Safety, performance and user satisfaction study of the new ABLE lower-limb exoskeleton for individuals with SCI: the result of a co-creation process with clinicians and patients

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Safety, performance and user satisfaction study of the new ABLE lower-limb exoskeleton for individuals with SCI: the result of a co-creation process with clinicians and patients

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Abstract

Background: This study assessed the safety, performance and user satisfaction of a new version of the ABLE Exoskeleton for gait training in people with spinal cord injury (SCI). This new hip-knee-powered version of the exoskeleton (i.e. ABLEhipknee) has been developed taking into account the results of clinical trials with the previous knee-powered version (i.e. ABLEknee) and feedback from clinicians and patients.

Methods: In this quasi-experimental study, a 10-session training program with the ABLEhipknee version was conducted on five participants with chronic, thoracic motor-complete SCI. Safety (device-related adverse events) and performance outcomes (level of assistance, donning/doffing time, therapy metrics) were recorded at every session. Standard clinical tests including 6MWT, 10MWT and TUG were carried out in the last session. The results from the present study were compared against the results obtained by a similar subset of participants from previous clinical trials with the ABLEknee version.

Results: The participants achieved a significantly better performance (higher walking time, number of steps, and distance walked, \( p < 0.001 \)) and experienced fewer device-related adverse events than participants from previous clinical trials where the ABLEknee was used. Participants of the present study also required...
lower levels of assistance to complete the therapy activities and achieved a significantly higher walking distance during the 6MWT compared to the previous clinical trials. The time to don/doff the ABLEhipknee took on average 3 minutes more than the ABLEknee with comparable levels of assistance. Regarding user satisfaction, the ABLEhipknee presented on average higher scores than the ABLEknee.

Conclusions: This study shows that, after the design changes performed on the ABLE Exoskeleton, the device continues to be safe for gait rehabilitation in people with SCI in a hospital setting. Moreover, the ABLEhipknee proved to be superior in terms of performance, with higher satisfaction scores as rated by participants and therapists. Overall, the results highlight the importance of co-creation to develop meaningful rehabilitation technology, engaging with people living with SCI and therapists as part of the team, to integrate their feedback into the design and better address their needs.

Trial Registration: NCT05590065

Keywords: Spinal cord injury, Wearable exoskeleton, Gait training

1 Background

Spinal cord injury (SCI) produces a complex syndrome characterized by the loss of sensory and/or motor function below the neurological level of injury (NLI) [1]. Derived from the lack of physical activity due to limited motor function, individuals with SCI also suffer secondary health complications including diminished bladder, bowel, and sexual function, neuropathic pain, pressure sores, spasticity, bone density loss, and pulmonary and cardiovascular problems [2], all affecting their quality of life. One of the main rehabilitation goals for patients after SCI is to regain independence as well as to improve mobility function and well-being [3, 4]. Therefore, rehabilitation programs for SCI are recommended to include (task-specific) locomotor training as a primary component.

In the last decade, wearable lower-limb exoskeletons have emerged as a promising tool to assist locomotor training transforming the way rehabilitation is delivered [5], as their use may reduce labor load on therapists, improve gait efficiency, elicit a more physiological gait pattern, and provide safer walking compared to manual assisted gait training [6]. Nevertheless, the widespread acceptance of overground exoskeleton devices has been hindered by their bulky size, high cost, and limited usability. Therefore, to improve the adoption of this kind of technology, the development process of new devices requires understanding and adapting the design to the needs of both people with SCI and clinicians.

A co-creation process with clinicians and patients

The ABLE Exoskeleton is a wearable lower-limb exoskeleton, designed by ABLE Human Motion, S.L. (Barcelona, Spain) for gait training in a clinical setting. The
Design methodology followed an iterative co-creating process to integrate the feedback of people with living with SCI and clinicians to better address their needs.

The first version of the ABLE Exoskeleton (i.e. ABLEknee) had two battery-powered motors that assisted the flexion and extension of each knee joint, and two non-motorized, passive hip joints that allowed free movement in the sagittal plane (Figure 1). The ABLEknee was tested in two different clinical trials.

The first study (ABLEknee_S1) aimed to determine the safety, feasibility, and usability of the ABLEknee for gait training in individuals with SCI in a hospital setting [7]. Meanwhile, the purpose of the second study (ABLEknee_S2) was to compare the use of the ABLEknee against conventional knee-ankle-foot orthosis (KAFO) in people with SCI, regarding gait biomechanics and energetics [8]. Both studies concluded that the ABLE Exoskeleton performs as intended and is safe for gait training in persons with SCI in a clinical setting. Nevertheless, it was found that the free, non-actuated hip flexion-extension motion made it difficult for some participants to maintain their trunk upright while walking [7, 8]. Particularly, for those with cervical and high thoracic injuries [7]. From the latter study, it was identified that the lack of trunk stability caused a high metabolic cost, similar to walking with KAFOs [8]. Also, some episodes of mild pain and skin issues related to the use of the device were reported in both studies [7, 8]. In particular, skin lesions were mostly located at the lower back, caused by friction with the exoskeleton structure [7].

After these findings, the ABLE Human Motion team decided to improve the design of the device to enhance performance among users with limited trunk control and reduce the identified adverse events. Active end-user feedback from both clinicians and people with SCI was a key aspect involved in the development process, as an input for engineers to ensure the focus on meaningful priorities. Two main types of feedback data were collected, following guidance from IEC 62366-1:2015 standard on usability engineering for medical devices: 1) semi-structured interviews or focus groups, and 2) observations from usability tests (formative evaluations). Semi-structured interviews were facilitated with therapists working in rehabilitation. The interviews were recorded, transcribed, and analyzed with thematic analysis. Observations were collected during usability tests with different iterations of the prototype device. These were tested in semi-structured sessions, at a frequency of 2-4 users per week over 6 months. Users with SCI participated in usability testing in 2-hour blocks in a representative and safe testing environment, and members of the ABLE Human Motion team visited rehabilitation centers to test with therapists for half or full-day learning sessions. Goals for these sessions were planned weekly to align with the design and development schedule, and findings were documented in photos, videos, exoskeleton performance data, and notes. Conclusions or requested changes from both interview and observation results were translated into technical requirements and communicated to the engineering team through biweekly meetings.

