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ORIGINAL RESEARCH



Evaluation of the Keeogo™ Deroskeleton

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ABSTRACT

Purpose: (1) To determine the specific functional characteristics of individuals with neurological impairments that may predict successful use of Keeogo™ deroskeleton and (2) to quantify the specific benefit Keeogo™ provides to a regular user of the device.

Methods: Thirteen individuals (seven males; six females; 52 ± 4.6 years old) with mobility impairments due to neurological disease or injury were recruited. Berg Balance Scale (BBS) score and Timed Up and Go (TUG) performance were used to identify baseline characteristics in participants. The 6-min walk test (6MWT) and 25-foot walk test (25FWT) were performed with the participants wearing and not wearing the deroskeleton; a successful user of Keeogo™ displayed a $\geq 5\%$ improvement in walking performance while wearing the device. A chronic stroke survivor (hemiparesis on left side) completed the stair climb test (SCT) and the 30-second chair stand test (30CST) with and without Keeogo™. Muscle activity, kinetics and postural control were analyzed during the sit-to-stand (sitTS), and compared to an age- and sex-matched healthy control.

Results: Successful users of Keeogo™ have a moderate level of functionality (BBS: 46–51 s and/or TUG: 8–12 s). Wearing Keeogo™ improved performance on the 30CST, SCT and improved motor control, postural control and movement kinetics during the sitTS task in a chronic stroke survivor with significant hemiparesis.

Conclusion: This is the first study providing data to help to identify which individuals with neurological impairment might benefit from using Keeogo™ deroskeleton, together with new information quantifying its functional benefit to the user.

ARTICLE HISTORY

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KEYWORDS

Keeogo™; deroskeleton; neurological impairments; criteria development; stroke; functional benefits; ADLs

► IMPLICATIONS FOR REHABILITATION

- Keeogo™ is a user-initiated deroskeleton that has been designed to assist individuals with mobility impairments to participate more effectively in activities of daily living (ADLs).
- Moderately impaired individuals have the greatest potential to benefit from using the device.
- Benefits of wearing the device include improvements in walking speed and endurance, performance on ADLs, motor control, kinetics, and postural control.

Introduction

An estimated 3.6 million Canadians are living with neurological diseases or injury to the central nervous system (CNS) such as stroke, multiple sclerosis, spinal cord injury, Parkinson's disease and cerebral palsy [1]. Advances in medical care, longer life expectancies and ageing of the global population all are contributing to a rise in the prevalence of neurological and/or chronic disorders [2,3]. Some of the common challenges that patients with neurological diseases or injury face include reduced quality of life (QoL), pain and reduced life satisfaction [4,5]. Factors associated with reduced life satisfaction among these patients include decreases in mobility due to impaired gait and balance, and decreased ability to perform activities of daily living (ADLs) independently [6]. For example, following a stroke, decreased performance in two functional tasks related to ADLs, the sit-to-stand (sitTS) task [7,8] and the stair climb test (SCT) [9–11] have been reported. Independent performance of ADLs is important in preventing patients from becoming bedridden and preventing falls in persons with disabilities [12–16]. Thus, restoring an individual's ability to perform ADLs remains important goals as they can

directly impact independence, community participation and the probability of being moved to a nursing home [12–16].

Over the last decade, advancements in technology have led to the development of devices that help to restore patients' abilities to perform ADLs and increase their QoL [17,18]. One of these advancements is the production of over-ground robotic exoskeletons, which are worn by the user and consist of lower leg orthoses, closely fitting to the body, that work in concert with the user's movements [19]. The purpose of over-ground exoskeletons is to mimic a natural gait pattern for persons with severe motor impairments, by allowing them to rise from their wheelchair and perform upright over ground walking [4,17–19]. Commercially available exoskeletons include, but are not limited to, the ReWalk [20], Indego [21] and Hybrid Assistive Limb (HAL) [22]. Over-ground robotic exoskeletons permit upright locomotion in individuals who normally are either unable to walk or require significant support to do so [23–26]. These traditional exoskeletons are capable of providing assistance in performing ADLs [8]. Studies have demonstrated that using over-ground robotic exoskeletons during locomotion may be effective in activating dormant cortical pathways and may provide adequate muscle loading and sensory

Table 1. Participant characteristics.

Subject ID	Gender	Age	Impairment/injury	Severity	Time from injury/ impairment (years)
1	M	65	iSCI	T10; ASIA: A	1
2	M	65	MS	EDSS: 6	4
3	F	20	CP	GMFCS: 1	n/a
4	F	57	MS	EDSS: 2	14
5	F	55	MS	EDSS: 4	24
6	M	65	Stroke	Spinal	2
7	F	20	Stroke	n/a	3
8	M	50	MS	EDSS: 6	6
9	F	56	MS	EDSS: 6.5	21
10	M	44	MS	EDSS: 2	19
11	M	65	CA	Progressive	12
12	M	55	iSCI	C2;ASIA: D	2
13	F	45	MS	EDSS: 2	19

iSCI: incomplete spinal cord injury; ASIA: American Spinal Cord Injury Association; MS: multiple sclerosis; EDSS: expanded disability status scale; CP: cerebral palsy; GMFCS: gross motor function classification system; n/a: not available; CA: cerebellar ataxia.

feedback for motor recovery in individuals with severe motor impairments [27].

