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CASE REPORT

Effects of training with the ReWalk exoskeleton on quality of life in incomplete spinal cord injury: a single case study

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It is a single case study. An investigation to what extent the quality of life (QoL) of patients with spinal cord injury can be influenced by the training with an exoskeleton. The study was carried out at a Hospital for neurological rehabilitation, Germany. One patient (male, 22 years), initially unable to walk independently after traumatic spinal cord injury with neurological level Th11 (ASIA Impairment Scale C) was recruited for this study 1 year after injury. The progress of the first 6 months of ReWalk training was documented and as primary outcome measure the QoL was measured with SF-36 questionnaire. Secondary outcome measures were ASIA scale, Berg-Balance-Scale and Dynamic Gait Index. At the end of the studyperiod the patient was able to walk independently supervised by one person. QoL, mobility, risk of falling, motor skills and control of bladder and bowel functions were improved. A positive effect of robot-assisted gait training on various areas of the QoL was shown. Subsequent studies should aim to verify this effect through a higher number of patients and to different injury levels.

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In most cases spinal cord injury (SCI) causes life-long disability and restrictions in the area of mobility. As a result, many of the patients remain nonambulatory and dependent on a wheelchair. Life-long inability to stand up and to walk may increase the risk of secondary complications, as there are osteoporosis and cardiovascular diseases. Also SCI is known as a reason for reduced quality of life.

In order to allow patients to stand up, to walk and to climb stairs, despite the lack of neuromuscular function of the lower extremity,[1] the Company ReWalk Robitics from Israel developed the ReWalk system. Electric motors at the knee and hip joints of the exoskeleton replace the step movements of the user.

The aim of this investigation is to evaluate how training with the ReWalk exoskeleton will affect the quality of life of a patient with SCI.

The empirical case study was designed using an A-B-format and conducted over a period of 7 months.

In phase A (1 month) the patient was prepared for the exoskeleton and baseline measurements were carried out. During this phase the patient received standard physiotherapy three times per week (2 × 60 min and 1 × 30 min) including standing and trunk stability exercises.[1]

Intervention phase (Phase B) with gait training using the ReWalk exoskeleton lasted 6 months and outcome measures were taken at predefined intervals.

A male inpatient of Asklepios Neurological Hospital Falkenstein was recruited and informed consent was given. The patient had suffered a traumatic SCI after a traffic accident one year earlier, level of Injury was Th11 and ASIA Impairment Scale rated C.

Interventional treatment included ReWalk (Rewalk Robotics, Berlin, Germany) training five times per week with each session lasting 1 h. Initial goals were being able to walk for longer distances without involuntary interruption, and to gradually reduce the support of the accompanying physiotherapist and performing donning and doffing without assistance. Walking outdoors, around obstacles and walking without assistance were supposed to be gradually increasing challenges. The long-term goal was walking independently in everyday life when accompanied by family or friends.

Quality of life survey SF-36, goal attainment scale (GAS) and American Spinal Injury Association (ASIA) Impairment Scale (AIS) were scored before and after intervention phase.

The SF-36 survey[2] is a validated assessment to evaluate the health status of SCI patients.[3] The validated German version we used has shown a good reliability (0.80).[4]

The GAS is a patient-oriented method and was described by Kiresuk and Sherman[5] for the first time. It senses the subjective opinion of the patients.[6]

Three personal main goals of the patients were documented and evaluated on a 5-point-scale by Tuner-Stokes.[7]

The AIS was originally developed by American Spinal Injury Association,[8] and is annually reviewed and further developed by an international panel.[9]

A modified Berg-Balance-Scale (BBS)[10] was recorded monthly during the study period. Standing on one leg, standing with one foot in front of the other and picking up objects from the ground is not possible when using the ReWalk exoskeleton. Therefore we modified the BBS and removed these three items. Validity and reliability of this assessment has been demonstrated in neurological rehabilitation[11–13] and as well in patients with SCI.[14]

The Dynamic Gait Index (DGI)[15] was also filled out on a monthly basis. In this study, the maximum score was reduced from 24 to 21 because changing the walkingspeed with the ReWalk is not possible. Item five was only carried out with small obstacles like cables or carpets. This assessment was classified as a valid and reliable method (0.96) with incoordination or stroke patients.[13,16]

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Table 1. Evaluation of SF-36 - Percentage change