This iterative co-creation process enabled feature discovery and modifications for a more usable device that better addresses users’ needs. The lumbar module of the device is an example of how a design change followed this process. During interviews, therapists commented that “Patients have a hard time going to a standing position because... the low back, they have pain, and they hate doing exercises that improve this
strength. They want to walk but they find it hard to improve their low back strength.”
Another therapist commented “In a clinic, an exoskeleton is the tool that [has the potential to] stand a patient most upright. If you’re trying to work on trunk and core, this is very valuable.” These insights led the team to prototype a device with active hip actuation and a lumbar module that contacted the patient’s back over a wider area, including the sacrum, to put them into the correct posture for walking. Multiple iterations of this design were tested and results recorded with a wide range of SCI users, with injury levels varying from C5 to T12. The new design was demonstrated to several clinicians for validation and feedback, so they could express if the design change was an improvement and whether this had introduced any new concerns (in the specific case of the wider lumbar module, the need for additional padding on the sacrum). Finally, it was decided that this improvement was valuable and should be included in the final device design.

From the insights of the previous clinical trials and the co-creating process involving end-users feedback, a new version of the ABLE Exoskeleton (i.e. ABLEhipknee) was developed featuring the following major design changes: (1) addition of hip actuation to provide better trunk stability and proximal assistance to achieve the desired foot clearance during the swing phase, (2) an articulated ankle to provide better balance in standing and to achieve a more natural gait pattern, (3) a redesigned lumbar module that covers a wider area, including the sacrum, (4) optional shoulder straps for users who need extra upper trunk support, (5) implementation of variable assistance control that allows to adjust the amount of support provided by the motors at each joint and phase of the gait cycle, which is especially useful for users with incomplete, asymmetric or low neurologic level injuries, (6) new textile fixtures, padding and rigid supports to improve ergonomics, usability and avoid skin lesions at contact points, and (7) a

Study aims

The purpose of the present study was to evaluate the safety, performance, and user satisfaction of the ABLEhipknee for gait training in people with SCI in a clinical setting. The results of the present study were then used for comparative analysis against the results obtained in previous clinical trials conducted with the ABLEknee version. Specifically, the present study aimed to answer the following research questions:

1. Is the use of the new ABLE Exoskeleton (i.e. ABLEhipknee) still safe for gait training in people with SCI after implementing the aforementioned design changes?
2. Is the gait training performance of individuals with SCI better with the ABLEhipknee compared to the ABLEknee?
3. Are end-users (i.e. participants with SCI and therapists) more satisfied with the ABLEhipknee than with the ABLEknee?

The main hypothesis was that after the design changes were made to the device, its use would remain safe for the intended population. The secondary hypothesis was that the ABLEhipknee design would show a better performance and higher satisfaction scores from both participants and therapists than the ABLEknee.
Fig. 1 General overview of the ABLE Exoskeleton. The main characteristics and differences between the (A) ABLEknee and the (B) ABLEhipknee versions of the ABLE Exoskeleton.

2 Methods

2.1 Device description

A detailed description of the ABLEknee version can be found in [7, 8]. In this clinical study, the device used was the ABLEhipknee version: a wearable lower-limb robotic exoskeleton that actively assists individuals with mobility impairments to stand up, walk, turn and sit down. It consists of a bilateral rigid frame that attaches to the torso, legs, and feet of the user through straps and rigid supports, weighing a total of 17 kg. It has four battery-powered motors that drive the knee and hip joints, assisting in flexion and extension. The remaining degrees of freedom of the knee and hip joints are restricted. The ankle joints are articulated in plantarflexion-dorsiflexion using a spring mechanism. The exoskeleton is used with crutches or a walker for stability. It comes with an Android mobile phone with a pre-installed software application (ABLE Care), which communicates wirelessly to the device via Bluetooth and allows the therapist to configure and monitor the exoskeleton during a therapy session.

The device is controlled using either the Therapist Controller (up and down buttons located on the lumbar module of the exoskeleton) or the Patient Controller (up and down buttons located on the Remote Controller attached to the walker or crutches). These controllers allow the user to transition between the different states of the exoskeleton: from sitting to standing, from standing to walking, from walking to turning, and vice versa.

During walking, each step can be triggered by either the therapist or the patient. When done by the therapist, they hold the device using the handles and decide when
to activate each step by pressing either of the pushbuttons (left for triggering the left hip and knee flexion-extension motion and right for the right one) that are located on the lumbar module of the device. When done by the patient, their intention to take a step is detected automatically using inertial measurement unit (IMU) sensors embedded in the exoskeleton. IMU sensors send motion data to the electronic control unit, which then analyses the data and identifies the time instant to start a step cycle. There are two automatic modes: Center of Mass, which triggers a step with the leg that is behind when the patient shifts their weight laterally and frontally, surpassing a predefined threshold; and Dynamic, which detects a forward motion of the pelvis measured through a change in the thigh angular velocity of the stance leg, to then trigger a step.

2.2 Study design

A quasi-experimental clinical trial was conducted at Aspeyo Sant Cugat Hospital (Barcelona, Spain), a center specialized in SCI, from October to December 2022. The clinical trial was approved by the responsible local ethics committee (CEIm Grupo Hospitalario Quirónsalud-Catalunya; study code: 2022/55-REH-ASEPEYO) and national competent authorities (Spanish Agency of Medicines and Medical Devices (AEMPS); EUDAMED: CIV-ES-22-09-040647). The study was conducted under the principles of the Declaration of Helsinki (revised version 2013), the requirements of ISO 14155:2020, and the European Regulation 2017/745 on medical devices (MDR). The study protocol was prospectively registered at ClinicalTrials.gov on 18/10/2022 (NCT05590065).

2.3 Study protocol

The study protocol was based on the design of previous clinical studies with the ABLEknee (ABLEknee_S1 [7] and ABLEknee_S2 [8]). Nevertheless, there were some protocol differences between the studies. A summary of the three study protocols is provided in Table 1.

In the present study, the number of participants was set to 5, which was considered an appropriate representative sample for a safety and performance trial. The decision was based on the background of other clinical investigations conducted with a similar number of participants [9–11] and the learnings from the two previous clinical trials with the ABLEknee. Sampling was completed by the pre-screening of all in- and outpatients. All patients who were potential participants were asked to participate in the clinical trial. After signing the informed consent, the individuals were screened to assess the inclusion/exclusion criteria. During screening, participants were exposed to a 30-minute standing test with the device to assess if they experienced orthostatic hypotension while being upright. After inclusion, a pre-training evaluation without the device was conducted.

In the same manner as in the ABLEknee_S2 study [8], participants underwent a training program of 10 sessions with the ABLEhipknee, 2 times a week for 5 weeks. Each session was scheduled for 90 minutes to provide enough time for initial adjustments, donning and doffing, data collection, and gait training. Missed sessions could
Table 1 Protocols used in each clinical investigation. The main similarities and differences between the three protocols are summarized.

