Examining the Efficacy of Lower Extremity Exoskeletons in the Rehabilitation Process of Spinal Cord Injury Patients – Case Studies

Benjamin Shenker[1], Melinda Fehér[1], Petra Erdősi[1], Leila Papp[1], Kitti Vadai[1], Gergely Hrivnák[1], Luca Tóth[2], Péter Maróti[3], Csaba Horváth[4], Péter Cserháti[1,2]

[1]National Institute of Locomotor Diseases and Disabilities – National Institute of Medical Rehabilitation, Szanatórium utca 19, 1528 Budapest, Hungary, e-mail: shenkerb@revitarendelo.hu; Feher.Melinda@omint.hu; Erdosi.Petra@omint.hu; Papp.Leila@omint.hu; Vadai.Kitti@omint.hu; Hrivnak.Gergely@omint.hu; Cserhati.Peter@omint.hu

[2]University of Pécs, Medical School, Department of Neurosurgery, Rét u. 2, 7623 Pecs, Hungary, e-mail: toth.luca@pte.hu

[3]University of Pécs, Medical School, Medical Skills Education and Innovation Centre, Szigeti u. 12, 7624 Pecs, Hungary; e-mail: peter.maroti@aok.pte.hu

[4]Semmelweis University, Faculty of Medicine, Department of Internal Medicine and Oncology, Korányi Sándor utca 2/a, 1083 Budapest, Hungary, e-mail: horvath.csaba@med.semmelweis-univ.hu

Abstract: Patients suffering from spinal cord injury (SCI) have shown a growing number in recent times. The effects of SCI have severe consequences, not only to the individual but their family and close surroundings too. The secondary medical issues related to SCIs have further negative effects, thus the rehabilitation of locomotion is becoming a key element for patients with SCI. Numerous devices are being tested and used to assist locomotion and gait therapy, one of them being exoskeletons. Lower extremity exoskeletons (LEE) have shown growing interest within health professionals, industrial and military stakeholders and of course SCI patients. This article documents 2 SCI patients using a LEE for gait training. Firstly, a literature review demonstrates the scientific relevance of the topic. Secondly, presentation of the study. Thirdly, the demonstration of the case studies, changes of the 2 SCI patients' functional and physiological parameters during the process. The aim of the study is to show the effects and efficacy of intensive gait training with LEE of SCI patients.

Keywords: Medical rehabilitation; Lower extremity exoskeleton; Spinal cord injuries

1 Introduction

The field of medical rehabilitation is beginning to involve automated technologies at a growing rate, with the social robotics sector seemingly growing faster than other areas [1]. Exoskeletons are revolutionizing medical rehabilitation with biomechanics, robotics, and healthcare. They help individuals with mobility impairments regain independence and functional mobility. This study explores exoskeleton's historical evolution, biomechanical foundations, technological advancements, clinical efficacy, patient outcomes, practical implementation challenges, and knowledge gaps in medical rehabilitation.

1.1 Historical Trajectory: Pioneering Visionaries to Real-World Applications

The concept of exoskeletons dates back to 1890 with Nicholas Yagn's patent "Apparatus for facilitating walking, running, and jumping" [2]. The Hardiman exoskeleton developed by General Electric in the 1960s aimed to enhance industrial labor, but technical limitations such as power supply constraints and complex controls limited practical applications [3]. The 21st Century saw advancements in materials, robotics, and control systems, leading to the development of the Berkeley Lower Extremity Exoskeleton (BLEEX) by Kazerooni et al. BLEEX bridged the gap between concept and reality [4]. Today, exoskeletons are revolutionizing medical rehabilitation and transforming the landscape of mobility challenges.

1.2 Biomechanical Fundamentals: Fusing Human Physiology with Technological Innovation

A nuanced understanding of human biomechanics is crucial for exoskeleton efficacy. Replicating and augmenting natural movements requires a delicate comprehension of joint mechanics, muscle coordination, and gait dynamics. Key biomechanical studies by Winter and Cappellini have shed light on human locomotion [5, 6]. These biomechanical foundations support exoskeletons that seamlessly integrate with the body, mitigate disparities, and enhance comfort.

1.3 Technological Strides: Precision and Adaptation

Exoskeletons have evolved with advancements in materials, actuators, and control systems. Durable yet comfortable materials, such as lightweight alloys and carbon fiber composites have been developed. Various actuation mechanisms are available, including electric motors and hydraulic, and pneumatic systems, which enable exoskeletons to mimic natural joint movements and provide support [7]. Sophisticated control algorithms and sensor integration strategies have been created

for adaptability, allowing exoskeletons to navigate different terrains and respond to user intent [8].

1.4 Clinical Efficacy: Accelerating Recovery and Fostering Independence

Exoskeletons are making a significant shift in medical rehabilitation, offering new methods for recovery and functional augmentation. In neurorehabilitation, exoskeleton-assisted gait training benefits individuals with spinal cord injuries, stroke survivors, and neuromuscular disorders. Esquenazi's work has demonstrated the potential of exoskeletons to hasten recovery and restore ambulation [9]. A meta-analysis by Liu suggests that exoskeleton robotic training improves ambulation recovery in patients with spinal cord injuries, particularly in those with an injury [10]. Exoskeletons are also making a mark in pediatric rehabilitation, as evidenced by devices such as the PediAnklebot, which holds promise for enhancing motor outcomes in children with cerebral palsy [11]. Beyond physical recovery, exoskeletons foster psychological well-being and a renewed sense of accomplishment.

