Research Article

Improvement of quality of life after 2-month exoskeleton training in patients with chronic spinal cord injury

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Objective: To examine changes in quality of life (QoL) after an eight-week period of robotic exoskeleton training in a homogeneous group of patients with chronic complete spinal cord injury (SCI).
Design: Prospective single-group pre-post study.
Setting: Rehabilitation center.
Participants: Patients with a chronic (>6 months) motor complete SCI (T1-L1).
Intervention: Twenty-four training sessions with the ReWalk exoskeleton over an eight-week period.
Main outcome measure: QoL, assessed with the sum score of the Short Form-36 with Walk Wheel modification (SF-36ww). Secondary outcome measures were the eight SF-36ww subdomains, satisfaction with bladder and bowel management, lower extremity joint passive range of motion (pROM), and lower extremity spasticity.
Results: Twenty-one participants completed the training. QoL significantly improved after the training period (average SF-36 sum score 621 ± 90) compared to baseline (571 ± 133) ($t(20)=-2.5$, $P=.02$). Improvements were seen on the SF-36ww subdomains for pain ($P=.003$), social functioning ($P=.03$), mental health ($P=.02$), and general health perception ($P=.01$). Satisfaction with bladder management (range 1-5) improved from median 3 at baseline to 4 after exoskeleton training ($P=0.01$). No changes in satisfaction with bowel management ($P=.11$), pROM (hip-extension ($P=.49$), knee-extension ($P=.36$), ankle dorsiflexion ($P=.69$)), or spasticity ($P=.94$) were found.
Conclusion: Even in patients with chronic motor complete SCI and a relatively high level of QoL at baseline, a short-term exoskeleton training improved their QoL, pain and satisfaction with bladder management; findings that warrant further controlled studies in this specific SCI population.

Keywords: Spinal cord injury, Powered exoskeleton, Quality of life, Health state

Introduction

Despite advances in the acute medical care for patients with spinal cord injury (SCI), full recovery of mobility after complete SCI is uncommon.[1] Of the approximately 450 new cases each year in the Netherlands,[2] a majority will remain (at least substantially) dependent on a wheelchair. This wheelchair dependance coincides with a sedentary lifestyle, which has a significant impact on one's daily life activities, social participation, and quality of life (QoL).[3–5] Moreover, patients with complete SCI are predisposed to multiple secondary health complications. A lifetime of sitting has been associated with an increased risk of osteoporosis, cardiovascular disease, pressure ulcers, bladder and bowel malfunctioning, infections, joint contractures and (increased) spasticity.[6–8] These secondary health complications are related to a lower general health state, poorer QoL, and a lower life expectancy compared to

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the general population.[8] They typically lead to high levels of healthcare utilization and health care costs.[9] Hence, reducing the occurrence and effects of secondary health complications is an important target in the lifelong care for people living with SCI.

Technological developments such as powered exoskeletons give patients with complete SCI the possibility to stand, walk and even climb stairs.[10–12] In comparison with other orthotic devices, such as hip-knee-ankle-foot orthoses (HKAFO) and a reciprocating gait orthosis (RGO), powered exoskeletons are less metabolically demanding and allow a higher walking speed.[4,13–15] Moreover, gait training with a powered exoskeleton in people with complete SCI may contribute to a reduction of secondary health complications, in particular, those that are caused by loss of the standing and walking capacity.[4,16–20] Previous studies have reported improved bowel[4] and bladder function [21] generated through task specific stepping and/or loading, leading to stimulation of the neural circuitries controlling urogenital and bowel functions.[21] Furthermore, previous exoskeleton training studies have reported enhanced ankle dorsiflexion and hip extension,[19] reduced spasticity,[16,20,22] and less severe (neuropathic) pain.[20] However, evidence for these health benefits of powered exoskeletons is still low due to small-sized studies (sample sizes 5–12).[16,23] In addition, inclusion of mixed research populations (often combinations of paraplegia and tetraplegia as well as complete and incomplete injuries with different time periods since injury) hamper the interpretation of results for specific populations, such as patients with a chronic complete SCI.[17] Moreover, for people with chronic complete SCI, full-body training opportunities outside a clinical setting are scarce. Nevertheless, exoskeleton training may be a promising up-right training opportunity to enhance health benefits in people with chronic complete SCI.