<table>
<thead>
<tr>
<th>Present study</th>
<th>ABLEknee_S1 [7]</th>
<th>ABLEknee_S2 [8]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>5</td>
<td>24(^1)</td>
</tr>
<tr>
<td>Number of sessions</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Session duration</td>
<td>90 min</td>
<td>60 min</td>
</tr>
<tr>
<td>Minimum therapy time</td>
<td>30 min</td>
<td>30 min</td>
</tr>
<tr>
<td>- AEs</td>
<td>- AEs</td>
<td>- AEs</td>
</tr>
<tr>
<td>- Donning/doffing time</td>
<td>- Donning/doffing time</td>
<td>- Donning/doffing time</td>
</tr>
<tr>
<td>- LoA to sit-to-stand, walk, turn 180(^0), and stand-to-sit</td>
<td>- LoA to sit-to-stand, walk, turn 180(^0), and stand-to-sit</td>
<td>- LoA to sit-to-stand, walk, turn 180(^0), and stand-to-sit</td>
</tr>
<tr>
<td>Outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Walking and standing times</td>
<td>- Walking and standing times</td>
<td>- Walking and standing times</td>
</tr>
<tr>
<td>- Number of steps and distance walked</td>
<td>- Number of steps and distance walked</td>
<td>- Number of steps and distance walked</td>
</tr>
<tr>
<td>- TUG, 10MWT and 6MWT</td>
<td>- TUG, 10MWT and 6MWT</td>
<td>- TUG, 10MWT and 6MWT</td>
</tr>
<tr>
<td>- RPE</td>
<td>- RPE</td>
<td>- RPE</td>
</tr>
<tr>
<td>- User satisfaction</td>
<td>- User satisfaction</td>
<td>- User satisfaction</td>
</tr>
<tr>
<td>Gait assessments measurement point</td>
<td>Session 10</td>
<td>Sessions 1 and 12</td>
</tr>
</tbody>
</table>

\(^1\)Note that this number corresponds to the total number of participants included in the study and does not represent the number of participants considered in the comparative analysis.

AEs: Adverse events, LoA: Level of assistance, TUG: Timed-up-and-go test, 10MWT: 10-meter walk test, 6MWT: 6-minute walk test, RPE: Rate of perceived exertion.

be made up by doing 1 more session per week during the training or afterward using an extra week (week 6). As in the two previous clinical studies with the ABLEknee, therapy time was required to be at least 30 minutes, which included the time spent standing, walking, or sitting in the exoskeleton [7, 8].

In each training session, participants were required to complete four therapy activities: sit-to-stand, walk 10 meters, turn 180\(^0\), and stand-to-sit, the same activities performed in the ABLEknee_S1 [7]. Participants were encouraged to do all the activities with as little assistance as needed from the therapist. Each session was carried out by one trained therapist. Different outcomes related to safety and performance were measured during the training sessions. In the last training session, a user satisfaction questionnaire was completed and standardized clinical gait tests were performed followed by a post-training assessment session. Two weeks after the final post-training session, a follow-up by phone call was conducted. The study protocol is summarized in Figure 2.

2.4 Study participants

Informed consent from potential participants was obtained before performing any clinical study-related activity. Fifty potential participants were screened for eligibility. Seven individuals met all inclusion/exclusion criteria (see Additional file ??), from which two declined to participate and five were included in the clinical trial. The five
participants were male, with traumatic, chronic (≥ 1 year), motor-complete injuries. The neurological level of injury (NLI) ranged from T4 to T9. Participants were on average 44.00 ± 7.97 years old. Detailed demographics of the study participants are provided in Additional file 2.

#### 2.5 Outcome parameters

To evaluate the impact on safety, performance, and user satisfaction of the design changes made to the ABLE Exoskeleton, the following outcomes were measured.

##### 2.5.1 Adverse events

Adverse events (AEs) and serious adverse events (SAEs) were documented during the whole study, particularly monitoring skin integrity issues, pain, and falls. Skin integrity was evaluated by doing a visual inspection of the participants’ skin in the areas susceptible to increased pressure or friction with the device. If a lesion was identified, it was assessed using the European Pressure Ulcer Advisory Panel (EPUAP) scale. Pain was measured using the Visual Analog Scale (VAS). Both skin integrity and pain were assessed at every session before and after walking with the device. The occurrence of falls was recorded at every session for each participant.

Following the methodology of the previous studies with the ABLEknee and based on the MDCG 2020-10/1 guidance, causality of AEs was rated by the investigators as ‘related’, ‘probably related’, ‘possibly related’, and ‘not related’ within four categories: device, procedure, disease, and other causes. Only those AEs rated as ‘related’ were classified as device/procedure/disease-related AEs. The number and cause of device-related adverse events were considered the main safety outcomes.

##### Time to don/doff

The recording of the time for donning started when the participant was prepared to transfer from the wheelchair to the bed where the device was placed, and ended when all the attachments or straps of the device were securely tightened. The doffing period started when the participant started removing the device until transferred back to the wheelchair.
Level of assistance

The level of assistance (LoA) was measured using the same scale as in previous studies with the ABLEknee (see Additional file ??). In every session, the therapist rated the assistance provided to complete each of the therapy activities as well as the donning and doffing of the device.

Therapy metrics

The following parameters were chosen as therapy metrics: standing time, walking time, distance walked, and number of steps. These parameters were directly collected from the session summary provided by the ABLE Care app.

Clinical gait assessments

In the last session, three standardized clinical gait assessments were performed: the timed-up-and-go (TUG) test, the 10-meter walk test (10MWT), and the 6-minute walk test (6MWT). These tests were carried out in a (previously marked) 60 meters pathway at the beginning of the session to avoid fatigue. The first assessment done was the TUG test and the time taken to complete it was recorded. Then, there was a 10 minutes resting period, in which the participants were asked to complete the user satisfaction questionnaire. Once the participants recovered, the 6MWT was conducted. The test was done at a self-selected speed walking back and forth the pathway until the 6 minutes had elapsed. The distance covered by the participants during this time was recorded. Additionally, the time to complete the first 10 meters was recorded as part of the 10MWT.

Physical exertion

The rate of perceived exertion (RPE) was measured using the Borg scale (6-20). It was reported by participants immediately after finishing the 6MWT.

Level of satisfaction

The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) questionnaire was used to measure participants’ and therapists’ satisfaction regarding the use of the device. The QUEST 2.0 questionnaire was administered to the participants in the last session of the training program and to the therapists at the end of the study.

2.6 Comparative analysis

The safety, performance, and user satisfaction outcomes of the present study were compared against the results obtained from the ABLEknee_S1 [7] and ABLEknee_S2 [8] studies. Some considerations were taken for the data included in each analysis regarding the participants’ injury level and severity, and the study protocol differences (see Table 1). Detailed demographics of the participants included in each analysis are given in Additional file 2.
Safety and user satisfaction analysis

As safety and satisfaction are metrics of interest despite the motor function and injury characteristics of the individuals, the data of all the participants included in each of the studies was considered in the comparative analysis of safety and user satisfaction.