1.5 Measurement of Patient Outcomes and Compliance: A Pathway to Objective Progress

The effectiveness of exoskeletons depends on measuring patient outcomes and adherence to treatment using metrics such as objective assessment, gait parameters, energy expenditure, and functional independence. Real-time observations can be obtained through wearable sensors, as demonstrated by Kim et al [12]. However, the limited number of high-quality studies on exoskeletons makes it difficult to draw general conclusions, as pointed out in the systematic review by Tamburella et al. [13]. Additionally, user feedback and wearable devices are crucial for monitoring compliance, providing valuable data to refine exoskeleton interventions and optimize rehabilitation protocols.

1.6 Patient Outcomes and Compliance: A Holistic Perspective

The successful use of exoskeletons requires understanding patient outcomes and compliance. Research emphasizes the significance of patient satisfaction and acceptance, such as the systematic review by Cumplido-Trasmonte et al. in neurological pathology [14]. Combining objective measurements with patient-reported outcomes provides a comprehensive understanding of the impact of exoskeleton interventions on patients' lives.

1.7 Practical Implementation Challenges: Navigating Real-world Complexities

Exoskeletons in clinical practice face challenges such as ensuring proper fit, customizing settings, and user training to optimize user experience and rehabilitation outcomes. A systematic review by Charette et al. found that the implementation of exoskeleton locomotor training programs for individuals with spinal cord injuries (SCI) is hindered by gaps in knowledge in the context and implementation process domains [15]. In upper limb rehabilitation, traditional methods can be costly, limiting the amount of time patients can spend on exercises. Bauer et al. introduced a hand rehabilitation module with a direct drive and force measurement for patients with spastic hemiplegia [16]. To maximize the potential of exoskeleton technologies, safety considerations, user education, and integration into rehabilitation settings are crucial.

1.8 Knowledge Gaps and Future Exploration

There is significant potential for exoskeletons, but gaps in knowledge remain, particularly in the areas of physiological changes during exoskeleton-assisted walking, long-term effects of exoskeleton training, and the interaction between exoskeletons and the neuromuscular system [17]. Yip et al. found that underground exoskeletons can help individuals with spinal cord injuries maintain healthy lifestyles and improve their quality of life. Additionally, there are secondary health complications associated with prolonged immobilization, and individuals with spinal cord injuries are interested in the potential to reintegrate into the community [18]. To improve rehabilitation protocols and realize the full potential of exoskeleton interventions, it is crucial to address these knowledge gaps.

1.9 Cost-effectiveness Analysis: Balancing Clinical Gains and Economic Realities

Exoskeletons can improve medical rehabilitation cost-effectiveness. Consider long-term financial implications, insurance coverage, and societal benefits for fair access and sustainable integration into healthcare systems. A study by Pinto et al. found that cost-effectiveness of training strategies varies depending on the completeness of SCI. Conventional training was more cost-effective for incomplete SCI, while overground robotic training was more cost-effective for complete SCI [19].

2 A Lower Extremity Exoskeleton Study with SCI Patients

2.1 Summary

In 2018, the University of Pécs won a European Union tender that enabled the purchase of two ReWalk 6.0 lower extremity exoskeletons (LEE) and the establishment of a research project in collaboration with the National Institute of Medical Rehabilitation. The objective of this study was to evaluate the effectiveness of exoskeletons in the rehabilitation of patients with SCI. The investigation also encompassed the indications for the therapeutic use of the exoskeleton, its physiological effects, and its role in ambulatory rehabilitation.

In December 2019, official training of the ReWalk company took place at the National Institute of Medical Rehabilitation. Nine movement therapists and five medical doctors attended and received certificates to operate and use the ReWalk 6.0 lower extremity exoskeleton.

Six patients from the spinal cord injury patient database at the National Institute of Medical Rehabilitation were selected for the study, which was originally planned to commence in the spring of 2020. However, the COVID-19 pandemic forced the postponement of this study. Due to the continuously changing medical protocols related to the pandemic, the study could not be resumed in autumn 2020.

The University of Pécs had already been using a device for gait training of an SCI patient before the start of the study; however, no patients from this institution were included in the study. Therefore, our work exclusively presents case studies of two individuals with SCI at the National Institute of Medical Rehabilitation.

2.2 Objectives and Method

The purpose of this study was to evaluate the effects of gait therapy on certain functional and physiological parameters in patients who had suffered an injury four months prior. To achieve this, we conducted a prospective, controlled trial over a six-month period, during which we registered and followed these parameters in patients who received traditional rehabilitation. The parameters included DEXA scans for determining bone density and body composition, body impedance measurement for analyzing gastrointestinal and urogenital functions, and questionnaires about general well-being and compliance.

2.3 The Device

To ensure the user's safety, comfort, and functionality, the ReWalk 6.0 Personal Exoskeleton was tailored to their body (Figure 1). The battery-powered system includes a wearable exoskeleton that can support its own weight, with motors at the knee and hip joints, and adjustable ankle joints that allow the user to stand up, sit down, and walk in a natural gait pattern. ReWalkers use buttons on a wristband to control the movement of their exoskeletons and make subtle adjustments to their trunk motion during walking. The body of the device shifts repeatedly, generating a series of steps that simulate a natural and functional gait. Customizable ankle joints and software settings allow clinicians to adjust the gait pattern of each patient for efficiency and comfort. The device is designed for use with crutches, and users can navigate the curbs and stairs using wrist-based controls or hip-mounted buttons [20].

