Deep Core Activation Method Utilizing Wearable Cyborg HAL in Supine Position for Improving Anorectal Motility: A Case Study for a Patient with Chronic Spinal Cord Injury

〇Hayato TAMAI[1], Hiroaki KAWAMOTO[2, 3], Akira UEHARA[2, 3, 6], Masao KODA[4], Yoshiyuki SANKAI[2, 3, 5, 6]

1 Ph.D. Program in Humanics, School of Integrative and Global Majors, University of Tsukuba, Ibaraki, Japan.
2 Institute of Systems and Information Technology, University of Tsukuba, Japan.
3 Center for Cybernics Research, University of Tsukuba, Japan.
4 Department of Orthopedic Surgery, Institute of Medicine, University of Tsukuba, Japan.
5 CYBERDYNE Inc., Tsukuba, Japan
6 R&D Center for Frontiers of MIRAI in Policy and Technology, University of Tsukuba, Ibaraki, Japan.

〇 Corresponding author (tamai_h@golem.iit.tsukuba.ac.jp)

Supine HAL-Intervention Raised Anorectal Motility

Abstract

Neurogenic bowel dysfunction (NBD) is the most prevalent problem among patients with spinal cord injury (SCI) and greatly affects their quality of life. A major cause of NBD is a well associated with lack of anorectal motility, which helps to evacuate stool or maintain continence by increasing/decreasing intra-abdominal pressure (IAP) and relaxing/contracting sphincters. Current programs for anorectal dysmotility have only temporary effects or are highly invasive. In order to overcome the difficulties caused by NBD, a novel treatment method is urgently needed for anorectal dysmotility, with a sustained effect and without invasive procedures. We have previously proposed a minimally invasive method using the wearable cyborg Hybrid Assistive Limb (HAL) to sustainably improve anorectal motility. In our proposed method, long-term repetition of supine HAL-assisted hip flexions are thought to activate deep core and induce its neural plasticity, potentially regenerating anorectal function. It has been previously confirmed that the supine HAL-assisted hip flexion was realized in healthy individuals; however, it has not yet been confirmed that feasibility of our proposed methodology and its sustained functional improvement on anorectum in patients with SCI have yet to be confirmed. Here, we aimed to validate this methodology in terms of feasibility and sustained functional improvement in the anorectum of a patient with chronic SCI. A 24-year-old man with chronic SCI accompanied by anorectal dysmotility underwent four weeks of supine HAL-assisted hip flexion for thirty minutes, four times per week. To evaluate the effect of the intervention on anorectal motility, IAP measurement and sphincter electromyography were conducted for seven days pre-/post-intervention. The assessment was repeated at a two-month follow-up after the intervention to verify the persistence of the effects. The increasing trends were observed in all periods of both IAP and in sphincter electromyogram. There was a significant increase in IAP and sphincter electromyogram between the pre-intervention and two-month follow-up periods ($p < 0.001$). These results demonstrate not only the feasibility of the proposed methodology but also the potential for a sustained effect in improving anorectal motility in patients with chronic SCI.

Keywords: Neurogenic bowel dysfunction, Anorectal motility, Spinal cord injury, Hybrid Assistive Limb, Case study.

1. Introduction

Neurogenic bowel dysfunction (NBD) is a major problem in patients with spinal cord injury (SCI) caused by gastrointestinal and anorectal dysmotility [1,2]. The primary symptoms of NBD include constipation, difficulty with evacuation, and fecal incontinence, which cause psychological distress for patients with SCI. The National Spinal Cord Injury Statistical Center Database [3] indicates that over 60% of patients with SCI currently experience defecation problems. For many of them, the psychological distress caused by these problems, such as daily abdominal pain and fear of incontinence, reduces their quality of life [4]. Thus, an effective treatment program for NBD is urgently needed so that patients can live comfortably.

To resolve NBD in patients with SCI, it is essential to improve anorectal and colonic dysmotility. Vallès et al. identified pathophysiological counterparts of NBD in patients with SCI [2]; patients who have experienced frequent constipation were unable to increase intra-abdominal pressure (IAP) and exhibited a lack of sphincter relaxation during defecation. Those with significant defecatory difficulty demonstrated paradoxical sphincter contraction during straining. Additionally, patients with severe incontinence lacked sphincter contraction during rectal distension. Furthermore, all patients exhibited delayed colonic transit time, which was attributed to inadequate colonic motility [2]. In summary, to eliminate NBD, it is necessary to improve anorectal motility in order to permit voluntary control of IAP and sphincters, as well as to enhance colonic motility in order to reduce colonic transit time.

