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J. Nitschke, D. Kuhn, K. Fischer, K. Röhl

Comparison of the Usability of the ReWalk, Ekso and HAL Exoskeletons in a Clinical Setting

Since the 1970s, research has been conducted to design exoskeletons to help paraplegics overcome limited mobility. Three different devices (ReWalk*, Ekso, and HAL***) were tested in the following study. Two of these systems (Ekso and HAL) have been an integral part of the treatment of paraplegic patients at our centre Bergmannstrost in Halle (Saale) since April 2014. The Ekso is used to treat complete and incomplete paraplegic patients; with a device called Variable Assist it is possible to use remaining muscle function when paraplegia is incomplete. The HAL is used for therapy of paraplegic patients with a Janda strength level of at least 3/5 for hip flexion and knee extension. The results show that while exoskeletons can be used as therapy aids to supplement existing options, they are not an alternative to a wheelchair and should not be prescribed as orthopaedic devices. The systems require further optimisation to make them safe enough to be used as orthopaedic devices.**

Key words: exoskeleton, therapy aid, orthopaedic device, paraplegia

Introduction

Every year, there are around 130,000 new cases of paraplegia worldwide. The consequence is usually permanent dependence on a wheelchair. In addition to the physical changes, those affected perceive the obviousness of their condition to be particularly unpleasant. Sitting in a wheelchair and "looking up" to other people combined with limited mobility, especially on uneven ground or when overcoming differences in height such as stairs are described as particularly stressful. To improve this situation and give a paraplegic individual the chance to stand and walk again, meet other people at eye level, and overcome the current limitations of mobility, there has been ongoing research into the development of exoskeletons since the 1970s. The study presented here tested the clinical feasibility of three different exoskeleton systems.

Methods

From January to June 2013, the ReWalk and Ekso exoskeletons were tested at the Centre for Spine Injuries of the occupational health and safety hospital in Halle (Saale), Germany. Exoskeleton therapy has been an integral component of treatment there since April 2014. In addition to the Ekso, the HAL is now also used for therapy.

To date, 22 patients have received therapy with one of the exoskeletons. The level of the patients' lesions varied from C7 to L1, ASIA A. The patients' weights were between 55 and 100 kg and their ages between 34 and 62 years. The paraplegia had been present between 6 months and 29 years. All patients used an active wheelchair in their daily activities.

To test the time required for therapy, the times for converting and adapting the exoskeletons and for putting them on and taking them off was measured. The length of each balance and gait training session was determined. The number of therapists required was also noted. The therapy period was between 2 and 10 weeks and the number of therapy sessions per patient was between 2 and 30; a therapy session consisted of a maximum of 45 minutes of walking including donning and doffing the exoskeleton. Parallel to various medical examinations, the practicality of each exoskeleton in clinical routine was tested. The goal was and is to discover indications and contraindications for exoskeleton therapy, develop a therapy algorithm, determine the physical and mental impact of therapy, and detect potential technical weak points.

Results

Thus far 110 therapy sessions have been conducted with the ReWalk, 61 with the Ekso, and 41 with the HAL. For both the ReWalk and Ekso, the average duration of balance training was between 4 and 5 minutes; duration of walking 29 to 34 minutes. No balance training was needed with the HAL; the average duration of walking was 15 to 25 minutes per therapy session.

The average time required for converting the exoskeletons was 45 minutes for the ReWalk, 10 minutes for the Ekso, and 20 minutes for the HAL. The average time required for donning and doffing the exoskeletons was 25 minutes for the ReWalk, 10 minutes for the Ekso, and 30 minutes for the HAL. This yields a total time required per therapy session of

Fig. 1 *Standing up with the ReWalk: The arms must be positioned far to the rear and the torso must be bent forward. The ring-like devices for securing the forearm crutches cause painful pressure at the bends of the elbows.*

105 minutes for ReWalk, 60 minutes for Ekso, and 85 minutes for HAL for 35 minutes of walking. None of the patients were able to put on the therapy device without help.

For all exoskeletons, two therapists were always needed per therapy session at the start; for the Ekso and HAL this could be later reduced to one therapist depending on the level of paralysis.

The following special characteristics were found during therapy:

ReWalk and Ekso

Computer-controlled motors assist standing, walking, and standing up / sitting down. During therapy, the desired program must be selected using a "dial". The program is started by inclining the torso and thus shifting the centre of gravity. Stride length, width, duration, etc. must be set before therapy and adjusted during therapy as needed. Therapy must be interrupted for this. For the ReWalk, the parameters must be determined on a trial basis; for the Ekso there is a dimension sheet with recommendations depending on height, leg length, etc.

Patients with contractures greater than 10° in the hip or knee joint, leg length differences of more than 2 cm, or total hip replacements cannot use the exoskeleton. Hip flexion of approx. 130° is required to achieve the position for standing up. In patients with a total hip replacement, this can lead to dislocation.

