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Adapted Assistance and Resistance Training With a Knee Exoskeleton After Stroke

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***Abstract*—Studies on robotic interventions for gait rehabilitation after stroke require: (i) rigorous performance evidence; (ii) systematic procedures to tune the control parameters; and (iii) combination of control modes. In this study, we investigated how stroke individuals responded to training for two weeks with a knee exoskeleton (ABLE-KS) using both *Assistance* and *Resistance* training modes together with auditory feedback to train peak knee flexion angle. During the training, the torque provided by the ABLE-KS and the biofeedback were systematically adapted based on the subject's performance and perceived exertion level. We carried out a comprehensive experimental analysis that evaluated a wide range of biomechanical metrics, together with usability and users' perception metrics. We found significant improvements in peak knee flexion ($p = 0.0016$), minimum knee angle during stance ($p = 0.0053$), paretic single support time ($p = 0.0087$) and gait endurance ($p = 0.022$) when walking without the exoskeleton after the two weeks of training. Participants significantly ($p < 0.00025$) improved the knee angle during the stance and swing phases when walking with the exoskeleton powered in the high *Assistance* mode in comparison to the *No Exo* and the *Unpowered* conditions. No clinically relevant differences were found between *Assistance* and *Resistance* training sessions. Participants improved their performance with the exoskeleton (24-55 %) for the peak knee flexion angle throughout the training sessions. Moreover, participants showed a high level of acceptability of the ABLE-KS (QUEST 2.0 score: 4.5 ± 0.3 out of 5). Our preliminary findings suggest that the proposed training approach can produce similar or larger improvements in post-stroke individuals than other studies with knee exoskeletons that used higher training intensities.**

***Index Terms*—Rehabilitation robotics, prosthetics and exoskeletons, wearable robotics.**

I. INTRODUCTION

MOTOR disorders, together with cognitive impairments, hinder community ambulation after stroke [1]. The extent and amount of deficits are heterogeneous in this population, but more than 60 % of post-stroke individuals have a lack of control and stability of the knee during gait [2]. The conventional solution to improve knee stability after stroke is to use a passive knee-ankle-foot orthosis (KAFO). Although these orthoses can support knee instability during weight bearing; they encourage compensatory gait strategies, and do not provide knee flexion assistance during swing nor a training effect beyond their passive support [3].

Robotic-assisted therapy in combination with conventional rehabilitation training can play a promising role for individuals post-stroke to increase their ability to walk independently [4]. As an alternative solution to conventional KAFOs, wearable knee exoskeletons are emerging as rehabilitation and assistive devices for individuals with brain injuries [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15], [16]. However, despite the substantial interest on this technology, there is still a gap in the clinical evidence on the efficacy of lower-limb exoskeletons in pathological populations [17], [18], [19]. The limited information on the interventions, and the lack of experimental conditions necessary to isolate the effects of the hardware and the control separately (i.e., no exoskeleton, exoskeleton powered, and exoskeleton unpowered) hinder the extraction of reliable data for rigorous comparisons.

Focusing on the exoskeleton controllers, the most common control strategy implemented to date in lower-limb exoskeletons is based on providing assistance to the user [18]. The use of challenge-based controllers, e.g., functional resistance training, might be particularly beneficial for people in late stages of rehabilitation or with mild impairments, but their implementation is limited in exoskeletons for

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This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Medical Research Ethical Committee (MREC) of the Hospital Universitari Mútua de Terrassa under Application No. E/22-082/S1.

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gait rehabilitation [20]. Another important aspect related to exoskeleton control is parameter tuning, which has been shown to be strongly connected with the potential clinical effect of the robotic device [21]. Nevertheless, to date, systematic or automatic procedures to adjust control parameter values based on subject-specific and task-specific necessities are still scarce [17], [18].

With the present work, we provide an experimental analysis (including biomechanical, usability and user's satisfaction analysis) and protocol to generate rigorous clinical evidence on the training effect of walking with a knee exoskeleton after stroke. Furthermore, we evaluate the combination of assistance and resistance training modes with auditory feedback, and implement a systematic method to tune the exoskeleton control parameters based on the participant's perceived exertion and task performance. To carry out our study, we developed the ABLE-KS, a unilateral, knee-powered exoskeleton that can provide time-adapted assistance and/or resistance based on the duration of previous strides and the current walking state. In addition, the ABLE-KS can provide auditory feedback when the knee flexion angle exceeds a predefined threshold.

We carried out a pilot study with six participants post-stroke with the objective of evaluating the effects of performing a two-week gait training program using the ABLE-KS exoskeleton. Specifically, we sought answers to the following research questions:

1) Do individuals with stroke improve their gait performance (i.e., in terms of peak knee flexion angle, spatiotemporal parameters, gait endurance and speed) after training with the ABLE-KS for two weeks?
2) Do individuals with stroke improve their gait performance (i.e., in terms of peak knee flexion angle and spatiotemporal parameters) while wearing the ABLE-KS in *Assistance* mode?
3) Do individuals with stroke benefit more from a *Resistance* or *Assistance* training for improving peak knee flexion?
4) What is the training effect of using the ABLE-KS for two weeks to improve peak knee flexion?

As secondary objectives, we carried out usability and user's perception assessments to answer the following questions:

1) What is the opinion of post-stroke individuals on the ABLE-KS?
2) What is the time needed to set up the ABLE-KS for post-stroke gait rehabilitation?

II. METHODS

A. Study Design and Experimental Protocol

We carried out an interventional trial that evaluated the effects of performing a gait training with a knee exoskeleton on six post-stroke individuals. The clinical trial was carried out at the Hospital Universitari Mútua de Terrassa (Barcelona, Spain) in December 2022 and the participants were recruited from the same center. The experimental protocol consisted of six sessions: (1) *Baseline* assessment, exoskeleton fitting and controller parameter tuning, (2-5) exoskeleton training sessions, and (6) *Endline* assessment (see Fig. 1). The total duration of the study was 2 weeks with 3 sessions per week and a total duration per session of 1 hour and 30 minutes.

