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Using a robotic exoskeleton at home: An activity tolerance case study of a child with spinal muscular atrophy

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ABSTRACT

Purpose: Spinal Muscular Atrophy (SMA) Type II is a neurodegenerative disease that leads to progressive muscle weakness. It prevents children from walking and affects their respiratory function and their activity tolerance, among other health problems. We aimed to assess the activity tolerance showed by a child with SMA using a pediatric gait exoskeleton at home when walking and performing activities.

Design and methods: This study presents the case of a 6-year-old boy with SMA Type II and respiratory failure who used a pediatric gait exoskeleton at home for a period of two months. A nursing assessment was done before and during the use of the device to evaluate the child's activity tolerance during the sessions. Nursing interviews, performance, vital signs, fatigue, field notes, and functional scales were analyzed.

Results: The nursing assessment showed a good activity tolerance of the child. Performance using the device improved over time; vital signs did not vary significantly during the sessions; fatigue perception decreased over time; and the child reached a higher score on some functional outcomes.

Conclusions: A first step has been taken to evaluate the impact of exoskeleton technology in children with SMA Type II from the nursing point of view, exposing the potential of this technology for the care of children with neuromuscular diseases, and the need for more research on the topic.

Practice implications: The information in this study will be useful to nurses to know the effects of gait exoskeletons in pediatric care of children with neuromuscular diseases like SMA.

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Background

Spinal muscular atrophy (SMA) is a degenerative neuromuscular disease, which entails progressive muscle deterioration and general weakness (Wang et al., 2007). It is caused by the mutation of the SMN1 gene (Arnold & Fishbeck, 2018) and the most common genetic

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cause of infant mortality, with a global prevalence of approximately 1–2 per 100,000 persons and an incidence of 1 in 10,000 live births (Verhaart et al., 2017). There are four different ranges of SMA phenotypes (Mercuri et al., 2012). The three main types in children are SMA Type I (children unable to sit), SMA Type II (able to sit but not to walk) and SMA Type III (able to walk) (Finkel et al., 2015). The first sign of weakness in children with SMA Type II usually appears before the 18 months of age and these children can never manage to walk and stand independently without aid (Arnold & Fishbeck, 2018). A multidisciplinary team, which includes nursing professionals, is needed to provide the necessary attention to these children.

Regarding the conventional rehabilitation treatment, joint mobilizations, gait therapy, exercise and orthotic intervention for positioning and standing have been proved to be effective for SMA patients able to sit, (i.e. type II patients, Mercuri et al., 2018). However, there were no technical aids that allowed these children to walk until the creation of gait exoskeletons. This is due to of the noticeable deficit of strength at the lower and upper limbs and at the trunk, which causes them excessive fatigue when using conventional orthoses (Wang et al., 2007).

Gait exoskeletons are an emerging technology of wearable robotics devices that can be used to assist the gait of people with lower limb weakness (Gorgey et al., 2019). Pediatric lower limb exoskeletons are quite new devices, and ATLAS 2025 was the first exoskeleton specifically designed for children affected by neurological diseases (García et al., 2017). The ATLAS 2025 is an active overground exoskeleton created for rehabilitation purposes that attaches to the child's legs and trunk and allows walking in a functional gait pattern (see the Methods section for details).

The ATLAS 2020, a research prototype of the exoskeleton, has been tested with children with SMA Type II at the EXO-Trainer project. In that study seven children with SMA Type II used the ATLAS 2020 for eight walking sessions, achieving good results in aspects related to safety and operation/functionality (Sanz-Merodio et al., 2017, 2018). Also, a recent publication with the commercialized version of the device (ATLAS 2030) showed an improvement in range of motion and strength in three children with SMA that received nine sessions of rehabilitation therapy with the exoskeleton (Cumplido-Trasmonte et al., 2022). However, the effects of the ATLAS exoskeleton have never been assessed before from a nursing point of view, considering the device not only as a rehabilitation tool but also a device for providing pediatric care. Doing so is necessary because nurses need to know its effects on care aspects beforehand in order to align the use of this technology with the goal of achieving health and wellbeing to patients. We also believe that evaluating exoskeleton technology from the nursing perspective can help understanding its effects on humans in a more complete and holistic way because nursing science gaze understands and evaluates the person as a whole.