Performance analysis

For the comparative analysis of the performance metrics, we decided to use a subset of data from the ABLEknee_S1 [7] and ABLEknee_S2 [8] studies, including only participants that presented similar clinical characteristics as the ones included in the present study. Therefore, only participants with motor-complete lesions and NLI between T1 and T9 were selected from the studies ABLEknee_S1 [7] and ABLEknee_S2 [8] for the comparative analysis of the performance metrics. This decision was taken to avoid bias caused by the differences in motor function between the participants of the different studies.

The therapy activities (sit-to-stand, walk 10 meters, turn 180° and stand-to-sit) and the RPE were only measured in the present study and in the ABLEknee_S1 [7], therefore the comparative analysis of these outcomes did not include the ABLEknee_S2 [8]. The walking times were normalized by the standing time resulting in the walking-standing time ratio, which accounts for the difference in session duration between studies. Additionally, the therapy metrics results from sessions where gait assessments were performed were not considered in the comparative analysis since participants had long rest breaks between assessments, leaving less remaining time to carry out the therapy activities. In all the cases, the outcomes of the clinical gait assessments used in the comparative analysis were the ones performed in the last session.

2.7 Statistical analysis

Categorical variables such as AEs and LoA were described using group sizes and frequencies. Quantitative variables were summarized using standard descriptive statistics (i.e. mean, standard deviation (SD), minimum, and maximum). For the therapy metrics and the outcomes of gait assessments, distribution normality and homogeneity of variance of data were assessed using the Shapiro–Wilk and Fligner-Killeen tests, respectively. Nonparametric statistics were used as the sample size was small (n < 50), and the data did not show a normal distribution in the Shapiro–Wilk test (p < 0.05). The changes in outcomes before and after training (within groups) were analyzed using the paired two-tailed Wilcoxon signed-rank tests. The differences in outcomes between the groups were analyzed using a Kruskal-Wallis test. A post hoc pairwise two-tailed Wilcoxon rank-sum test was used to compare the groups where a significant difference was found. The level of significance was set to p < 0.05 for all tests. All statistical analyses were carried out using R Statistical Software (v4.2.1) [12].
3 Results

3.1 Study completion

All five participants completed the entire protocol without missing any session. The last training session of all participants was conducted on the 7th week of the training program due to required maintenance activities of the device performed by the manufacturer. All participants remained in the study until the follow-up visit, thus there were no dropouts.

Fig. 3 Flow diagram in compliance with the CONSORT statement (modified for non-randomized trial design). The chart shows the flow followed by the study participants and the flow of the data used in the comparative analysis.

3.2 Safety outcomes

A total of 22 AEs were reported during the 50 sessions performed throughout the clinical trial (Table 2). From these events, only one (4.5%) was considered to be related to the device and the rest (95.5%) were non-related. The device-related AE was reported by one of the physiotherapists due to bruises on both shins caused by a hit of the heel of the exoskeleton with the therapist’s legs while walking during the training sessions. The bruises resolved in the following days without any complication, thus it was considered of low severity.
Table 2 Number of adverse events and device-related adverse events. The AEs are categorized by type and cause, considering the data of all participants in each of the studies (Present study: N = 5, ABLEknee S1: N = 24, and ABLEknee S2: N = 10).

<table>
<thead>
<tr>
<th></th>
<th>Present study</th>
<th>ABLEknee S1 [7]</th>
<th>ABLEhipknee S2 [8]</th>
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<tbody>
<tr>
<td></td>
<td>Total (%)</td>
<td>Device-related (%)</td>
<td>Total (%)</td>
</tr>
<tr>
<td>Skin integrity</td>
<td>0 (0)</td>
<td>27 (33.3)</td>
<td>5 (6.2)</td>
</tr>
<tr>
<td>Pain</td>
<td>10 (45.5)</td>
<td>22 (27.2)</td>
<td>3 (3.7)</td>
</tr>
<tr>
<td>Neuropathic pain</td>
<td>5 (22.7)</td>
<td>9 (11.1)</td>
<td>0</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>1 (4.5)</td>
<td>8 (9.9)</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>4 (18.2)</td>
<td>0 (0)</td>
<td>0</td>
</tr>
<tr>
<td>Others</td>
<td>2 (9.1)</td>
<td>1 (4.5)</td>
<td>15 (18.5)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>22 (100)</strong></td>
<td><strong>81 (100)</strong></td>
<td><strong>8 (9.9)</strong></td>
</tr>
</tbody>
</table>

One (4.5%) AE, corresponding to a hospitalization caused by a urinary tract infection, was reported as serious (SAE) but without any relation to the device or the procedure. Mostly, the AEs reported were pain (45.5%), neuropathic pain (22.7%), and dizziness (18.2%) but none of them were considered to be caused by the device. Other reported events without a medical occurrence were classified as device deficiencies according to ISO 14155:2020.

Compared to the studies with the ABLEknee, the number of device-related AEs in the ABLEhipknee study was considerably lower and no skin damage nor device-related pain were reported. As in the previous studies, no falls or fractures occurred. However, one near fall was reported in one of the sessions with the exoskeleton: after a sit-to-stand transition, the patient lost balance and the therapist helped to prevent the fall with their arm. This event was evaluated by the site investigators to be unrelated to the device -since the behavior of the device during the transition was as expected-but related to the procedure considering that it could have happened with any other device used for standing assistance. The risk of imbalance and potential falls while standing is inherent to SCI due to reduced postural control and decreased sensation and proprioception.

3.3 Performance outcomes

**Time to don/doff**

Donning and doffing the ABLEhipknee required an average total time of 11 minutes and 52 seconds. This time decreased as participants progressed throughout the study, even though no significant differences were found between the first and last session (session 1: 13:15 ± 3:47 min:sec; session 10: 11:05 ± 3:09 min:sec; p = 0.44). The time taken by participants to don and doff the ABLEhipknee version was higher compared to previous studies with the ABLEknee in participants with similar characteristics (ABLEknee S1 [7]: 9:08 ± 3:07 min:sec, p < 0.001 and ABLEknee S2 [8]: 9:55 ± 2:59 min:sec, p = 0.002, see Table 3, donning and doffing).
3.3.1 Level of assistance to don/doff

In the first session with the ABLEhipknee, all the participants required either maximum (60%) or moderate assistance (40%) to don the device (Figure 4A). For doffing the device, the LoA was very similar, 40% needed maximum assistance, 40% required moderate assistance and only 20% could achieve supervision in the first session (Figure 4B). As expected, as participants progressed through the sessions, the amount of assistance required to don/doff the device decreased. By the last session, the majority of participants (60%) were able to don the device with complete independence, 20% did it with only supervision, and 20% required minimum assistance (Figure 4A). Meanwhile, the doffing was performed with total independence by 80% of the individuals, and only 20% required minimum assistance (Figure 4B). Compared to the studies with the ABLEknee, the level of assistance required by the participants to don and doff the ABLEhipknee was lower than in the ABLEknee_S1 [7] (Figure 4C and 4D) and similar to the ABLEknee_S2 [8] (Figure 4E and 4F).

