Enhancing Safety and Usability in the Design of a Powered Exoskeleton for Spinal Cord Injury

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KEYWORDS: powered exoskeleton, spinal cord injury, assistive technology, safety, usability

ABSTRACT

A powered exoskeleton, a robot that generates walking motion, offers significant benefits to individuals with spinal cord injury (SCI). This technology has the potential to restore motor function and facilitate seamless integration into daily life and work. However, despite the positive effects noted in clinical studies, challenges, such as device malfunctions, skin injuries, user errors, and falls, persist. This study aimed to address these challenges by designing and evaluating the safety and usability of a prototype exoskeleton for SCI. Ten healthy adults participated in the study and performed walking tasks with and without the prototype. The prototype consists of an adjustable frame, computer-controlled hip and knee joint actuators, and a gait-trigger sensor. Safety outcomes included vital signs, numerical rating scale (NRS) scores for pain and discomfort, and clearance between the prototype and human body. The usability outcomes included donning and doffing times, subjective ratings, gait speed, stride length, and kinematic parameters of the hip and knee joint angles. Safety outcomes showed no significant differences in the pre- and post-session vital signs, minimal NRS scores, or acceptable device body clearance. The usability outcomes showed high efficiency and received positive ratings. Kinematic analysis revealed positive correlations in the hip and knee joint angles between walking with and without the prototype, thus confirming its effectiveness in assisting walking. Further improvement of the device and fine-tuning of the gait parameters are essential for its application in future clinical settings.

1 INTRODUCTION

Exoskeleton technology holds promise for gait rehabilitation in individuals with spinal cord injury (SCI), potentially allowing recovery of motor function and facilitating reintegration into daily life and work. Clinical studies and systematic reviews have underscored the positive impact of exoskeletons in helping individuals with paraplegia regain walking independence [1][2]. However, persistent challenges, such as device malfunctions, skin injuries, misalignments, user errors, and falls, have been reported [3][4]. The size and weight of exoskeletons, coupled with their potential fitting problems related to lower-limb alignments, present additional hurdles. In addition, safety depends heavily on caregivers' assistance. These challenges emphasize the importance of designing safety measures to minimize risk for both SCI users and their caregivers while maintaining usability. The development and operation of safe exoskeletons require comprehensive risk-reduction measures that utilize both human support and engineering protection. At the previous SIAS 2021 conference, we introduced a safety checklist designed for individuals with SCI and their caregivers focusing on human support [5]. Subsequently, we developed a prototype exoskeleton that considered safety and usability from an alternative perspective, thus emphasizing engineering protection [6]. This study provides an overview of the prototype exoskeleton along with experimental results regarding its safety and usability.

2 METHOD

2.1 Participants

Ten healthy adults (seven males and three females) participated in this study. The mean height was 167 ± 10 cm (range: 152–179 cm), weight was 58 ± 9 kg (41–70 kg), and body mass index was 21 ± 2 (17–25).

2.2 Device

A prototype exoskeleton was used as an experimental device (Figure 1). The prototype has basic features, including hip and knee joint actuators controlled by a programmable logic controller (PLC), to generate walking, standing, and sitting movements. The actuator was equipped with a 1:101 reduction gear and a brushless DC motor that