When walking, the hip joint is extended by the motor. If there are contractures, there is a risk of tendon avulsion. Flexion contractures in the knee joint lead to a functional difference in leg length. This means that the swing leg cannot be adequately relieved; walking is difficult.

For patients with rotational errors or axis deviations in the lower limbs, therapy can be attempted on a trial basis, however, the greater the deviation from normal anatomy, the greater the risk of putting excessive stress on the adjacent joints.

The forearm crutches included must be placed far to the rear for standing up / sitting down. This requires good mobility in the shoulder girdle (Fig. 1).

It is not possible with either of these two devices to change stride height or width while walking. This means that it is not possible to overcome obstacles or compensate for uneven ground. In the authors' opinion, they should therefore be used only on level ground and with a therapist's assistance. The patients agree with this appraisal.

ReWalk

The torso is not secured in the orthosis, making active torso control necessary. The direct adaptation of patients to the orthosis using straps led to pressure points and skin abrasions in the area of the trochanters, the fibular head, and the malleoli, especially the medial malleolus.

The straps do not allow patients, especially overweight patients, to be secured adequately. Unintended flexion occurs in the knee joints, resulting in a posterior shift of the body's centre of gravity. This is compounded by the backpack containing the battery for the device. To counteract this situation and avoid falling backwards, the torso had to be bent forward disproportionately, which put a very high load on the upper limbs. In some patients, this reactivated existing osteoarthritis. In addition, anterolateral shifting of the body's centre of gravity was considerably more difficult, the swing leg could not be adequately relieved and the stride could not be correctly initiated. Error messages and an activation of the safety mode occurred frequently (Fig. 2). The method of securing the lower limbs has since been modified. However, no data is available on any improvements this has led to.

The three-point gait pattern in the ReWalk is not physiological. Using stairs, which is possible according to the manufacturer, was tested, but was shown to be associated with a very high risk of falling when ascending stairs, but especially when descending stairs. The hand rail and a crutch were used to ascend stairs. The torso must be shifted backwards on the swing leg side and flexed toward the contralateral side after initiating a step in order to place the swing leg onto the next step of the stairs. When descending stairs, the difference in height must be overcome and the centre of gravity is shifted far to the front. An attempt to descend stairs was broken off because it was deemed to be too dangerous.

Walking with forearm crutches was sometimes difficult for patients because of existing instability. When standing up / sitting down, the ring-like device for securing the forearm crutches exerts pressure at the bend of the elbow. This led to haematomas (Fig. 2). According to the manufacturer, a modification will be made.

In the authors' opinion, the ReWalk is suitable as a therapy device under a therapist's supervision for the following patients: max. weight 100 kg; height 160 to 190 cm; complete paraplegia with torso stability maintained; an attempt should be made to achieve a normal weight due to the problems described in securing the device.

Fig. 2 *Therapy with the ReWalk: 3-point gait on forearm crutches, patient secured by straps. Due to the insufficient method of securing overweight patients, the centre of gravity is shifted backwards, the stride cannot be initiated correctly and therapists must give assistance. Note also the padding added to prevent pressure points.*

Ekso

The torso is secured by a system of straps to a back plate that is firmly attached to the orthosis. The patient can be adequately stabilised in the orthosis with a wide abdominal strap; the centre of gravity remains in the middle. The required battery is located in a backpack, however, due to the back plate, it does not pull the patient backwards as the back plate effectively secures the torso. The lower limbs are secured by a system of clamps attached to the orthosis itself at a certain distance. This ensures very high stability even for overweight patients (Fig. 3 and 4). The centre of gravity was not shifted backwards in any of the patients. No pressure points were found.

The reciprocal gait is similar to a physiological gait pattern. Patients can walk with the aid of a rollator or with forearm crutches. The rollator is perceived very positively by patients because it feels safer than forearm crutches, especially in the beginning (Fig. 4).

Furthermore, with the Ekso there is the option of using the Variable Assist device. This allows the active use of any existing residual muscle function in the lower limbs; the motor power is adjusted accordingly. The necessity of adapting the stride cycle of the exoskeleton is described as difficult, as it cannot be actively controlled by the patient.