Regarding the scientific evidence on robotics in nursing science, there is a growing body of literature about robots (different from exoskeletons) designed with caring purposes, along with new nursing and caring theories related to robotics (Locsin, 2017; Tanioka, 2017). In addition, first steps to understand the implication of exoskeletons in nursing practice has been taken (Hasegawa & Muramatsu, 2013; O'Connor, 2021). However, there is no other clinical study, to our knowledge, addressing the effects of robotic exoskeleton on real patients from the nursing point of view. In order to do so, we used as a theoretical background, the Orem's self-care deficit nursing theory (SCDNT; Orem et al., 2001). This is one of the most popular nursing theories worldwide. In this theory, several theoretical concepts are defined, whose relationships establish the content of the theory itself (Orem et al., 2001; see also Biggs, 2008). These basic concepts are: (a) self-care: the ability of taking care of one self; (b) self-care requisites: the needs that must be satisfied to achieve an adequate self-care; (c) self-care agency: the ability for satisfying the self-care requisites; (d) self-care demand: the set of self-care activities that need to be carried out to satisfy self-care requisites; (e) self-care deficit: a deficit appears when the person's self-care agency is not high enough to satisfy an

specific self-care demand (Orem et al., 2001). Another important concept is the Basic Conditioning Factors (BCFs) which are the factors that affect the type and amount of care required. These are age, sex, developmental status, sociocultural orientation, family support system, health situation, health care system, life patterns and environmental factors (Orem et al., 2001). According to SCDNT, the universal self-care requisites are the needs common to all human beings. These requisites, defined by Orem, are the maintenance of a sufficient air and water supply, maintenance of a sufficient food intake, provision of care associated with elimination processes and excrements, maintaining a balance between activity and rest and also between solitude and human interaction, the prevention of dangers, and the promotion of human functioning and development within social groups. The universal requisite of maintaining a balance between activity and rest is based on the premise that this balance is essential for promoting, maintaining, and restoring the human life process (Orem et al., 2001; see also Allison, 2007). In addition, in children with SMA this specific universal requisite can be specially affected. The reason for this is that their ability (self-care agency) to make the activities needed to satisfy the needs (self-care demands) of this specific requisite are diminished due to the physical limitations. Another aspect to take into consideration is that many of their self-care agency depends on, and is performed, by their caregivers because they are still children and due and they have a high level of dependence.

Anticipating the possible effects of using the ATLAS 2025 on the children self-care, we suspected that performing physical activities with an exoskeleton are new and potentially demanding exercise for children with SMA Type II. That is because children with this condition are not used to walk, and their activity tolerance is low because of their muscle weakness and their respiratory problems. Activity tolerance is one aspect related to the universal requisite of maintaining a balance between activity and rest in Orem's theory and is defined as "the amount and type of activity a person is able to complete without excessive physical, emotional, or psychological fatigue, stress or discomfort" (Molineux, 2017, p. 4). It can be measured by subjective scales of perceived fatigue or objective variables, such as vital signs (Molineux, 2017, p.4). Other authors have defined the opposite term, activity intolerance, as "the insufficient physiologic or psychological energy to endure or complete required or desired daily activities" (Herdman et al., 2015, p. 225). According to these authors, some of the defining characteristics are fatigue, abnormal heart rate or anomalous blood pressure in response to the activity performed.

Understanding how the exoskeleton technology use affects patient care is crucial for nurses because it is likely that these technologies will be incorporated into the treatment and caring of patients all around the world in the future (Lefmann et al., 2017).

Purpose and design

The purpose of this case study is to evaluate the activity tolerance shown by a child with SMA type II and respiratory failure, when using the ATLAS 2025 exoskeleton at home for walking and performing activities daily. A secondary objective is to assess any change in the functional capacity of the child after using the exoskeleton for two months. To address the objectives of this study, we used a mixed-method research design, collecting quantitative and qualitative data.

Methods

Participant characteristics

The current study on activity tolerance was part of a larger clinical study about the impact of using the ATLAS 2025 exoskeleton on the quality of life of three children with SMA Type II. The inclusion criteria for the participants were a confirmed diagnosis of SMA Type II and age between 4 and 9 years. The exclusion criteria were established based on the recommended physical limits of the device so as not to exceed the exoskeleton's safe use: (a) weight over 40 kg; (b) hip-knee

distance <22 cm or >38 cm; (c) knee-ankle distance <21 cm or >37 cm; (d) distance between trochanter <24 cm or >40 cm; and (e) limit of joint range >20°. Three children fulfilled the inclusion criteria for the larger study and were recruited by the pediatric neurology department at the hospital.