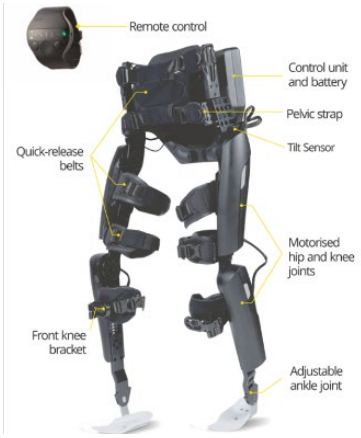

Figure 1
ReWalk 6.0. lower extremity exoskeleton

2.4 Inclusion Criteria

The inclusion criteria for the study were established in accordance with the ReWalk Robotics. These criteria included

- spinal cord injury (SCI) with paraplegia or paraparesis below the 4th thoracic vertebrae,
- a minimum of 4 months since the injury,
- functional use of the hand, shoulder complex and upper extremity to use mandatory crutches,
- a hip T-score ≤ -3.5 on a DEXA test,

- an intact skeleton with only stable or stabilized spine injuries and no other unstable fractures,
- the ability to stand with the device similar to Easystand,
- good general health,
- a height of 160-190 cm,
- an upper leg length (hip axis to knee axis) of 36-48.5 cm and a lower leg length (knee axis to bottom of foot) of 43.5-56 cm,
- a maximum body weight of 100 kg,
- and sufficient physiological lower extremity range of motion without contractures.

27 patients were identified as eligible from the SCI patient database at the National Institute of Medical Rehabilitation, of which 6 agreed to participate in the study.

2.5 Protocol

- Each patient was accompanied by at least two certified therapists during sessions.
- The therapy program was divided into four stages, with the first three stages consisting of intensive training five times a week for, 60-90 minutes each. The last stage offered lower-intensity training to maintain safe and functional gait.
- Patient training was scheduled for a period of 6 months.
- Psychologists were available during the study and the follow-up periods to monitor for any psychological issues.

However, due to practical constraints, we found that it was difficult to maintain the original schedule. Five sessions per week proved to be too much time off work for both patients and physiotherapists, so we adjusted to three sessions per week.

2.6 Therapy, Gait Training

The gait training with the ReWalk LEE was divided into 4 phases:

- 1.: Personalized preparatory therapy improves sitting balance and upper extremity strength if needed. This phase also included learning to use the device and transferring it in and out of the wheelchair.
- 2.: Independent application of the device, stand-up and sitting-down maneuvers, and sufficient use of crutches. The patient should be safe in a standing position and able to shift body weight in all directions.

- 3.: Independent walking, ability to use the controller alone. The patient should be able to safely manage starting and stopping walking as desired.
- 4.: Lower intensity, sustaining gait therapy.

2.7 Limitations

The study had several limitations, including:

- Limited access to transport services for SCI patients makes it difficult for them to attend institutes.
- The lack of financial reimbursement and time off work made the initial phase of intensive gait training (5 times a week, 60-90 minutes/session) unmanageable. This was the main reason why the patients did not participate in the study.
- The COVID-19 pandemic and related restrictions on patients, therapists, and regulatory agencies affected the progress of the study.
- Patients' health issues and lack of continuity also presented challenges.

3 Case Studies

Due to the pandemic, the commencement of this study was delayed. However, the National Institute for Medical Rehabilitation successfully mobilized two hospitalized patients, who attempted to use of the device on three separate occasions. Although we were able to use the device with another SCI patient who was originally enrolled in the study, medical adverse events ultimately led to the cessation of further training.

3.1 Case Study 1

K.Á.

- 2017: fracture of 4th and 5th thoracic vertebrae, complete SCI, underwent rehabilitation at the National Institute of Medical Rehabilitation
- 2019 autumn: Conducted an exoskeleton study.
- 2021 autumn: After 30 successful sessions, reached a maximum of 288 steps per session.
- 2022 February: Experienced left leg spasms that restricted gait training with LEE.
- 2022 March: Infected with COVID, suffered from post-COVID symptoms, underwent pulmonology control. Additionally, the patient had

severe toenail and prolonged skin injuries, which prevented further LEE training.

- 2023 May: Reopened the exoskeleton study (Figure 2).

Figure 2
K.Á. exoskeleton gait training

3.2 Case Study 2

A.Á.

- 2022 June: The patient was diagnosed with polytrauma, including bilateral pneumothorax, lung and liver contusion, fractured ribs, an unstable fracture of the vertebral body at the level of the 12th thoracic vertebrae, a fracture of the transverse process of the vertebral column at the level of the 11th thoracic to 2nd lumbar vertebrae, and a fracture of the pelvic bone. Surgical intervention involved spinal stabilization, and vertebral decompression, and laminectomy.
- 2022 July: the patient underwent complex rehabilitation at the National Institute of Medical Rehabilitation, where they learned to use wheelchairs and perform intermittent catheterization independently.
- 2022 September: continues rehabilitation at the National Institute of Medical Rehabilitation
- Status:
    - Sensorium: anaesthesia below the 12th thoracic vertebrae on the right side and below the 11th thoracic vertebrae on the left side of the trunk.