To evaluate the effect of the hardware and the training modes separately, we evaluated one condition walking without the exoskeleton (*No Exo*) and three conditions walking with the exoskeleton: (1) unpowered (*Unpowered*); (2) assistance mode with peak knee flexion feedback (*Assistance*); and (3) resistance mode with peak knee flexion feedback (*Resistance*). The order of the training sessions for all the participants was: *Assistance*, *Resistance*, *Assistance* and *Resistance*. The *No Exo* condition was evaluated at 10 time points: (1) at the first session (*Baseline*; session 1), (2) at the last session (*Endline*; session 6), (3) at the beginning (*Pre*), and (4) at the end (*Post*) of each training session (sessions 2-5).

B. Study Participants

Suitable candidates were identified as post-stroke individuals capable of performing independent gait, exhibiting mild-to-moderate gait deviations due to knee impairments, such as knee hyperextension or buckling during stance and/or deficit of knee flexion or stiff knee during swing [22], [23]. Individuals were eligible for inclusion if they met the following criteria: (1) age above 18 years, (2) unilateral ischemic or haemorrhagic chronic ($\geq$ 6 months) stroke, (3) Functional Ambulation Categories (FAC) score $\geq$ 2, and (4) comfortable treadmill walking speed $\geq$ 0.14 m/s. The exclusion criteria included: (1) high levels of spasticity of muscle tone (resistance to passive movement), as represented by modified Ashworth scale scores $\geq$ 3, (2) premorbid disability of lower extremity, (3) skin problems or ongoing infections in areas in contact with the exoskeleton, (4) impaired cognition, (5) relevant comorbidities (e.g., chronic heart failure, uncontrolled diabetes or hypertension, chronic obstructive pulmonary disease, medical or family history of osteoporosis or a history of fragility fractures in the last two years), and (6) pregnancy or breastfeeding.

In total, six subjects with left-side hemiplegia due to stroke were enrolled for this study. A description of all six participants is reported in Table I. All participants provided informed consent before starting the study.

C. Exoskeleton Hardware

The ABLE-KS device is a wearable, unilateral, knee-powered exoskeleton that can provide knee stability during the stance phase, and assistance or resistance to knee flexion/extension motions during the swing phase (see Fig. 2.A). The ABLE-KS weighs a total of 3.33 kg (actuated leg: 2.09 kg; non-actuated leg: 0.35 kg; lumbar: 0.89 kg). The actuator has a maximum velocity of 25.65 rad/s and can provide a peak torque of 30 Nm, i.e., 85 % of the maximum flexion/extension peak value for a person who weighs 85 kg [24]. Other hardware and firmware components are similar to the ones of the ABLE-S [25].

Compared to other knee exoskeletons, the ABLE-KS is one of the few untethered knee exoskeletons with on-board actuation tested on people with hemiplegia that has one of the best characteristics in terms of peak torque and distal weight,

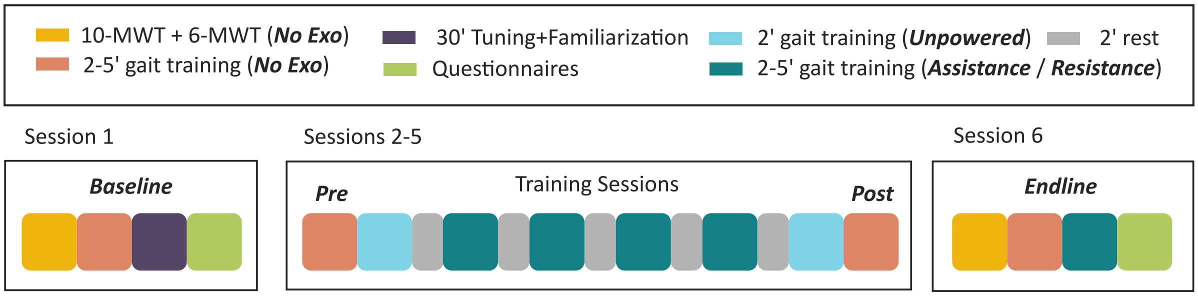

Fig. 1. **Experimental protocol overview.** The experimental protocol included 6 sessions, namely *Baseline*, Training (4x), and *Endline* sessions. In the training sessions, the participants were recorded walking without the exoskeleton on the treadmill for 2 minutes before donning (*Pre*) and after doffing (*Post*) the exoskeleton. The participants walked with the exoskeleton *Unpowered* at the beginning and at the end of the Training sessions.

TABLE I

PARTICIPANTS' BASELINE CHARACTERISTICS. I: ISCHEMIC, H: HAEMORRHAGIC, AFO: ANKLE FOOT ORTHOSIS, FAC: FUNCTIONAL AMBULATION CATEGORY, MAS: MODIFIED ASHWORTH SCALE, 10MWT: 10-METER WALK TEST, 6MWT: 6-MINUTE WALK TEST

ID	Age (years)	Weight (kg)	Height (cm)	Gender	Stroke	Chronicity (years)	Assistive device	FAC	MAS Knee Ext/Flex	10MWT (m/s)	Treadmill speed (m/s)	6MWT (m)
ID1	71	64	165	Male	I	11.0	None	4	0/1	1.14	0.36	285
ID2	56	62	150	Female	I	0.5	Cane/AFO	2	0/0	0.34	0.14	98
ID3	68	66	169	Male	H	12.0	Cane/AFO	4	0/1	0.69	0.22	211
ID4	58	56	156	Female	H	30.0	Cane	3	0/1	0.55	0.27	200
ID5	40	85	169	Male	I	0.5	AFO	4	0/0	0.93	0.42	275
ID6	58	61	154	Male	I	7.0	Cane	4	1/2	0.48	0.25	182

