Improved Walking Capabilities after Eight Weeks of Hal® Exoskeleton-Supported Treadmill Therapy in a Patient with Limb-Girdle Muscular Dystrophy Type 2I

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Abstract
Objective: HAL® robot suit is a new voluntary driven exoskeleton for the lower limbs. It has already been demonstrated to improve walking functions in spinal cord injury and stroke patients. So far, it is not known if HAL® training may be beneficial in patients with limb-girdle muscular dystrophy, too.

Design/methods: In this short report, HAL® exoskeleton assisted body-weight supported treadmill training has been applied in a patient with limb-girdle muscular dystrophy type 2I for eight weeks (3 times × 8 weeks = 24 sessions). For training success, standardized walking tests were assessed prior and after training session, and after 6 weeks serving as follow-up measurement (10-meter-walk test, 6-minute-walk test, timed-up-and-go test).

Results: The patient improved in all walking functions. Follow-up measurements showed outlasting effects after 6 weeks without HAL® training. No adverse events occurred.

Conclusions: HAL®-supported treadmill training can be a promising new rehabilitation approach also for patients with muscular dystrophy. Systematic clinical trials with respect to genetic LGMD subtype should prove beneficial effects in a larger cohort.

Keywords
Myopathy, Muscular dystrophy, Rehabilitation

Introduction
Over the last 15 years, a lot of robotic technology has been developed to improve effects of rehabilitation therapy especially for walking functions in spinal cord injury and stroke patients [1,2]. Different driven gait orthosis, end-effector machines and exoskeletons are available on the market. The hybrid-assistive limb (HAL®, Cyberdyne Inc., Japan) is the first exoskeleton that can be driven voluntary by the patient [3]. In contrast to other exoskeletons, it offers the possibility of monitoring muscle contractions via surface EMG-electrodes at the extensor-flexor muscle region of the upper leg. This allows for voluntary robot-supported motion using EMG-signals recorded from hip and knee flexors and extensors. Pilot studies showed the feasibility, safety and efficiency of HAL® training on patients with acute and chronic spinal cord injury, and stroke [4-7]. HAL®-supported locomotor training in neuromuscular diseases, esp. myopathies, are only described in a large cohort of 38 patients with a widespread spectrum of diseases causing limited mobility [8]. Beneficial effects of HAL® training have not been documented for every different entity or disease. Because there are very limited therapeutic approaches for patients with muscular dystrophies, innovative rehabilitation techniques are very attractive. In this short report, we describe the effect of HAL®-supported BWSTT in a single patient with limb-girdle muscular dystrophy type 2I.

Case Report
A 57-year-old woman suffering from limb-girdle muscular dystrophy type 2I (LGMD, fukutin-related protein gene mutation) took part in body-weight supported treadmill therapy with the voluntary driven exoskeleton HAL® [4,8]. First clinical signs were evident 11 years ago. The diagnosis has been determined genetically in 2009. Clinical examination showed floppy quadriparesis with typical proximal pronouncement (MRC 3-4/5), positive trendelenburg sign bilateral and lumbar hyperlordosis. Due to the muscular dystrophy, the patient is retired. She needs a wheeled walker to deal with longer distances, e.g. shopping. Her muscle weakness causes falls regularly. The patient gave written informed consent to participate in a clinical application observation.

Methods and Treatment
The patient performed HAL® exoskeleton-supported and body-weight supported treadmill therapy over a period of eight weeks (three days/week, see First part of the video). Improvement of walking function and balance were defined as an aim of therapy in order to


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reduce the risk of falling. The 10-meter walk test (10 MWT) was done before and after each training session. It detected the time to walk a 10 m distance [9]. The timed-up-and-go test (TUG) describes the time and assistance required for standing up from the chair, walk 3 meters, turn around, walk back and sit down [10]. The 6-minute walk test (6 MWT) and TUG test were done at the beginning, at half time and at the end if possible, depending on the patient. The 6 MWT evaluates the distance while walking for 6 minutes [11]. At least, the Berg Balance Scale (BBS) assessed dynamic and static balance abilities [12].

Results

The patient reported no adverse events, especially no myalgia or muscular weakness after the training. The 10 MWT showed an increase in time from 24.97 s to 18.49 s (see Second part of the video). The patient also improved in the 6MWT (265 m to 296 m), in the TUG test (32.84 s to 23.88 s) as well as in the BBS (39 to 44 points). In the follow-up assessments, we obtained 20.19 s in the 10 MWT, 252 in the 6 MWT and 25.17 s in the TUG test.

Discussion

These result simply that the HAL® exoskeleton-supported treadmill therapy can improve walking capabilities and balance abilities in patients suffering from LGMD and that these effects can persist for several weeks. Therefore, HAL® training can be considered a novel and innovative symptomatic therapy which can be repeated on a regular basis without side effects. It may be even more important to stabilize disease progression particularly before more causative oriented therapeutic options become available in the future. Further controlled clinical trials have to be performed in the future to assess valid and reliable training effects in LGMD or different types of myopathy. In these studies, an intensive supervision of HAL training should be performed including serum creatinkinase, serum lactate, spiroergometry with $V_{O2max}$ and heart rate analysis. In this single case, these parameters were not assessed.

Ethics

Ethic Committee of the Medical Faculty, Ruhr University Bochum, reg. No. 4733-13.

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Competing Interests

MSK, RK, MA, DG, MV and MT have no conflicting interests. TAS reports personal fees from Cyberdyne, Inc. outside the submitted work.

Author’s Contribution

MSK: patient recruitment, clinical examination, data collection, data analysis, data interpretation, writing; RK: patient recruitment, data collection, data analysis, data interpretation, writing; TAS, DG, MA: study concept, writing, data interpretation, critical revision; MV: study concept, writing, data interpretation, critical revision; MT: study concept, writing, data interpretation, critical revision.

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