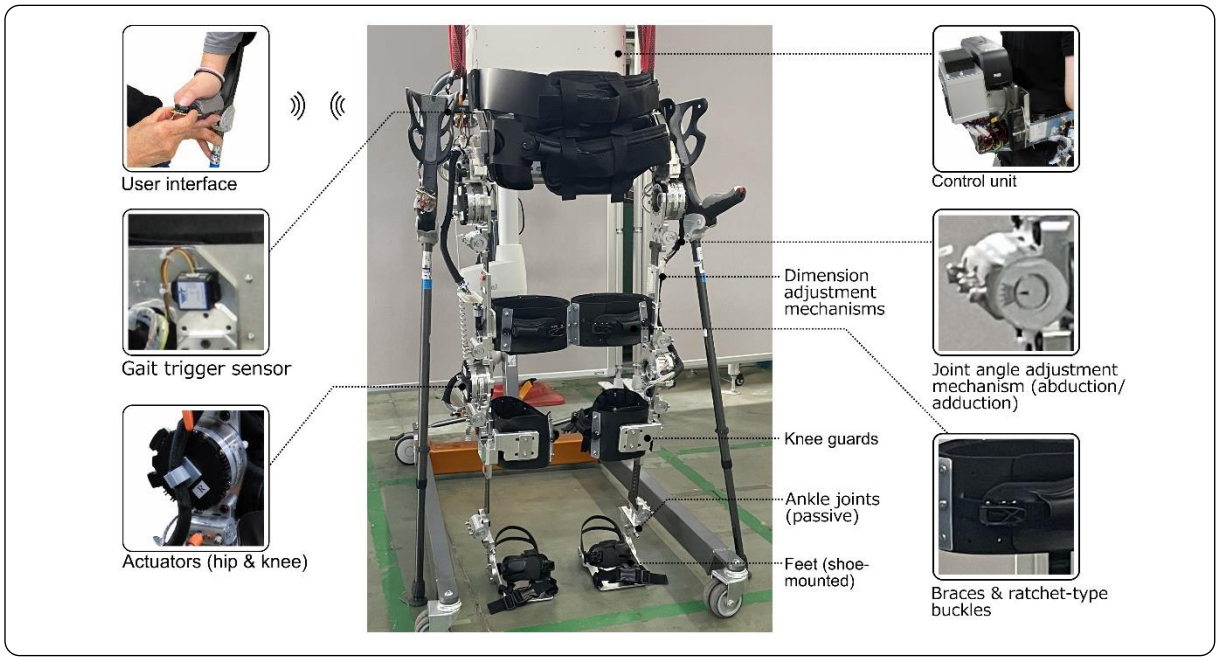

Figure 1. *Prototype exoskeleton for spinal cord injury.*

could generate a maximum torque of 90.9 Nm, thereby satisfying the torque requirements for standing up from a chair. The design incorporates a motion sensor for gait triggering, which activates the gait sequence based on the forward trunk tilt of the user, considering the potential neuroplasticity in voluntary movements. Additionally, the prototype included a dimensional adjustment mechanism to fit the human body size and a joint angle adjustment mechanism to fit the lower-limb alignments, addressing variations, such as X- and O-legs, while also reducing the risk of skin injuries. Attachment to the body was achieved using strap belts on the waist, thighs, shanks, and feet. These belts feature ratchet-type buckles for added convenience, unlike traditional Velcro closures. The user interface was integrated into the grips of the forearm-supported clutches (Lofstrand clutch). The design also incorporates intentional choices to minimize the risk of user error. The mode selection switch was located on the right grip, whereas the stop switch was on the left grip. These switch outputs were transmitted to the exoskeleton controller via Bluetooth. Voice guidance is also available to aid in recognizing and transitioning the operating state of the exoskeleton.

Figure 2 shows a flowchart of the operational program, which has the following steps: (1) The user attaches the exoskeleton while in a servo-stopped state at the origin. (2) To initiate the standing movement, the standing mode was selected and confirmed. (3) After a successful standing movement, each axis actuator maintains its standing position in a servo-stopped state. (4) To start walking, the user selects the walking mode and waits for the walking start trigger. Walking was automatically initiated when the motion sensors detected a forward inclination beyond the preset angle. Pressing the walking-stop switch causes the swinging leg to return to the standing position via the shortest route in the servo-stopped state. If the sitting mode is selected, the system returns from the standing position to the servo-stopped state upon completion of the sitting movement.

2.3 Items measured

2.3.1 Safety and usability outcomes

Potential adverse events were assessed by measuring the following vital signs before and after each session using a smartwatch-type device (H2; itDEAL, China): heart rate, systolic and diastolic blood pressure, and oxygen saturation (SpO_2). Pain and discomfort levels were evaluated using an 11-point numerical rating scale (NRS), where 0 indicated no pain or discomfort, and 10 indicated unbearable pain or discomfort. The target sites were the three areas (pelvis, thighs, and shanks) where the fixation device was in contact. Additionally, the clearances between the human thigh and lower limb and the thigh and shank segments of the prototype were measured using a caliper. This measurement evaluated compliance with the checkout criteria for lower-limb orthotics, where clearance was set at approximately 5–7 mm for non-articulated regions [7]. A narrow clearance indicates an increased risk of skin injuries, whereas an excessively wide clearance may lead to increased friction with the clothing.