Even though previous studies have demonstrated enhanced colonic motility for patients with SCI [5,6], in terms of improvement for anorectal motility, existing treatments have a limited efficacy duration or are only effective in certain patients. Sacral nerve electrical stimulation, one of the most representative treatments, produces only temporary improvements in most patients [7]. Moreover, the need for surgery, as well as the risks of abolishing reflex erection and reflex ejaculation, further restricts the number of eligible patients [8–10]. The biofeedback therapy is also accompanied by highly invasive insertion of electrodes into the anal canal [11]. Functional magnetic stimulation is relatively less invasive procedure; however, it is only applicable to individuals with retained spinal sacral reflexes [12]. Therefore, a novel non-invasive treatment is needed for anorectal dysmotility with sustained effects in order to overcome the difficulties caused by NBD.

Cybernics treatment, on the other hand, can potentially improve muscular dysmotility without causing pain but with sustained therapeutic effects. It could potentially be applied to any individual, even those without spinal sacral reflexes. Cybernics treatment is used to improve/regenerate motor functions in patients with various neurogenic dysmotility issues using wearable cyborg Hybrid Assistive Limbs® (HAL; CYBERDYNE Inc.). The HAL assists the wearer's voluntary movement by detecting bio-electrical signals (BES) leaking out to the skin surface that reflect wearer's motor intention. These signals control power units in the HAL joints that assist movement in unison with the wearer's intentions. HAL-assisted motion generates sensory inputs from muscle spindles, ears, eyes, and other sensory receptors back to the wearer's brain. This intention-based sensory feedback activates the nervus system which in turn alters the patient's brain, nerves, and muscle function. Repeating this HAL-assisted motion has been considered to promote neural plasticity and sustain the effects of recovery on muscle motility. Obviously, this technique is minimally invasive and can be applied to any individual, as long as their BES can be detected from their skin surface. [13–15]

Considering the need to functionally improve the musculatures involved in anorectal motility for recovery from NBD, we previously proposed a method using HAL for improving anorectal dysmotility based on the cybernics treatment [16]. Our proposed methodology aims to recover anorectal motility through long-term repetition of supine HAL-assisted hip flexion in accordance with wearer's motion intention toward deep core. The deep core is the body region encompassing the internal oblique (IO), transversus abdominis (TrA) (which contribute to increased IAP), and the pelvic floor muscles (PFM) (which aid in sphincter contraction/relaxation) [17–19]; they engage each other in tandem as they work for anorectal motility and other functions [19] (**Figure 1**). In our method, the HAL detects the patient's motion intention toward the deep core from surface electrodes placed at the fusion site of the internal oblique and transversus abdominis (IO-TrA). Supine hip flexion based on this motion intention co-contracts all deep core muscles, including the IO, TrA, and PFM, along with the fascial connected iliopsoas (**Figure 2**). This dynamic joint movement leads to the perception of sensory feedback from all deep core muscles. In turn, as described in the paragraph above,

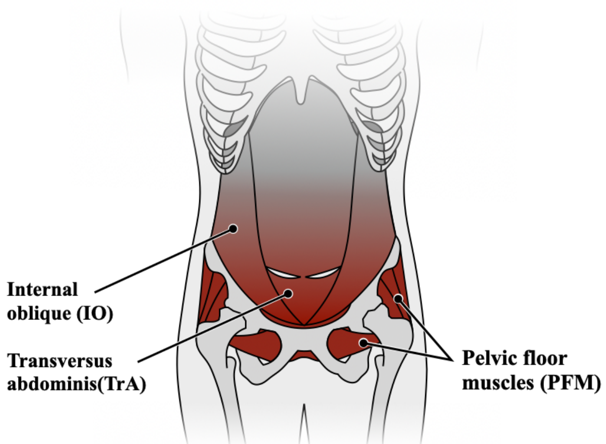

Figure 1. The specific segment of deep core. These musculatures work in tandem.

repeating this supine HAL-assisted hip flexion promotes neural plasticity of the nerves which comprehensively innervate the deep core, resulting in the sustained effects of recovery on anorectal motility under the principles of cybernics treatment.

It was previously confirmed that the supine HAL-assisted hip flexion was realized in healthy individuals [16]. However, it has not yet been confirmed that feasibility of our proposed methodology and its sustained functional improvement on anorectum in patients with SCI. This study aimed to confirm that our proposed method is feasible and provides sustained functional improvement in the anorectum of a patient with chronic SCI.

