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# Examining the Effects of a Powered Exoskeleton on Quality of Life and Secondary Impairments in People Living with Spinal Cord Injury

Michael Juszczak, BS,<sup>1</sup> Estelle Gallo, DPT,<sup>1</sup> and Tamara Bushnik, PhD, FACRM<sup>1</sup>

<sup>1</sup>Rusk Rehabilitation, NYU Langone Health, New York, New York

**Background:** Secondary impairments associated with spinal cord injury (SCI) limit one's independent functionality and negatively impact quality of life (QoL). **Objective:** The purpose of this study was to explore changes in secondary health conditions that may result from using a powered exoskeleton as well as their potential impact on QoL. **Methods:** Forty-five participants presenting with SCI ranging from T3-L2 were included in this study. Outcome measures included self-reported assessments of pain, spasticity, bladder/bowel function, Satisfaction with Life Scale (SWLS), and Modified Ashworth Scale (MAS). **Results:** Participants reported significantly less spasticity at the conclusion of the study,  $0.9 \pm 1.7$ , compared to baseline,  $1.6 \pm 0.9$  [ $t(44) = 2.83, p < .001$ ]. MAS testing revealed that 26.7% of participants presented with decreased spasticity at the conclusion of the trial. Participants reported less pain at the end of the trial,  $0.9 \pm 1.6$ , compared to the start,  $1.1 \pm 1.7$  [ $t(44) = 1.42, p > .05$ ]. No negative changes in bowel and bladder were reported; positive changes were reported by 20% and 9% of participants with respect to bowel and bladder management. There was no statistically significant change in SWLS sum score from baseline,  $20.4 \pm 8.0$ , to conclusion of the study,  $21.3 \pm 7.6$  [ $t(44) = -1.1, p > .05$ ]. **Conclusion:** Findings suggest using a powered exoskeleton may decrease spasticity in people living with SCI. Although improvements in secondary impairments did not result in a significant improvement in QoL, it is believed that using a powered exoskeleton in one's community will lead to increased community integration facilitating an improvement in QoL. **Key words:** ambulation, powered orthotics, rehabilitation, robotics, spasticity, spinal cord injury

It is estimated that there are approximately 282,000 persons currently living in the United States with spinal cord injury (SCI). The mean age at time of injury is 34.9 years, with nearly half (48.5%) of all SCIs occurring between the ages of 16 and 30 years.<sup>1</sup>

SCI commonly leads to decreased independence in activities of daily living, with some people unable to ambulate without the assistance of an assistive device or another individual. Brown-Triolo et al reported that regardless of time since injury, people's top two priorities post SCI were being able to regain the ability to stand and walk again.<sup>2</sup> However, secondary impairments of SCI can limit one's independent functionality as well as negatively impact quality of life (QoL). Typical secondary impairments include spasticity,

urinary tract infection, hypotension, pressure sores, and symptoms resulting from overuse of the upper limbs because of overcompensation mechanisms.<sup>3</sup> With the advancements being made in rehabilitation medicine, people can expect an excellent QoL post SCI if they are able to avoid secondary complications.<sup>3</sup>

Recent research has examined the effects and feasibility of people living with SCI using a powered exoskeleton for everyday use and ambulation. One study showed that after only five training sessions, people with either paraplegia or tetraplegia were able to safely ambulate using a powered exoskeleton on a variety of different surfaces.<sup>4</sup> Another study concluded that using a powered exoskeleton is beneficial for people living with SCI due to less effort being required

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Corresponding author: Michael Juszczak, Rusk Rehabilitation, NYU Langone Health, 240 East 38th Street, 17th Floor, Office 17-45, New York, NY 10016; phone: 646-501-9185; email: Michael.juszczak@nyumc.org

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to ambulate independently, as people living with SCI tend to have reduced endurance levels due to chronic physical inactivity.<sup>5</sup>

The primary purpose of this study was to explore changes in secondary health conditions that may result from using a powered exoskeleton, as well as their potential impact on QoL. A secondary aim of the study was to explore the safety and feasibility of utilizing an exoskeleton for everyday use in a clinical setting.