The usability was assessed by measuring the time taken by the participants to wear and remove the device. Donning time refers to the time required to attach the strap belts to the pelvis, thighs, and shanks while the participant was

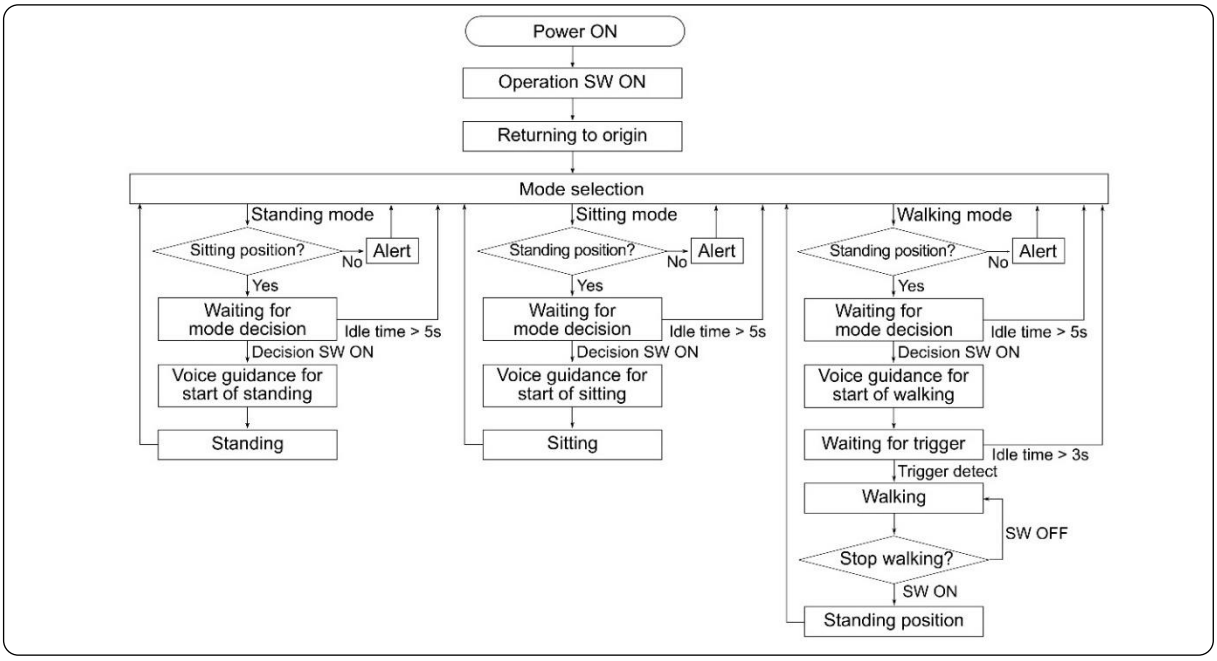

Figure 2*. Flowchart of the operating program for controlling the prototype exoskeleton.*

seated. Conversely, the doffing time was used to describe the duration required to remove the strap belts from the same location. Additionally, a questionnaire was administered to assess the ease of donning and doffing as well as the subjective sensation of fit at three specific sites: the pelvis, thighs, and shanks. The rating scale consisted of 11 points, aligned with the previously described NRS, ranging from 0 (difficult to don/doff) to 10 (easy to don/doff), and from 0 (not fit) to 10 (fit). Gait velocity was calculated based on the walking distance and time using a stopwatch. Additionally, the stride length was calculated using the walking distance and number of steps taken during walking with and without the prototype.

2.3.2 Kinematic parameters

The gait of the prototype was tested to determine whether the gait was successfully performed. This study used a marker-less motion capture system (e-skin MEVA; Xenoma Inc., Tokyo, Japan) to measure the hip and knee joint angles during walking. Measuring kinematic parameters using conventional methods when using exoskeletons presents challenges owing to the marker being covered by the exoskeleton frame in optical motion capture systems. Additionally, mechanical joint goniometers may encounter interference issues from the exoskeleton frame, which could compromise measurement accuracy. In contrast, the e-skin system has a bodysuit-type design that can be worn like clothing, ensuring minimal interference with the exoskeleton frame. The system uses an inertial measurement unit (IMU) sensor that comprises 3-axis acceleration and gyro sensors to calculate motion based on sensor data. The algorithm developed by Teufl et al. [8] enables motion calculations based solely on accelerometers and gyro sensors without relying on geomagnetism. Consequently, the system is unaffected by geomagnetic interference, which is a drawback of IMU. This ensured stable measurements, even in the presence of a motor in the exoskeleton. The IMU sensors were positioned at 18 locations: one on the headband, 10 on the upper-body shirt, and seven on the lower-body pants. The sensors were considerably thin, measuring 20 mm in width, 35 mm in length, and 2 mm in thickness. Compared with optical methods, this method produces joint angle differences of only 2º with a correlation coefficient of 0.98 for the hip and knee joint angles in the sagittal plane [8]. The data were recorded at a sampling frequency of 100 Hz and transferred to a PC via Bluetooth.