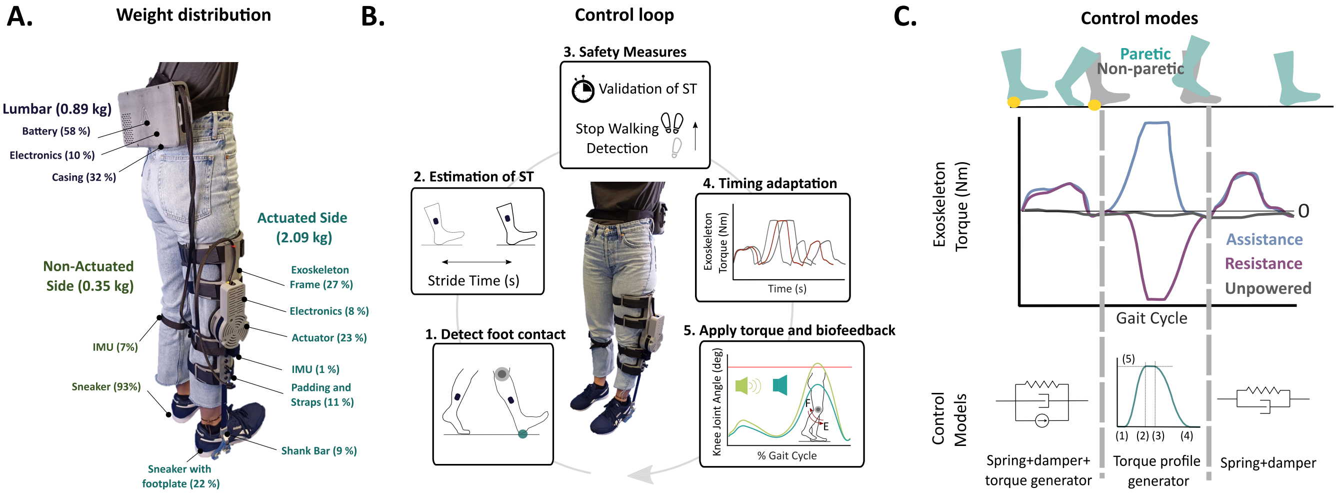

Fig. 2. **Overview of the hardware and control of the ABLE-KS exoskeleton. (A)** Picture of ABLE-KS showing its components and mass distribution. **(B)** Control strategy implemented in the ABLE-KS. **(C)** The three control modes evaluated in this study were: *Unpowered*, *Assistance* and *Resistance*. A first-order impedance model, i.e., spring and damper, with a feed-forward torque generator was implemented to provide support to the knee joint during the stance phase. Torque generation starts when the ipsilateral foot contacts the ground and is applied until the contra-lateral foot contacts the ground to ensure the weight transfer towards the non-paretic leg. Then, the exoskeleton generates torque profiles for flexion assistance or resistance, with adjustable timing and magnitude following a pi-shaped function. The curve has 5 degrees of freedom: (1) onset time (% gait cycle), (2) peak rise time (% gait cycle), (3) peak fall time (% gait cycle), (4) offset time (% gait cycle), and (5) peak torque (Nm/kg). Finally, another first-order impedance model was applied for the knee extension model to ensure the positioning of the shank at the end of the gait cycle and regulate the knee extension speed.

while providing both flexion and extension assistance [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15], [16]. Figure 3 shows the relation between the weight per limb and the peak torque for knee-powered exoskeletons tested on people with brain injuries.

D. Exoskeleton Control

The operation of the ABLE-KS exoskeleton is based on the accurate detection of initial foot contact events through information collected by IMUs (BNO055, Bosch, Germany) placed in the calves of both legs, and then it provides knee *Assistance* or *Resistance* (see Fig. 2.C). Bilateral shank kinematic information obtained with the two IMUs was fed to the exoskeleton controller to detect foot contact and determine the stride time to adapt the timing parameters of the flexion and extension torque profiles. This exoskeleton control scheme is similar to the one that we previously validated on the ABLE-S (i.e., ankle exoskeleton) with individuals with stroke [25].

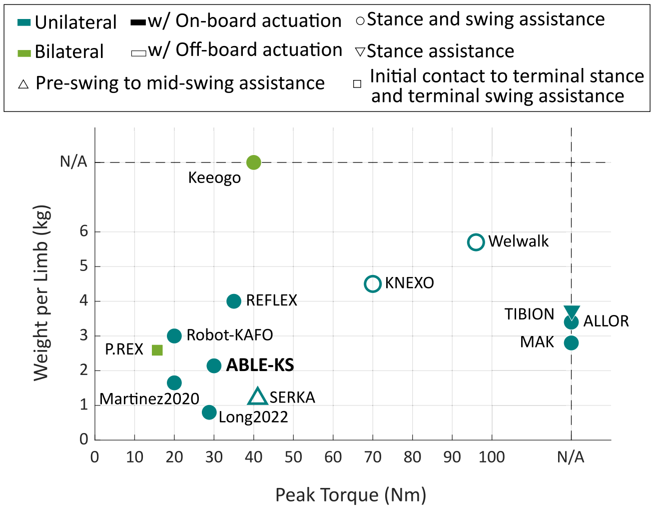

Fig. 3. **Mechanical characteristics of knee-powered exoskeletons found in the literature and tested on people with brain injuries.** The plot shows the weight per limb of the exoskeletons in relation with the maximum knee torque produced by the exoskeletons. The plot also indicates the location (off-board or on-board) of the actuators and the gait phase when the devices provide assistance.

The rationale for alternating between *Assistance* and *Resistance* modes in exoskeleton training is to provide a comprehensive and progressive rehabilitation approach. By offering *Assistance* training, the exoskeleton can help the patient regain a sense of movement and become familiar with the device and the gait sub-task of interest; while *Resistance* training might be useful to enhance endurance, motor control and participation [18]. Alternating between the two training modes capitalizes on the benefits of each one, with the aim of promoting motor recovery and improving functional outcomes for stroke survivors while ensuring engagement with the gait training. This approach can be tailored to individual patient needs and goals, and can also facilitate skill transfer and generalization, as the patient learns to adapt their movements in different contexts. Each stroke survivor may have unique challenges and deficits, and by adjusting the balance between *Assistance* and *Resistance* modes, therapists can personalize the training to optimize outcomes for each individual.