  - Motorium: Complete on the upper extremities (UE), no voluntary movements in the lower extremities (LE).
  - Vegetativum: daily 5x clean intermittent self-catheterization (CISC), sufficient bowel management
  - Muscle tone: moderate spasticity in lower extremities
  - Reflexes: UE: normal, LE: increased patellar and foot reflexes, bilateral positive Babinski reflex
  - No contractures, sitting posture maintained, self-sufficient.
- 2023 May: the patient participates in an exoskeleton study (Figure 3)

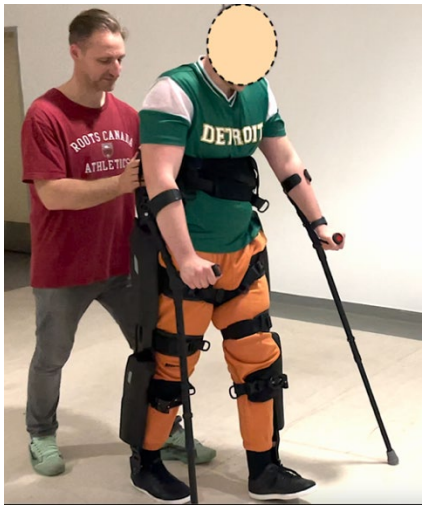

Figure 3
A.Á. exoskeleton gait training

4 Results

4.1 Bone Density

Bone density data were measured using DEXA. All scans were performed by the team of Prof. Dr. Csaba Horváth at Semmelweis University - Department of Internal Medicine and Oncology. A DEXA is a type of medical imaging test. It uses very low levels of X-rays to measure bone density. DEXA stands for “dual-energy X-ray absorptiometry.” Medical experts consider it to be the most useful, quick, and painless test for diagnosing osteoporosis [21].

K.Á.'s BMD measurements for 2nd to 4th lumbar vertebrae showed a 4.6% decrease, a decrease of 1.6% in the left side femur and a 1.1% increase in the left side radius (Table 1).

A.Á.'s datasets recorded a 1.8% increase in BMD values for 2nd to 4th lumbar vertebrae, a 0.9% decrease at the left side of the femur neck, while a 4.7% increase was noted at the left side radius (Table 2).

Table 1
K.Á. osteodensitometry data

Osteodensitometry		**K.Á.**	
		28.03.2023	**04.08.2023**
2nd-4th lumb.vert.	BMD [g/cm^2]	1,558	1,487
2nd-4th lumb.vert.	Z-Score	2,3	1,3
Left side femur neck	BMD [g/cm^2]	1,079	1,062
Left side femur neck	Z-Score	-0,4	-0,8
Hip	BMD [g/cm^2]	0,954	0,966
Hip	Z-Score	-1,5	-1,6
Left side radius	BMD [g/cm^2]	1,035	1,046
Left side radius	Z-Score	0,5	0,6

Table 2
A.Á. osteodensitometry data

Osteodensitometry		**A.Á.**	
		08.03.2023	**04.08.2023**
2nd-4th lumb.vert.	BMD [g/cm^2]	1,049	1,068
2nd-4th lumb.vert.	Z-Score	-1,2	-1,2
Left side femur neck	BMD [g/cm^2]	1,096	1,086
Left side femur neck	Z-Score	0,0	-0,2
Hip	BMD [g/cm^2]	0,872	0,846
Hip	Z-Score	-1,7	-2,0
Left side radius	BMD [g/cm^2]	0,974	1,020
Left side radius	Z-Score	-	-

4.2 Body Composition

Bioelectrical impedance analysis (BIA) is a technique used to determine body composition by measuring the rate at which a painless low-level electrical current travels through the body. Different tissues in the body allow electrical currents to travel at different speeds, with fat being more resistant than muscle or water. Therefore, a higher resistance (impedance) indicates higher body fat percentage. Most BIA scales estimate the total fat, muscle, water, and bone weight and percentage based on this rate and use other data such as height, sex, and weight

measurements to determine the body's fat percentage. To improve the accuracy of the BIA scale, patients were advised to fast overnight before the test, as suggested by the institute's dietician. Other studies have found that a training program using exoskeletons is effective in preventing continuous muscle loss in patients with SCI and reducing body fat to maintain health [22].

K.Á.'s initial BIA was performed at the start of the original study, and the measurements were repeated after a 3-month period of LEE gait training. Overall, his data showed a decline in weight value (2.1%), fat-free mass index value (0.47%), and visceral adipose tissue value (1.2%). An increase in absolute fat mass (1.14%) was observed, whereas skeletal muscle mass decreased by 1.21%.

The body composition measurements of A.Á. showed a lower absolute fat mass value of 0.14%, and an increase in skeletal muscle mass value (0.45%) and weight value (1.6%). However, the FFMI value dropped by 0.47% and the visceral adipose tissue value decreased by 0.32%.