KeeogoTM is a newly commercialized (2014, available for purchase and/or rental) powered bilateral walking device, which is classified as a powered dermoskeleton. KeeogoTM is designed to assist individuals with mobility-related impairments to participate more effectively in daily activities such as walking, stair climbing, sitTS and stand-to-sit (standTS) [28,29]. What differentiates KeeogoTM from traditional over-ground exoskeletons is that the dermoskeleton is lightweight and requires users to initiate all movements [28,29]. KeeogoTM operates through sensors in the hip and the knee joints to help to identify and interpret what movement the user is trying to perform [28]. A complementary torque is then provided by a motor aligned with the knee joints of the user to help to complete the movement [28]. Ultimately, the purpose of KeeogoTM is to allow individuals who experience fatigue, muscle weakness and joint pain to utilize the dermoskeleton in the home and the community to improve locomotor capability and endurance, and to maintain independence with ADLs [28,29].

KeeogoTM has been shown to benefit able-bodied military personnel by limiting muscular fatigue when performing repetitive, physically demanding tasks [28,29]. However, KeeogoTM is a user-initiated device, and the severity of an individual's disability may affect the functionality of the system. Thus, this device may not provide significant benefit to all users. Missing from the literature to date is the identification of specific clinical criteria that might predict who might benefit from using KeeogoTM. The first objective of this study was to determine the specific functional characteristics in users suffering from neurological impairments that may aid in predicting who would show benefit (in terms of improved walking endurance and walking speed) from using the device. The second objective of the study was to evaluate and quantify the specific benefit KeeogoTM provides to a chronic stroke survivor (impairment on left side) who is a regular user of the device on improving ADLs, in terms of performance, motor control, kinetics and postural control.

Methods

Participants and ethics

Participants were recruited from the McMaster University Physical Activity Centre of Excellence (PACE) according to the following inclusion criteria: at least one year post injury or diagnosis of disease, aged between 18 and 65 years old, shows limitations in mobility due to neurological impairment or injury, and ability to

initiate knee flexion and hip extension to some degree with or without the use of a walking aid. The study received approval from the Hamilton Integrated Research Ethics Board (HiREB). Thirteen participants (seven males; six females; mean age 52 ± 4.6 years old) were recruited and completed the study. A wide range of neurological disorders were represented (multiple sclerosis, $n = 7$; incomplete spinal cord injury, $n = 2$; stroke, $n = 2$; cerebellar ataxia, $n = 1$; cerebral palsy, $n = 1$) with varying levels of severity of neurological impairment or injury (Table 1).

Study design

Participants came to the lab on two occasions for assessments. On the first testing session, participants were fitted to KeeogoTM and given the opportunity to practice walking with it on. A clinical specialist from B-Temia fitted KeeogoTM to participants based on their anthropomorphic measurements. Participants were given an hour to walk, perform sitTS, ascend and descend a flight of stairs, and become familiar with the device and its control. Two control parameters on the device associated with the swing phase of gait (i.e. knee flexion/extension torque assistance and knee flexion/extension range of assistance) and assistance levels (level 1 = 60% of device's max torque production [40 Nm], level 2 = 80%, level 3 = 90% and level 4 = 100%) were adjusted in order to maximize performance with the dermoskeleton on primary outcome tests. The adjustments made were unique to each participant and saved to their personal portfolio for future testing with the device. During the first session, participants also performed the Berg Balance Scale (BBS) [30,31] score and the Timed Up and Go (TUG) test [31,32] (without wearing the dermoskeleton) to identify baseline characteristics (details provided below). On the second testing session, participants completed two walking tests (the 6-min walk test [6MWT] and the 25-foot walk test [25FWT]) twice, either without KeeogoTM or with KeeogoTM (order randomized between participants). Participants were allowed to use walking aids throughout the study, and those who did were encouraged to use them across both conditions.

Following criterion determination, one participant (stroke survivor [Table 1, Subject ID 7]; hemiparesis on left side) who used KeeogoTM on a day-to-day basis for 12 months was asked to come in for a third testing session to further characterize the functional benefits gained when wearing the dermoskeleton. She performed two additional functional tests (SCT and the 30-second chair stand task [30CST]) under the two randomized conditions previously described. Briefly, the SCT involved ascending and descending a

flight of stairs (nine steps, 20 cm step height, with handrails) as quickly and as safely as possible [33]. The time needed to complete the task was recorded. For the 30CST, the participant was seated in a chair of standardized seat height (46 cm) [34,35], and instructed to complete as many repetitions possible (one repetition entailed rising from the chair and sitting back down in the chair) within 30 s. Vertical ground reaction forces (vGRF) and moments were recorded from a force platform (AMTI OR6, Watertown, MA) placed underneath the participant, and electromyography (EMG) surface electrodes (Delsys, Boston, MA) were placed bilaterally on the vastus lateralis (VL; knee extensor) to record muscle activity. Results from these tasks were compared to those from an age- and sex-matched healthy control.