Data from the second trial were used for gait analysis. To account for variations in walking times among the participants, the joint angle data were normalized within a single gait cycle encompassing both the swing and stance phases, defined as 100%. We then used the maximum (peak flexion angle) and minimum (peak extension angle) hip and knee joint angles to represent and compare the differences attributed to the exoskeleton usage. The gait cycle was divided into eight distinct phases (initial contact 0% of the gait cycle, loading response = 0–12%, mid stance = 12–31%, terminal stance = 31–50%, pre-swing = 50–62%, initial swing = 62–75%, mid swing = 75–87%, and terminal swing = 87–100%) based on the Rancho Los Amigos Hospital method [9]. The stable hip and knee joint angles were extracted for each phase. Subsequently, correlations were determined between normal walking and gait using the prototype for the aforementioned datasets.

2.4 Procedure

As part of the experimental preparation, the participants were provided detailed instructions on how to operate the prototype. A Martin anthropometer (Tsutsumi Work Inc., Chiba, Japan) was used to measure the thigh, lower leg, and waist widths. The lengths and widths of the exoskeleton frames were adjusted based on their respective measurements. Finally, the participants donned the prototype while being seated. During this process, the participants performed a standing motion to evaluate the tightness of the straps or belts with necessary adjustments. Simultaneously, the joint angles of the left and right lower limbs were adjusted, and clearance was measured. After completing this stage, the participants returned to their seats, and the prototype was removed.

The participants wore calibrated marker-less motion capture suits, and each participant completed two 6-m walks at their usual pace. Joint angles were recorded using motion-capture technology, walking time was measured using a stopwatch, and frontal and side views were captured using video cameras.

Then, the participants again donned the prototype while being seated. The time required to don the prototype was recorded using a stopwatch. The participants were trained to use the prototype with a specialized walker and practiced using crutches. The participants were instructed not to exert any force on their lower limbs while walking using the prototype. A caregiver stood behind each participant to ensure their safety and prevent falls. Air mats were placed on both sides of the walking path. The participants completed a 6-m walk twice using the prototype. Joint angles were recorded using motion-capture technology, walking time was measured using a stopwatch, and frontal and side views were captured using video cameras. After the activities, the prototype was removed, and the time taken for doffing was measured using a stopwatch. Finally, the participants completed the NRS questionnaire.

2.5 Statistical analyses

The data are presented as mean ± standard deviation. Paired t-tests were used to compare mean vital data before and after the session. It was also used to compare the gait velocity, stride length, and peak flexion/extension angles of the hip and knee joints with and without the prototype. Pearson's correlation coefficients were calculated for the hip and knee joints during a single gait cycle while walking with and without the prototype. All statistical analyses were performed using IBM SPSS Statistics version 28 (IBM Corp., Armonk, N.Y., USA). Statistical significance was set at $p < 0.05$.

2.6 Ethical considerations

This study was approved by the Ethics Committee of the Japan Organization of Occupational Health and Safety (reference number: 2022-17). All the participants provided written informed consent to participate in the study.

3 RESULTS

The mean heart rate was 74.3 ± 12.1 bpm before the session and 79.6 ± 12.5 bpm after the session. Mean systolic blood pressure was 125.0 ± 19.7 mmHg before the session and 119.8 ± 9.8 mmHg after the session, while mean diastolic blood pressure was 76.6 ± 11.8 mmHg before the session and 73.6 ± 3.0 mmHg after the session. Mean SpO_2 was 97.4 ± 0.7% before the session and 97.7 ± 0.9% after the session. No significant differences were observed between the pre-session and post-session measurements for any of the parameters. The mean pain and discomfort ratings were as follows: pelvis= 0.0 ± 0.0, 0.2 ± 0.7; thighs= 0.1 ± 0.3, 0.3 ± 0.7; and shanks = 0.7 ± 1.1, 0.4 ± 0.7, respectively. No pain or discomfort ratings exceeded 3 during the sessions. The ratings for the feeling of fit were as follows: pelvis= 6.2 ± 3.0; thighs= 7.0 ± 3.0; and shanks= 7.1 ± 3.0. The mean distance between the device and the human body was 10.2 ± 4.6 mm for the thigh and 10.9 ± 5.2 mm for the shank.