### The Indego Powered Exoskeleton

The Indego Exoskeleton, displayed in **Figure 1**, was utilized in this study. The device is lightweight, 12 kg (26 lb) and, unlike most exoskeletons, does not require a backpack to be worn while operating the device. This enables the user to sit comfortably for extended periods of time in a chair, motor vehicle, or wheelchair while still wearing the device. The device consists of five individual components that are assembled to form the exoskeleton. The hip unit contains a rechargeable lithium ion battery and associated electronics. Different sized torso wing pads are used to help ensure an ideal fit for users. The hip unit connects to right and left upper leg units, which contain a pair of brushless DC motors that aid movement of the hip and knee joints through speed reduction transmissions. These four motors allow for powered movement of bilateral hip and knee joints in the sagittal plane. The bilateral upper leg units connect to lower leg units that contain built in ankle-foot orthoses



**Figure 1.** The Indego Powered Exoskeleton.

(AFO) to help ensure safe ambulation through stabilization of the ankle as well as assisting with transfer of weight from the exoskeleton to the ground. Padding can be added as needed throughout the upper and lower leg units to help ensure an ideal and comfortable fit. The units all connect via hip and knee quick connects, which provide easy mechanical retention and release between the individual units of the exoskeleton. Self-aligning connections of the individual components help facilitate efficient donning and doffing of the exoskeleton. Assistive devices such as loftstrand crutches and rollators can also be used in conjunction with the exoskeleton.

The exoskeleton enables users to walk, sit, and stand through the use of a developed control system that calculates the user's center of pressure (CoP). The CoP is estimated by using the user's center of mass projection on the horizontal plane of the ground and the distance between the CoP and the location of the forward ankle joint as the primary command input. Users can transition from different activities by tilting their hips forward and backwards, thus changing the their CoP in the anterior or posterior directions. Feedback is provided to the users from the device through vibration and color changing LEDs located on the anterior aspect of the hip unit.

An Apple iPod Touch in conjunction with Bluetooth connection enables users to modify their gait as necessary by adjusting stride length, frequency, height, and even speed while still wearing the device. Detailed reports of each session provide additional ambulatory information such as the amount of steps taken per session and time spent wearing the device; other important exoskeleton features such as the amount of battery life remaining before depletion are also available. A more detailed explanation on the development of this powered exoskeleton has been previously reported, with additional information provided on how users can control the device during ambulation and other aspects related to ambulation.<sup>6</sup>

### Methods

This cross-sectional analysis recruited participants with SCI from five major rehabilitation institutes from across the United States. Informed

consent was obtained from each participant after receiving approval from each site's Institutional Review Board. Inclusion criteria for this study were age 18+ years old, height between 155 and 191 cm, and weight of 113 kg or less. Participants were required to present with SCI and neurological level of injury of C5 and lower, classified as American Spinal Injury Association Impairment Scale (AIS) A, B, C, or D, non-ambulatory in both their home and community environments. Prior to beginning the trial, participants were required to obtain signed medical clearance from a physician stating they were in adequate health to begin full weight bearing and locomotor training and had the appropriate joint range of motion required for gait training. There were no restrictions with respect to time since injury. Participants attended three to four gait training sessions per week over an 8-week trial period. All sessions were led by a licensed physical therapist. In total, 26 sessions were completed in an outpatient clinical setting. At the beginning of the trial, participants were taught how to sit and stand using the device and how to ambulate indoors on smooth surfaces. As participants developed proficiency using the exoskeleton, their training progressed to include more difficult activities, such as managing doors, ramps, sidewalk curbs, and various indoor and outdoor surfaces such as carpet and concrete. Donning and doffing time of the exoskeleton, as well as level of assistance required to do so, was recorded for each session.

Prior to the beginning of each session, participants reported any changes in pain, spasticity, and bladder/bowel function experienced from using the device. Self-reported pain and spasticity were reported using a numerical rating scale of 0 to 10, with higher scores indicating more pain and spasticity. With respect to bladder and bowel function, participants were asked to self-report whether they experienced a change in either bladder or bowel function and, if so, whether they classified the change as positive or negative. Spasticity was objectively measured by a physical therapist using the Modified Ashworth Scale (MAS) prior to and immediately after completion of each training session throughout the trial. A MAS score of zero reflects no additional increase in muscle tone. Scores of 1, 1+, 2, 3, and 4 reflect progressively increasing levels of observed spasticity.<sup>7</sup>

The Satisfaction with Life Scale (SWLS) subjectively measures life satisfaction as a global entity.<sup>8</sup> The SWLS was utilized as a QoL measure and was administered to participants at the initial, midpoint (13th session), and final sessions of the trial. Scores range from 5 to 35, with higher scores indicating a higher satisfaction with life. A total score of 20 to 24 reflects an average satisfaction with life in economically developed nations.<sup>9</sup>