We utilized an auditory biofeedback feature that provided real-time feedback on the knee flexion angle relying solely on an embedded joint angle sensor (see Fig. 2.B). The auditory biofeedback indicates success for every stride in which the peak knee flexion angle reached the angle threshold in *Assistance* and *Resistance* modes. The aim of the feedback was to guide participants during the *Assistance* and *Resistance* modes and maximize user engagement by providing a task-specific objective. The knee angle threshold was adapted to each participant in each session as described in the following section.

E. Exoskeleton Parameter Tuning

Baseline *Assistance* control parameters of the ABLE-KS were tuned based on knee joint angle thresholds associated to physiological values. Supplemental table S1 provides detailed information on the control parameters selected for each participant. Values close to 5° were used as goals for the minimum knee flexion angle during stance phase, and values around 60° for the maximum knee flexion angle during the swing phase. The participants' feedback was always taken into account to ensure their comfort and maximum stability. Examples of the questions asked were: (1) are the movements of the exoskeleton too abrupt?; (2) do you feel unbalanced at any point of the gait cycle?; or (3) are you comfortable with the assistance to flex your knee? See Supplemental Methods section for a more detailed description of the methodology regarding the exoskeleton parameter tuning.

1) Knee Flexion Assistance or Resistance During Swing: The values of the peak knee flexion assistance were defined as 0 Nm (no torque), 2 Nm (low) and 4 Nm (high). The three levels selected for knee flexion resistance were defined as 0 Nm (no torque), -1 Nm (low) and -2 Nm (high). Peak torque values were increased or decreased based on heuristics related to peak knee flexion angle, i.e., the peak knee flexion angle had to be equal or higher than the threshold set for 70 % of the steps; and the participant's Rate of Perceived Exertion (RPE), i.e., the result of the RPE scale administered to the participants at the end of each block, had to be lower than 7. We consider that including the perceived exertion during training is crucial as it was listed as the main predictor of functional capacity in individuals with chronic stroke [26].

2) Peak Knee Flexion Feedback: The threshold of the biofeedback was adjusted for each type of control mode and participant. For the *Assistance* training, the threshold was set to 10 degrees higher than the mean value measured during the *Unpowered* condition. For the three first *Resistance* training blocks, the values were set to 10 degrees lower than the mean value measured in *Unpowered* condition at the beginning of the session. For the last block of the *Resistance* training with the exoskeleton powered, the threshold was set to 10 degrees higher than the mean values measured in the *Unpowered* condition, and the peak torque to 0 Nm. The proposed methodology was chosen to avoid frustration during the treatment and maximize participants' engagement for the task of reaching the target knee angle threshold during swing. Participants were asked to flex their knee until they heard the beeping sound of the biofeedback in each stride without doing exaggerated movements and keeping the pace for which they felt comfortable.

F. Outcomes and Data Analysis

Primary outcomes included spatio-temporal, gait symmetry parameters and knee joint angle. Spatial outcome measures included step length, stride length, minimum toe clearance, maximum heel clearance, circumduction and hip hiking. Temporal outcome measures included: stride time; and swing, stance, single support and double support phase percentages. Gait symmetry was assessed by spatial and temporal symmetry indexes, computed both from paretic and non-paretic step lengths and from the relationship between the stance and swing phase durations, respectively. Secondary outcomes were the usability and user experience assessments.

During the tests on the treadmill (er2100, Custo Med GmbH, Germany), kinematic data were recorded using reflective markers according to a reduced version of the Helen-Hayes marker protocol [27]. The three-dimensional marker positions were recorded at a sampling rate of 120 Hz with a V120:Trio motion capture system (OptiTrack, NaturalPoint Inc., Corvallis, OR, USA). The software used for all data analysis was MATLAB (MATLAB R2021b, The MathWorks Inc., Natick, MA, USA). Treadmill speeds were kept constant throughout all the sessions of the study to the values presented in Table I. Each of the participants had the option to increase or decrease the treadmill speed with the support of the therapist at the beginning of each session, but none of them decided to change it through the study. Note that the difference between the overground and the treadmill speeds is most likely related to the participants' poor endurance, balance, and the individual's perceived limits of stability while walking on the treadmill with the exoskeleton.

A usability assessment was carried out focusing on the time to don and doff, and to tune the device, measured by a digital stopwatch. During the donning of the device, participants inserted their feet into the shoes and tied them tightly. Depending on the upper-extremity impairment level of the participant, a clinical specialist partially assisted in fitting and adjusting the straps on each shank and the lumbar module. During doffing, participants required a level of assistance similar to the donning. To assess subjective user experience and quantify the usability of the exoskeleton, each participant completed a modified version (only the first eight questions) of the Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 (QUEST 2.0), and answered to open-ended questions about their experience with the ABLE-KS device. The participant's Rate of Perceived Exertion (RPE) and Discomfort (RPE-D) on the Borg Scale (ranging from 0 = very light/no discomfort to 10 = very exhaustive/maximal discomfort) were recorded at the end of each session and experimental condition.

1) Statistical and Minimum Clinically Important Difference Analyses: For each condition and outcome measure, means and standard errors were calculated. First, normality was assessed with the small-sample Lilliefors correction of the Kolmogorov-Smirnov test. If the data followed a normal distribution, a linear mixed-effects analysis was performed to compare the performance metrics (*Values*) of the *Subjects* over the different *Conditions*. We modeled *Conditions* as fixed effect, and introduced an error term with random intercept and slope, grouped by *Subjects*. However, if normality was violated, Wilcoxon matched pairs or Friedman's test were performed. Statistical significance was set to $\alpha < 0.05$ and Bonferroni correction was used when applicable. To evaluate the clinical effects of intervention at the *Endline* with respect to the *Baseline*, the outcome measures of 10MWT and 6MWT were compared with the minimal clinically important differences (MCID) used in similar studies with exoskeletons [23], [28]. MCIDs for the 10MWT and 6MWT were set to 0.14 m/s and 34.4 m, respectively.