![Fig. 4 Level of assistance to don and doff the device. The progression in the level of assistance required is shown over the course of the training sessions for each clinical study.](image)

3.3.2 Level of assistance in therapy activities

The assistance needed by the participants to complete each of the four therapy activities was less compared to the results obtained in the study ABLEknee_S1 [7] (Figure 5). In the present study, by the end of the training, all participants could complete the four tasks with moderate (60%) or minimum assistance (40%) (Figures 5A to 5D). In the study ABLEknee_S1 [7] instead, by the end of the training program, 25% of participants still needed total assistance to perform all four tasks (Figures 5E to 5H).
The most remarkable differences were found for the tasks of walking 10 meters and turning 180°. In the study *ABLEknee_S1* [7], 80% of the participants were not able to perform the aforementioned tasks in the first session (Figures 5F and 5G). Even by the end of the training, 25% of participants required total assistance to walk 10 meters (Figure 5F), and 25% could not complete the task of turning 180° (Figure 5G).
In the present study with the ABLEhipknee, all the participants achieved these tasks since the first session and 60% did it with moderate assistance (Figures 5B and 5C). Furthermore, by the end of the training program, 40% were already able to walk 10 meters and turn 180° with no more than minimal assistance. In fact, in the session prior to the final assessments (session 9), 80% of the participants were able to complete all therapy activities with minimum assistance.

### 3.3.3 Therapy metrics

The average per session in all the therapy metrics with the ABLEhipknee was significantly higher ($p < 0.001$) than the ones achieved in the studies with the ABLEknee. In the present study, participants walked an average of 28.7 ± 6.2 minutes per session. Analyzing the walking-standing ratio, it was found that the average per session (53.7 ± 11.0%) represented an increase of 77.2% over the results accomplished with the ABLEknee, with higher standing times (ABLEknee, S1 [7]: 30.3 ± 20.4% time walking of 13.8 ± 6.7 minutes standing and ABLEknee, S2 [8]: 28.9 ± 8.7% time walking of 28.4 ± 9.6 minutes standing). As a result of the longer time spent walking, the average number of steps and distance walked per session by the participants was also superior in the present trial. Participants achieved at least 3 times more steps and covered 7 times more distance than in the previous studies with the ABLEknee (Present study: 599.1 ± 249.1 steps, 281.2 ± 134.1 meters; ABLEknee, S1 [7]: 106.6 ± 90.1 steps, 31.733.9 meters; ABLEknee, S2 [8]: 160.5 ± 68.7 steps, 39.5 ± 17.9 meters).

Significantly ($p < 0.05$) better outcomes in all therapy metrics were achieved in the second session of the training program, compared to the results obtained by a similar subset of participants in the studies with the ABLEknee version (Table 3, therapy metrics). This represents an outstanding improvement, since the start of the training program, in the walking-standing ratio (144.8%), the number of steps (267.8%) and distance walked (560%) in participants using the ABLEhipknee version in contrast with a similar group of participants using the ABLEknee.

Similarly, the outcomes from the present study were remarkably higher by the end of the training program compared to the studies using the ABLEknee version (Table 3, therapy metrics). Although in session 9 statistical significance ($p < 0.05$) was found only for the differences in the number of steps and distance covered, the results still constitute an improvement in the walking-standing ratio (41.7%), the number of steps (207.4%) and distance walked (439.4%) compared to the ABLEknee studies.

Participants showed a positive learning curve with improvements in all the therapy metrics from the beginning to the end of the training program. In the first session, on average, they stood for 41.4 ± 11.4 minutes and walked 16.8 ± 6.1 minutes (40.6% of walking-standing ratio), did 145.2 ± 99.0 steps and covered a distance of 56.3 ± 43.5 meters. In session 9, participants spent an hour standing (62.8 ± 8.8 minutes) and doubled the walking time (37.2 ± 3.7 minutes), representing an increase (of 47.2%) in the walking-standing ratio (59.8%). In a similar trend, there was a considerable improvement in the average number of steps (455.2%) and distance walked (615.2%), with participants achieving 806.2 ± 318.0 steps and 402.4 ± 176.78 meters by session 9 (see Table 3, therapy metrics).
Fig. 6 Therapy metrics. The progression in the average (A) walking-standing ratio, (B) number of steps, and (C) distance walked is shown over the course of the training sessions for each clinical study. Note that standardized assessment sessions were not included in the figures and that the number of sessions was not equal in all studies.
3.3.4 Gait assessments

An improvement in all the standardized clinical assessments was observed with the ABLEhipknee (see Table 3, clinical gait assessments) compared to the studies with the ABLEknee, although only the distance covered during the 6MWT showed statistically significant differences when compared against the ABLEknee_S2 trial [8]. All the participants in the present study and in the ABLEknee_S2 [8] study were able to complete the three assessments (TUG, 10MWT, and 6MWT) in the last session. In contrast, only 75% of the participants evaluated in the ABLEknee_S1 [7] study were able to complete the TUG and 10MWT, and only 50% of the participants completed the 6MWT.

The majority of participants (60%) using the ABLEhipknee completed the 10MWT in less than 60 seconds (i.e. gait speeds above 0.17 m/s), while in the previous clinical trials, none of the individuals in the ABLEknee_S1 [7] and only 33% of the participants in the ABLEknee_S2 [8] achieved this performance. In addition, during the 6MWT all participants from the present study walked more than 50 meters (69.9 ± 8.3 meters). Meanwhile, only one of the two participants of the ABLEknee_S1 [7] who completed the 6MWT was able to walk more than 50 meters and none of the users in the study ABLEknee_S2 [8] could accomplish this performance (28.2 ± 8.1 meters). The physical exertion perceived by the participants of the present study was less (10.2 ± 3.2) than in the ABLEknee_S1 [7] study (13.0 ± 3.2) as rated by the Borg scale (Table 3, clinical gait assessments).