Primary outcome measures

Six-minute walk test (6MWT)

The 6MWT objectively measures walking endurance by recording the distance (in meters), an individual can cover within six minutes [36]. The 6MWT was administered and monitored according to the American Thoracic Society (ATS) guidelines [37]: along a flat, 30-m hallway, with standardized instructions and encouragement. To avoid influence of walking speed, the rater did not walk alongside the participant [37]. Testing was terminated immediately if individuals expressed any signs of discomfort. Participants were given as much time needed for rest before completing the task for the second time (either with or without Keeogo™).

Twenty-five-foot walk test (25FWT)

The 25FWT is a useful quantitative measure of walking speed and muscle strength and has been extensively validated in clinical populations, such as multiple sclerosis [38]. Participants were instructed to walk eight meters, distinctly marked by pylons, as fast and as safely as possible [39]. The time to complete the task was recorded.

Secondary outcome measures

Berg Balance Scale (BBS)

The BBS is a valid and reliable measure for predicting falls in a variety of populations [30,31]. The test consists of 14 static and dynamic measures that progress in difficulty: from sitting and standing, to standing on one leg [30,31]. Scoring on each measure is based off a 4-point ordinal scale (0 = unable to complete the task, 4 = able to complete the task independently) [30,31]. Before completing a measure, participants were provided with a demonstration by the rater. If a participant felt that they could have performed better on a measure, they were given the opportunity to retry. Scores for each measure were added up to yield a cumulative score; the maximum total score on the test is a 56. Participants were not allowed to use any assistive aid throughout the BBS.

The Timed Up and Go (TUG)

The TUG is an objective, valid and reliable measure of lower extremity function, mobility and falls-risk in elderly and clinical populations [32]. The test measures, in seconds, the time it takes for an individual to rise up from a chair (containing arms), walk three meters (indicated by a pylon), turn around, walk back to the chair and sit down [32]. The stopwatch was started when the rater said "Go", and was stopped as soon as the participant's buttocks touched the seat. Each participant completed two trials, and the

Table 2. Functional composite.

Outcome measure	Performance	Relative score
BBS	≤45/56	1
	>45/56	2
TUG	≥14 s	1
	<14 s	2
6MWT (without Keeogo™)	≤300 m	1
	>300 m	2
25FWT (without Keeogo™)	>8 s	1
	≤8 s	2

BBS: Berg Balance Scale; TUG: timed up and go; 6MWT: 6-min walk test; 25FWT: 25 foot walk test.

average of the two trials was recorded. If needed, participants were allowed to use assistive aids throughout this task.

Characterization of responders

A minimal detectable change (MDC) representing a significant improvement on primary outcome measures (6MWT, 25FWT) is dependent upon the clinical population of interest [40,41]. As there was a wide range of neurological conditions represented in the sample of participants recruited for the study (Table 1), and to collectively represent the varying levels of ability of the participants, a ≥5% relative improvement in performance was considered to be a significant change in performance. Participants were characterized as "responders" if performance improved by ≥5% while wearing Keeogo™ compared with not wearing it. Participants were characterized as "non-responders" if walking performance when wearing Keeogo™ was <5% different than performance without the dermoskeleton.

Functional composite generation

We sought to generate a composite based on an individual's overall functionality. Based loosely on a method previously described by Vita et al. [42], we selected four outcome measures (TUG, BBS, 6MWT-without Keeogo™ and 25FWT-without Keeogo™) from the study design to be used as stratification variables. Participants were assigned a relative score of 1 or 2 based on performance on each outcome measure. The cut-off scores determining a classification of "1" versus "2" represented a threshold for mobility impairment (based on previous literature): ≥14 s for the TUG [32,43], >8 s for the 25FWT [44], ≤45/56 on the BBS [34,45] and <300 m for the 6MWT [46,47]. Cut-off scores for outcome measures are highlighted in Table 2. An overall score was then generated by summing the scores from each measure, placing individuals into one of two groups. Participants scoring ≤5 on the functional composite were deemed the low-end group; these individuals were considered to be more motor-impaired than others. If participants scored >5 on the composite, they were in the high-end group, i.e. less motor-impaired.

Data processing

Five repetitions from the 30CST were averaged together for analysis of EMG and force plate data. Each repetition was partitioned into a sitTS and standTS phase by identifying the local maximum of vGRF data [48,49]. EMG data were de-biased by taking a 30 s quiet trial prior to performing the task. EMG signals were full-wave rectified and low-pass filtered at 2.5 Hz to create a linear envelope. Linear envelope EMGs were time normalized to the duration of the sitTS, and muscle activation of the stroke survivor was compared across both conditions (without and with