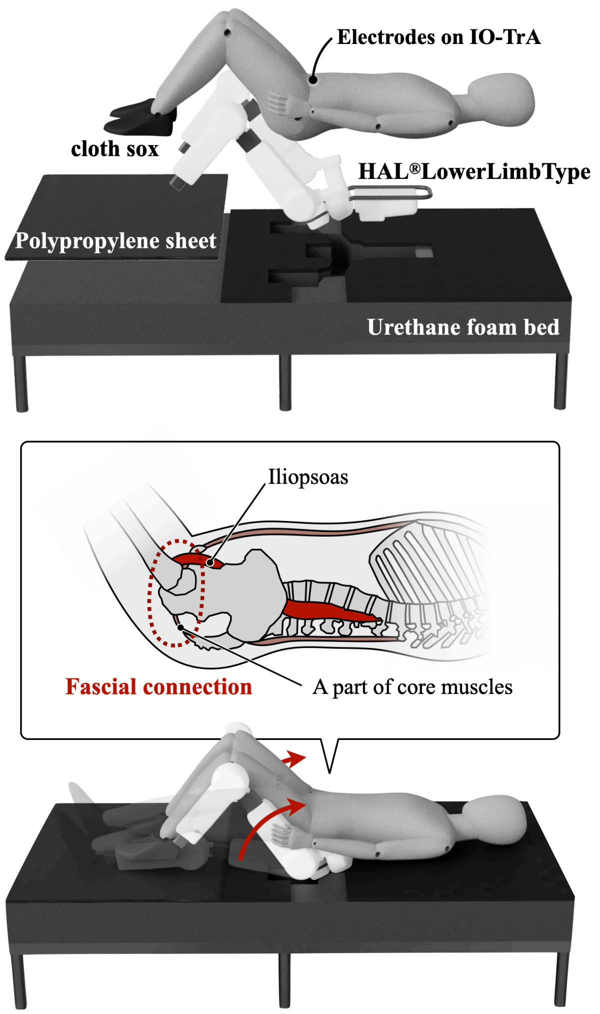

Figure 2. Overview of our proposed method. HAL realizes hip flexion based on the wearer's motor intentions detected from the surface electrode on IO-TrA. The sensory feedback from the deep core and iliopsoas, which are fascial connected, activates the innervating nerves of the deep core. Repeating this spine HAL-assisted hip flexion induces neural plasticity in the deep core, resulting in sustained anorectal improvement.

2. Materials and Methods

2.1 Study Design

A case study was conducted involving a preclinical test and a four-weeks of HAL intervention. A preclinical test was performed to validate the applicability of our methodology for a patient with SCI. Clinical assessments were carried out before, immediately after, and two months following the HAL intervention, each for one week, to verify the sustained functional improvement in anorectal motility (**Figure 3**).

2.2 System Configuration

The system used for this method consisted of the HAL, a polypropylene sheet, and a urethane molded bed. The wearer attached electrodes to the IO-TrA and connected them to the HAL (**Figure 2**).

The surface electrodes on the IO-TrA transmitted the wearer's motor intention sent toward all of the entire deep core muscles to the HAL. As the deep core muscles move in coordination with each other [19] and some of their motor unit potentials leak from the IO-TrA [20,21], the BES on the wearer's IO-TrA can be regarded as the motion intention to the deep core muscles.

The HAL was equipped with actuators at both the hip and knee joints. Details of the HAL control algorithm are described in other literature [22]. Briefly, we used two control modes of HAL: Cybernic Voluntary Control (CVC) and Cybernic Impedance Control (CIC). The CVC mode determins the actuator torque based on the intensity of the wearer's BES. In contrast, the CIC mode determines the torque according to the angular velocity of joint motion. In our method, the hip joint was operated in CVC mode to reflect the BES from the IO-TrA into the hip flexion torque. The knee joint was controlled in CIC mode and to make it behave as a free axis.

A polypropylene sheet was placed under the wearer's feet to reduces friction with the ground. This prevents the wearer from stepping on the ground with the lower limbs during hip flexion. The sheet enables the wearer to perform hip flexion by selectively contracting the core muscles without relying solely on the compensatory movement of the lower extremity muscles.

2.3 Participant

This case focused on a 24-year-old male patient (height, 178 cm; weight, 60 kg), one of the authors of this paper,

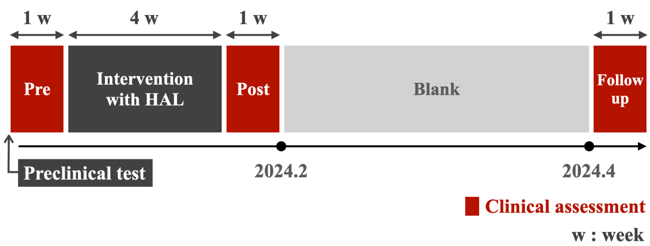

Figure 3. Assessment protocol.

who had injured his spinal cord due to a lumbar burst fracture at L1 four years before this study. The neurological level of injury (NLI), ASIA impairment scale (AIS), sensory zone of partial preservation (sensory ZPP), motor zone of partial preservation (motor ZPP) of the patient are presented in the following table (**Table 1**). Voluntary anal contraction was not preserved. The participant was not taking any medications or treatments for bowel control. He had undergone physical therapy for six months immediately following hospital discharge but had not received HAL training prior to this study.

Regarding his bowel function, the participant exhibited a slight perception of the urge to defecate. However, due to paralysis of the anorectum, the participant was required to strain excessively in order to evacuate the stools. Frequently, even with straining, it was challenging to adequately expel the stool. Although his voluntary anal contraction was not preserved, he had managed to control defecation by adhering to a scheduled toilet routine, resulting in the absence of incontinence episodes for several years (Wexner score = 0).