3.4 User satisfaction outcomes

The average satisfaction among participants (total QUEST 2.0 score) using the ABLEhipknee was rated 34.20 ± 4.38 points over 40. Most of the categories (6 out of 8) of the QUEST 2.0 showed better scores with the ABLEhipknee compared to those obtained in the ABLEknee studies (Figure 7A) (ABLEknee_S1 [7]: 31.71 ± 5.50 and ABLEknee_S2 [8]: 32.00 ± 8.26). The categories of safety (4.80 ± 0.45), comfort (4.80 ± 0.45), and effectiveness (4.60 ± 0.89) were the highest-rated ones by the participants in this study and notably superior to the scores obtained in the other two clinical trials with the ABLEknee. The only category that was considered to be better in the previous studies with the ABLEknee was durability (Present study: 3.20 ± 1.10; ABLEknee_S1 [7]: 4.00 ± 0.82; and ABLEknee_S2 [8]: 4.10 ± 0.99). In a similar trend, the therapists rated with better scores the ABLEhipknee version of the device compared to the ABLEknee in 5 out of the 8 categories (Figure 7B) but their scores were slightly lower than the participants, with an average satisfaction of 31.00 ± 2.83 points out of 40 (ABLEknee_S1 [7]: 29.45 ± 4.16 and ABLEknee_S2 [8]: 24.00 ± 8.49). The effectiveness, weight, and dimensions were the highest-rated scores, all of them with a rating of 4.50 ± 0.71 points. Safety was found to be scored higher by the participants than the therapists (participants: 4.80 ± 0.45; therapists: 3.00 ± 0.00). However, the safety score given by therapists was on average, similar to the ratings obtained in the ABLEknee_S1 [7] (3.64 ± 0.92) and ABLEknee_S2 [8] (2.50 ± 0.71) studies. In correlation with the scores obtained by participants, durability was found to be the lowest rated compared to the other trials.
Table 3 Performance outcomes. The mean, standard deviation and range of the performance outcomes are shown, considering the data of the subset of participants in each of the studies (Present study: N = 5, ABLEknee_S1: N = 5, and ABLEknee_S2: N = 6).

<table>
<thead>
<tr>
<th>Therapy metrics</th>
<th>Present study Mean±SD</th>
<th>ABLEknee_S1 Mean±SD</th>
<th>p-value</th>
<th>ABLEknee_S2 Mean±SD</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>[Range]</td>
<td>[Range]</td>
<td></td>
<td>[Range]</td>
<td></td>
</tr>
<tr>
<td>Donning and doffing</td>
<td>9.00 ± 2.06</td>
<td>6.13 ± 2.07</td>
<td>&lt; 0.001</td>
<td>7.18 ± 2.23</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>t_DON (min:sec)</td>
<td>2.58 ± 1.00</td>
<td>3.04 ± 1.02</td>
<td>0.42</td>
<td>2.39 ± 0.45</td>
<td>0.17</td>
</tr>
<tr>
<td></td>
<td>[1:24 – 6:23]</td>
<td>[0:59 – 5:23]</td>
<td></td>
<td>[3:18 – 4:18]</td>
<td></td>
</tr>
<tr>
<td>t_DOFF (min:sec)</td>
<td>11.52 ± 2.51</td>
<td>9.17 ± 2.59</td>
<td>&lt; 0.001</td>
<td>9.55 ± 2.59</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Walking - Standing ratio (%) - Recession 2</td>
<td>49.7 ± 9.1</td>
<td>15.9 ± 22.0</td>
<td>&lt; 0.05</td>
<td>20.3 ± 6.1</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td></td>
<td>[38.8 – 60.9]</td>
<td>[0.0 – 44.4]</td>
<td></td>
<td>[8.7 – 25.9]</td>
<td></td>
</tr>
<tr>
<td>Walking - Standing ratio (%) - Session 9</td>
<td>59.8 ± 6.4</td>
<td>33.0 ± 22.1</td>
<td>0.10</td>
<td>42.2 ± 13.7</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>[51.4 – 69.2]</td>
<td>[11.8 – 61.9]</td>
<td></td>
<td>[28.6 – 66.7]</td>
<td></td>
</tr>
<tr>
<td>Steps (n) - Session 2</td>
<td>377.0 ± 217.1</td>
<td>41.6 ± 45.5</td>
<td>&lt; 0.05</td>
<td>102.5 ± 58.2</td>
<td>&lt; 0.05</td>
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<tr>
<td></td>
<td>[182.0 – 677.0]</td>
<td>[3.0 – 98.0]</td>
<td></td>
<td>[38.0 – 180.0]</td>
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</tr>
<tr>
<td>Steps (n) - Session 9</td>
<td>806.2 ± 317.9</td>
<td>139.8 ± 115.7</td>
<td>&lt; 0.05</td>
<td>262.3 ± 123.5</td>
<td>&lt; 0.05</td>
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<tr>
<td></td>
<td>[247.0 – 1037.0]</td>
<td>[26.0 – 326.0]</td>
<td></td>
<td>[133.0 – 460.0]</td>
<td></td>
</tr>
<tr>
<td>Distance (m) - Session 2</td>
<td>158.4 ± 106.1</td>
<td>24.0 ± 36.1</td>
<td>&lt; 0.05</td>
<td>23.1 ± 15.2</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td></td>
<td>[71.5 – 308.0]</td>
<td>[1.0 – 84.0]</td>
<td></td>
<td>[9.3 – 48.8]</td>
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<tr>
<td>Distance (m) - Session 9</td>
<td>402.4 ± 176.8</td>
<td>41.9 ± 42.5</td>
<td>&lt; 0.05</td>
<td>74.6 ± 35.3</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td></td>
<td>[91.6 – 512.4]</td>
<td>[6.0 – 112.0]</td>
<td></td>
<td>[32.2 – 122.7]</td>
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</table>

4 Discussion

Better outcomes in safety, performance, and user satisfaction were observed in the present study, using the ABLEhipknee, compared to the results from a similar subset of participants in the previous clinical trials with the ABLEknee version [7, 8]. These improvements can be associated with the design changes performed to the ABLE Exoskeleton, resulting from integrating end-user feedback. In this section, we discuss the impact of the new design implemented through co-creation on safety, performance, and user satisfaction results.
4.1 Safety

Despite skin damage in areas of contact with the device has been described as the most common risk of using a wearable exoskeleton [13], in the present study no AE was reported within this category. Previous studies involving exoskeletons have documented varying numbers of device-related skin alterations when using similar devices [14–16]. Note that the two previous clinical studies done with the ABLEknee also reported mild skin issues (ABLEknee_S1 [7]: n = 5 and ABLEknee_S2 [8]: n = 1). The absence of skin injuries with the new ABLEhipknee design may suggest that the changes in the textile parts, padding and the redesigned rigid supports improved the ergonomics and comfortability of the system, being able to fit properly all the study participants without causing any skin damage during its use. Additionally, the new wider lumbar module and the hip-powered joints in the ABLEhipknee eliminated the continuous uncontrolled hip flexion-extension movements, contributing to reducing the skin lesions in the sacrum area caused by friction with the lumbar module.