When doing the previous nursing assessment to the participants (see below), a new self-care demand arised that captured our attention: “to be able to tolerate the activity performed with the exoskeleton”. To carry out this case study on the self-care demand of activity tolerance, the subject with the highest muscular weakness and functional limitations was selected, as a lower tolerance was expected to emerge.

A description of the child was developed as a first step to complete the nursing assessment prior to the use of the exoskeleton, using the basic conditioning factors (BCFs) of the SCDNT theoretical background. The participant was a 6-year-old male child diagnosed with SMA Type II at 10 months of age with a history of admission to the intensive unit care for pneumonia. He had generalized muscle weakness and was unable to walk but was able to sit up on his own. He was unable to do transfers by himself and in need of an electric wheelchair to move around. He had ineffective cough and chronic respiratory failure and required mechanical ventilation during sleep. He was a gastrostomy and tracheostomy carrier with a visual limitation (myopia) compensated with glasses. He was receiving medical treatment with Spinraza® every 4 months, 4 ml of oral salbutamol and physiotherapy every day. The child showed an appropriate development and cognitive status, and appropriate family support. He attended an adapted-motor handicapped school. He had dependent care in all Activities of Daily Living (ADLs) provided every day by parents and at school by a caregiver. Finally, he had a sleep pattern of 10 h at night and social interaction with other children, at school and with his brother at home. As it can be derived from the above description of the patient, this was a child with a risk of intolerance to activity, so the present study was convenient to ensure his safety.

Instruments

ATLAS 2025 pediatric exoskeleton

This exoskeleton consists of two robotic legs, a trunk and eight motors (four in each leg). The exoskeleton hangs on a frame that supports

the entire weight of the device and provides stability, allowing freedom of movement. It attaches to the human body by an ergonomic system of pads, straps, and braces. It provides forward and backward overground walking assistance and is fully adjustable to different sizes. Regarding its functionality, it is operated through an app and has two modes of action: automatic (in which the exoskeleton gives a full gait assistance to the patient) and active (in which the exoskeleton only takes the step if the child exerts enough force to overcome the threshold previously established by the therapist). Fig. 1 shows a schematic of the device.

OMNI Perceived Exertion Scale (Utter et al., 2002)

It consists of a visual scale for assessing fatigue, with pictorial and verbal descriptors placed along a numeric ascendant line from 0 (not tired at all) to 10 (very, very tired) (Utter et al., 2002). This scale was assessed by verbally asking the patient how “tired” he felt (from 0 to 10), showing him the picture and let him point out his level of fatigue.

Field notes

Another qualitative assessment consisted of field notes collected during participant observation during the sessions in which any activity performed, and any sign or aspect related to activity tolerance were registered (Shah, 2017).

Hammersmith Functional Motor Scale for SMA II and III patients (HFMS) (Ramsey et al., 2017)

The HFMS has 21 items related to motor skills.

Revised Upper Limb Module (RULM) (Mazzone et al., 2017)

This scale assesses upper limb motor function in children with SMA in 19 scorable items (Mazzone et al., 2017).

Egen Klassifikation 2 (EK2) (Fagoaga et al., 2015)

This scale assesses the overall physical functions at the activity performance level in non-ambulant patients with SMA; it consists of 17 scoring items.