2.4 Preclinical Testing

A preclinical test was conducted to validate that the proposed method was applicable to the participant by validating that HAL could achieve supine hip flexion based on his intention, engage all of the deep core muscles, and ensure that hip flexion is driven by the deep core muscles rather than by compensatory movements of the hip flexors.

Figure 4 illustrates the experimental setup. The participant performed hip flexions with and without the HAL while measuring BES from IO-TrA, PFM, and rectus femoris (RF). Initially, surface electrodes (Vitrode; Nihon Koden) were attached to the IO-TrA and RF, and an intra-anal electrode (Anuform®; Neen) was inserted into the anal canal, where the PFM are concentrated. At first, in the configuration without the HAL, the participant lay supine. A speaker placed beside the participant emitted a beep every 5 s. The participant was instructed to engage his deep core muscles and perform hip flexion in order to achieve a hip angle of over 60 degrees only while the beep was sounding. This exercise was repeated three times. Subsequently, the participant donned the HAL and repeated the same test with HAL's assistance in the supine position. During both experimental sessions with and without the HAL, the electrodes on the IO-TrA were connected to the HAL, and BES were recorded using its associated software (HAL Monitor; CYBERDYNE Inc.) at a sampling frequency of 1 kHz. The electrodes on the RF and PFM were connected to a recording computer, and BES was logged at a sampling rate of 500 Hz using a microcomputer (ESP32; Espressif Systems).

To determine that the HAL could achieve hip flexion based on the participant's motor intention, we verified the synchronization between the hip joint angle and the BES from the participant's IO-TrA during HAL-assisted hip flexion. Additionally, to ascertain whether all of the deep core muscles were engaged during the hip flexion, we confirmed the increase in the amplitude of BES in both IO-TrA and PFM during the beep playback. The BES was rectified by applying a low-pass filter with a cutoff frequency of 10 Hz and the root mean square over a time window of 10 ms. The mean amplitude was calculated from the signals during the middle 3 s of the 5 s hip flexion period, with the initial and concluding seconds excluded to minimize the impact of variability at the onset and offset of the signal. The mean values derived from three measurements were employed as representative values. The BES when the beep was not played was recorded as the baseline value with the same calculation procedure. Furthermore, to ensure that hip flexion is driven by the deep core muscles rather than by compensatory movements of the hip flexors, we measured the BES of one of the hip flexors, RF, and the deep core muscles (IO-TrA and PFM). The activity ratios of these muscles were compared between protocols with and without HAL. The

Table 1 The neurological level of injury (NLI), ASIA impairment scale (AIS), sensory zone of partial preservation (ZPP), motor ZPP.

		Diagnosis
NLI		L3
AIS		A
Sensory level	Left	L5
	Right	L3
Motor level	Left	L5
	Right	L3
Sensory ZPP	Left	S1
	Right	L4
Motor ZPP	Left	S1
	Right	L3

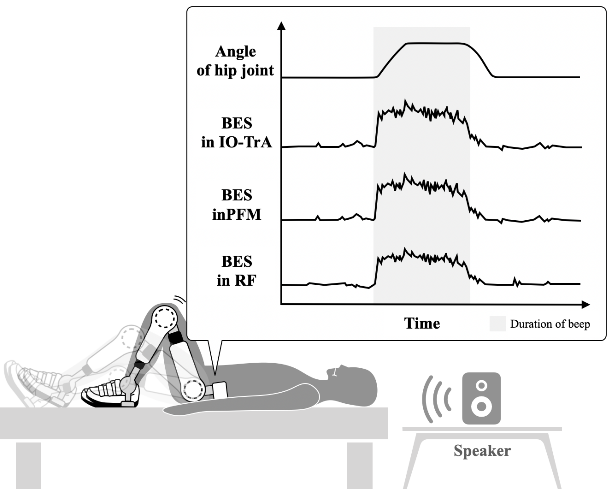

Figure 4. Overview of the experimental setup. The hip joint angle and the BES of IO-TrA, PFM, and RF were measured during hip flexion in both with- and without the HAL.

muscle activity ratio was calculated by dividing the amplitude of IO-TrA, PFM, and RF with HAL assistance by their respective amplitudes without the HAL.

2.5 Intervention

The participant performed HAL-assisted hip flexions while in a supine position four times a week for a total of four weeks (**Figure 5**). In the intervention program, the participant first attached electrodes to the IO-TrA and connected these electrodes to the HAL's hip actuator with cables. Subsequently, the participant engaged in approximately twenty to thirty repetitions of hip flexion while wearing the HAL, to familiarize himself with the wearable cyborg. The instruction for engaging the deep core muscles was as follows: "Please flex the hip over approximately 60 degrees while contracting the pelvic floor as if closing the anus." Subsequently, five sets of ten HAL-assisted hip flexions were carried out per session. The duration of each session with the HAL, including the time required for attachment and detachment of the de-vices, was was approximately 60 min.