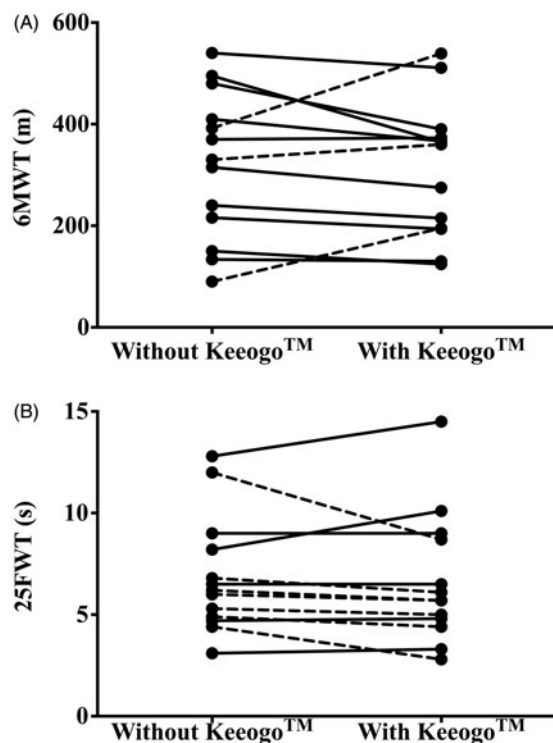


Figure 1. (A) Distance covered on 6MWT in meters (m) and (B) time to complete the 25FWT in seconds (s) without and with Keeogo™. Individual data are plotted for 13 participants. Dotted lines denote responders (those who display a $\geq 5\%$ improvement on performance when wearing the dermoskeleton), and solid lines represent non-responders (those who display a $< 5\%$ improvement on performance when wearing the dermoskeleton) to Keeogo™, for each outcome measure.

Keeogo™) and expressed in microvolts (μV). To compare patterns of muscle activity to the control, the EMG data from the sitTS phase were normalized to the peak activation level produced during each repetition [50]. To eliminate the influence of the force due to body weight (FBW) on vGRF production, prior to performing the 30CST, participants were asked to stand over top of the force plate, which was calibrated to their body weight. Maximal rate of force development (RFD) was defined as steepest gradient of the vGRF-time curve during the sitTS, and expressed in units of newton seconds (N s^{-1}). The center of pressure (CoP) along the mediolateral plane, in millimeters (mm), was calculated using the following formula [51]:

$$\text{CoP} = M_x' / F_z (M_x' = M_x + F_y \times AZ_0; F_z = \text{vGRF}). \quad (1)$$

Data analysis

Differences in baseline characteristics (BBS and TUG) across responders and non-responders were analyzed using an independent *T*-test. Differences in baseline characteristics across responders, low-end non-responders and high-end non-responders were analyzed using an independent sample one-way ANOVA, followed by Tukey's *post hoc* if the ANOVA was significant. All statistical calculations were performed using SPSS (IBM, Armonk, NY) ver. 20; alpha was set to 0.05.

Results

Individual performance

Performances on the two walking tests (6MWT and 25FWT) are depicted in Figure 1. Responders were classified as those

Table 3. Clinical criteria for responders and non-responders to Keeogo™ on primary outcome measures.

	6MWT		25FWT	
	Responders	Non-responders	Responders	Non-responders
TUG (s)	10.1 \pm 2.2	12 \pm 6.9	11.1 \pm 4.4	12.1 \pm 8.2
BBS (score)	50 \pm 6	48 \pm 6	50 \pm 5	48 \pm 8

6MWT: 6-min walk test; 25FWT: 25-foot walk test; TUG: timed up and go; BBS: Berg Balance Scale.

individuals who displayed a relative improvement of $\geq 5\%$ when wearing Keeogo™ (compared with not wearing it). Three of the 13 participants were categorized as responders to Keeogo™ based on 6MWT performance (Figure 1(A)), and seven were considered responders based on the 25FWT performance (Figure 1(B)).

Criteria determination

Timed Up and Go (TUG)

There was no significant difference in TUG performance between responders and non-responders to Keeogo™ (Table 3). Non-responders tended to fall into performance categories that were either worse (low-end) or better (high-end) than the responders (based on the functional composite; Table 2), and because of this, non-responders were placed into one of two groups (high-end non-responders and low-end non-responders). A significant main effect of group (responders vs. high-end non-responders vs. low-end non-responders) appeared in TUG scores for performance in both the 6MWT ($p < .05$) and 25FWT ($p < .05$). *Post-hoc* analysis revealed that high-end non-responders completed the TUG significantly quicker than low-end non-responders in both the 6MWT ($p < .05$) and 25FWT ($p < .05$). Responders to Keeogo™ in either 6MWT or 25FWT had a TUG performance that fell in between the low-end non-responders (6MWT: 18 ± 6.8 s, 25FWT: 17.9 ± 8.1 s), and the high-end non-responders (6MWT: 7.7 ± 1.9 s, 25FWT: 6.6 ± 0.9 s). These results are depicted in Figure 2.

Berg Balance Scale (BBS)

There was no significant difference in BBS scores between responders and non-responders to Keeogo™ (Table 3). Similar to the TUG results, a significant main effect of group (responders vs. high-end non-responders vs. low-end non-responders) on BBS scores appeared for performance on the 6MWT ($p < .05$) and 25FWT ($p < .05$). *Post-hoc* analysis revealed that high-end non-responders scored significantly higher on the BBS than low-end non-responders in both walking tests ($p < .05$). BBS scores for responders to Keeogo™ on either 6MWT (50 ± 6) or 25FWT (49 ± 5) were significantly ($p < .05$) higher than low-end non-responders. These results are depicted in Figure 3.

Development of criterion scale

Based on performance on the TUG and BBS, we determined that people who complete the TUG in a time between 8 and 12 s, and have a score on the BBS between 46 and 51, have the greatest potential to benefit from using Keeogo™ to improve walking performance (Table 4). Individuals scoring below or above these ranges may not benefit from this dermoskeleton because their neurological impairment is either too severe or not severe enough.

