1 in the left side.

- ASIA: in the initial evaluation, the sensitive level was T11 and in the final evaluation it was L1. The motor level remained the same in the two evaluations, however in the final evaluation a slight contraction of the hip flexors was found.
- In the postural analysis the following results were found:
 - Postural alignment in sitting position: pelvic obliquity changed the score from slight elevation of 10° to the right side to normal; the lateral displacement of the trunk was maintained in a grade of mild, going from a displacement of 5° to the left to a 5° displacement to the right; lateral head tilt changed from Tilt 10° to the right (slight) to normal; hip rotation remained normal in both evaluations; posterior pelvic tilt, thoracic and lumbar curvature remained the same in the two evaluations; in the posterior inclination of the head there was a decrease of 13°, going from slight to normal; slight pelvic rotation remained the same in both evaluations; in the adduction and abduction of the hips a grade of normal was maintained.
 - Positive Galeazzi sign, finding a decrease in the difference of 0.9 cm, with the lower right limb is the lowered one.
 - Spine: mobility was evaluated with the Schober test, finding an increase of 1 cm in the displacement of the vertebrae. The alignment of the spine was also

evaluated with the Adams test, which shows an increase in curvature toward the left side in the dorsal area, maintaining the same result in both evaluations.

The researchers also consider it pertinent mentioning other changes that occurred in the study subject during assisted standing; These data were obtained from the parents' narratives during the course of the investigation and will be presented below:

- In relation to the musculoskeletal system, the parents report that “when palpating the muscles of the thighs and legs of the study subject, they found a considerable increase in their hardness (muscular turgor).”
- In relation to the stability and postsurgical ossification of the pelvis and hip, radiographic images are obtained after the process of standing, whose examinations are in the hands of the parents and which, according to them, in an appointment made with orthopedics, the doctor The practitioner noted a rare improvement in the stability and ossification of the pelvis and hip.
- Regarding urine color, appearance and volume, the parents decreased the consumption of this drug in the study subject, even stopping the use of this antibiotic during standing.
- In the digestive system, the parents reported that from the second week of assisted standing, the fecal bolus changed its appearance, going from hard goat-type stools to soft stools that looked more like normal. Parents mentioned that this event had never been presented; It is also important to mention that the use of the medicated laxative (PEG) were suspended due to the positive change in the consistency of the stool.
- Regarding the participation of the individual, a favorable change was achieved in the emotional part of the study subject, a better disposition was also generated to perform activities in which they did not usually participate, such as cleaning the home, helping their parents with work typical of home and work.
- Regarding the movement of the subject, the parents report an improvement in stability, alignment of the trunk and lower limbs, and the ease with which they crawl inside the home.

According to these results, it is observed that it is necessary to design these devices based on the individual characteristics of each patient/user, so as to guarantee an adequate man-machine correlation and therefore obtain better results derived from the use of the device. This is why this research bets on a personalized design and not in series, economic, light and esthetic, unlike most of the stanchions.

The researchers recognize the importance of having received training in various areas that contributed to the development of the research, however, a limitation of the study corresponds to a gap in training in terms of basic elements of design and production of orthotic devices or attachments and the review of other systems, such as bladder and gastrointestinal function, which are also a fundamental part of the human body movement, but which still do not have a concrete argument from the point of view of the physiotherapist. Therefore researchers would hope that a project will be proposed, hopefully in the short term, where this area is deepened and subjects are offered, where these issues and views are explored and reflected by physiotherapists in training.

5. Conclusions

After completing this investigative process, the researchers have reached the following conclusions:

- The intervention of the physiotherapists in terms of design and generation of structures and technologies that facilitate the habilitation and rehabilitation of the patient, from the paradigm of design applied to the user, are one of the intervention modalities that is most respectful of individual characteristics and context in which the orthosis is going to be implemented, so in the mediation between the human and the technological, a judicious monitoring of the process is necessary.
- The experiences reported by the experts show us that with the prototype produced in this research it is necessary and useful, while without neglecting its esthetic appearance, greater functionality was always sought in the patient.
- Assisted standing should be a right for the population with spina bifida, since kidney, gastrointestinal and respiratory diseases are the main reasons why these patients have a high level of morbidity and mortality. Therefore, devices such as the one proposed in this work, made with national materials and with Colombian design, 10 times cheaper than those on the market, could respond to these needs.

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