The gain of the assistive torque for the HAL's hip actuator was set using the controller to enable the deep core to exert approximately 60–70% of the maximum force produced by the participant. This setting was informed by the literature which introduced pelvic floor muscle training [23,24]. As the sessions progressed, the gain of the assistive torque gradually decreased as the participant became accustomed to the training.

2.6 Outcome Measures

To determin the impact of the intervention on anorectal motility, two anorectal motility assessment indices were employed: IAP measurement and sphincter electromyography. These assessments were carried out at pre-, post-, and two-month follow-up of the HAL intervention for a week respectively to determine the persistence of the intervention effects.

2.6.1 IAP Measurement

One of the anorectal motilities that contributes to stool evacuation was evaluated by measuring the IAP increase during straining. The change in IAP is accurately reflected by the change in rectal pressure measured at a 10 cm depth of the anal canal [25]; thus, changes in rectal pressure at this depth were recorded and assessed as changes in IAP in this study. Rectal pressure measurement was carried out by inserting an air-filled balloon catheter into the participant's anal canal as previously described by Miller et al. [26]. The balloon catheter (Safired® Balloon Catheter; Terumo) was equipped with a transducer (2SMPP-02; Omron) connected to its balloon tube. The pressure change inside the balloon caused by the patient's straining was converted into discretized values by the transducer. The values were amplified by an differential amplifier circuit with a gain of 21x and recorded by a microcomputer (ESP32; Espressif Systems) at a sampling rate of 500 Hz. Prior to use, the measuring equipment was calibrated in a glass container connected to a gauge pressure sensor (MPS-C35R-NCA; CONVUM), which exhibited a linear response per unit rise in actual pressure.

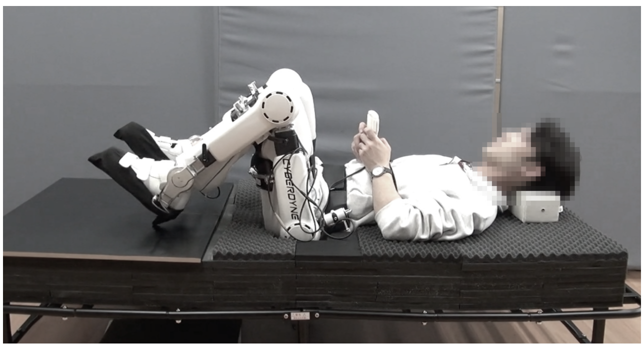

Figure 5. HAL-assisted hip flexion was performed by the participant for sixty minutes per a time, four times a week for a total of four weeks.

In the left lateral position with the hip and knee flexed at 90 degrees, a catheter was placed 10 cm proximal from the participant's anal orifice, and 10 ml of air was injected into the balloon. Once the pressure within the balloon had reached equilibrium with the rectal pressure, the participant was instructed to strain for 5 s at a time, for a total of five repetitions, with a 5 s interval between each strain. To eliminate variations in amplitude during the onset and offset, the average pressure during the middle 3 s of each straining period was calculated, excluding the first and last 1 s. The median of the five measurements was used as the representative value. IAP measurements were conducted over seven days during each of the pre-, post-intervention, and two-month follow-up periods.

2.6.2 Sphincter Electromyography

The motor function of the anorectum necessary for maintaining fecal continence was assessed using sphincter electromyography. Sphincter electromyography allows for the evaluation of motor unit potential recruitment during voluntary sphincter contraction, including denervation-reinnervation potentials [27,28]. Therefore, in this study, sphincter electromyography via a transanal electrode was used to assess changes in neural activity in the sphincter. The change in potential while the participant was squeezing was obtained from the transanal electrode (Anuform®; Neen). These signals were amplified using an differential amplifier circuit with a gain of 220x and recorded by a microcomputer (ESP32; Espressif Systems) at a sampling rate of 500 Hz.

In the left lateral position with the hip and knee flexed at 90 degrees, a transanal electrode was inserted into the participant's anal canal. The participant was instructed to perform a squeezing action for 5 s for a total of five repetitions with 5 s intervals between each. The acquired signals were processed by the BES and rectified by applying a low-pass filter with a cutoff frequency of 10 Hz and the root mean square over a time window of 10 ms. To eliminate variations in amplitude at the onset and offset of the signal, the average amplitude during the middle 3 s of each squeezing period was calculated. The median of the five measurements was used as the representative value. Sphincter electromyography was conducted over seven days during each of the pre-, post-intervention, and two-month follow-up periods.

2.7 Statistical Analysis

To assess the plausibility of the intervention effects on anorectal motility, IAP measurement and sphincter electromyography data were statistically analyzed. The Dunn-Bonferroni multiple comparison test followed by the Kruskal-Wallis test were used to compare between pre- and post-intervention measurements, as well as pre-intervention and two-month follow-up measurements. Statistical significance for all measures was set at $p < 0.05$ after the Bonferroni adjustment. Given the small sample size, the effect size r was calculated as a standardized measure to assess the magnitude of the observed effects. Effect sizes were calculated by dividing the test statistic Z by the square root of the sample size n. Standardized effect sizes were categorized as small ($r = 0.10$), medium ($r = 0.30$), and large ($r = 0.50$) [29]. All statistical analyses were performed using SPSS software version 29.0 (SPSS Inc., Chicago, IL, USA).