In addition to the health benefits, the evidence of improving QoL with exoskeleton training is low, especially in people with chronic complete SCI. The group of Baunsgaard *et al.* found positive effects on QoL, but 41% of their participants had some walking capacity outside the exoskeleton and 48% were recently injured.[17] In contrast, Juszczak and colleagues did not find an effect on QoL in a similar heterogeneous group of SCI patients.[24] Because changes in QoL are more likely to be expected in people with a recent injury or people with the prospect of functional recovery (i.e. people with an incomplete SCI), a positive effect of exoskeleton training on QoL in people without spontaneous functional recovery (i.e. chronic complete SCI) is less likely. Nevertheless, with the exception of exoskeletons, there are virtually no full-body training options for people with chronic complete SCI which potentially impact QoL. Hence, for future developments in exoskeletons, it is important to know if exoskeleton training can improve the QoL of patient with chronic complete SCI and reduce the occurrence and effects of secondary health complications.

Therefore, the primary aim of this study was to examine the potential effects of short-term training with an exoskeleton on QoL in a homogeneous group of patients with chronic motor complete SCI. The secondary aim was to examine the effects of this training on satisfaction with bladder and bowel management, lower extremity joint passive range of motion (pROM), and lower extremity spasticity.

Material and methods

Participants and training program

This study is part of a larger study to investigate the home and community use of a powered exoskeleton by people with complete SCI.[25,26] People with complete SCI who were known at the rehabilitation center of the Sint Maartenskliniek and who were interested to participate were enrolled. The in- and exclusion criteria are presented in Table 1.

The training program consisted of 24 sessions with the ReWalk exoskeleton (ReWalk™ Rehabilitation System and the ReWalk™ Personal 6.0) of 1.5 h each, distributed over an eight-week period. All participants used crutches while using the exoskeleton and all training sessions were performed in the sports hall at the Sint Maartenskliniek rehabilitation center. During each session, at least two certified physical therapists were present and a maximum of four physical therapists were involved in the entire training program. The study was approved by the medical ethics committee of the region Arnhem-Nijmegen (nr. 2016-2418) and the internal review board of the Sint Maartenskliniek. All participants signed informed consent forms in accordance with the Declaration of Helsinki.

Procedure

Patients were first screened by telephone, after which an appointment was scheduled with a rehabilitation physician, experienced with SCI, for a complete check of the in- and exclusion criteria (see Table 1).

At the start of the study the following **demographic parameters** were registered: sex (male, female), age (years), time since SCI (years), SCI-classification (AIS A or B), neurological level of SCI, and level of anxiety and depression (Hospital Anxiety and Depression Scale (HADS)).[27] The HADS score ranges

Table 1 In- and exclusion criteria.

Inclusion criteria	Exclusion criteria
• SCI classification AIS A or B • Neurological level of SCI between T1 and L1 • Age ≥ 18 years • Injury onset > 6 months • Body height sufficient to fit into the ReWalk device: >1.60 m and <1.90 m • Body weight less than 100 kg • Able to make a transfer from a chair to wheelchair independently • Good upper extremity function (capacity to use crutches)	• Skin integrity problems/ pressure ulcers on surfaces that would contact the ReWalk device • Heterotopic ossifications • Pregnancy • Fractures of the lower extremities in the past 2 years • Medical history of spontaneous bone fractures • Insufficient mastery of the Dutch language • Other interfering neurological conditions (*e.g.* stroke or multiple sclerosis) • Severe lower extremity spasticity (Modified Ashworth Scale > 3) • Limited passive range of motion at the hip or knee joints on either body side (hip flexion / extension less than 90-0-0°, knee flexion / extension less than 90-5-0°, ankle dorsiflexion less than 0° with extended knee) • Insufficient time to train

SCI = Spinal Cord Injury, AIS, American Spinal Injury Association [ASIA] Impairment Scale, T = Thoracic, L = Lumbar.

between 0 and 21 points, with higher scores indicating higher levels of anxiety and depressed mood.

Prior to the first and the last session of the eight-week clinical training period, the participants filled out questionnaires concerning QoL, and satisfaction with bladder and bowel function. In addition, the lower extremity passive joint mobility and level of spasticity were assessed by a physical therapist who had ample experience with SCI patients.