III. RESULTS

A. Walking Without Exoskeleton: Baseline vs Endline

Participants significantly increased maximum knee flexion angle during swing at the *Endline* with respect to the *Baseline* by 17 % ($p = 0.0016$; see Fig. 4.A). Minimum knee angle during the stance phase was significantly closer to the physiological value (7.2 deg) at the Endline than at the Baseline by 58 % (p=0.0053; see Fig. 4.B). Paretic single support duration significantly increased (3 %, $p = 0.0087$; see Fig. 4.C) at the *Endline* session with respect to the *Baseline* session. No other significant variations were found for the rest of the outcome metrics of interest (see Supplemental Figure 2). Participants significantly ($p = 0.0220$) improved gait endurance during the 6MWT by 21 m (10 %) between the first and last sessions, with two of the participants achieving a score higher than the MCID (see Fig. 4.D).

B. Walking in the Assistance Training Mode: No Exo vs Unpowered vs Assistance

Maximum knee angle during swing (*Assistance* vs *No Exo*: 29 deg, $p < 0.00025$; *Assistance* vs *Unpowered*: 29 deg $p < 0.00025$; see Fig. 4.F) was increased while the participants walked with the exoskeleton using the high *Assistance* mode in comparison with the *No Exo* and *Unpowered* conditions. Minimum knee angle during stance (*Assistance* vs *No Exo*: 15 deg, $p < 0.00025$; *Assistance* vs *Unpowered*: 11 deg, $p < 0.00025$; see Fig. 4.G) was closer to more physiological values when participants walked with the exoskeleton in the high *Assistance* mode in comparison to walk without exoskeleton or with the device *Unpowered*.

Minimum toe clearance (35 %, $p = 0.0260$; see Fig. 4.H) significantly increased when participants walked with the exoskeleton in the *Assistance* mode in comparison to the *Unpowered* condition. Step length (-9 %, $p = 0.0144$; see Fig. 4.I) and minimum foot clearance (-31 %, $p = 0.0141$; see Fig. 4.H) significantly reduced when the participants walked with the exoskeleton *Unpowered* with respect to the *No Exo* condition. Supplemental Figures 3 and 4 shows the results obtained for the other outcome metrics of interest.

C. Assistance vs Resistance Training

When participants walked with the *Assistance* and *Resistance* modes, the minimum knee angle during stance was similar for the two types of training (*Assistance* vs *Resistance*: 0.9 deg, $p = 0.0725$; see Fig. 4.G), and the maximum knee angle during swing was significantly higher with the *Assistance* mode (*Assistance* vs *Resistance*: 31 deg, $p < 0.00025$; see Fig. 4.F).

After the sessions with the *Resistance* training, participants significantly ($p = 0.0230$) increased the step length (*Post* vs *Pre*: 0.1 cm; see Fig. 4.E) in comparison with the *Assistance* training for which this outcome metric decreased (*Post* vs *Pre*: -0.7 cm). The other metrics did not reveal significant changes (see Supplemental Figure 5).

D. Training Effect

The performance of the participants improved with time as the difficulty of the sessions became harder (see Fig. 5). For the *Assistance* mode, participants significantly increased by 24 % the mean success rate of the fourth trial when comparing the first and second training sessions (walking trial 4: 76 %

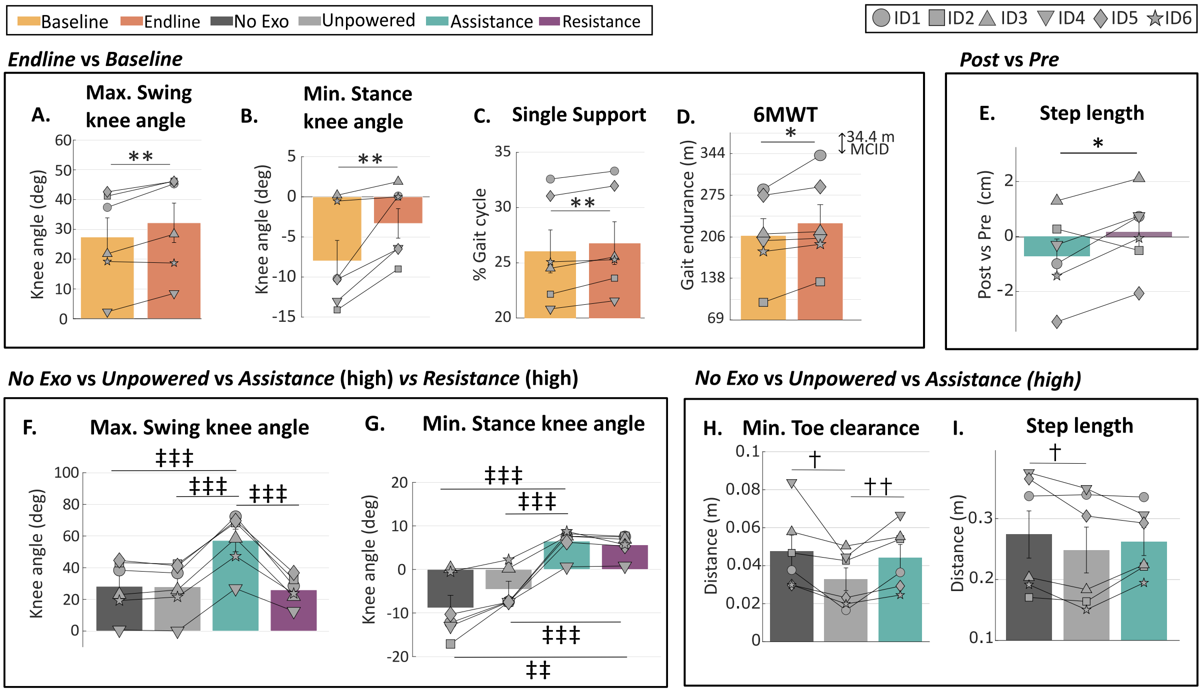

Fig. 4. **Summary of the biomechanical outcomes of interest.** Mean and standard errors for the comparison between: **(A-D)** *Baseline* and *Endline*; **(E)** walking at the beginning (*Pre*) and at the end (*Post*) of the training sessions with *Assistance* and *Resistance* modes; **(H-I)** walking without exoskeleton (*No Exo*), with the exoskeleton unpowered (*Unpowered*), and with the exoskeleton powered in the high assistance mode (*Assistance*); **(F-G)**. Bar plots including mean and standard error of the minimum knee angle during stance and maximum angle during swing for the *No Exo*, *Unpowered*, *Assistance* with a peak knee flexion torque of 4 Nm, and *Resistance* with a peak knee flexion torque of -2 Nm. Unilateral metrics correspond to the paretic side, e.g., step length. MCID: Minimal Clinically Important Difference, SI: Symmetry Index. $* = p < 0.05$, $** = p < 0.01$, † = p<0.0167, †† = p<0.0033, ‡‡ = p<0.0025, ‡‡‡= p<0.00025.