For usability outcomes, the average time required for donning the device was 3.8 ± 0.6 min, while the mean doffing time was 0.6 ± 0.2 min. The ease of donning or doffing was reported as follows: pelvis = 4.8 ± 2.3; thighs= 5.1 ± 2.1; and shanks= 4.7 ± 2.4. Participants achieved a mean gait velocity of 1.0 ± 0.1 m/s during normal walking, which decreased to 0.1 ± 0.1 m/s when using the prototype. Similarly, stride lengths were 1.2 ± 0.1 m during normal walking but decreased to 0.8 ± 0.3 m when using the prototype. Statistical analysis revealed significant differences in gait velocity ($p < 0.001$) and stride length ($p = 0.0025$) between walking with and without the prototype. The hip and knee joint angles throughout the gait cycle are shown in Figure 3. Positive correlations were observed between walking with and without the prototype in hip joint angle ($r = 0.70$, $p < 0.001$) and knee joint angle ($r = 0.84$, $p < 0.001$). The mean peak flexion angles of the hip joint were 30 ± 3.5° for normal walking and 30 ± 6.1° when using the prototype. The mean peak extension angles of the hip joint were -13 ± 3.7° for normal walking and -6 ± 5.1° when using the prototype. Significant differences in these parameters were observed between the two conditions ($p = 0.002$). The peak flexion angles of the knee joint were 74 ± 4.5° for normal walking and 44 ± 5.2° when using the prototype, with significant differences observed between the two conditions ($p < 0.001$).

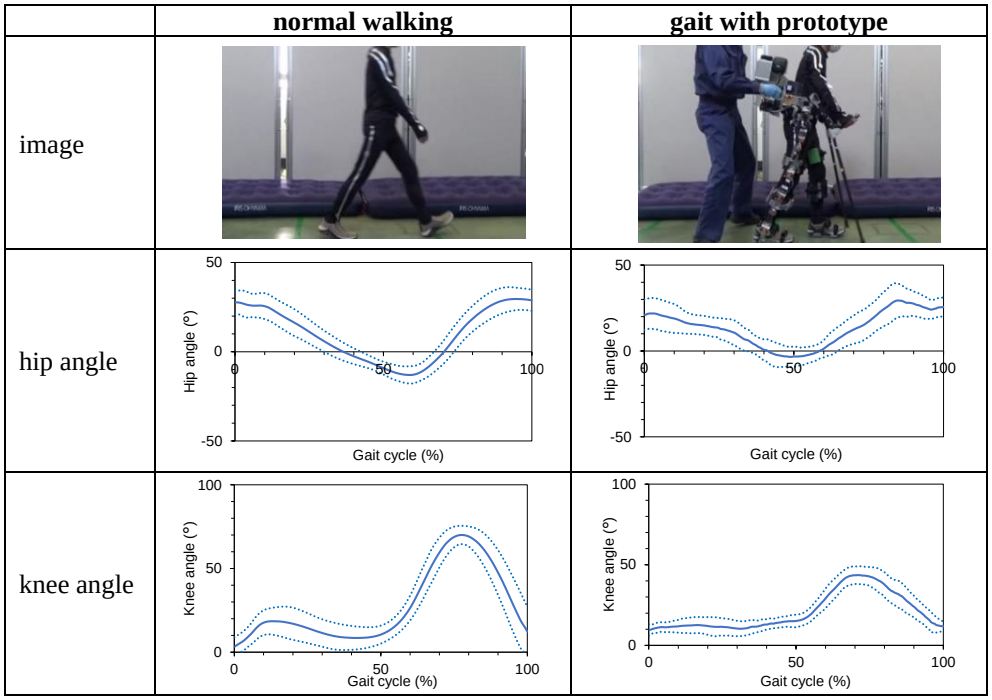

Figure 3. *Change in hip and knee joint angles during one gait cycle while walking with and without the prototype.*
Notes. The vertical axis in the figure represents joint angles, with (+) indicating flexion and (−) indicating extension. The solid line represents the average value for the participants, and the dashed line represents the standard deviation.