Characterizing benefits of the Keeogo™

Functional performance

Performances on tests related to ADLs for the stroke survivor (hemiparesis on the left side) without Keeogo™, and with

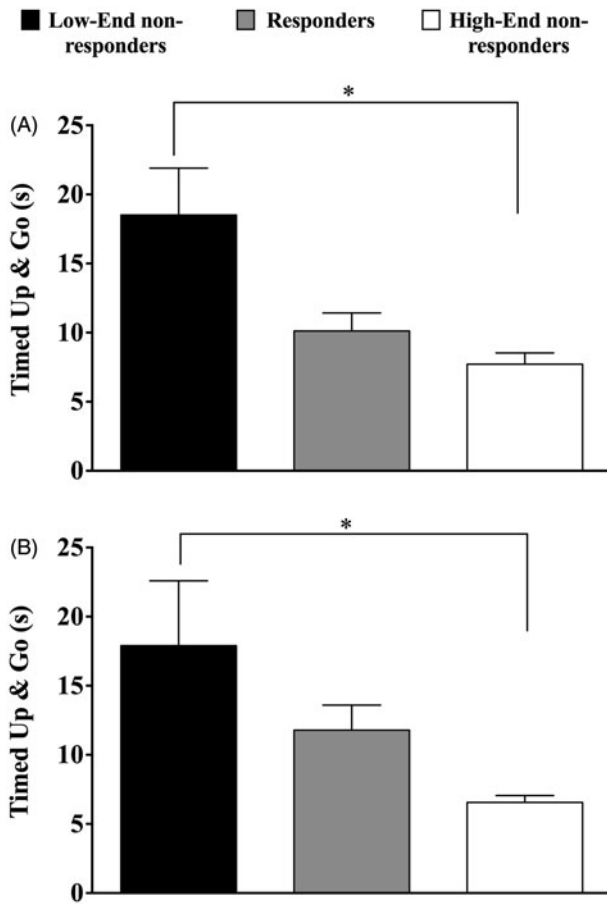


Figure 2. Mean TUG (seconds) \pm SD performance for (A) 6MWT and (B) 25FWT responders (6MWT: $n=3$, 25FWT: $n=7$), high-end non-responders (6MWT: $n=6$, 25FWT: $n=3$), and low-end non-responders (6MWT: $n=4$, 25FWT: $n=3$); * $p \leq .05$.

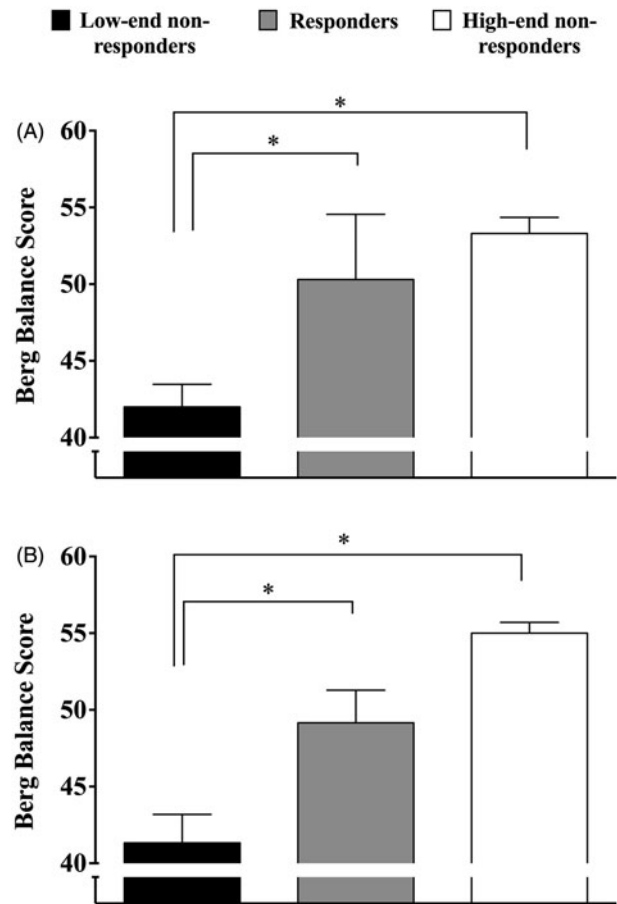


Figure 3. Mean BBS score \pm SD performance for (A) 6MWT and (B) 25FWT responders (6MWT: $n=3$, 25FWT: $n=7$), high-end non-responders (6MWT: $n=6$, 25FWT: $n=3$) and low-end non-responders (6MWT: $n=4$, 25FWT: $n=3$); * $p \leq .05$.

Keeogo™, along with the age-sex matched healthy control are presented in Table 5. Compared to the control, it took the stroke survivor without Keeogo™ approximately six times longer to ascend and descend a flight of stairs, and she completed only 50% of the repetitions during the 30CST task. When the stroke survivor utilized Keeogo™, performance on both functional tasks improved to almost match that of the control.