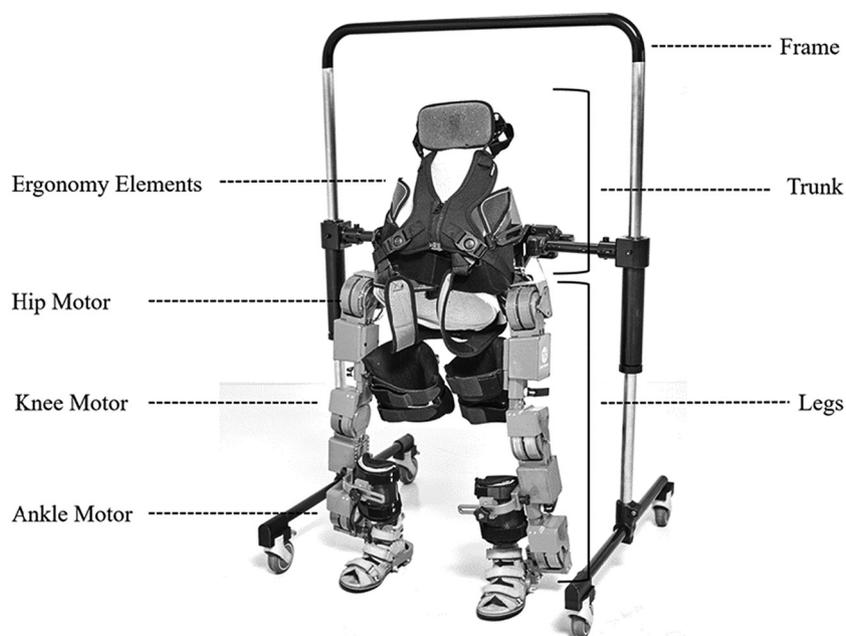


Fig. 1. ATLAS 2025 exoskeleton.

Procedure

The sessions with the exoskeleton were implemented by a physical therapist and conducted at the participant's home, and it was established that the child would use the device at home from Monday to Friday during a period of two months. Each session of use of the exoskeleton consisted of a previous participant's musculoskeletal preparation performed by the physiotherapist. Subsequently, vital signs and perceived fatigue were taken (Utter et al., 2002). Then, the child was placed in the exoskeleton. The child walked back and forth for almost an hour both in automatic and active modes. The walking activity was accompanied by other types of ludic, sports and daily activities. Field notes were taken during the sessions. Vital signs were taken again in sitting position at the end and the level of fatigue was recorded.

Based on SCDNT theoretical background, two nursing assessments were performed. One prior to the use of the exoskeleton to find out the basic self-care status of the child (see Participant Characteristics). The other one was performed at the end of the study to know the changes in the child's self-care after using the device. The first nursing assessment was based on the data collected from the interview with the main caregiver and the review of the medical records of interest. The second assessment focused on evaluating the self-care requisite of maintaining a balance between activity and rest, and specially, determining the activity tolerance shown by the child when using the exoskeleton. To this end, specific variables were defined and evaluated, which results finally make it possible to achieve the objective of the study.

Data collection

The data collection process took place from June till August 2018. It included qualitative and quantitative data. Data on baseline self-care status were collected through a semi-structured nursing interview based in the SCDNT conducted with the main caregiver at the beginning and at the end of the study. The information was complemented by reviewing medical records of interest. Data collected during the sessions also included gait length and number of steps in automatic mode, number of steps in active mode and length of the activities performed. Vital signs were also taken before and after the sessions to evaluate any objective sign of activity intolerance, such as an abnormal respiratory rate or blood pressure along with cardiac rate and oxygen saturation. The OMNI perceived exertion scale was administered before and after each session. Also, the two functional scales (HFMSE and RULM) and the EK2 were administered prior to the use of the exoskeleton, in the middle (RULM only) and at the end of the study.

Ethical considerations

This study was performed in accordance with the Declaration of Helsinki (Rohrich, 2013) and the European Medicines Agency Guidelines for Good Clinical Practices. Approval was obtained by the University Hospital Ramón y Cajal Ethics Committee with Medical Products and the parents of the participant gave written informed consent.

Data analysis

A nursing assessment was performed by conducting SCDNT-based interviews with the main caregiver of the child before using the exoskeleton to assess the previous self-care condition of the child. Then, changes in self-care related to the use of the exoskeleton were also found. In the assessment, data about BCF were obtained, as well as data on aspects related to the universal care requirement of maintaining a balance between activity and rest. Then a set of self-care demands were established both before and during the session period.

A descriptive analysis of all quantitative data was also performed. Quantitative variables were summarized using the mean and standard

deviation. Pre- and post-session measurements were compared via *t*-test for paired samples or Wilcoxon signed-rank test ($\alpha = 0.05$), which was used in case the rules of parametric statistics were not followed. Depending on the amount of data, the Shapiro-Wilk or Kolmogorov-Smirnov test with Q-Q plots and histograms was used to check the distribution of the data. Broadly, the results are shown for weekly groupings of treatment sessions. Bar plots were used to visually summarize the mean and standard deviation of walking time, number of steps, and length of activities. All analyses were performed using IBM® SPSS® Statistics v27 software (IBM Corporation, Armonk, NY, USA).

The field notes that were collected during the sessions were descriptive. The thematic analysis that was carried out was made up of two phases: coding and categorization (Vaismoradi et al., 2013). The coding consisted of establishing which of the codes, which appeared after the analysis of the field notes after the participant observation, were directly related to the tolerance to the child's activity. The second phase, categorization, consisted of grouping the codes into general categories and subcategories, to finally obtain the description and knowledge of the observed phenomenon (Graneheim et al., 2017). During the analysis, a total of 20 codes related to activity tolerance were found.