Pain is another well-known potential risk when using robotic exoskeletons [5, 14, 17, 18]. In this study, all the reported AEs falling into this category were sporadic episodes of pain in shoulders, arms, or hands that participants felt before the session and remained at the same level of pain (according to the VAS) or even decreased after the training session. These events were considered to be caused by daily life activities not related to the study. Therefore, none of the pain AEs were classified as device-related. The absence of pain episodes associated with the ABLEhipknee represents an improvement compared to the previous ABLEknee studies where some pain episodes were reported (ABLEknee_S1 [7]: n = 3 and ABLEknee_S2 [8]: n = 1) can be attributed to the enhanced stability provided by the hip actuation while walking, potentially minimizing the load on the upper limbs and discomfort experienced by participants.

Fig. 7 User satisfaction results. Mean scores of the QUEST 2.0 given by (A) participants and (B) therapists in each of the items.

(A) Participants

(B) Therapists

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Weight</th>
<th>Comfort</th>
<th>Adjustments</th>
<th>Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
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<td>4</td>
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<td>3</td>
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</table>

- Present study
- ABLEknee_S2
- ABLEknee_S1
Other AEs that also occurred in this study were isolated episodes of dizziness that could be related either to orthostatic hypotension due to the standing-up procedure or fatigue as a result of moderate-intensity gait training sessions. Finally, some underlying disease-related AEs of neuropathic pain were also reported during the clinical study. However, these are to be expected given the propensity of this type of issue in the SCI population and have also been noted in other exoskeleton trials [19, 20]. As in the two previous studies, no falls occurred.

Altogether, these findings indicate that, in terms of safety, the ABLEhipknee version of the device is equal and potentially better, compared to the ABLEknee version and to other commercially available exoskeletons.

4.2 Performance

After ten training sessions, participants achieved a high degree of independence donning and doffing the ABLEhipknee. Compared to the ABLEknee, donning and doffing the ABLEhipknee was better in terms of assistance needed, but slightly worse in terms of time. Nevertheless, the increase was less than 3 minutes on average. Also, it should be noted that the ABLEhipknee has more attachment points than the ABLEknee to reduce the relative movement and increase the alignment between the device and the participant’s body, providing the user with more stability and reducing the risk of fractures. Therefore, a minor increment in the time to don and doff the device was already expected. An average donning and doffing of 11 minutes and 52 seconds, with low levels of assistance, suggests that the use of ABLE Exoskeleton is feasible within the timeframes available in real-world rehabilitation settings [15, 17, 21] and positions the device as one of the fastest to set up. Existing literature for commercially available exoskeletons reported times ranging from 10 to 30 minutes [5], with levels of assistance from moderate to independence [15, 17, 21].

Participants using the ABLEhipknee also showed a remarkable improvement in the amount of assistance required to perform the therapy activities compared to the results from the ABLEknee_S1 [7]. Particularly, the assistance in the tasks of walking 10 meters straight and turning 180º was greatly reduced. Since the first session, all participants using the ABLEhipknee completed the aforementioned tasks, while with the ABLEknee 80% of participants could not walk nor do the 180º turn. This suggests that the new features added and the design changes (i.e. Turning Assistance state, hip-powered joints) made on the ABLE Exoskeleton, improved the easiness of use and helped participants to complete the therapy activities requiring lower assistance from the physiotherapist. Achieving a high level of mobility independence in tasks such as sit-stand transitions, walking 10 meters straight, or turning 180º, is one of the main goals of rehabilitation, preparing patients for a successful reintegration into the community. This acquired independence also translates into a reduction of the physical burden on the physiotherapist during the training sessions. Moreover, in all the sessions, the training was delivered with the assistance of only one physiotherapist, showing the potential of the ABLE Exoskeleton to reduce the human resources required to deliver effective and functional gait training in people with complete SCI.

In general, the time that participants spent walking with the ABLEhipknee was outstandingly superior to the ABLEknee, as measured by the average walking-standing
ratio per session. This ratio constituted an improvement of 77.2% over the results accomplished in the studies with the ABLEknee, with higher standing times as well. Moreover, it was noticed that at the beginning of the training program, the walking-standing ratio with the ABLEhipknee was considerably higher than the ABLEknee. In contrast, by session 9 this difference was not significant. This change suggests that participants were able to walk more since the beginning, therefore no significant increase was seen by the end of the training program. Consistent with the longer time spent walking, the number of steps and distance walked were also significantly superior achieving at least 3 times more steps and covering 7 times more distance. These findings may be attributed to the design changes made on the ABLE Exoskeleton providing users with better stability, causing less fatigue and, therefore, increasing tolerance for gait training and allowing them to endure more intensive sessions since the beginning of the program.

Another outcome supporting the enhanced endurance for gait training is the lower physical exertion perceived by the participants after the 6MWT compared to the ABLEknee_S1 [7], albeit this difference was not statistically significant. This decrease seems to indicate that participants likely required less effort to walk with the device, maintaining the physical activity for a longer time without reaching exhaustion. Despite this, the results still suggest that training with the ABLEhipknee constitutes moderate-intensity physical exercise. Achieving this is a key factor in any locomotor training program for SCI people since their ability to exercise at high intensities is further limited by intrinsic factors caused by the disability. Furthermore, the time spent walking with the ABLEhipknee (28.7 minutes per session), met the recommended guidelines on exercise for people with SCI (20 minutes of moderate to vigorous intensity exercise) to increase aerobic fitness [22]. Consequently, regular gait training with the ABLEhipknee version of the ABLE Exoskeleton is expected to have a positive impact on the cardiovascular system [23].

Additionally, the average scores of all the gait assessments improved, compared to the trials with the previous ABLEknee. Better outcomes in the TUG test may suggest that the balance during gait and turning achieved by participants with the ABLEhipknee was potentially better compared to the ABLEknee. Also, the results from the 10MWT showed an increase in the gait speed compared to the one achieved with the ABLEknee. The significantly higher distance covered during the 6MWT by participants using the ABLEhipknee, in comparison to those using the ABLEknee, indicates an increased endurance to gait training. These results from the subset of participants analyzed are comparable to the outcomes reported by studies with similar devices available in the market [15, 24].

4.3 User satisfaction

Study participants considered the ABLEhipknee version of the ABLE Exoskeleton to be more effective and comfortable, easier to use, and safer than the ABLEknee. In general, both the participants and the therapists have rated the ABLEhipknee with higher scores for adjustments and easiness of use compared to the ABLEknee. This indicates that they perceive the ABLEhipknee to be more intuitive and easy to adjust. However, both groups considered it to be less durable. This is attributable to
the 16 minor device deficiencies reported during the study. None of these deficiencies
resulted in adverse events and were resolved by the manufacturer throughout the study
without significantly altering the study conduct. Efforts are currently being made by
the engineering team to improve the durability and robustness of the device.