4.3 Gastrointestinal and Urogenital Changes

Urodynamic testing is a diagnostic procedure that evaluates the functioning of the lower urinary tract, including the bladder, sphincters, and urethra, in relation to the storage and release of urine. The focus of these tests is on the bladder's ability to store and empty urine, as well as to monitor bladder contractions [23]. We observed an improvement in bladder compliance and subsequently prescribed antimuscarinic medications. Interestingly, there was no significant change in the patient's stool type, as measured using the Bristol stool form scale.

4.4 Questionnaires Related to the Patients' General Condition and Compliance

Questionnaires were used for both patients, focusing on well-being, functionality, movement, and gastrointestinal functions. The recording dates of the questionnaires were marked as follows unless marked otherwise.

- K.Á.: T1.1.: 27.09.2021; T1.2.: 03.08.2023
- A.Á.: T2.1.: 08.05.2023; T2.2.: 31.07.2023

4.4.1 Trunk Control Test

The Trunk Control Test (TCT) was used to evaluate the trunk movements in patients with neurological disorders. The test was conducted on a bed and consisted of four tasks: rolling to the weak side, rolling to the strong side, maintaining balance in a sitting position on the edge of the bed with both feet off the ground for at least 30 seconds, and sitting up from a lying down position. The TCT score was determined by adding the scores obtained from each of the four tasks (ranging from 0 to 100).

Both patients displayed equal performance at the beginning and end of the three-month period, with a score of 74.

4.4.2 Spinal Cord Independence Measure

The Spinal Cord Independence Measure (SCIM) was created to evaluate the function of patients with spinal cord injuries in three specific areas: self-care (feeding, grooming, bathing, and dressing), respiration and sphincter management, and mobility (bed and transfer abilities both indoors and outdoors). The scores ranged from 0 to 100, with a score of 0 indicating total dependence and a score of 100 indicating complete independence. SCIM can also aid clinicians in setting treatment goals and objectives for patients with SCI [24]. Both patients showed similar test outcomes and changes.

4.4.3 Barthel Index

The Barthel Index for Activities of Daily Living (ADL) is an ordinal scale that measures a person's ability to complete activities of daily living [25]. The guidelines for interpreting Barthel scores are as follows [26].

- Scores of 0-20 indicate "total" dependency
- Scores of 21-60 indicate "severe" dependency
- Scores of 61-90 indicate "moderate" dependency
- Scores of 91-99 indicate "slight" dependency.

K.Á. performed equally at the beginning and at the end of the study. A.Á. reported on minor changes in toilet use and bathing, improved bladder function, and a total score improvement of 1. Both cases indicate moderate dependency.

4.4.4 Berg Balance Scale

The Berg Balance Scale (BBS) is used to measure a patient's ability to balance safely during a series of predetermined tasks. It is a 14-item list, with each item having a five-point ordinal scale ranging from 0 to 4, with 0 indicating the lowest level of function and 4 indicating the highest level of function [27]. A score of

- 0 to 20 indicates that the person will likely need assistance from a wheelchair to move around safely, while a score of
- 21 to 40 indicates that the person will need some type of walking assistance, such as a cane or walker.

In this case, minor improvements were seen in both patients, with K.Á. improving by 1 point (22-›23) and A.Á. improving by 2 points (20-›22).

4.4.5 36-Item Short Form Survey

The 36-Item Short Form Survey (SF-36) is a widely used self-reported measure of health that was originally developed as a tool for assessing quality of life in the Medical Outcomes Study [28]. It comprises 36 questions that cover eight domains of health [29], and scores for each domain range from 0 to 100, with higher scores indicating better health. Scores for the different domains were converted and pooled using a scoring key, and the total score provided an overall measure of quality of life (QOL), ranging from low to high. The total score can be divided into two parts: a physical component summary and a mental component summary. Research suggests that interpreting SF-36 scores can be difficult and should be done in comparison to the overall score or profile [30] and that SF-36 cannot be used as a single index of overall health-related QOL because it measures two dimensions (physical and mental) [31]. In this study, the SF-36 outcome had a lower score on most dimensions of the questionnaire with a minor reduction particularly in the areas of mental health (Table 3).

Table 3
SF-36 scores for K.Á. and A.Á.

SF-36	**K.Á.**		**A.Á.**	
0-100 scores mean 0-100%	**T.1.1.**	**T1.2.**	**T2.1.**	**T2.2.**
physical functioning	35	10	55	55
bodily pain	100	100	90	90
role limitations due to physical health	75	50	25	25
role limitations due to emotional problems	100	0	100	66,7
emotional well-being	92	72	64	60
social functioning	75	37,5	75	75
energy/fatigue	80	50	55	50
general health perceptions	85	75	90	90

4.4.6 WHOQOL-BREF Questionnaire

The WHOQOL-BREF is a 26-item version of the WHOQOL-100 that assesses the quality of life, health, and well-being of people with and without disease as well as health professionals. Each item on the WHOQOL-BREF was scored from 1 to 5 on a response scale and the scores were then converted to a 0-100 scale. A score of 0 represents the worst possible health state, whereas a score of 100 represents the best possible health state in the respective domain. The physical, psychological, social, and environmental health status of the patients was assessed separately [32]. The WHOQOL-BREF showed that K.Á. experienced a 4-point improvement, while A.Á. indicated a 10-point decrease in the total score (Table 4).

Table 4

WHOQOL-BREF Questionnaire scores for K.Á. and A.Á.