Questionnaires and physical measurements

QoL was assessed with the Short Form-36 with Walk Wheel modification (SF-36ww).[28] In addition to the total SF-36 score (sum score range: 0-800), eight subdomains of health were considered: physical functioning, physical role limitation, emotional role limitation, bodily pain, general health perception, vitality, social functioning, and mental health (subdomain scores range: 0-100). Calculation of the SF-36 sum score and subdomain scores was done in a similar approach as previously reported.[29–31] A higher score indicates a more favorable health state. Reliability and validity have been established as good to excellent in populations with SCI.[32]

Satisfaction with bladder and bowel function was assessed with parts of the Neurogenic Bladder Symptom Score (NBSS)[33] and the Neurogenic Bowel Dysfunction Score (NBDS).[34] General satisfaction with bladder and bowel management was assessed with a question derived from the NBSS (item 25) "All things considered, how satisfied are you with the way your [bladder or urinary reservoir]/[bowel] currently works?". This general satisfaction question was scored on a 5-point ordinal scale, ranging from 1 (very unsatisfied) to 5 (very satisfied). In addition, we assessed the reported number of urinary incontinences per week, time used for bowel management per week, and number of fecal incontinences.

pROM was measured by the physiotherapist using goniometry. Bilateral joint movements at the hips, knees and ankles were assessed and rounded to 5 degrees. A mean score of the bilateral hip extension, knee extension and ankle dorsiflexion was calculated.

Spasticity was assessed bilaterally with the Modified Ashworth Scale (MAS)[35] for the following muscles: hip flexors and extensors, knee flexors and extensors, and ankle dorsiflexors and plantar flexors (12 muscle groups in total). As a measure of overall spasticity, the MAS sum score of all 12 muscle groups was calculated (0-60 scale), which is a similar approach as used by Baunsgaard *et al.*[17]

Data and statistical analysis

Descriptive statistics (mean ± standard deviation or median [range]) were calculated for the demographic parameters: sex, age, time since injury, neurological level of injury, SCI-classification, and HADS score. All numeric outcome variables were assessed for normality with the Kolmogorov–Smirnov test. Paired *t*-tests (normally distributed parameters) or Wilcoxon-signed rank test (not normally distributed parameters) were utilized to compare changes in SF-36ww sum score, SF-36 subdomains, satisfaction with bladder and bowel management, pROM score, and MAS sum score. Only if the SF-36ww sum score significantly improved, analyses of the SF-36 subdomains were performed to assess which specific QoL subdomain significantly contributed to the increase in SF-36ww sum score. The α-level was always set at 0.05 for the primary outcome (SF-36ww sum score) as well as the secondary outcomes, as the latter were exploratory in nature.

Results

Demographic and clinical parameters

Twenty-one out of 25 participants completed the training program. Reasons for not completing the program were inability to learn the basic exoskeleton skills ($n=1$), development of hematoma in the sacral area ($n=1$), musculoskeletal shoulder pain ($n=1$), and fracture of the distal tibia ($n=1$). A more detailed description of the fracture is described in van Herpen *et al.*[36] The data of these four participants were not included in the statistical analysis. An overview of the baseline characteristics of the 21 included patients is given in Table 2.

Quality of life

SF-36ww sum score significantly improved after the exoskeleton training period (mean = 621, SD = 90) compared to baseline (mean = 571, SD = 133) (t (20) = −2.5, P = .02) (Table 3). Significant improvements were also seen in the subdomains for bodily pain, social functioning, mental health, and general health perception. No significant changes in the other four SF-36ww subdomains were found (Table 3).

Bladder and bowel management

General satisfaction with bladder management improved from median 3 ('neutral') at baseline to 4 ('mostly satisfied') ($Z=-2.5$, $P=.01$) after the exoskeleton training (see Table 3). No significant change in the number of urinary incontinence incidents per week was found. Likewise, no change in satisfaction with bowel management, time used for bowel management, or the number of fecal incontinence incidents was seen.

Passive range of motion and spasticity

No significant changes in lower extremity pROM scores or MAS sum score (N = 19) were found after the exoskeleton training (see Table 3).

Table 2 Clinical and demographical characteristics of participants.

	Total (N = 21)
Sex (M/F)	13/8
Age (years), median [range]	36 [24-57]
Neurological level of SCI[a], median [range]	Thoracic 6 [T3-L1]
Time since injury (years), median [range]	5.4 [0.8-27]
AIS[b] (A/B)	20/1
HADS[c], median [range]	7 [1-18]

[a]SCI = Spinal Cord Injury.
[b]AIS = American Spinal Injury Association (ASIA) Impairment Scale.
[c]HADS = Hospital Anxiety and Depression Scale.