vs walking trial 12: 95 %, $p < 0.001$). The success rate also increased by 107 % (from 26.5 % to 55 %, $p = 0.2804$), when comparing the third walking trial of the two training sessions with the *Assistance* mode (walking trial 3 vs walking trial 11). Furthermore, they required 50 % less mean peak knee flexion torque (from 2 Nm to 1 Nm, $p = 0.2501$) and the mean peak knee flexion angle threshold for the biofeedback was 10 % higher (from 42 deg to 45 deg, $p = 0.0142$), when comparing the third trials of the two training sessions with the *Assistance* mode and the fourth trials of the same training sessions (see Fig. 5).

When participants walked in the *Resistance* mode during the fourth trial, they increased the mean success rate by 55 % (from 31 % to 48 %, $p = 0.5656$; see Fig. 5) with the same peak torque, i.e., zero torque; but higher peak knee angle for the biofeedback was 8 % higher (from 43 deg to 46 deg, $p = 0.0533$) for the second *Resistance* session compared to the first one. For the first three trials of the second *Resistance* training session, participants kept the same success rate than in the first training session with this mode, with an increment of 14 % in the threshold angle for the biofeedback with respect to the first training session using this mode (from 23 deg to 27 deg, $p = 0.0533$).

E. Participant's Perception

The participant's perception related to the use of the ABLE-KS exoskeleton according to the modified QUEST 2.0 (see Fig. 6.A) showed a high level of acceptability after the first (average score: 4.2 ± 0.3) and last sessions (average score: 4.5 ± 0.3). The wearable exoskeleton was perceived to be safe and secure (*Baseline*: 5.0 ± 0.0; *Endline*: 4.8 ± 0.4), robust (*Baseline*: 4.5 ± 0.5; *Endline*: 5.0 ± 0.0), easy to use (*Baseline*: 4.7 ± 0.8; *Endline*: 5.0 ± 0.0), and comfortable (*Baseline*: 4.3 ± 0.8; *Endline*: 4.8 ± 0.4). The weight (*Baseline*: 3.7 ± 1.0; *Endline*: 3.7 ± 1.2) and dimensions (*Baseline*:

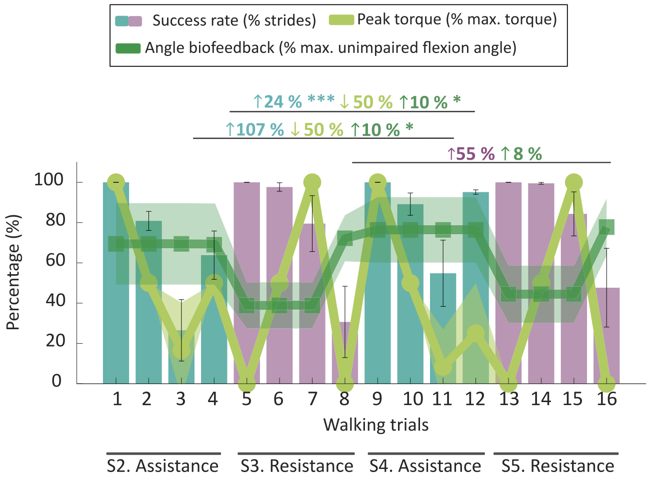

Fig. 5. **Progression of the success rate, peak knee flexion torque and threshold angle for the biofeedback along the four experimental sessions.** Mean and standard error of the success rate, the peak *Assistance*/*Resistance* torque, and threshold angle of the biofeedback expressed as percentage of their maximum (max. *Assistance* torque: 4 Nm, max. *Resistance* torque: -2 Nm, max. threshold angle: 65 degrees). Each session is composed of four walking trials, resulting in a total of 16 walking trials. ***p<0.001, *p<0.05. S: Session.

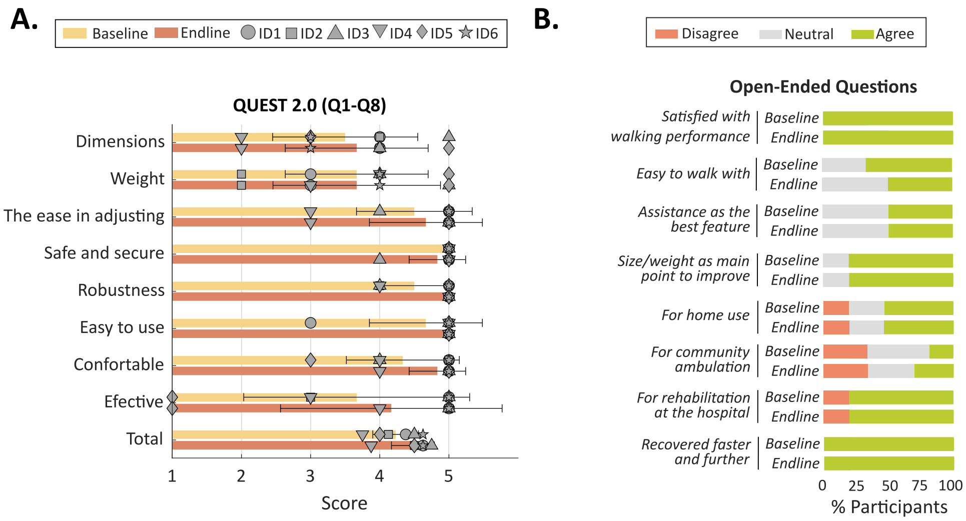

Fig. 6. **Participants' perception.** (A) Mean and standard deviation of the scores for the QUEST 2.0 (score of 5 indicates "very satisfied" while 1 indicates "not satisfied at all"). (B) Main ideas collected from the open-ended questions.