WHOQOL-BREF	**K.Á.**		**A.Á.**	
1: very poor; 2: poor; 3: neither poor nor good; 4: good; 5: very good	**T.1.1.**	**T1.2.**	**T2.1.**	**T2.2.**
How would you rate your quality of life?	4	4	4	5
How satisfied are you with your health?	3	4	4	3
To what extent do you feel that physical pain prevents you from doing what you need to do?	1	1	1	3
How much do you need any medical treatment to function in your daily life?	1	1	1	2
How much do you enjoy life?	4	4	3	1
To what extent do you feel your life to be meaningful?	5	4	3	2
How well are you able to concentrate?	4	4	4	3
How safe do you feel in your daily life?	5	5	4	4
How healthy is your physical environment?	5	4	4	4
Do you have enough energy for everyday life?	4	4	5	4
Are you able to accept your bodily appearance?	5	4	3	3
Have you enough money to meet your needs?	4	5	4	4
How available to you is the information that you need in your day-to-day life?	4	5	3	2
To what extent do you have the opportunity for leisure activities?	2	3	4	4
How well are you able to get around?	2	1	5	4
How satisfied are you with your sleep?	3	4	4	3
How satisfied are you with your ability to perform your daily living activities?	4	4	3	3
How satisfied are you with your capacity for work?	4	4	4	2
How satisfied are you with yourself?	4	4	3	2
How satisfied are you with your personal relationships?	4	4	3	2
How satisfied are you with your sex life?	4	4	2	2
How satisfied are you with the support you get from your friends?	4	5	2	2
How satisfied are you with the conditions of your living place?	5	4	5	5
How satisfied are you with your access to health services?	2	4	3	2
How satisfied are you with your transport?	3	4	4	3
How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	1	3	4
Total	**91**	**95**	**88**	**78**

4.4.7 Beck's Depression Inventory

The Beck Depression Inventory Short Form (BDI-SF) is a 13-item self-report rating scale that measures the characteristic attitudes and symptoms of depression [33]. The scoring system for the BDI-SF was as follows:

- 1-10: These ups and downs are considered normal
- 11-16: Mild mood disturbance
- 17-20: Borderline clinical depression
- 21-30: Moderate depression
- 31-40: Severe depression
- 40 < : Extreme depression [34]

In the case of K.Á., their BDI-SF score remained within the normal range before and after LEE gait training and increased by 3 points (0-›3).

Meanwhile, A.Á.'s evaluation showed an initial score of 9, which increased to a score of 12 by the end of the 3-month trial period. According to the BDI-SF scoring system, A.Á.'s score increased from the normal range to mild mood disturbances (9-›12).

4.4.8 Beck Anxiety Inventory

The Beck Anxiety Inventory (BAI) was used to measure the severity of anxiety. It is a 21-question multiple-choice self-report inventory that focuses on an individual's feelings in the previous week, primarily on somatic symptoms [35]. The total score was calculated by summing up the 21 items.

- Score of 0 – 21 = low anxiety.
- Score of 22 – 35 = moderate anxiety.
- Score of 36 and above = potentially concerning levels of anxiety [36].

During the trial period, both patient scores changed, but they remained within the range of low anxiety (0-21).

4.5 Gait Training Outcomes

The patient's pulse and blood pressure were measured using the exoskeleton before, during, and after each session of the 3-month gait training period. The number of steps taken with the device's assistance was also registered, and any adverse events were documented. K.Á. had 17 sessions, twice a week, each lasting approximately 60 minutes. A maximum of 640 steps were achieved in session 12, with an average of 301 steps performed per session. The peak heart rate was measured at 127 during session 16. The 10 metre walking test time was 32.44 seconds. A.Á. had 14 sessions,

twice a week. The maximum heart rate observed was 112 in session 6 and 12 in session 12, with high blood pressure recorded in sessions 6 (162/95) and 14 (143/93). The patient experienced vertigo and gait training was not possible at those times. The maximum step count was 1727 in session 12, with an average of 480 steps taken during the training period. The 10 metre walking test time was 26.39 seconds.

Conclusions

In conclusion, the body composition data indicated a decrease in weight and visceral adipose tissue for K.Á. due to the long-lasting COVID-19 and post-COVID syndrome. The patient's immobility contributed to a more sedentary lifestyle. Further BIA tests are planned for this patient. A.Á.'s skeletal muscle mass and weight increased, suggesting the benefits of LEE gait training.

Regarding bone density, the changes were minimal due to the brief trial period.

The first stage of hyperactive detrusor syndrome showed improvement in bladder compliance. Both patients experienced an increase in the volume of involuntary detrusor contractions; however, the administration of antimuscarinic medication was justified.

We found no significant differences in the TCT, SCIM, Barthel index, and BBS scores among the patients. This may have contributed to the successful rehabilitation, as sufficient mobility was achieved. However, decreasing scores on the SF-36, WHOQOL-BREF, BDI-SF, and BAI tests suggest a lower mental health state. A.Á.'s data showed an improvement in physical parameters, but a decrease in mental health measures, which may be related to the documented suicidal ideation at the time of SCI.

The patients showed significant improvements in LEE gait training, and their motivation remained high throughout the trial period. Seeing the patients evolve and mastering the basic skills of LEE training is a motivating experience. The next chapter of LEE training involved stair climbing.