Muscle activity and pattern of activation

A graphical representation of knee extensor EMG activity, in microvolts (μ V) of the stroke survivor with and without Keeogo™, and normalized knee extensor activity (compared to the control) during the sitTS is illustrated in Figure 4. Compared to not wearing Keeogo™, utilizing the dermoskeleton increased the activity of the paretic left vastus-lateralis (L.VL; Figure 4(A)), while the activity of the non-paretic right vastus-lateralis (R.VL; Figure 4(B)) decreased. During the sitTS task, the pattern of knee extensor activation while wearing Keeogo™ was analogous to the control, whereas it was irregular without Keeogo™ (Figure 4(C,D)).

Center of pressure (CoP)

A CoP trace along the mediolateral plane during the sitTS is illustrated in Figure 5. Unlike the control, performing the sitTS task without Keeogo™ resulted in a greater CoP sway towards the right side (non-paretic limb). Utilizing Keeogo™ decreased the CoP sway in the mediolateral plane towards the center of the force plate, closely matching that of the control.

Table 4. Clinical criteria for responders, high-end- and low-end non-responders to Keeogo™.

	Non-responders	Responders	Non-responders
TUG (s)	<8	8–12	>12
BBS (score)	<46	46–51	>51

TUG: Timed Up and Go; BBS: Berg Balance Scale.

Table 5. Performances on tests related to ADLs.

	Stroke survivor		
	Control	Without Keeogo™	With Keeogo™
SCT (s)	6.92	47.83	8.83
30CST (# of reps)	16	8	13

SCT: stair climb test; 30CST: 30-s chair stand test.

Vertical ground reaction forces (vGRF)

Peak vGRF and the maximal RFD during the sitTS in the stroke survivor without Keeogo™, and with Keeogo™, along with the control are presented in Table 6. Compared to without Keeogo™, utilizing Keeogo™ increased peak vGRF production and maximal RFD by approximately 200% and 50%, respectively.

Discussion

This study represents the first investigation of Keeogo™ dermoskeleton in individuals with mobility limitations due to a

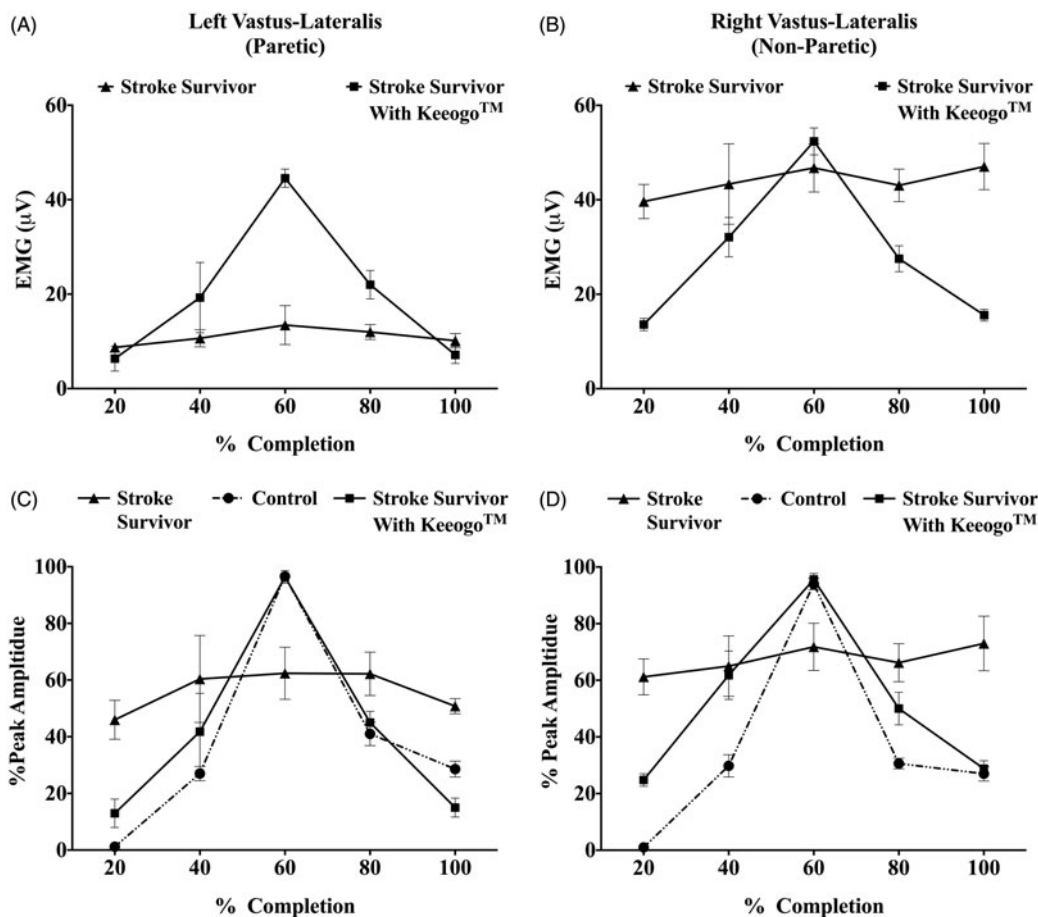


Figure 4. Mean EMG \pm SD, in microvolts (μ V) of the LVL (A), and RVL (B) during the sitTS of the stroke survivor without and with Keeego™. To compare to an age-sex-matched healthy control, LVL (C), and RVL (D) EMG activity during the sitTS is normalized, and expressed as a percentage (%) \pm SD of peak activation during the task. All figures are time-normalized to the duration of the sitTS.