After each session participants rated their self-perceived exertion for that day's training session using the Borg Scale of Perceived Exertion (BRPE). Scores range from 6 to 20, with higher scores indicating more strenuous activity.<sup>10</sup>

### Statistical analysis

Descriptive statistics, including age, gender, time since injury, and level of injury, were collected. Percentages, means, and standard deviations for descriptive variables were calculated as appropriate. Paired *t* tests were utilized to compare changes in spasticity, pain, exertion experienced while using the exoskeleton, time spent donning/doffing the device, and scores on the SWLS. Unless noted otherwise, only differences between groups that were statistically significant are discussed, which is defined as having a *p* value less than .05.

## Results

### Demographics

Forty-five participants were enrolled to participate in this study. A complete demographic summary of all participants can be found in **Table 1**.

### Spasticity

Participants reported significantly less spasticity at the end of the study,  $0.9 \pm 1.7$ , compared to the start,  $1.6 \pm 0.9$  [ $t(44) = 2.83, p < .001$ ]. Results of MAS testing revealed that 26.7% of participants ( $n = 12$ ) presented with a decrease in spasticity from pre to post trial. The majority of participants did not experience a change in spasticity, 62.2% ( $n = 28$ ), while 11.1% ( $n = 5$ ) of participants displayed an increase in spasticity. **Figure 2**

**Table 1.** Participant demographics

Demographics	<i>n</i> (%) or <i>M</i> ( <i>SD</i> )
Gender	
Male	37 (82)
Female	8 (19)
Age	35 years old ( <i>SD</i> = 12.65)
Average time since injury	3.9 years ( <i>SD</i> = 5.13) (range, 0.25-23.75 years)
Level of injury	
Upper paraplegia (T1-T8)	27 (60.1)
Lower paraplegia (T9-L2)	18 (39.9)
ASIA Impairment Scale	
A Complete	30 (67)
B Incomplete	5 (11)
C Incomplete	10 (22)

displays the change in frequency of MAS values among participants from pre to post trial.

### Pain

There was no statistically significant change in self-reported pain from the start of the study,  $1.1 \pm 1.7$ , to the end of the study,  $0.9 \pm 1.6$  [ $t(44) = 1.42$ ,  $p > .05$ ].

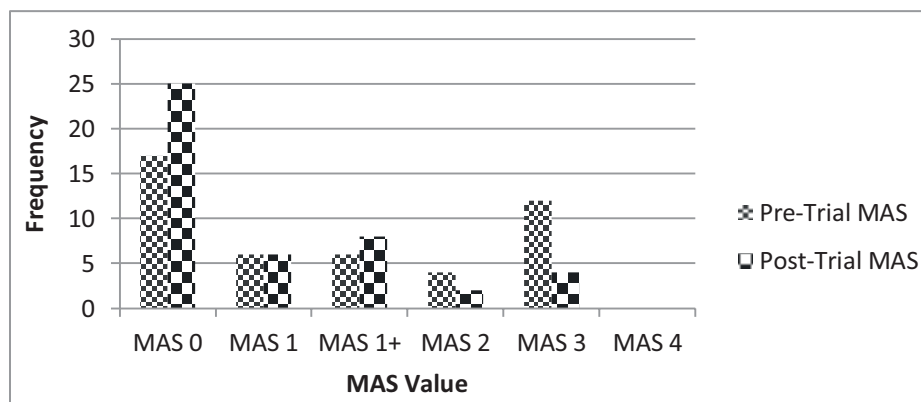
### Bladder/Bowel

Eighty percent ( $n = 36$ ) of participants did not report any change in bowel management. Of the 20% ( $n = 9$ ) of participants who did report a change in bowel management, eight reported

a positive change in bowel management, citing fewer instances of neurogenic bowel dysfunction, including less incontinence and constipation, as well as decreased time and assistance required for bowel management. The participant reporting a negative change in bowel management cited a single isolated episode of incontinence while wearing the device. Ninety-one percent ( $n = 41$ ) of participants reported no change in their bladder management. Four participants reported a positive change in their bladder management routines, citing fewer episodes of incontinence and increased bladder control.