3.5 ± 1.0; *Endline*: 3.7 ± 1.0) of the device were the items with the lowest scores.

Regarding the answers to the open-ended questions (see Fig. 6.B), all the participants were satisfied with their performance during the tests and considered that the ABLE-KS could have been useful for their rehabilitation. More than 80 % of the participants pointed out that the size and weight of the device were the main points to be improved. Rehabilitation at the hospital was considered the best intended use of ABLE-KS (83 % of the participants agreed) and community ambulation the worst (33 % of the participants agreed).

No relevant levels of discomfort were perceived by the participants. During the first session, the participant ID5 felt the highest level of discomfort in this study (level 5) due to ankle inversion related to bad fitting of the exoskeleton. This problem was corrected for the following sessions. Supplemental Figure 5 shows the results for the RPE-D for each session.

F. Usability Timings

The usability assessment results showed that the majority of the preparation time was spent during the donning (mean of all the sessions: 1.95 ± 0.57 minutes) and doffing (0.65 ± 0.31 minutes) of the device. The tuning of the control parameters required the least amount of time (0.055 ± 0.33 minutes). The mean total time including all processes was of 2.94 ± 1.37 minutes and was reduced through the sessions. Supplemental Figure 7 shows the results for the usability timings for each training session.

IV. DISCUSSION

In this study, we investigated how post-stroke individuals responded to training for two weeks with a unilateral knee-powered exoskeleton using both *Assistance* and *Resistance* training modes. We adapted the peak knee flexion torque and the biofeedback threshold based on the needs of each individual in a systematic way based on fatigue level and task completion rate. The main contributions of the present work are: (i) the wide experimental protocol and analysis; (ii) the combination of *Assistance* and *Resistance* training together with auditory biofeedback to increase peak knee flexion angle during swing; and (iii) the systematic and personalized procedure to tune the exoskeleton control parameters. In the following subsections, we answer to the posed research questions of this study.

A. Do Individuals With Stroke Improve Their Gait Performance After Training With the ABLE-KS for Two Weeks?

We found that the average peak knee flexion angle during swing significantly increased by 17 % at the *Endline* with respect to the *Baseline*, while Ogino et al. [29] found a statistically non-significant yet moderate increment of 3 % and Li et al. [30] found a decrease in the peak knee flexion angle of 8 % after a treatment with higher training intensity (540 min/week vs 4250 min/week). Although hip hiking and circumduction are known to be compensatory movements for the lack of knee flexion and ankle dorsiflexion during swing [31], these metrics did not vary despite observing improvements on knee flexion angle during the swing phase. Ogino et al. [29] also did not observe significant variations for the hip hiking and circumduction in a study in which the participants trained considerably more intensively with a knee exoskeleton (540 min/week vs 4000 min/week).

Although most of the participants exhibited knee hyperextension at the *Baseline* and *Endline*, the minimum knee angle during stance was significantly closer to the unimpaired value (7.2 deg) at the *Endline* (58 % higher). In another study with post-stroke participants that had a flexed knee gait pattern, the average minimum knee value was 13 % higher (more flexed and less close to the physiological value) at the end compared to the beginning of the treatment for a higher training intensity with a knee exoskeleton (540 min/week vs 4000 min/week) [29].

At the end of the treatment, participants significantly improved balance control, as single support time on the paretic limb significantly increased while average double support time decreased although this decrease was statistically non-significant (see Supplemental Figure 2.G) [32]. Ogino et al. [29] obtained similar results with higher training intensity (540 min/week vs 4000 min/week).

Regarding the clinical tests, gait endurance for the 6MWT significantly increased (10 %) at the *Endline* with respect to the *Baseline*. The level of improvement on gait endurance was aligned with other studies in the literature (from 9 % to 32 %) in which participants trained more than 6 times more intensively than in the present study (540 min/week vs 3620 min/week) [10], [33], [34], [35].

Albeit statistically non-significant, the average gait speed during the 10MWT at the end of the *Endline* increased by 4 % with respect to the *Baseline* (see Supplemental Figure 2.K), which was slightly lower than other studies in the literature that compared the same conditions (from 6 % to 39 %) with higher training intensity (540 min/week vs 3620 min/week) [10], [33], [34], [35].

No statistically significant variations were found for the paretic stride and step length (see Supplemental Figures 2.D-E) probably due to the limited role of the knee joint in the propulsion during ground-level walking [24]. Nevertheless, we have seen an improvement in the symmetry of the spatial gait pattern at the end of the treatment (25 %; see Supplemental Figure 2.I). Other studies using knee exoskeletons did not find variations on these spatial metrics [30], [34], [35]. Only Ogino et al. [29] found significant improvements for paretic stride and step length when walking with a knee exoskeleton.

In summary, we have seen that the gait training intervention using the ABLE-KS yielded comparable or even superior benefits with considerably lower training intensity, i.e., more than 6 times lower, than other studies that tested a unilateral knee exoskeleton on people with stroke and evaluated the same conditions [10], [29], [30], [33], [34], [35]. Three factors that are different from other studies might have influenced this result: (i) adapted exoskeleton control parameters through and within the sessions, (ii) the combination of *Assistance* and *Resistance* training, and (iii) adapted auditory biofeedback threshold.

B. Do Individuals With Stroke Improve Their Gait Performance While Wearing the ABLE-KS in Assistance Mode?

Participants significantly improved their knee pattern to a more physiological one when they walked with the high *Assistance* mode compared to walking with the exoskeleton *Unpowered* and without exoskeleton, i.e., *No Exo*.