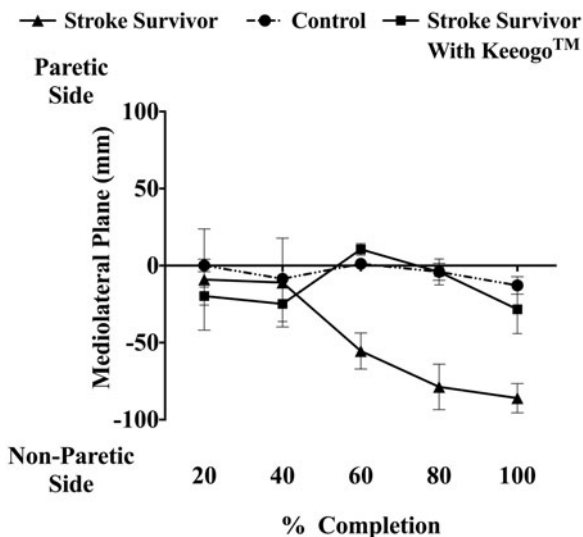


Figure 5. Mean \pm SD CoP in the mediolateral plane, in millimeters (mm) during the sitTS of the stroke survivor without, and with Keeego™, compared to the control. Positive values represent the CoP to the left (paretic limb), and negative values represent the CoP to the right (non-paretic limb) of the force plate. All graphs have been time normalized to the duration of the sitTS.

neurological impairment. Unlike traditional over-ground robotic exoskeletons, Keeego™ is a user-initiated device and for optimal benefit requires a certain level of function in the user. As seen from the results of the current study, some participants displayed

Table 6. Mean \pm SD peak vGRF and RFD during the sitTS task.

	Control	Stroke survivor	
		Without Keeego™	With Keeego™
Peak vGRF (N)	235 \pm 22	90 \pm 20	274 \pm 25
Maximal RFD (N s ⁻¹)	8825 \pm 218	7141 \pm 585	10663 \pm 913

Note: vGRF: vertical ground reaction force; RFD: rate of force development.

benefit from using the device, whereas in others the device did not seem to provide any benefit. Therefore, the first objective of the study was to identify the key functional characteristics in individuals suffering from neurological impairments that might predict benefit from using Keeego™. The second objective of the study aimed to characterize and quantify the benefit Keeego™ dermoskeleton provides to a habitual user of the device in tasks related to ADLs in terms of performance, motor control, kinetics and postural control.

Criteria determination

Our results revealed that participants who were most severely impaired by their neurological disorder (based on low scores on BBS and longer times on TUG) did not appear to benefit from using Keeego™ during the walking tests. This is likely due to the fact patients with severe motor impairments could not compensate for the mass and inherent stiffness of the device.

At the other end of the spectrum, there were a group of participants who scored the highest on the BBS and TUG tasks who

also did not seem to gain any benefit from using Keeogo™ during the walking tests. These individuals clearly have better muscular strength and endurance than more severely impaired individuals, and we predict that the device's assistance was not beneficial or needed. Our results revealed that individuals who responded best to Keeogo™ in terms of improved walking performance tended to be more moderately impaired by their neurological disorder, scoring in the mid-range on the BBS (score of 46–51) and the TUG (8–12 s).

Our secondary analysis was performed on a stroke survivor who was classified as a responder to Keeogo™ on both the 6MWT and 25FWT. She completed the TUG in 11 s, which aligns with the responder zone of the newly developed criteria (see Table 4). Her performance on the BBS (43/56), however, did not fall into the responder zone. It is important to point out that persons with significant hemiparesis will have difficulty performing some of the complex balance tasks on the BBS, so for these individuals performance on an agility task (like the TUG) might be a better predictor of benefit from Keeogo™.

Characterizing benefits of the Keeogo™

Stair climbing and moving from a sitting to a standing position are two of the most commonly performed ADLs and the ability of community-dwelling stroke survivors to perform these tasks are strong predictors of experiencing a fall [52] and QoL [13]. Improving the ability of individuals with hemiparesis to perform ADLs is a functional pre-requisite for community independence [13]. Over-ground robotic exoskeletons that have been designed for individuals with motor complete impairments who are unable to walk, perform sitTS and manage stairs independently enable these individuals to perform such tasks [4,8,17–20,53]. Furthermore, the robots allow these users to practice ADLs effectively on a day-to-day basis out in the community, which may lead to an enhanced functional recovery [53]. However, the existing exoskeletons are not designed for less impaired individuals living in the community (those who can ambulate with the use of an assistive device), as the characteristics of the exoskeleton are too cumbersome (i.e. weight, assistance required, time required to put on the device) to provide benefit on a daily basis [17]. In contrast, Keeogo™ dermoskeleton may be of significant benefit to ambulatory individuals with mobility impairments, as our results revealed dramatic improvements in both the 30CST and the SCT in a stroke survivor who was a habitual user of the device. Specifically, we demonstrated that when a stroke survivor utilized Keeogo™ during the sitTS task, compared to without the device, there was increased knee extensor activity in the paretic limb, and decreased knee extensor activity in the non-paretic limb. Furthermore, we found when the stroke survivor wore Keeogo™; the pattern of knee extensor activation more closely matched that of a healthy control. The increased muscle activation we observed in the paretic limb while the stroke survivor was wearing Keeogo™ was unexpected, but it is possible that wearing the dermoskeleton suit may have caused the individual to have more confidence in her ability and direct more effort in activating the paretic limb [54,55].