Discussion

In the current study, a significant increase in SF-36ww sum score indicates an improvement of QoL after a short-term training period of eight weeks exoskeleton training in chronic complete SCI patients. Four of the eight SF-36ww subdomains significantly improved: bodily pain, social functioning, mental health and general health perception. In addition, improved satisfaction with bladder management was found. There was no improvement in satisfaction with bowel management, lower extremity pROM or spasticity.

In contrast to previous studies assessing the health effects of exoskeleton training,[4,16,17,20] we included a homogeneous group of 21 people with chronic complete SCI. The advantage of including only chronic complete SCI patients is that the chance of spontaneous functional recovery is negligible. Hence, the health effects found in the current study are most likely attributable to the training with the powered exoskeleton.

Despite the short training period and relatively high QoL at baseline, patients significantly improved on the SF-36ww subdomains bodily pain, social functioning, mental health, and general health perception. The largest group difference between pre and post score was seen for pain reduction (mean difference of 12, see Table 3). This improvement in bodily pain exceeded the reported minimal detectable change (MDC) of 20.6 for SCI, calculated from data in Lin *et al.*[32] in seven out of 21 participants. Importantly, it has been argued that pain reduction is crucial for QoL improvement in people with chronic SCI.[37] Some participants specifically improved in the domains of social functioning, mental health, and general health perception, although the number of participants who exceeded the MDC for these subscales was low (ranging between one and four participants). These improvements may be directly related to the training as an activity in itself. During the training sessions, participants learned to perform a new activity with the attention and guidance from dedicated physical therapists. This new experience of interaction at eye level during the training sessions may have improved their perceived social functioning, mental health, and general health perception.

Since the analyses of the secondary outcome measures were exploratory in nature, the results on the secondary outcome measures should be interpreted with caution. Similar to other studies, we found a significant improvement of satisfaction with bladder management,[16,17] while no participant reported worsening of bladder function satisfaction. In contrast to our study, several other studies reported a positive change

Table 3 Changes in health outcome measures before (pre) and after (post) exoskeleton training.

		Pre score (mean ± SD or median [range])	Post score (mean ± SD or median [range])	Statistics (paired *t*-test or Wilcoxon signed-rank (*Z*))
Health state	SF-36ww[a] sum score	571 ± 133	621 ± 90	$t(20) = -2.5$, $P = .02$
	Bodily pain	63 ± 22	75 ± 16	$t(20) = -3.4$, $P = .003$
	Social functioning	88 [25–100]	88 [63–100]	$Z = -2.1$, $P = .03$
	Mental health	84 [52–96]	84 [60–100]	$Z = -2.3$, $P = .02$
	General health perception	62 ± 17	70 ± 20	$t(20) = -2.7$, $P = .01$
	Physical functioning	67 ± 27	67 ± 25	$t(20) = -0.1$, $P = .91$
	Physical role limitation	100 [0–100]	100 [0–100]	$Z = -1.1$, $P = .27$
	Emotional role limitation	100 [0–100]	100 [0–100]	$Z = -0.3$, $P = .76$
	Vitality	68 ± 16	70 ± 19	$t(20) = -0.5$, $P = .59$
Bladder & bowel	Bladder management satisfaction	3 [1–5]	4 [1–5]	$Z = -2.5$, $P = .01$
	Urinary incontinence (/week)	0 [0–63]	0 [0–35]	$Z = -0.2$, $P = .83$
	Bowel management satisfaction	4 [1–5]	4 [3–5]	$Z = -1.6$, $P = .11$
	Bowel time	115 ± 75	102 ± 65	$t(20) = 1.3$, $P = .21$
	Fecal incontinence	0 [0–1]	0 [0–1]	$Z = -1.4$, $P = .15$
pROM[b] & spasticity	Hip extension[d] (°)	16 ± 10	18 ± 9	$t(18) = -0.7$, $P = .49$
	Ankle dorsiflexion[d] (°)	10 [0–20]	10 [3–20]	$Z = -0.4$, $P = .69$
	Knee extension[d] (°)	5 [0–10]	5 [0–10]	$Z = -0.9$, $P = .36$
	MAS[c] sum score[d]	4 [0–48]	5 [0–26]	$Z = -0.1$, $P = .94$