The experiences obtained from our work highlight the need to explore patients' and their caregivers' attitudes towards exoskeletons, to determine the minimum number of weekly treatments needed to achieve clinically significant efficacy on the primary and secondary outcomes, and to investigate whether inpatient versus ambulatory care would be a better form of exoskeleton treatment for SCI patients in a given jurisdiction and infrastructure. The study included multiple outcome measures to track patient parameters, such as physiological indicators, mobility, functioning, health status, and quality of life. The connection between digitally measured parameters and patient-reported outcomes has not been thoroughly explored. An important point to consider is which outcomes should be recorded at which intervals, considering the measurement properties of the measurement tools, the human/technical resource needs for a comprehensive measurement, and patients' tolerance for a comprehensive measurement. Identifying highly relevant

outcomes for patients and caregivers and developing a standardized set of primary and secondary outcomes for clinical trials and practice are crucial. This set can then be customized according to the specific study requirements.

The case studies demonstrated the potential for SCI patients to use robotic rehabilitation devices independently, and the indirect success of the project was the modification of the social security funding regulation for national health care [37]. New therapeutic modalities, including ambulatory gait training with LEE have been accepted, moving Hungary closer to countries that use robotic technology in their therapeutic practice.

Future plans

Our future plans involve exploring the adaptability of LEE gait training in the rehabilitation process of patients with SCI with the aim of including more patients and identifying more effective evaluation methods. This also allows us to examine the financial viability and feasibility of implementing such devices.

Acknowledgement

We extend our gratitude to the staff at the University of Pécs and the National Institute of Locomotor Diseases and Disabilities – National Institute of Medical Rehabilitation for their ongoing support and assistance throughout this study. Their professional expertise, initial contributions, and coordination have been invaluable for the success of this research.

This work was supported by the Project no. TKP2021-NVA-06 with the support provided from the National Research, Development and Innovation Fund of Hungary, financed under the TKP2021-NVA funding scheme.

References

[1] T. Haidegger, G. S. Virk, C. Herman, R. Bostelman, P. Galambos, Gy. Györök & I. J. Rudas: Industrial and Medical Cyber-Physical Systems: Tackling User Requirements and Challenges in Robotics. Recent Advances in Intelligent Engineering : Volume Dedicated to Imre J. Rudas' Seventieth Birthday Cham, Switzerland : Springer-Verlag (2020) 308 p. pp. 253-277. Paper: Chapter 13 , 25 p.

[2] N. Yagn: "Apparatus for facilitating walking, running, and jumping", U.S. Patents 420 179 and 438 830, 1890

[3] C-J Yang, J-F Zhang,Y Chen,Y-M Dong, & Y Zhang: "A review of exoskeleton-type systems and their key technologies. Proceedings of the Institution of Mechanical Engineers Part C Journal of Mechanical Engineering Science 1989-1996 (vols 203-210) 222(8):1599-1612. August 2008

[4] Kazerooni H., Racine J. L., & Huang L. (2005) On the control of the Berkeley lower extremity exoskeleton (BLEEX). Proceedings-IEEE International Conference on Robotics and Automation, 2005:4353-4360

[5] Winter D. A. (2009) Biomechanics and motor control of human movement. John Wiley & Sons

[6] Cappellini G., Ivanenko Y. P., Poppele R. E., & Lacquaniti F. (2006) Motor patterns in human walking and running. Journal of Neurophysiology, 95(6), 3426-3437

[7] Gregory S Sawicki, Antoinette Domingo, Daniel P Ferris (2006) The effects of powered ankle-foot orthoses on joint kinematics and muscle activation during walking in individuals with incomplete spinal cord injury. Journal of NeuroEngineering and Rehabilitation, 2006; 3:3

[8] Galle S., Malcolm P., Derave W., & De Clercq D. (2013) Adaptation to walking with an exoskeleton that assists ankle extension. Gait & Posture, 38(3), 495-499

[9] Esquenazi A., Talaty M., Packel A., & Saulino M. (2012) The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury. American Journal of Physical Medicine & Rehabilitation, 2012 Nov;91(11):911-21

[10] Wentan Liu, Jianer Chen (2023) The efficacy of exoskeleton robotic training on ambulation recovery in patients with spinal cord injury: A meta-analysis. Journal of Spinal Cord Medicine, 3;1-10

[11] Colombo G., Joerg M., Schreier R., & Dietz V. (2000) Treadmill training of paraplegic patients using a robotic orthosis. Journal of Rehabilitation Research & Development, 2000 Nov-Dec;37(6):693-700

[12] Grace J Kim, Avinash Parnandi, Sharon Eva, Heidi Schambra (2022) The use of wearable sensors to assess and treat the upper extremity after stroke: a scoping review. Disability and Rehabilitation. 2022 Oct;44(20):6119-6138

[13] Federica Tamburella, Matteo Lorusso, Marco Tramontano, Silvia Fadlun, Marcella Masciullo, Giorgio Scivoletto (2022) Overground robotic training effects on walking and secondary health conditions in individuals with spinal cord injury: systematic review. Journal of NeuroEngineering and Rehabilitation, 19(1):27

[14] C. Cumplido-Trasmonte, F. Molina-Rueda, G. Puyuelo-Quintana, A. Plaza-Flores, M. Hernández-Melero, E. Barquín-Santos, MA. Destarac-Eguizabal & E. García-Armada (2023) Satisfaction analysis of overground gait exoskeletons in people with neurological pathology: a systematic review. Journal of NeuroEngineering and Rehabilitation, 18(1), 1-12