3. Results

The participant completed preclinical test and all sixteen HAL-sessions. No intervention-related adverse events were observed.

3.1 Preclinical Testing

Figure 6 presents the representative time series data of hip joint angles and BES in IO-TrA during HAL-assisted hip flexion. The upper panel represents the hip joint angle, while the lower panel represents BES in IO-TrA. As the participant performed symmetrical movements for both legs, only the data for the right leg are shown as a representative result. The shaded area in the graph indicates the duration of the beep sound playing, signaling the participant to flex his hip joint. **Figure 7** shows the time series data of BES in IO-TrA, PFM, and RF during hip flexion both with and without HAL assistance. The red and blue lines represent the data obtained during hip flexion with- and without HAL assistance, respectively. Table 2 shows the average amplitude of BES in IO-TrA, PFM, and RF at the baseline and during hip flexion, both with- and without HAL assistance. Figure 8 shows the ratio of muscle ac-tivity in IO-TrA, PFM, and RF with the HAL compared to without the HAL.

With HAL assistance, the hip joint angle and BES in the IO-TrA were synchronized (**Figure 6**). The BES increased in all measured areas at the onset of the beep. Thereafter, BES levels remained above baseline and then decreased to baseline levels after the beep stopped. Similarly, without HAL assistance, the BES showed comparable changes (**Figure 7**, **Table 2**). The ratios of muscle activity in both IO-TrA and PFM were > 1.0. Conversely, the ratio in RF was < 1.0 (**Figure 8**).

3.2 Pre / Post and Follow-up Comparison

Figure 9 presents the median of the IAP measurements during the pre-intervention, post-intervention, and two-month follow-up periods. Error bars represent the 95% confidence intervals (95%CI) calculated using the bootstrap method. Increasing trends were observed in IAP (pre: Mdn = 2.96 kPa, 95%CI = [2.44, 3.43], post: Mdn =

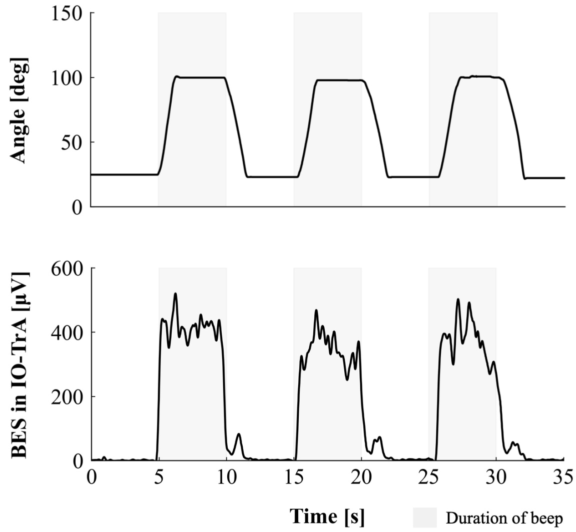

Figure 6. Time series data of the hip joint angle and BES in IO-TrA during HAL-assisted hip flexion. The shaded area indicates the duration of beep playing.

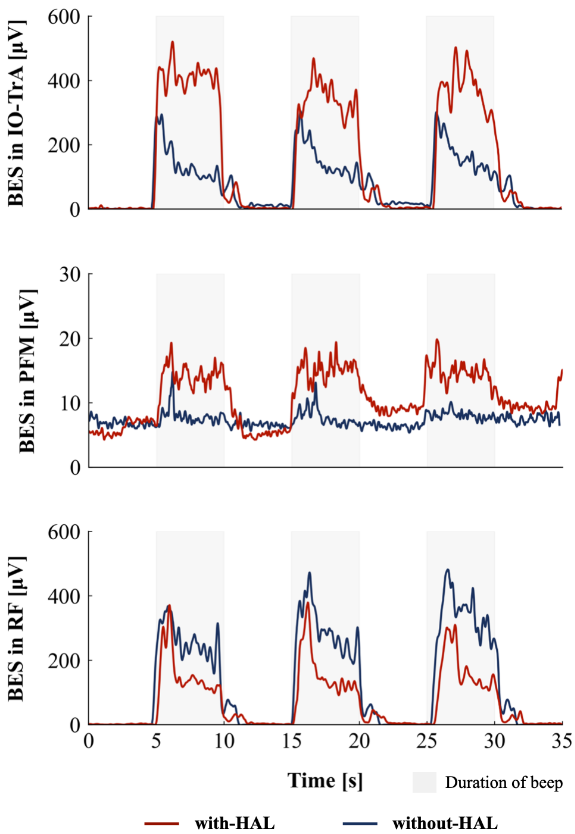

Figure 7. Time series data of BES in IO-TrA, PFM, and RF both with- and without-HAL assistance.