[a]SF-36ww = short form 36 with walk-wheel modification.
[b]pROM = passive Range of Motion.
[c]MAS = Modified Ashworth Scale.
[d]$N = 19$.

in bowel management (less incontinence and constipation) as well as decreased time and assistance required for bowel management.[4,16,24,38] We had expected this result as well, because in healthy individuals regular walking activity can stimulate bowel movement and prevent constipation.[39] Our discrepant finding may be explained by a more homogeneous and more severely affected (complete SCI) group, by the relatively short training period, or by the fact that the initial satisfaction with bowel management was already high pre-training (median of 4 on a 1–5 scale) allowing little room for improvement.

The fact that we did not find effects of the exoskeleton training on lower extremity pROM or spasticity may be explained by our stringent exclusion criteria regarding limited pROM at the ankles, knees and hips, and the presence of spasticity. For training in the Rewalk exoskeleton, hip extension and ankle dorsiflexion had to be at least 0°. Due to the walking in the Rewalk exoskeleton, a small improvement on hip extension (10°) and ankle dorsiflexion (20°) should theoretically be possible, but we did not see that in our results.

Limitations

A limitation of the study is that we did not include a control group. Yet, because we only included people in the chronic phase of a SCI, improvements in QoL or secondary health complications could not be attributed to spontaneous neurological recovery. However, improvement in QoL could still be attributed to the positive, nonspecific effects of training and not merely to exoskeleton use. The observed positive effects of exoskeleton training may also have been inflated due to the inclusion of a group highly motivated individuals, although they already had a high level of QoL at enrollment. The eight-week training period in the current study may have been too short to find other improvements in secondary health complications *e.g.* regarding satisfaction with bowel management. Previous studies have emphasized a variety of possible benefits of exoskeleton use on secondary health complications and reduction of costs associated with SCI.[9] Future studies should therefore implement a longer training period and include additional measures, *e.g.* regarding bone density, skin problems, and cardiopulmonary status, to be able to assess a broader effect of exoskeleton training on secondary health complications in complete SCI patients. Longer training periods could be attained if people would have their own exoskeleton that they could use in the home environment. A previous study looked at exoskeleton use in the home environment.[26] They found that participants with complete SCI were satisfied with exoskeleton use in the community and that this type of exoskeleton use (with a caregiver as a buddy) was safe. Secondary health benefits would even be more likely if people with chronic complete SCI would be able to use an exoskeleton as an assistive and/or exercise device in daily

life.[4,40] Also, control groups using other training devices should be included in future studies to be able to assess the specific benefits of exoskeleton training on QoL in people with chronic complete SCI. To assess if these training benefits are retained long-term, future studies should also include additional follow-up measurements.

The relative short period of exoskeleton use was the most probable reason why we did not assess any cardiovascular risk factors, *e.g.* lipid profile, blood pressure or glucose. Nevertheless, such metabolic parameters would be relevant to assess in future studies with a longer period of training or home use.

Four patients were not able to finish the training period due to an inability to learn the basic exoskeleton skills (1 participant) or the occurrence of complications ($n=3$). We expect that these injuries occurred due to an increase in the general activity level and not solely because of the exoskeleton training. This will also happen in patients with a SCI when they become more active, *e.g.* during wheeling or standing upright in a stance table. We therefore advise to concentrate powered exoskeleton training in people with complete SCI to specialized rehabilitation centers, with ample experience and knowledge of this technology and population, to minimize the number of complications.

Lastly, our team of physical therapists was closely involved in the introduction of the exoskeleton in our clinic, so they could not be blinded to the objectives or assessments of this study. However, most assessments were questionnaires that the participants could answer themselves.

Conclusion

This study has shown that a short-term (eight-week) training program with a powered exoskeleton may improve the QoL and satisfaction with bladder management in people with chronic complete SCI. These findings warrant larger, controlled studies in this specific SCI subpopulation.

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Conflict of interest

No potential conflict of interest was reported by the author(s).

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Declaration of interests

The exoskeleton training of the physiotherapists by ReWalk Robotics was given before the start of the study. ReWalk Robotics did not have any influence on the study design, data analysis, or writing. The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Data availability

All data associated with this study are present in the paper.

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