Topics of SF-36	*Ø*	T_0	T_1	*%*
Physical functioning	96.44%	18.50%	68.50%	+50.00
Physical role function	95.82%	30.00%	55.00%	+25.00
Physical pain	88.91%	70.80%	98.80%	+28.00
General health	77.12%	75.75%	95.75%	+20.00
Vitality	67.52%	53.80%	73.80%	+20.00
Social efficiency	93.12%	98.75%	98.75%	±0.00
Emotional role function	94.46%	80.00%	13.33%	−66.67
Psychical well-being	76.49%	78.80%	90.80%	+12.00

Abbreviations: Results of SF-36, Short Form 36 Health Survey; Ø (average scores of German men of the year of 1998[2,6] T_0 (Baseline-Measurements in phase A), T_1 (Outcome-Measurements in phase B), % (percentage change).

Table 2. Evaluation BBS & DGI

Measurements	*DGI*	*BBS*
T_0	0	7
T_1	4	11
T_2	7	20
T_3	11	26
T_4	13	31
T_5	17	33
T_6	18	34

Abbreviations: BBS, Berg-Balance-Scale; DGI, Dynamic Gait Index; T_0, Baseline; T_{1-6}, monthly measurements in phase B.

Table 3. Evaluation BBS and DGI - minimum/maximum values

	BBS	*DGI*
Max. attainable points	44	21
Minimum	7	0
Maximum	34	18
Range	27	18
Percantage	61.36%	85.71%

Abbreviations: BBS, Berg-Balance Scale; DGI, Dynamic Gait Index.

Vital signs like blood pressure and heart rate were documented prior to the exercise and after the first 10 min of walking.

The therapists recorded the daily maximum walking distance. The necessary support the patient received when walking was documented using the Functional Ambulation Category (FAC) scale.

Descriptive statistics were calculated with the help of Microsoft Excel (Microsoft Ireland Operations Ltd., Dublin, Ireland).

Table 1 shows the results of the SF-36 Survey compaired to the average scores of German men in the year 1998.[2] T_0 is the first measurement in phase A before the ReWalk-gait training and T_1 shows the scores achieved after 6 months of training. The percentages were calculated according to a formula provided by Bullinger and Kirchberger.[2] The total score of six thematic areas of the SF-36 questionnaire has changed positively over the course of the study. Table 1 also shows that four categories of the SF-36 were >90% in the outcome measurement. The highest percentage change (+50) was in the area of 'physical functioning'.

The GAS showed 30.36 points improvement. The three goals: 'being able to walk alone', 'being able to climb stairs' and 'more

Table 4. Heart rate and blood preasure

Measurements	*Heart rate before movement*	*Heart rate after 10-min training*	*Difference*	*Blood preasure before movement*	*Blood preasure after 10-min training*
T_0	80	80	0	115/90	115/90
T_1	80	100	20	110/80	120/90
T_2	68	80	12	110/80	120/90
T_3	70	80	10	120/80	130/90
T_4	74	80	6	120/70	130/80
T_5	80	88	8	120/90	130/90
T_6	68	78	10	120/70	115/70

Abbreviations: T_0, Baseline; T_{1-6}, monthly measurements in phase B.

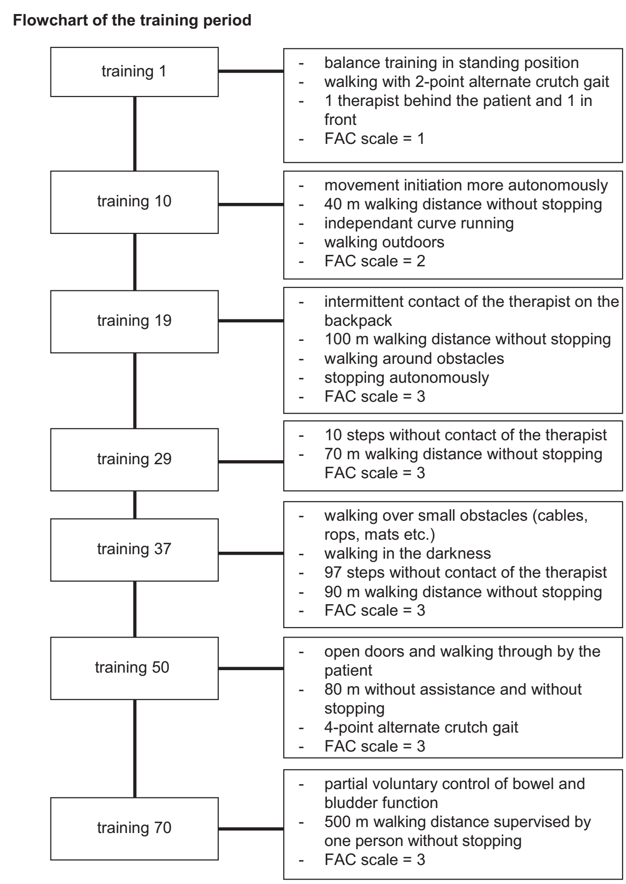

Figure 1. Flowchart of the training period (FAC, Functional Ambulation Category).