Albeit statistically non-significant, we have seen a reduction of the compensatory movements, i.e., in average hip hiking and circumduction, when the participants walked in the *Assistance* mode with respect to the *No Exo* condition (see Supplemental Figures 3.E-F). However, this decrement was due to the added extra weight of the device and not as a consequence of the active action of the exoskeleton, as similar reductions were observed when comparing *No Exo* vs *Unpowered* and *No Exo* vs *Assistance*. Similar than in the study by Sulzer et al. [36], we did not find significant differences for the hip hiking when the participants walked with the exoskeleton in the *Assistance* mode in comparison to the *Unpowered* condition, despite the significant correction of the knee joint angle. Furthermore, we have seen a statistically non-significant increase in the average circumduction (12 %), due to knee flexion *Assistance* with respect to the *Unpowered* condition as in [36].

As a negative effect, the weight of the device significantly compromised gait performance when comparing the *Unpowered* with the *No Exo* conditions in terms of step length and minimum foot clearance. This negative effect was corrected when the device was turned on in the *Assistance* mode, as the values of these metrics were similar to the ones measured in the *No Exo* condition.

The null effect of the ABLE-KS on the spatial metrics, i.e., paretic step and stride length (see Supplemental Figure 3.A), when the participants walked in *Assistance* mode, in comparison with *Unpowered* or *No Exo* conditions, was expected due to the limited role of the knee during limb propulsion in contrast with the hip or ankle joints [24]. This finding is consistent with other studies that examined the same conditions with knee exoskeletons on individuals with stroke [6] and cerebral palsy [11], [37], [38], [39].

C. Do Individuals With Stroke Benefit More From a Resistance or Assistance Training for Improving Peak Knee Flexion?

From a clinical perspective, we did not find relevant differences between the *Resistance* and *Assistance* training modes for the outcomes selected, when comparing the participants walking without exoskeleton at the *Pre* and *Post* instants of each session. This finding is in accordance with other studies that evaluated the effect of providing *Assistance* and *Resistance* training using forces provided through cuffs strapped around the ankles on individuals with stroke [40], [41]. However, as discussed previously, we believe that the combination of the two training modes might lead to faster gait improvements than using the *Assistance* mode alone.

D. What Is the Training Effect of Using the ABLE-KS to Improve Peak Knee Flexion for Two Weeks?

Participants improved their ability to use the ABLE-KS device through the trial period for the task of increasing the peak knee flexion angle during swing. Participants significantly increased their success rate, i.e., the percentage of strides for which the peak knee flexion angle was higher than the threshold, even though the conditions for the peak torque and knee flexion threshold became more challenging through the sessions. These findings are aligned with the ones presented by Park et al. [21], who showed that progressively reducing the level of *Assistance* may be more beneficial than setting it to a fixed value for improving locomotor function in patients with stroke.

The proposed systematic method to tune control parameters complemented other systematic methods used in the literature based solely on kinematic errors [42], muscular activity [43], gait speed [44] or the level of perceived soreness [45]. We combined objective, i.e., task performance after each walking trial based on participant-specific objectives, with subjective descriptors, i.e., perception of exertion, to adapt the control settings through and within the treatment.

E. What Is the Opinion of Post-Stroke Individuals on the ABLE-KS?

The results obtained in this study regarding the participant's perception contribute to the increasing evidence on the acceptance of robotic devices for gait training. Similar or higher scores in QUEST 2.0 were obtained in comparison to other joint-specific exoskeletons for people with stroke [5], [9], [46]. Safety, robustness, efficacy, ease of use, and comfort were the points scored the highest. Since the weight of the device did affect significantly the gait performance, it is not surprising that the dimensions and weight of the exoskeleton were the items with the lowest score.

F. What Is the Time Needed to Set up the ABLE-KS for Post-Stroke Gait Rehabilitation?

The time to set up our exoskeleton, i.e., less than 3 minutes, was considerably lower than the one in other exoskeletons, which has been reported to take up to 30 minutes only for donning [19]. We found that more than 60 % of the setup time was needed to don the device. Therefore, we think that the ergonomics of the device should be simplified to allow a faster and easier donning to improve the usability of the device.

G. Limitations

There are several limitations in the present study that should be considered. The preliminary findings described above should be interpreted with caution due to the small and heterogeneous sample, and the relatively low training time with the ABLE-KS. The noticeable differences in the gait patterns of the participants and the compensatory movements made it difficult to identify group trends and generalize the results.

Given the short duration and the uncontrolled design of our study, a fair discussion of the achieved results shall consider that the observed improvements of some of the outcome metrics could be influenced by: (i) practising with a treadmill, and (ii) weight training due to the weight of the exoskeleton [23]. However, since the training intensity of the present study (i.e., 540 min/week) was lower than the intensity required to reach meaningful changes due to walking in a treadmill (i.e., 3600 min/week [47]) and weight training (i.e. 1080 min/week [48]), the results presented here are most likely due to the effect of training with the ABLE-KS exoskeleton.

V. CONCLUSION

The present study has used a comprehensive experimental protocol and analysis to examine how post-stroke individuals responded to training with the ABLE-KS exoskeleton. The training protocol consisted in combining *Assistance* and *Resistance* training modes, together with a systematic method for tuning the control parameters and auditory biofeedback. The results of the study showed that participants significantly increased gait endurance and paretic single support at the end of the study while walking without exoskeleton. When the exoskeleton was in *Assistance* mode, the only immediate significant improvements were seen for the knee joint angle in comparison to the *No Exo* and *Unpowered* conditions. Regarding the comparison between the post-effects of the *Assistance* and *Resistance* training, we did not find significant differences in the analyzed outcome metrics. Participants showed a high level of acceptability for the ABLE-KS. The total time to don, doff and set-up the device was lower that 3 minutes. Our study results highlighted that the proposed methodology can induce similar or higher changes in post-stroke individuals than other studies with knee exoskeletons that had a higher training intensity. Thus, we consider that future work should focus on expanding this study with a larger post-stroke population for more reliable generalization of the results.

COMPETING INTEREST

Helena López-Matas and Joan Lobo-Prat are employees and receive salary from ABLE Human Motion S.L., Barcelona, Spain, which was the sponsor of the present study. Josep M. Font-Llagunes is Co-Founder and owns stock in the company ABLE Human Motion S.L.

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