4 DISCUSSIONS

4.1 Safety and usability

Subjective pain and discomfort ratings were minimal, with no session interruptions. Therefore, it can be inferred that the health risks associated with exoskeletal use are low. The mean clearance between the thigh and lower leg was 10 mm. Compared with the criteria for lower-limb orthotics, the clearance values of the prototype are slightly large; however, they are within a reasonable range. The subjective fit ratings consistently indicated high levels of comfort in all areas. The ergonomic approach of combining adjustable structures and soft materials within a brace effectively minimized skin problems and misalignment, as evidenced by the low pain and discomfort ratings. These results could also benefit physical therapists by eliminating traditional tasks, such as applying and removing pads, thereby streamlining the preparation process in clinical settings.
The time required to don and doff the device was reasonable, and the subjective ratings of the ease of donning and doffing suggested that the process was relatively straightforward. Conversely, according to a previous study, it took approximately 7 min to don and 2 min to doff a conventional exoskeleton for SCI [4]. Notably, these durations include the time required to apply and remove the pads to prevent skin abrasion; therefore, it is difficult to make direct comparisons. However, our prototype successfully achieved lower donning and doffing times than a conventional exoskeleton. This improvement was due to the switch from the traditional Velcro system to the ratchet system, which allowed easy adjustment, secure attachment, and quick one-touch removal.

4.2 Kinematic parameters

The prototype successfully executed the intended walking program. The kinematic results during walking indicated nearly identical hip and knee joint patterns with and without the prototype, thus proving that the prototype provided gait assistance. However, significant differences were observed in the peak values of knee joint flexion and hip joint extension. During the stance phase of walking with the prototype, the knee was inadequately flexed, particularly during the weight response phase. In addition, the maximum knee flexion angle during the swing phase was smaller than that during normal walking. Furthermore, the maximum hip extension angle of the prototype was smaller than that during normal walking. Upon observation, it appeared that the foot makes ground contact before the knee fully extends, and there is a forward-leaning posture owing to the use of crutches. These factors may be related to the shorter stride length for prototype walking than that for normal walking. Therefore, adjusting the settings of the prototype walking program will be necessary in the future. Additionally, the mean gait velocity achieved using the prototype was only 10% that achieved during normal walking. This was because the participants

used the exoskeleton for the first time, and some expressed apprehension regarding walking at increased speeds. Hence, the speed of the exoskeleton was intentionally set to a slow pace to improve safety. As the prototype's specifications allow it to reach speeds of up to 0.5 m/s, equivalent to that of a conventional exoskeleton, it is necessary to gradually adjust the speed according to the user's condition and proficiency level.

4.3 Study strengths and limitations

A major strength of this study is that we developed a novel exoskeleton for SCI and quantitatively measured subtle body movements within the exoskeleton frame using marker-less motion capture, which was previously considered difficult. Our results demonstrate that the prototype can successfully perform a walking program when worn by healthy participants. This suggests that the prototype has properties similar to those of conventional exoskeletons and can potentially improve the walking ability of individuals with SCI. In addition, the prototype exoskeleton effectively addresses common problems, including skin injuries and misalignment, associated with exoskeletons. Key features, such as adjustable dimensions and joint angles, cushioning materials, ratcheting fasteners, and a wireless user interface in the clutch, enhance the safety and usability of the exoskeleton.
However, this study has some limitations. We used a small sample size and a relatively short experimental duration, which could have introduced some bias in our findings. This could be addressed by expanding the study to include an increased number of participants and performing long-term investigations. In addition, there were technical challenges, particularly the weight of the prototype, which exceeded that of conventional devices. Lightweight materials, such as carbon fibers, battery capacity adjustments, and a specially designed control system, instead of a general-purpose PLC can be used in future studies to achieve the desired weight target. Adjusting gait parameters based on normal gait data and reevaluating basic gait patterns are also necessary. Given these limitations, it is imperative to continue improving and adapting the prototype. It is essential to comprehensively evaluate patients with SCI in a clinical setting for an improved understanding of the prototype and its potential applications.

5 CONCLUSIONS

A prototype exoskeleton was designed for individuals with SCI. Experimental evaluations with healthy participants showed high safety and usability. Additionally, our findings demonstrated its ability to facilitate walking movements. However, further improvement of the device and fine-tuning of the gait parameters are essential for its application in future clinical settings.

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ACKNOWLEDGEMENTS

The authors thank Dr. Kazunari Furusawa and Mr. Yoshinori Yamada for their valuable advice and the medical staff at the Kibi Kogen Rehabilitation Center for their cooperation.