### BRPE

The rate of perceived exertion for indoor walking significantly decreased from pre to post trial,  $11.7 \pm 2.1$  versus  $10.4 \pm 2.2$ , respectively [ $t(44) = 3.02$ ,  $p < .05$ ]. BRPE scores for outdoor walking did not significantly change from the start of the study,  $11.5 \pm 0.6$ , to the end of the study,  $11.8 \pm 2.2$  [ $t(44) = -0.18$ ,  $p > .05$ ]. However, only four participants were able to complete outdoor walking at both pre- and posttrial assessment due to site-specific conditions such as inclement weather. In addition to rating their exertion during ambulation, participants rated their perceived exertion using the exoskeleton to perform other ambulation-related actions such as To Sit and To Stand. Participants rated both of these activities as requiring minimal exertion, with scores of  $8.9 \pm 3.0$  and  $9.8 \pm 2.6$  for performing To Sit and To Stand functions, respectively. Participants were only required to assess their To Sit and To Stand



**Figure 2.** Frequency of pre- versus post-trial Modified Ashworth Scale values.

exertion once during the trial after they had mastered the ability to successfully execute the function using the exoskeleton.

### SWLS

There was no statistically significant change in SWLS sum score from pre study,  $20.4 \pm 8.0$ , to post study,  $21.3 \pm 7.6$  [ $t(44) = -1.1, p > .05$ ]. **Table 2** displays the average SWLS score for all participants at each assessment point throughout the trial with respect to level of injury.

### General observations

Over the course of this 8-week trial, participants were also able to decrease the amount of time spent donning and doffing the exoskeleton. There was a statistically significant decrease in the amount of time spent to don the device;  $11.1 \pm 5.4$  minutes at the start of the study and  $9.3 \pm 4.5$  minutes at the end of the study [ $t(44) = -2.43, p < .05$ ]. No statistically significant decrease in the time to doff the device was found:  $3.1 \pm 1.5$  minutes at the start of the study and  $2.6 \pm 1.4$  minutes at the end of the study [ $t(44) = -1.36, p > .05$ ]. The level of assistance and time required to don and doff the exoskeleton with reference to level of injury at the conclusion of the trial is summarized in **Table 3**.

With respect to the safety of the Indego Exoskeleton, no adverse events were reported across all sites for any subject participating in this clinical trial.

### Discussion

The findings of this study suggest that the use of an exoskeleton for 26 sessions over 8 weeks can help reduce secondary health impairments, particularly spasticity, experienced by those living with SCI. Participants reported a decrease in spasticity at the conclusion of the trial measured by both subjective and objective means. This study is consistent with findings from a recent study by Stampacchia et al, which also observed a significant decrease in spasticity measured by both subjective and objective means, as well as pain reduction.<sup>11</sup> The use of an exoskeleton allows users to achieve mobility in an upright position. It is possible that increased time spent ambulating in an upright position is the mechanism responsible for reductions in spasticity and pain. Future research should aim to investigate the relationship between upright mobility and secondary health impairments associated with SCI by incorporating mobility measures into their research design.

Participants self-reported a relatively minor amount of pain pre trial ( $M = 1.07, SD = 1.72$ ). A decrease in the overall amount of pain experienced post trial after ambulating with the exoskeleton was reported ( $M = 0.87, SD = 1.65$ ); however, this was not statistically significant. It is notable that self-reported pain did not increase after exoskeleton use, which indicates an acceptable safety profile with respect to pain. The lack of statistically significant decrease of pain is probably attributable to a floor effect, since self-reported pain at the beginning of the study was low.

**Table 2.** Average SWLS score at assessment points

	Avg. SWLS pre trial	Avg. SWLS mid trial	Avg. SWLS post trial
Upper paraplegia (T1-T8)	19.81 ( $SD=8.59$ )	20.74 ( $SD=7.90$ )	20.74 ( $SD=7.74$ )
Lower paraplegia (T9-L1)	21.33 ( $SD=7.31$ )	21.55( $SD=7.86$ )	22.11 ( $SD=7.62$ )

Note: SWLS = Satisfaction with Life Scale.