To obtain a more complete vision of the phenomenon under study and to include all different aspects related to it, a methodological triangulation was carried out in which both qualitative and quantitative techniques were used (Flick, 2018). In addition, two different researchers performed the analysis of the field notes separately, the results of which were discussed later to reach a consensus on the results (Flick, 2018; Cypress, 2017). One researcher, who was an expert in the nursing model used as a theoretical framework in this study, validated the question guide for the self-care interviews with the main caregiver as well as the nursing assessment that was administered.

Findings

The total number of sessions held was 38, in which the child used the exoskeleton in 30 of them. The child did not walk in four of those eight sessions due to pain on a knee caused by an excessive joint stretching when receiving physiotherapy at the school. In the other four, the child could not carry out the exoskeleton sessions at home because he had to attend to some medical appointments.

Evaluating activity tolerance

Before bringing the exoskeleton to child's home, the necessary information to determine the child's BCFs was obtained from the nursing interview and medical records (see Participant Characteristics). After evaluating the universal requisite of maintaining a balance between activity and rest, self-care demands were obtained, and a dependent self-care deficit showed up: Parents' agency cannot satisfy the self-care demand of compensating for the child's incapacity to walk. This self-care deficit was expressed in the form of the following nursing diagnosis based on NANDA International: Impaired physical mobility related to neuromuscular impairment decreased muscle strength, activity intolerance, musculoskeletal impairment, and the inability of parents to compensate for them, as evidenced by the child's inability to walk (Herdman et al., 2015).

By incorporating the exoskeleton as a new therapy for two months, the impaired mobility self-care deficit found was resolved, and the BCF changed affecting the child's pattern of life and activity. These changes were: (a) Life pattern: changes in his normal routine from Monday to Friday by including one hour of exoskeleton treatment during the evenings, and an increase in his normal daily physical activity, including activities never done before, such as walking and playing sports and games using an exoskeleton. (b) Resource availability: a new resource for care, a robotic exoskeleton that allows the child to walk was added.

The new daily activity of using ATLAS 2025 demands extra physical effort by the child which have an impact on the universal requisite of maintaining a balance between activity and rest, so two new self-care demands were generated. On one hand, the child's self-care demand to be able to tolerate the activity carried out with the exoskeleton during the sessions of use, and on the other hand, the parent's demand to support and accept the use of the device by their child at home.

The self-care agency assessment for tolerating activity performed with the exoskeleton consisted of the collection of data from an overall performance and activity assessment as well as vital signs, fatigue, and field notes.

General Performance

During the therapeutic sessions, the patient undertook training tests with the exoskeleton in two walking modes: automatic and active. In the first one, he was supposed to first walk under the assistance of the device and, in a second stage, to practice several ludic activities. Performance in said stages was assessed by means of the total amount of time and number of steps given in each case.

When automatic mode was used, the patient was able to efficiently walk at home. In general, progressive improvement was noted both in terms of walking time (Fig. 2) and in the number of steps taken (Fig. 3). Even though strong deviations were reported, it could be stated that the time length of the sessions tended to stabilize at approximately 65 min in the final sessions, whereas the number of steps noticeably increased by following a moderate upward trend. As sessions progressed, the patient was more capable of overcoming his own previous milestones. Such improvement can be summarized with the number of steps, increasing from an average of 273.5 ($SD = 116.7$) steps in the first 10 sessions to 364.6 ($SD = 157.6$) steps in the 10 final sessions.

When active mode was used, the number of steps given and the number of sessions in which the mode could be successfully performed were rather limited. This fact can be attributed to the remarkable physical and psychological effort that movement-intended walking requires. Nevertheless, it could be globally observed that the average number of steps of the 10 sessions in which the participant walked in active mode was 24.1 ($SD = 19.5$) steps.

Activities performance

One of the main incentives of this study was to allow the patient to practice activities or games that he was previously unable to do because

of his disease. The participant performed activities using the exoskeleton in 29 of the 30 sessions in which walked in it. The patient practiced an average of 2.8 games per session ($SD = 1.4$), including darts, basketball, tennis, and other ball-related games, among others. As a result, a gradual improvement was noted in terms of session length since it tended to increase over time (Fig. 4).

Vital signs and fatigue

To assess the impact that the therapeutic sessions had on the patient, several vital signs were checked before and after engaging in the therapy with the device. Table 1 presents the average values reported for each vital sign.