Prior research [7] has shown stroke survivors to have less limb muscle activity on the paretic side, when compared to the non-paretic side. Stroke causes significant unilateral muscle impairments, which is the pathological basis of asymmetry when performing activities [7,53–56]. In contrast to the existing robotic exoskeletons on the market, utilizing a user-initiated device such as Keeogo™ might encourage more active participation from stroke survivors who have spared muscle activity, which may be

more effective in promoting motor learning in these types of individuals [57–59].

It is well established that the asymmetrical nature of stroke-related deficits result in altered postural control of patients [52,54–56,60,61]. Indeed, similar to previous work [52,54,56,60,61], when the stroke survivor in the current study performed the sitTS task without Keeogo™, there was significant sway in the CoP in the mediolateral plane towards the non-paretic limb. This sway was corrected and improved when she wore the device. Spontaneously, stroke patients avoid loading a fraction of their body weight on the paretic limb when performing the sitTS task [56,60,62]. This avoidance pattern can lead to the development of a learned non-use syndrome for the paretic limb [56]. Thus, a primary goal during stroke rehabilitation is directing patients' attention and effort in loading more weight on the paretic limb, allowing for a symmetrical execution of the sitTS task [56,62]. Although we did not measure weight-bearing distribution in each limb, Marigold et al. [63] recently demonstrated greater mediolateral sway to be moderately associated to greater asymmetrical weight bearing during quiet standing. With this in mind, improvements in postural control when utilizing Keeogo™ suggest that the stroke survivor might be able to load more weight on the paretic limb and rise from a chair in a more symmetrical fashion. To confirm this, future work involving the placement of two force platforms under each foot will help to confirm symmetrical weight bearing distribution when wearing Keeogo™.

Cheng et al. [52] reported that stroke survivors performing a sitTS task had a significantly smaller rise in the RFD and peak vGRF, compared to healthy controls. Results of the current study confirm their findings, but also highlight the normalization of RFD and peak vGRF when using Keeogo™. Fleming et al. [64] reported that stroke survivors able to generate a greater rise in the RFD had a lower fall occurrence. Further studies with more community-dwelling stroke survivors are needed to confirm the effects of wearing Keeogo™ on improving kinetics and how this might relate to fall occurrence.

Limitations

Although this study presents novel findings on Keeogo™ dermoskeleton, there are several limitations that need mention. Firstly, for the criteria development, we used a $\geq 5\%$ relative improvement on primary outcome tasks with the device as a cut-off in order to identify responders to Keeogo™, which is more liberal than the established MDC of 22% for the 6MWT [65] (there is no MDC established for the 25FWT). Given the short period of time participants received to become habituated with the device (only 1 h), we would predict that any sort of benefit ($\geq 5\%$) of wearing Keeogo™ would likely improve if people were able to practice with the device over an extended period of time (e.g. two weeks). Indeed, the improvement that the stroke survivor participant (a regular user of the device) had on both the 6MWT and the 25FWT was 28% and 40%, respectively. A second limitation in the study is that we recruited individuals who had a wide range of neurological diseases. Our difficulty to clearly isolate functional characteristics that would predict benefit from Keeogo™ may have been due to the fact that disturbances in gait are variable across neurological populations. It may be helpful for future studies to focus on a single neurological population to identify key functional characteristics that may predict benefit of utilizing Keeogo™. Thirdly, the case report involved one stroke survivor who was a habitual user of Keeogo™. This means that statistical analysis could not be performed, which makes it difficult to generalize the benefits of wearing the device to the general stroke population.

Furthermore, we were limited in acquiring EMG from only one leg muscle during the sitTS task due to both interference from the pads of Keeogo™ and the bulkiness of the surface electrodes. The sitTS task is a dynamic task involving the coordination of several lower limb muscles [7], so using thinner surface electrodes in future studies may help to gain a better understanding of how the coordination of the lower limb muscles is affected when utilizing Keeogo™ during the sitTS task.

Conclusion

This study was the first attempt to identify which functional characteristics might predict benefit from using Keeogo™ dermoskeleton in individuals suffering from neurological impairments. Our study results suggest that individuals must have a moderate level of functionality to benefit from the device. Specifically, individuals scoring between 46 and 51 on the BBS, and/or who can complete the TUG in approximately 8–12 s, have the greatest potential to benefit from Keeogo™. If individuals are too motor impaired, then they will be unable to compensate for the inherent mass and stiffness of the device. Likewise, if the neurological impairment is not severe enough to significantly impair balance and locomotion, the device may not provide meaningful benefit. We also attempted to quantify the functional benefits Keeogo™ provides to a regular user of the device. Wearing Keeogo™ improved performance on the 30CST, SCT and improved motor control, postural control and movement kinetics in a chronic stroke survivor with significant hemiparesis. These preliminary findings should help to inform the design of future clinical studies evaluating the assorted benefits that Keeogo™ may provide to successful users.

Disclosure statement

No potential conflict of interest was reported by the authors.

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