power for the activities in daily life' had a value of 25.71 points in the baseline measurement. Therefore importance, difficulty, weight, baseline and outcome score were calculated by a formular[7] and the difference of the outcome measurement (56.07) and the baseline leading to this result. Overall, the goals of the patient were 46% more achieved than in the baseline.

The ASIA motor function score improved from 52 to 54 points. Sensory functions remained unchanged. The patient partly regained control for bowel and bladder functions.

Tables 2 and 3 show the results of BBS and DGI. The monthly maximum points the patient received in these assessments are shown in Table 2. These data were used to find the minimum, the maximum and the range, to calculate the training-induced improvements during the course of the study (Table 3).

It is noteworthy that the resting heart rate and the difference between resting and training heart rate decreased at the end of the study (Table 4). The exercise induced increase of the blood pressure also lessons over the course of the study (Table 4).

Towards the end of the study, the patient was able to walk independently (indoors and on level surfaces) supervised by one person.

The maximum walking distance achieved without stopping was 500 m, signalling an improvement in the FAC scale to tier 3. Milestones of the training period are shown in Figure 1.

The data analysis of this single case study suggests that the independent variable 'ReWalk-training' has a positive influence on the studied dependent variable 'quality of life'.

Six of the eight thematic areas of the SF-36 have improved significantly compared to phase A, which leads to the assumption that ReWalk training has a positive effect on quality of life.

The study of Zeilig *et al.*,[17] with the help of a satisfaction questionnaire, subjectively pointed to a positive influence on the quality of life, too, which supports the result of this study.

The ASIA motor score improved from segment L2 to L3. At the end of the study period the patient was able to use his hipflexion better than before and he could make his first movements of the knee extension on his own. Before the study, the values relative to the AIS-sensori-motor neurological status were unchanged over a period of 3 months, leading to the assumption that the treatment of the patient had been completed. A follow-up measurement would be very interesting after another year of ReWalk training.

No other study with the ReWalk exoskeleton came to this result but two other studies of patients with SCI using the Lokomat, also found an improvement in motor function as measured by the Lower Extremity Motor Score.[18,19] The Lokomat is a frequently used gait trainer in rehabilitation centres and there are a lot of results with incomplete SCI patients to compare with.

Another significant improvement of the AIS in this single case study is the recovery of bladder and bowel control. Esquenazi *et al.*[1] obtained an improvement of intestinal regulation in 5 out of 11 patients with the ReWalk. If these results will be shown in further studies, then this would be an important foundation to justify the use of the exoskeleton in the rehabilitation centre or aid regulation for the use at home.

The positive effect of the BBS is not shown in other studies. For example, Freivogel *et al.*[20] could not find significant improvement of the BBS ($P = 0.168$) in patients who underwent Lokohelp training.

Pulse and blood pressure measurements are indicators of an improvement in physical condition, which is also recorded in two other studies.[1,17] This is only one result in accordance to other results which helps to reduce the risk factors of SCI patients.

FAC scale has increased to tier 3. The patient was able to walk on level surfaces and there is only one therapist needed for supervision. Contrary to these findings, Wirz *et al.*[19] could see no improvement of FAC using Lokomat.

The maximum walking distance was 500 m. Other robot-assisted therapies showed also an improvement.[1,17]

The intervention was free of complications in the study phase. There were no falls, no skin injury or technical problems. The safety of the ReWalk exoskeleton is also shown in the study of Esquenazi *et al.*[1]

For the cost-benefit factor it is noteworthy that two therapists are needed for 1-h training in the beginning. This is important for safety at the first training sessions and the donning and doffing needs a lot of time especially in the beginning of the training (about 10–20 min). Final aim of the ReWalk training is walking and training indepently with a family member or a friend.

This case report of treatment of a patient with SCI using the ReWalk system gives evidence of a positive impact on quality of life, ability to walk, cardiovascular endurance and motor neurological status.