In the authors' view, the Ekso is suitable as a therapy device under a therapist's supervision for the following: patients with complete and incomplete paraplegia and quadriplegia; max. weight 100 kg; height 150 to 190 cm; active stabilisation of the upper limbs, especially the el-

Fig. 3 *The Ekso in the initial position for transferring the patient from the wheelchair to the device; the "legs" can be adducted after transfer. The well padded clamps for securing the patient and the firm back plate are also visible.*

Fig. 4 *Rollator for the first therapy session in the Ekso. The image shows a patient with spinal cord injury below C7, ASIA A. The legs and torso are well secured and the body's centre of gravity remains in the middle even if the patients are very large and heavy.*

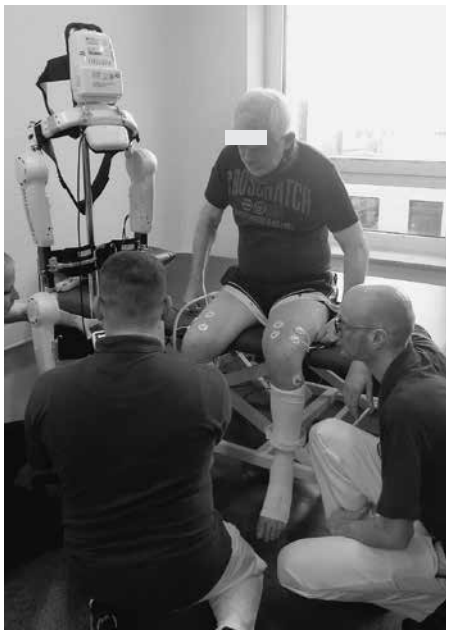

Fig. 5 *Preparing for therapy with the HAL. The electrodes have already been attached.*

Fig. 6 Resting phase in the HAL: Using the Woodway, the patient can hang in the straps to rest. The patient must actively extend the hip and knee joints to stand up.

Fig. 7 Therapy with the HAL on a rollator.

bows and wrists, must be possible; patient must be able to use the walking aids safely. For incomplete paraplegia, the patient must adapt to the gait cycle of the device, but can use his or her own muscle strength with the Variable Assist.

HAL

Unlike the ReWalk and Ekso, in the HAL, the stride is initiated and controlled by myoelectric potentials. To do this, electrodes that are connected with a computer are attached to the relevant muscle groups in the lower limb (Fig. 5). Depending on the potentials detected, the computer coordinates the stride cycle and the required support of the respective muscle groups depending on the current phase of the cycle. This mechanism allows patients to control the stride on their own. The height and length of the stride can also be varied, which makes it possible to overcome obstacles.

It is not possible for the patient to rest using fixed extension of the knee and hip joints during the resting phase. To allow the patient to rest, therapy must be conducted on the Woodway or the patient must have enough own strength to maintain extension of the hip and knee joints (Fig. 6).

These requirements means that therapy with HAL is suitable for patients with incomplete paraplegia with a strength level of 3/5 on the Janda scale for hip flexion and knee extension. Alternative therapy options should be considered for levels below this.

Patients can walk on a treadmill or, with the help of devices such as a rollator, on level ground (Fig. 7). No tests have been conducted yet for walking using forearm crutches and walking without devices, however, both are considered to be possible under the appropriate circumstances. Using the Woodway, therapy is presumably also possible for patients with reduced torso control and strength in the upper limbs, but there is no practical experience with this.

Therapy appears to be limited at this time by the standardisation of the existing therapy devices. This standardisation is based on an Asian standard that does not take adequate consideration of European patient populations. Regulating the width of the pelvic bar appears to be especially problematic. Another problem is the very short battery life during therapy. During active use, the battery needs to be replaced after just 15 to 20 minutes.

The authors' opinion is that the HAL is a suitable therapy device under a therapist's supervision for the following: patients with complete and incomplete paraplegia with strength level of at least 3/5 on the Janda scale for hip flexion and knee extension; height from 150 to 190 cm; max. weight 95 kg.

Conclusion

The development of exoskeletons is another option for improving the therapy of paraplegic patients. There is currently no device known to the authors that is suitable for private use. The main problem is that it is not possible to adjust the height and length of the stride while walking, which means that it is not possible to overcome obstacles or compensate for uneven ground. Walking with an exoskeleton is currently possible and safe on level ground and under the supervision of a trained therapist. Exoskeletons are therefore to be classified as therapy devices, not walking devices. All patients who had therapy with one of the exoskeletons agreed with this appraisal.

It is possible with the HAL to modify stride length and width during therapy, however, due to its complexity, the authors currently classify it solely as a therapy device.

Therapy with an exoskeleton is time-consuming and requires intensive input from a therapist. However, initial tests have shown many positive effects at both the physical and mental level that justify the effort.

The height and weight limitations currently existing for all devices tested limit practicality in clinical routine. In particular, the 100-kg weight limit often meant that patients could not be given therapy. The aim should be for a maximum weight of 125 kg.

Due to the current limitations to the practicality of exoskeletons, they cannot be considered to be a substitute for wheelchairs at this time. However, we are excited about further developments.

* ReWalk, ARGO Medical Technologies, Yokneam Ilit, Israel
** Ekso, Ekso Bionics, Richmond, California, USA
*** HAL, Cyberdyne Care Robotics, Bochum, Germany / Tsukuba, Japan

For the authors:
Jane Nitschke
BG Klinikum Bergmannstrost
Merseburger Straße 165
06112 Halle (Saale), Germany
j.nitschke@gmx.net

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