The data were taken from the 30 sessions in which the participant used the exoskeleton. Overall, the patient's fatigue tended to decrease as he completed more therapy sessions with the exoskeleton, reaching a final point where he expressed no fatigue at all.

Field notes

Out of the 38 sessions, 20 were observed and field notes were taken. An absence of signs of activity intolerance was noticed during the sessions. Only in one session out of the total of 20 sessions was the child asked to sit down due to his expressing tiredness. In the rest of the sessions, no signs or symptoms of activity intolerance were observed, such as shortness of breath, the need to stop, verbal expression of tiredness, the need to sit down or a desire to end the session, and the child's willingness to continue with the activities was observed throughout most of the sessions. Activity intolerance shown in three sessions was related to factors other than physical fatigue or muscle weakness, such as pain or discomfort.

An increase in the number of different activities and their level of intensity was observed over time. In the first three sessions, the child only performed the activity of walking with the exoskeleton using the automatic mode. However, in the final days, he was able to play sports while walking and play difficult games, such as catching small balls while walking. He also started to perform more interactive games.

The number of steps in each session increased over time, indicating that the activity tolerance also increased as the child progressed in the physical requirement of the activities.

It was also observed that there was an important psychological component in relation to the motivation to carry out activities that may have affected the psychological component of activity tolerance. Fear or

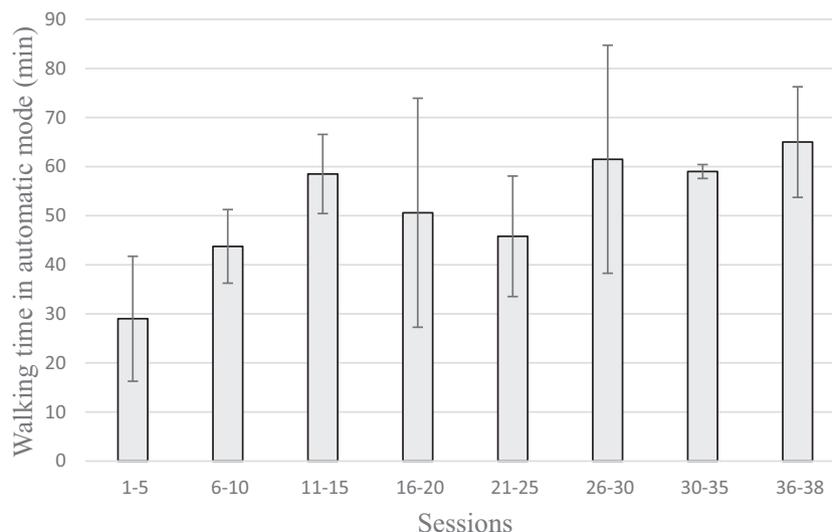


Fig. 2. Average evolution of the walking time in automatic mode. Mean and standard deviation.

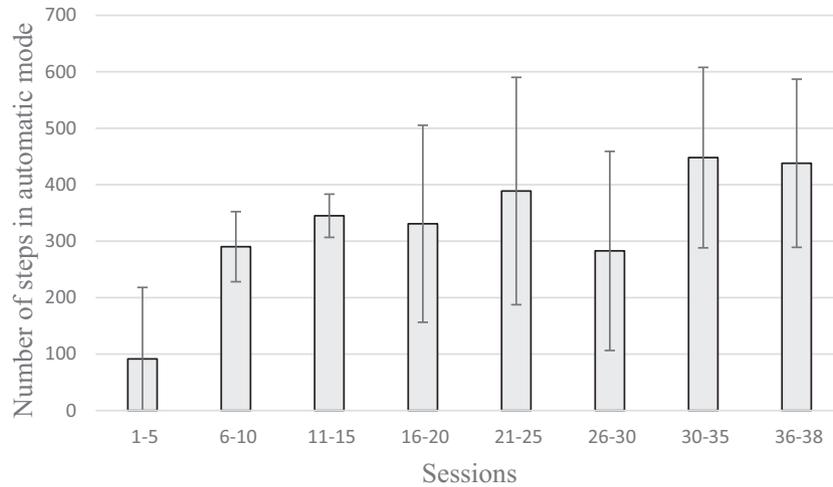


Fig. 3. Average evolution of the number of steps of gait in automatic mode. Mean and standard deviation.

insecurity are emotions that have a negative impact in regard to the willingness to perform activities with the robotic device.