Further studies with a larger number of subjects, and follow-up measurements to describe the everyday use of the device are neccessary.

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COMPETING INTERESTS

The authors declare no conflict of interest.

REFERENCES

1 Esquenazi A, Talaty M, Packel A, Saulino M. The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury. *Am J Phys Med Rehabil* 2012; **91**: 911–921.
2 Bullinger M, Kirchberger I. *SF-36 Fragebogen zum Gesundheitszustand-Handanweisung*. Hogrefe-Verlag für Psychologie: Göttingen, 1998.
3 Boakye M, Leigh BC, Skelly AC. Quality of life in persons with spinal cord injury: comparisons with other populations. *J Neurosurg Spine* 2012; **17**: 29–37.
4 Morfeld M, Bullinger M, Nantke J, Brahler E. The version 2.0 of the SF-36 Health Survey: results of a population-representative study. *Soz Praventivmed* 2005; **50**: 292–300.
5 Kiresuk T, Sherman R. Goal attainment scaling: a general method of evaluating comprehensive mental health programmes. *Community Mental Health J* 1968; **4**: 443–453.
6 Cox R, Amsters D. Goal attainment scaling: an effective outcome measure for rural and remote health services. *Aust J Rural Health* 2002; **10**: 256–261.
7 Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. *Clin Rehabil* 2009; **23**: 362–370.
8 American Spinal Injury Association *Standards for neurological classification of spinal injured patients*. ASIA: Chicago, 1982.
9 Kirshblum SC, Waring W, Biering-Sorensen F, Burns SP, Johansen M, Schmidt-Read M, Krassioukov A *et al.* Reference for the 2011 revision of the International Standards for Neurological Classification of Spinal Cord Injury. *J Spinal Cord Med* 2011; **34**: 547–554.
10 Berg KO, Wood-Dauphinee SL, Williams JI, Gayton D. Measuring balance in the elderly: preliminary development of an instrument. *Physiother Can* 1989; **41**: 304–311.
11 La Porta F, Caselli S, Susassi S, Cavallini P, Tennant A, Franceschini M. Is the Berg Balance Scale an internally valid and reliable measure of balance across different etiologies in neurorehabilitation? A revisited Rasch analysis study. *Arch Phys Med Rehabil* 2012; **93**: 1209–1216.
12 Newstead AH, Hinman MR, Tomberlin JA. Reliability of the Berg Balance Scale and balance master limits of stability tests for individuals with brain injury. *J Neurol Phys Ther* 2005; **29**: 18–23.
13 Whitney S, Wrisley D, Furman J. Concurrent validity of the Berg Balance Scale and the Dynamic Gait Index in people with vestibular dysfunction. *Physiother Res Int* 2003; **8**: 178–186.
14 Lemay JF, Nadeau S. Standing balance assessment in ASIA D paraplegic and tetraplegic participants: concurrent validity of the Berg Balance Scale. *Spinal Cord* 2010; **48**: 245–250.
15 Shumway-Cook A, Woollacott MH. Motor control: Theory and Practical Applications, 1st edn (Lippincott Williams & Wilkins, Baltimore, 1995).
16 Jonsdottir J, Cattaneo D. Reliability and validity of the dynamic gait index in persons with chronic stroke. *Arch Phys Med Rehabil* 2007; **88**: 1410–1415.
17 Zeilig G, Weingarden H, Zwecker M, Dudkiewicz I, Bloch A, Esquenazi A. Safety and tolerance of the ReWalk exoskeleton suit for ambulation by people with complete spinal cord injury: A pilot study. *J Spinal Cord Med* 2012; **35**: 96–101.
18 Hornby TG, Campbell DD, Zemon DH, Kahn JH. Clinical and quantitative evaluation of robotic-assisted treadmill walking to retrain ambulation after spinal cord injury. *Top Spinal Cord Inj Rehabil* 2005; **11**: 17.
19 Wirz M, Zemon DH, Rupp R, Scheel A, Colombo G, Dietz V, Hornby TG. Effectiveness of automated locomotor training in patients with chronic incomplete spinal cord injury: a multicenter trial. *Arch Phys Med Rehabil* 2005; **86**: 672–680.
20 Freivogel S, Mehrholz J, Husak-Sotomayor T, Schmalohr D. Gait training with the newly developed 'LokoHelp'-system is feasible for non-ambulatory patients after stroke, spinal cord and brain injury. A feasibility study. *Brain Inj* 2008; **22**: 625–632.