Table 2. Averaged BES in IO-TrA, PFM, and RF at baseline and during hip flexion.

Measured area	*Baseline* [μV] (±SD)	*Hip flexion* [μV] (±SD)
IO-TrA (with-HAL)	13.49 (± 10.22)	385.1 (± 26.75)
IO-TrA (without-HAL)	10.37 (± 10.50)	147.7 (± 24.72)
PFM (with-HAL)	6.848 (± 1.918)	14.99 (± 0.543)
PFM (without-HAL)	6.661 (± 0.247)	8.309 (± 0.130)
RF (with-HAL)	9.268 (± 7.088)	185.0 (± 5.971)
RF (without-HAL)	1.750 (± 0.247)	309.8 (± 59.08)

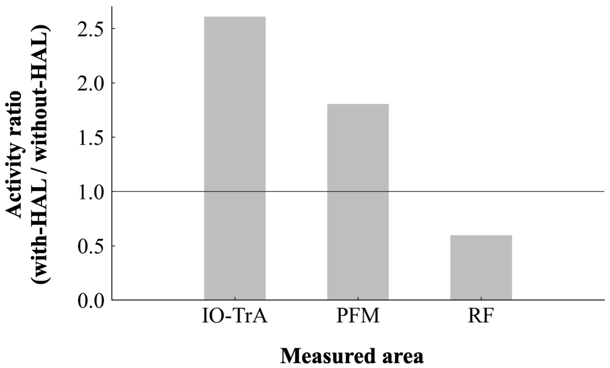

Figure 8. Activity ratio in IO-TrA, PFM, and RF with vs without HAL assistance during hip flexion.

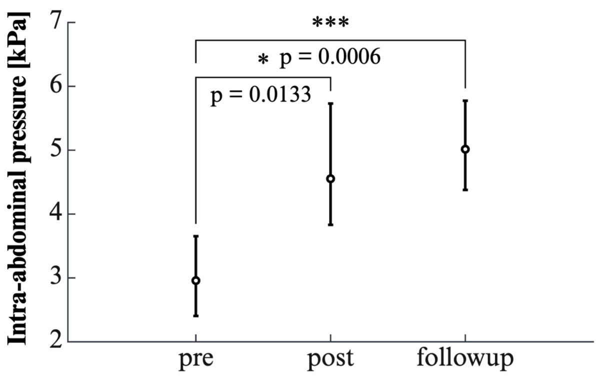

Figure 9. Pre/post and follow-up comparison in IAP measurements.

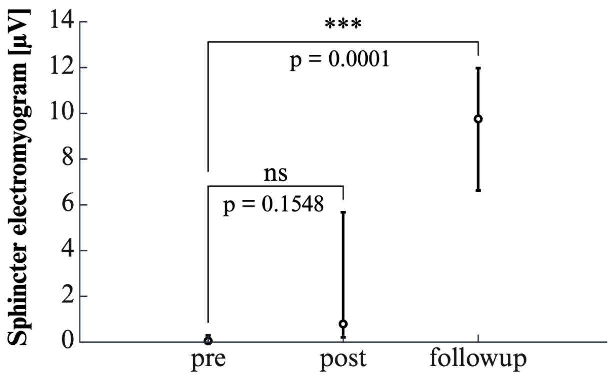

Figure 10. Pre/post and follow-up comparison in sphincter electromyography.

4.55 kPa, 95%CI = [4.13, 5.65], follow-up: Mdn = 5.02 kPa, 95%CI = [4.83, 5.51]). Statistically significant increases and large effect sizes in IAP were observed both from pre- to post-intervention ($p = 0.0133$, $r = 0.72$) and from pre- to two-month follow-up ($p = 0.0006$, $r = 0.97$).

Figure 10 illustrates the median of the sphincter electromyography values for the same periods along with their 95%CI. Increasing trends were observed (pre: Mdn = 0.05 μV, 95%CI = [0.09, 0.27], post: Mdn = 0.79 μV, 95%CI = [0.22, 1.42], follow-up: Mdn = 9.75 μV, 95%CI = [7.13, 11.9]). There were no significant differences between pre- and post-intervention ($p = 0.1548$). A significant increase and large effect size from pre-intervention to two-month follow-up was confirmed ($p = 0.0001$, $r = 1.08$).

4. Discussion

In the preclinical testing, we confirmed that HAL could realize hip flexion based on the wearer's motor intentions, resulting in all the deep core muscles working. The synchronized change in the hip joint angle and BES in IO-TrA during HAL-assisted hip flexion suggests that HAL successfully achieved hip flexion based on the participant's intentions. The increased of the BES in all measured segments of the deep core at the onset of the beep sound indicates that the entire deep core musculature was engaged during HAL-assisted hip flexion.