Once the results related to the child's agency of tolerating the activities performed with the exoskeleton were obtained, we were able to complete our assessment of the balance between activity and rest. As a final result of the analysis of the child's self-care agency results reported above, his agency satisfied the self-care demand of tolerating the activity carried out with the exoskeleton.

Functional outcomes

To perform the functional assessment, the patient was evaluated on the HFMSE, RULM and EK2 scales to assess whether any qualitative improvement had occurred with regard to the SMA and functionality effects. The HFMSE and EK2 scales were performed at the beginning and at the end of the therapy. The results on the HFMAE showed all items remaining unchanged except for item 2 (long seated), which increased by 1 point (namely, starting at 1 and ending at 2). The results on the EKS showed a 1-point increase in the child's ability to feed himself.

On the other hand, the RULM scale was undertaken at the beginning, after one month and at the end (monthly frequency). The patient obtained a better scale rating at the end. More concretely, 4 items on the test increased by 1 point: items A (Entry item, to establish maximal functional level), E (Place a piece in a glass located on a table at shoulder

height), F (Get to the side and touch the piece) and J (Lift a glass with a 200 g weight to mouth height), whereas item G (Push a button) increased by 2 points.

Discussion

We have performed a study evaluating the activity tolerance of a child SMA Type II, a neurological condition that causes muscle weakness and gait impairment, to walk with the ATLAS 2025 pediatric gait exoskeleton at home. The assessment was based on the SCDNT Theory described by Dorothea Orem.

The results obtained in the nursing assessment of the study suggest that exoskeleton technology could be considered a new caring resource that allows children with SMA Type II to walk, helps improve associated self-care problems, such as impaired mobility, and increases their self-care agency. Likewise, incorporating this resource into the daily lives of children should produce a change in their BCF and generate new self-care demands that must be satisfied.

This means that nurses working with children using exoskeletons must be able to establish new self-care demands in each case and evaluate the self-care agency of each child and/or main caregiver to satisfy them.

In this study, the participant showed an adequate activity tolerance allowing him to use and perform all kinds of activities with the exoskeleton during the two-month period of study. In Sanz-Merodio's study,

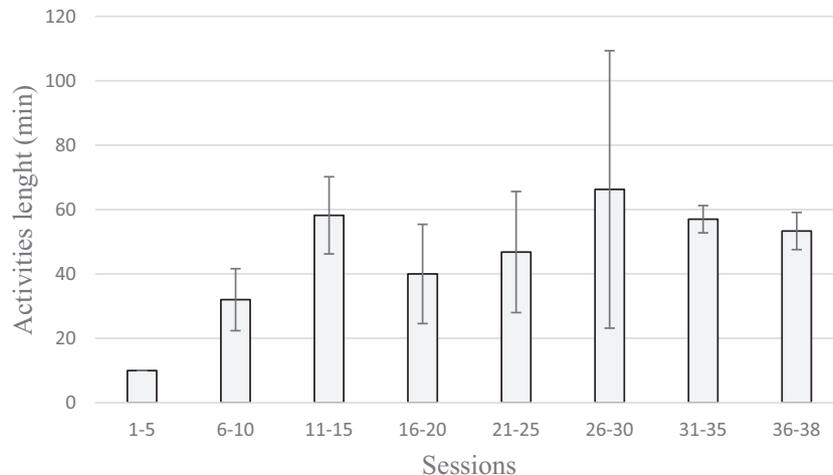


Fig. 4. Average change in the length of activities. Mean and standard deviation.

Table 1
Values of vital signs.

Vital sign	Before the session	After the session	p
	M (SD)	M (SD)	
Cardiac frequency (beats/min)	119.4 (5.8)	117.7 (6.7)	0.291
Breathing frequency (breaths/min) ^[1]	27.9 (2.5)	27.7 (2.3)	0.734
Systolic blood pressure (mmHg)	99.4 (7.4)	103.9 (7.8)	0.044*
Diastolic blood pressure (mmHg)	67.0 (5.0)	68.3 (5.4)	0.197
Blood oxygen saturation (%)	97.6 (0.8)	98.0 (0.4)	0.048*

Note. Result of 30 data collection. [1] Result of 27 data collection.