[15] Caroline Charette, Julien Déry, Andreanne K Blanchette, Céline Faure, François Routhier, Laurent J Bouyer, Marie-Eve Lamontagne (2023) A

systematic review of the determinants of implementation of a locomotor training program using a powered exoskeleton for individuals with a spinal cord injury. Clinical Rehabilitation, 37(8):1119-1138

[16] Márk Ottó Bauer, Máté Benjámin Vizi, Péter Galambos, Tibor Szalay (2021) Direct Drive Hand Exoskeleton for Robot-assisted Post Stroke Rehabilitation. Acta Polytechnica Hungarica 18(5):37-54

[17] Ethier, C., Oby, E. R., Bauman, M. J., & Miller, L. E. (2012) Restoration of grasp following paralysis through brain-controlled stimulation of muscles. Nature, 485(7398), 368-371

[18] Christopher C. H. Yip, Chor-Yin Lam, Kenneth M. C. Cheung, Yat Wa Wong, Paul A. Koljonen (2022) Knowledge Gaps in Biophysical Changes After Powered Robotic Exoskeleton Walking by Individuals With Spinal Cord Injury—A Scoping Review. Frontiers in Neurology, 13: 792295

[19] Daniel Pinto, Allen W Heinemann, Shuo-Hsiu Chang, Susan Charlifue, Edelle C Field-Fote, Catherine L Furbish, Arun Jayaraman, Candace Tefertiller, Heather B Taylor, Dustin D French (2023) Cost-effectiveness analysis of overground robotic training versus conventional locomotor training in people with spinal cord injury. Journal of NeuroEngineering and Rehabilitation, 20(1):10

[20] https://rewalk.com/rewalk-personal-3/(last accessed: 17.08.2023)

[21] https://my.clevelandclinic.org/health/diagnostics/10683-dexa-dxa-scan-bone-density-test (last accessed: 25.08.2023)

[22] Hyuk-Jae Choi, Gyoo-Suk Kim, Jung Hoon Chai, Chang-Yong Ko (2020). Effect of Gait Training Program with Mechanical Exoskeleton on Body Composition of Paraplegics. Journal of Multidisciplinary Healthcare 2020; 13: 1879–1886

[23] https://www.niddk.nih.gov/health-information/diagnostic-tests/urodynamic-testing (last accessed: 25.08.2023)

[24] Catz A, Itzkovich M. Spinal cord independence measure: comprehensive ability to rating scale for the spinal cord lesion. Journal of Rehabilitation Research and Development. 2007;44(1):65-68

[25] Mahoney FI, Barthel DW. Barthel index. Maryland state medical journal. 1965 Feb; 14:61-5

[26] Elite learning. The original Barthel index of ADLs. Available from: https://www.elitecme.com/resource-center/rehabilitation-therapy/the-original-barthel-index-of-adls/ (last accessed: 18.08.2023)

[27] https://www.physio-pedia.com/Berg_Balance_Scale (last accessed: 18.08.2023)

[28] Ware J. SF-36 Health Survey Update. Spine. 2000 Dec 15;25(24): 3130-3139

[29] Ware Jr., J.E. and Sherbourne, C.D. (1992) The MOS 36-Item Short-Form Health Survey (SF-36). I. Conceptual Framework and Item Selection. Medical Care, 1992 Jun;30(6):473-83

[30] Taft C, Karlsson J, Sullivan M. Do SF-36 summary component scores accurately summarize subscale scores? Qual Life Res. 2001. 10; 5:395-404

[31] Lins L, Carvalho F. SF-36 total score as a single measure of health-related quality of life: Scoping review. SAGE Open Med. 2016. Published online 2016 Oct 4. Accessed: 16 January 2020

[32] https://www.physio-pedia.com/WHOQOL-BREF (last accessed: 18.08.2023)

[33] Letícia M. Furlanetto, Mauro V. Mendlowicz, J. Romildo Bueno (2005) The validity of the Beck Depression Inventory-Short Form as a screening and diagnostic instrument for moderate and severe depression in medical inpatients. Journal of Affective Disorders. Volume 86, Issue 1, May 2005, Pages 87-91

[34] https://www.ismanet.org/doctoryourspirit/pdfs/Beck-Depression-Inventory-BDI.pdf. (last accessed: 18.08.2023)

[35] Beck, A. T., Epstein, N., Brown, G., & Steer, R. (1988) Beck Anxiety Inventory

[36] Beck, A. T., Epstein, N., Brown, G., Steer, R. A. (1988) An inventory for measuring clinical anxiety: Psychometric properties. Journal of Consulting and Clinical Psychology, 56, 893-897

[37] The decree 33/2023 (VIII. 24.) BM by the Home Secretary regarding the modification of statutes of certain health and social health insurance orders of financial procedures for innovative diagnostic and therapeutic modalities. The modification of decree 9/1993. (IV. 2.) NM regarding questions addressing the financing of healthcare. 1st attachment of decree 33/2023. (VIII. 24.) BM. The part of attachment n.: R1.2 „activity codes for outpatient specialist care" (...) (robotic) gait training with exoskeleton