Although the participant could perform hip flexion in a supine position without HAL, the increased activation ratio of IO-TrA and PFM, coupled with the decrease in that of RF, indicates that hip flexion without HAL predominantly involved compensatory actions using the hip flexors rather than the deep core, in contrast to HAL-assisted hip flexion. This demonstrates that HAL could selectively detected motion intentions directed towards the deep core and facilitate hip flexion accordingly. The finding suggests that the proposed methodology enabled the participant to consciously engage paralyzed muscles which were difficult for him to contract voluntarily. In other words, it can be assumed that the participant became able to relearn how to voluntarily contract the deep core muscles that he had previously forgotten the way to contract, through HAL-assisted hip flexion.

The significant increase in IAP with a large effect size from pre- to post-intervention suggests the participant seemingly relearned the correct way to strain. The significant difference in comparison between pre-intervention and two-month follow-up measurement allows us to assume that the proposed method enabled to repeat selective activation on the nerves related with deep core, which enhances its synaptic connections, resulting in the sustained regenerative effect on the participant's anorectal motility under the principles of cybernics treatment [13–15]. Although there were no significant differences between pre- and post-intervention sphincter electromyography, the significant increase and large effect sizes in the follow-up period further strengthen the inference that the synaptic connections between nerves and muscles were likely enhanced by the proposed method. We hypothesize that this neural plasticization would continue to provide the opportunity to move the anorectum correctly in daily defecations after intervention and that the repetition of the correct movement in daily life would further enhance the neural connections. This is reflected by the positive changes in IAP and sphincter electromyography values in the follow-up.

These findings confirm that the proposed deep core activation method is feasible for patients with SCI and provides a sustained regenerative function for anorectal motility. However, one limitation of this study is that the participant had relatively mild NBD, which makes the specific effects on improving bowel habits unclear. Furthermore, as this is a case study, it is unknown whether similar intervention effects can be achieved in patients with different types of SCI, such as supraconal or conal/infraconal injuries, or at different stages of injury, such as acute, subacute, or chronic.

Despite these limitations, our method of improving anorectal motility may provide defecation opportunities for patients with NBD and may help patients to regain healthy bowel habits, as suggested by some previous literature. Repeating the correct defecation maneuver could potentially induce extrinsic autonomic innervation directed to the rectum and decrease gut transit time [30]. In addition, HAL-assisted hip flexion has the potential to improve not only anorectal motility but also colonic motility at the same time. Several studies demonstrated that voluntary mild exercise in a supine position coordinate autonomic nervous system activity, such as in the vagus nerves [31,32] which innervate the intestine, potentially improving colonic motility. Accordingly, supine HAL-assisted hip flexion presumably modulates vagal activity and improve bowel inactivity. Other studies proved that aerobic exercises seemingly regulate the autonomic nervous activity associated with colonic propulsion as well [33–35]. This suggests the possibility of improving not only the anorectum function but also that of the entire intestinal tract by performing the supine HAL-assisted exercise combined with proper breathing, which uses more oxygen. In terms of patients with SCI of different severities, our previous studies on cybernics treatment have demonstrated its application to SCI patients with different injury locations and stages [36,37]. For patients whose BES cannot be appropriately measured from the skin surface, a preprogrammed control method called Cybernic Autonomous Control (CAC), which has been developed to automatically control the patient's lower limb and is now an alternative for them [22].

Further studies with larger sample sizes and various injury types are needed to confirm these assumptions. We intend to apply the proposed method to several patients with spinal cord injuries who also suffer from severe NBD. This will confirm the impact on the anorectum and gastrointestinal tract, which are innervated by both autonomic and somatic nerves. The results could eventually lead to the establishment of a completely new treatment for NBD.

5. Conclusion

This study aimed to confirm that our proposed methodology is feasible and provides sustained functional improvement in the anorectum of a patient with chronic SCI. A 24-year-old man with SCI accompanied by anorectal dysmotility underwent a four-week period of the supine HAL-assisted hip flexion for thirty minutes four times per week. Clinical assessments of its effect on anorectal motility were performed using IAP measurement and sphincter electromyography at pre-, post-intervention, and two-month follow-up periods. The results of the preclinical test confirmed that the proposed method enabled hip flexion based on the participant's motion intention and facilitated the engagement of the entire deep core musculature. Comparison of pre-/post-intervention measurements showed the increasing trends both in IAP and in sphincter electromyography. There were significant increases in IAP and sphincter electromyography between pre-intervention and two-month follow-up measurements. These results demonstrate not only the feasibility of the proposed methodology, but also its potential for a sustained effect on anorectal motility in patients with chronic SCI.

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Conflicts of Interest

The authors declare no conflicts of interest with any companies or commercial or organizations per the definition of Japanese Society for Medical and Biological Engineering.

Ethical declaration

This study was conducted after the contents of the experiment were fully explained and informed consent was obtained from the participant. The authors themselves participated in the experiment as subjects in this study. Therefore, approval from the ethics committee was not obtained.

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