Overall, the average satisfaction scores of both participants and therapists with the
ABLEhipknee were higher than with the ABLEknee with a score equivalent to “Very
satisfied”. The positive outcomes on satisfaction of participants and physiotherapists
in the present study may be the result of applying a co-creation process to integrate
end-user feedback during the development of the ABLEhipknee. These findings suggest
a high acceptance of the ABLE Exoskeleton for gait training of SCI people in a clinical
setting.

No other study reports user satisfaction for SCI participants or therapists for
a comparable robotic exoskeleton with a standard questionnaire such as QUEST
2.0, though studies with multiple sclerosis participants reported lower scores for the
EksoGT (31.3 ± 5.70) [25] and the ReWalk (29.4 ± 2.5) [26]. User satisfaction is an
extremely important factor for device adoption into standard of care, so future work
should focus on more standardized reporting of these metrics.

4.4 Study limitations

Some limitations were identified in this study. First, the sample size used in this
study does not reflect the SCI population as a whole. However, the comparison with a
similar population from previous studies provided an insightful analysis of the results.
Also, note that the gait assessments were conducted only in the last session. This
decision was based on the fact that we intended to capture the best performance of
the participants since the objective was the comparison between the two versions of
the device (ABLEhipknee vs ABLEknee) and not the improvement of participants in a
pre-post analysis. Additionally, a confounding factor was identified since the therapists
measured the LoA provided by them to the participants to keep the balance, but the
amount of assistance provided by the hip or knee motors of the exoskeleton and the
walking aid used were not registered. Keeping record of these variables would have
provided useful information about the functional progression of participants and a
better overview of the required assistance for each participant. Also, we consider that
a larger amount of training sessions is needed to fully capture the complete learning
process of using the ABLE Exoskeleton and to allow participants to progress towards
performing more challenging ambulation activities with increased independence. All
these observations will be considered for upcoming clinical trials. Finally, note that
this study was intended to be a safety and performance study and not an efficacy trial,
so there was no control group to determine whether participants using the exoskeleton
had a larger amount of recovery than those performing conventional therapy.

4.5 Future research

It is considered that the design changes to the ABLE Exoskeleton allowed to extend
the group of potential users with a better gait performance. Still, future clinical inves-
tigations should be conducted with a larger and more heterogeneous SCI population
to confirm this evidence. We also consider that SCI individuals’ ability to perform other essential daily mobility tasks aside from clinical environments using a wearable exoskeleton should be evaluated. Accordingly, there is an ongoing study to assess the feasibility of using the novel design of the ABLE Exoskeleton in home and community settings (Trial registration: NCT05643313). Moreover, further research is crucial to establish evidence for the long-term clinical benefits of exoskeleton use on individuals living with chronic SCI, including psychosocial effects, improvements in cardiovascular health, bowel and bladder function, motor function, and other health-related aspects. Finally, the socioeconomic impact of exoskeleton implementation, such as potential cost reduction in rehabilitation, should also be investigated.

5 Conclusions

This study supports the clinical safety and performance of the ABLE Exoskeleton for the defined indications and intended clinical use. After comparing the outcomes of the three clinical studies, it can be concluded that with the implementation of the design changes in the ABLE Exoskeleton, its use remains safe for gait training in a clinical setting with SCI people. Additionally, the findings of the comparative analysis suggest that the design changes implemented through co-creation led to a device that is superior in terms of performance compared to the previous ABLEknee, with better results in relevant metrics like mobility independence and endurance of gait training. The results also showed a positive impact on user satisfaction regarding the new design of the ABLE Exoskeleton compared to its previous version. Altogether, these findings highlight the importance and effectiveness of co-creation to develop meaningful technology for rehabilitation and demonstrate that this methodology can result in an improved product design with better performance and user acceptance.

Supplementary information. Supplementary information is provided in the additional files attached to the submission of this manuscript.

Additional file 1 — Inclusion and exclusion criteria Document listing the criteria used to assess the inclusion/exclusion of participants into the present study during the screening process.

Additional file 2 — Demographics of all the participants from each of the clinical investigations. Table showing the demographics of the participants included in each of the studies. The subset of participants considered in the performance comparative analysis is highlighted in bold font.

Additional file 3 — Level of assistance definitions Table listing the definitions of the scale used to measure the level of assistance required by participants for both the donning/doffing of the device and the therapy activity tasks.

Acknowledgments. The authors would like to thank all the study participants for their willingness to take part in this clinical trial. Additionally, we also thank Inigo Ruiz López for his comments and proofreading of the manuscript. Finally, from the ABLE Human Motion team, the authors would like to thank all the clinicians and users involved in the co-creation process of the ABLE Exoskeleton for their valuable time, contributions, and feedback from testing sessions.
Declarations

5.1 Funding
Not applicable

5.2 Competing interests
EPM, HLM, JLP and KKT, are employees and receive salary from ABLE Human Motion S.L. (Barcelona, Spain), which was the sponsor of the present clinical study and manufacturer of the ABLE Exoskeleton. ACC is co-founder and owns shares in the company ABLE Human Motion S.L. (Barcelona, Spain), which was the sponsor of the present clinical study and manufacturer of the ABLE Exoskeleton. The other authors declare no competing interests.

5.3 Ethics approval
This study received approval from the Ethics Committee CEIm Grupo Hospitalario Quirónsalud-Catalunya (study code: 2022/55-REH-ASEPEYO) and there was no major deviation from the original protocol altering the conduct of the study. This study protocol is registered at ClinicalTrials.gov with the following identifier: NCT05590065.

5.4 Consent to participate
All subjects provided signed informed consent prior to participation in any clinical study-related activity.

5.5 Consent for publication
Not applicable

5.6 Availability of data and materials
Not applicable

5.7 Code availability
Not applicable

5.8 Authors’ contributions
EPM collected and analyzed the data of the study, drafted the manuscript and prepared the figures. HLM designed the study protocol and provided clinical training on the use of the device. JLP contributed to the data analysis and preparation of the figures. KKT designed and facilitated the co-creation activities. HLM, JLP, and KKT were actively involved in the writing process of the manuscript and provided technical support throughout the study. ACC contributed to the design of the study protocol and the management of the approval process. MTC and FPC conducted the training.
sessions and gait tests with the participants. BSP and JEG helped with the recruitment and screening of participants. All authors reviewed and approved the manuscript.

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Supplementary Files

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- Additionalfile1Inclusionexclusioncriteria.pdf
- Additionalfile2Demographicsofalltheparticipantsincludedineachofthestudies.pdf
- Additionalfile3Levelofassisteddefinitions.pdf