**Table 3.** Level of assistance and time spent donning and doffing exoskeleton at conclusion of trial

Level of injury	Avg. don time (m:s)	Avg. doff time (m:s)	Percent able to don/doff independently
Upper paraplegia (T1-T8)	10:01 ( $SD=4.19$ )	2:08 ( $SD=1.43$ )	81.5%
Lower paraplegia (T9-L1)	8:29 ( $SD=4.88$ )	2:31 ( $SD=1.30$ )	83.3%

The use of the exoskeleton did not have an impact on bowel and bladder function for the majority of the participants. Consistent with Esquenazi et al's findings of bowel/bladder function after exoskeleton use, eight of nine of those who reported changes in bowel function classified the change as positive, with fewer instances of neurogenic bowel dysfunction as well as decreased time and assistance required for bowel management.<sup>12</sup> Of the four participants who reported positive changes in bladder management, commonly reported changes included experiencing "better control" of their bladder and a lower occurrence of urinary tract infection. While not statistically significant, these changes may be clinically significant for patients, as previous literature has cited that the loss of genitourinary and gastrointestinal function is one of the most devastating sequelae of SCI because it can severely disrupt QoL.<sup>13</sup>

Furthermore, participants reported significantly less exertion while using the device after 26 sessions as demonstrated by a significant decrease in BRPE scores. At the conclusion of the trial, participants on average rated their perceived exertion for outdoor ambulation as an 11 on the BRPE, which indicates "light amount of exertion." Participants were able to walk using the exoskeleton with less perceived exertion following training sessions, thereby demonstrating more efficient use of the device with proper instruction. Despite a steady increase in training volume as the trial progressed, participants continued to report light exertion during sessions while using the exoskeleton. This finding is clinically significant as the rate of perceived exertion can be directly related to energy consumption when using the device and have a significant impact on whether individuals choose to comply with using the device on a continual basis if given the opportunity.<sup>12</sup>

Other modes of locomotion have been previously used in this population. However, most patients do not comply with alternative methods for extended periods of time because of high energy consumption secondary to inefficient gait pattern and the potential for increased upper limb injury resulting in further secondary impairment.<sup>14</sup> Therefore, the light level of exertion while using the exoskeleton could potentially facilitate sustained patient compliance.

Findings demonstrate that the time required for donning the device significantly decreased with practice, which in turn could foster greater compliance with the device, as it has been established that donning (and doffing) of braces can be a barrier to their usage among patients with SCI.<sup>14</sup> As displayed in **Table 3**, the majority of participants were able to don and doff the exoskeleton independently and quickly, which could foster increased compliance with using the device on a consistent basis.

Our findings suggest that the intensive use of an exoskeleton in the clinic did not have a significant impact on participants' overall QoL. However, the use of an exoskeleton enabled individuals to walk and stand while in the clinic, which are the most desired activities for individuals after SCI.<sup>2</sup> The use of the exoskeleton positively impacted participants' spasticity, which is a significant factor associated with life satisfaction in people living with SCI.<sup>8</sup> Spasticity is a commonly reported secondary impairment regardless of severity or level of injury in adults with SCI.<sup>3</sup> Spasticity has the potential to profoundly impact QoL in people living with SCI. The SWLS is not a spasticity specific QoL measure,<sup>15,16</sup> which could be an explanation for a lack of association between decreased spasticity and increased QoL. A review of outcome measures by the Spinal Cord Injury EDGE Task Force recommended that the SWLS be used with caution as measuring satisfaction with life as responsiveness and meaningful change have not been established for this measure.<sup>17</sup> Furthermore, using the device solely for training in a clinical setting did not enable participants to change their overall mobility in the community or impact their social interactions, which are key contributors to overall life satisfaction. Despite the lack of a statistically significant relationship being found, average SWLS scores increased at each assessment point throughout the trial, presumably because of participants' continued independent ambulation. Other preliminary findings suggest that individuals when trained to use exoskeletons demonstrate a level of proficiency, walking speed, and distance that would enable some individuals with paraplegia to use such a device for everyday community ambulation. This could potentially foster improved community integration, which in

turn could significantly improve QoL.<sup>4,14</sup> Future research should evaluate the impact a powered exoskeleton has on QoL once individuals are able to use such a device in their community as well as their home environment.

## Conclusion

This multicenter clinical trial provides preliminary evidence exploring changes in secondary health impairments while utilizing an exoskeleton for upright ambulation in people living with SCI. The use of the device resulted in a statistically significant decrease in spasticity for participants measured by both subjective and objective means. Additionally, individuals demonstrated improved efficiency using the

device as they progressed through the trial, as well as minimal exertion, which could potentially foster greater compliance with this assistive device compared to other devices currently available to those living with SCI. Although a decrease in secondary impairments did not result in an increase in health-related QoL, it is believed that using a powered exoskeleton in one's community will lead to increased community integration that is not overly strenuous, thus allowing it to potentially significantly alter QoL among those living with SCI.

## Conflicts of Interest

The authors declare no conflicts of interest.

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