* p < 0.050 according to t-test for paired samples or Wilcoxon signed rank test.

self-perceived fatigue, as assessed with the OMNI scale after the activity, was distributed between the values of zero and 2 in 50% of cases, with the other 50% being distributed between 2 and 6. The participant's self-perceived fatigue in our study not only decreased over time, being zero in most of the last sessions, but also never exceeded a value of 5 on the OMNI scale (whose scores range from 0 to 10). That noted value falls between 4 (getting more tired) and 6 (tired), indicating that perceived exertion did not reach intolerable scores during the trial. Our results also indicate an improvement in the physical performance of the child over the weeks as evidenced by the results of the qualitative variables, the increase in the number of steps taken in each session, the rise in maintenance over time, the activities carried out and the total usage time of the device.

The child's vital signs did not vary significantly indicating that the exercise performed using the device was physically well tolerated. The same result was found in the EXOtrainer project (Sanz-Merodio et al., 2018). The increase in systolic pressure observed at the end of the sessions can be considered normal variation due to the practice of physical exercise (Sharman & LaGerche, 2014). There is also an increase in oxygen saturation following the use of the exoskeleton that can be caused by the association between a patient's position and ventilation that may lead to an increase in oxygen saturation while standing in the exoskeleton (Lumb & Nunn, 2000). In addition, the mean values of all the vital signs obtained were within normal ranges for the age and characteristics of the child (American Heart Association®, 2012; Sepanski et al., 2018).

The results on the HFMS, RULM and EK2 scales showed an improvement in the child's ability to perform functional activities. These results suggest that the therapy accomplished using the ATLAS 2025 could also benefit children with SMA Type II to elevate their self-care agency to perform ADLs with greater autonomy, but they must be confirmed with more studies.

It was also shown that the psychological dimension - specifically, emotions such as fear and insecurity, as well as pain and joint or muscle discomfort - were important aspects related to the tolerance of the exoskeleton. Other studies on robot-assisted gait training (RAGT) using similar exoskeletons with children with cerebral palsy have also found pain and fear to be important elements to assess (Bayón et al., 2018). Therefore, it would be convenient to pay attention to emotions and other psychological aspects in future studies, when evaluating the use of exoskeleton technology in children.

From the care science perspective, exoskeleton technology could be considered as an external environmental factor that would affect the person, which is considered as a unit of the body, mind and spirit. Exoskeletons would help to improve human harmony or health but can also generate needs that should be known and taken into consideration by nurses if they aim this technology to be well tolerated by patients.

Limitations

The main limitation of our study is that it was a case study, so the results cannot be generalized. The child was also receiving medical treatments, so possibly the functional and general performance

improvements are the result of a combination of all treatments including that with the exoskeleton. A follow-up after the study would have been adequate.

Implications for practice and conclusions

Exoskeleton technology could be considered a new resource for the professional care of children with neuromuscular diseases that cannot walk, that helps resolve the impaired physical mobility nursing diagnosis. However, more research is needed to address the impact on all aspects related to self-care and the changes expected in the state of care and health of the pediatric patients.

A child with SMA Type II and respiratory failure showed good activity tolerance while walking and performing activities with the ATLAS 2025 exoskeleton for two months at home in most of the sessions carried out. He also showed increasing global physical performance over time.

Likewise, the increases recorded on the functional scales suggest an improvement in the child's self-care agency that would positively affect his ability to perform ADLs autonomously.

More research from nursing and caring sciences perspective should be conducted to provide more evidence with a larger sample of participants to support or refute the results obtained in this study.

CRedit authorship contribution statement

Elena Garces: Conceptualization, Methodology, Investigation, Formal analysis, Data curation, Writing – original draft. **Gonzalo Puyuelo:** Methodology, Formal analysis. **Iván Sánchez-Iglesias:** Supervision, Validation. **J. Cristina Francisco del Rey:** Supervision, Validation. **Carlos Cumplido:** Formal analysis. **Marie Destarac:** Supervision, Writing – review & editing. **Alberto Plaza:** Writing – review & editing. **Mar Hernández:** Writing – review & editing. **Elena Delgado:** Writing – review & editing. **Elena García:** Supervision, Project administration, Funding acquisition.

Declaration of Competing Interest

Elena Garces reports a relationship with Marsi Bionics S.L. that includes: employment. Marie Destarac reports a relationship with Marsi Bionics S.L. that includes: employment. Gonzalo Puyuelo reports a relationship with Marsi Bionics that includes: employment. Alberto Plaza reports a relationship with Marsi Bionics S.L. that includes: employment. Elena Garcia reports a relationship with Marsi Bionics S.L. that includes: board membership.

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