Treadmill training of paraplegic patients using a robotic orthosis

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Abstract—Recent studies have confirmed that regular treadmill training can improve walking capabilities in incomplete spinal cord-injured subjects. At the beginning of this training the leg movements of the patients have to be assisted by physiotherapists during gait on the moving treadmill. The physical capabilities and the individual experience of the therapists usually limit this training. A driven gait orthosis (DGO) has been developed that can move the legs of a patient in a physiological way on the moving treadmill. The orthosis is adjustable in size so different patients can use it. Actuators at the knee and hip joints are controlled by a position controller. With the DGO the legs of patients with different degrees of paresis and spasticity could be trained for more than half an hour, and physiological gait patterns were obtained.

Key words: bipedal locomotion, driven gait orthosis, gait, orthosis, paraplegia, powered walking exoskeleton, treadmill training.

INTRODUCTION

It is possible to induce locomotor movements with appropriate leg muscle activation in the chronic spinal cat (for review see reference 1) when the body is partially unloaded while standing on a moving treadmill. Positive effects of this training were described for locomotor capability (2). Similarly to the effects seen in the cat, locomotor movements can be induced and trained in incomplete paraplegic patients using partial unloading of the body while standing on a moving treadmill (3). Indeed, recent studies with such patients have shown a significant increase in electromyographic (EMG) activity in the leg extensor muscles during training, an effect that was shown to be connected with improvement of locomotor function (4,5). Furthermore, it was possible to demonstrate that even in patients with complete paraplegia, a locomotor pattern could be induced and leg extensor EMG increased during training (4,5), although these patients did not improve in their locomotor ability. Meanwhile, the beneficial effect of such a locomotor training, which leads to greater mobility compared to a control group without training, is well established for incomplete paraplegic (6,7; for review see reference 3) and hemiplegic patients (8).

Locomotor training on a treadmill usually starts 4 to 6 weeks after a spinal cord injury, when the patients are
not yet capable of moving their legs themselves. They therefore have to be suspended by harness over the treadmill, with their body partially unloaded by a suspension system. Currently, during the first phase of the training, the leg movements of the patient have to be manually assisted in a physiological way by two physiotherapists sitting on either side of the patient. In this way, the patient can perform stepping movements on the treadmill. These movements are associated with a pattern of leg muscle activation that appears to be generated by locomotor centers within the spinal cord that become activated by an appropriate afferent input.

The assistance of leg movements during the training seems to be of crucial importance. An optimal afferent input to the spinal cord is only achieved if the legs are moved in a reproducible, rhythmical, and physiological manner. Adequate afferent input is necessary to stimulate the locomotor centers within the spinal cord to activate leg muscles that cannot be moved voluntarily.

For therapists, the moving of a patient's legs during the treadmill training represents ergonomically unfavorable and tiring work. That is why the training sessions usually have to be rather short, and in the case of excessive spasticity of the patient, training might even be impossible. Other problems are that each therapist assists the legs of patients according to individual practice and that the performance of a single therapist may even differ from day to day. Consequently, no reproducible and constant afferent input for the locomotor centers is provided and patients cannot optimally profit from manually assisted locomotor training.

In order to improve the treadmill training for patients and reduce the workload of the therapists we have developed a driven gait orthosis (DGO). With this new device, it will be possible to apply automated locomotor training to nonambulatory patients. This automated training will have a number of advantages compared to manual training: The rehabilitation can start earlier after trauma because the DGO is stronger than the physical abilities of the therapists. The duration of the training can be prolonged because the orthosis can provide sufficient power over a longer time and the induced gait pattern can be better adapted to the individual needs of each patient, i.e., will be more physiological and reproducible. The DGO also has advantages in respect to research purposes: It will become possible to measure different parameters of gait and the degree of assistance of leg movements (e.g., applied forces). This will facilitate investigation of the influence of these parameters on the effects of training. Furthermore, training will be less cost intensive with the DGO, because only one therapist is needed to carry out the therapy.

In the past there have been several other groups working to develop a DGO. In 1972, Hughes already had developed a plan for a pneumatically driven exoskeleton (9). Later, hydraulically moved systems of Seireg and Grundman (10) and of Miyamoto et al. (11) were presented. The first orthoses using direct current (DC) motors were constructed by Rabischong et al. (12) and by Ruthenberg et al. (13). All of these powered orthoses were designed to move patients on normal ground conditions, without giving additional support for balance. As these devices could not control upright balance of the body, additional support by crutches or parallel bars was required.

METHODS

During the last three years a DGO has been developed for locomotor training of paraplegic patients in the rehabilitation center ParaCare, of the University Hospital Balgrist in Zurich, Switzerland. Patients can be fixed into this orthosis by straps fastened around the breast, waist, and legs. Figures 1 and 2 show, by photograph and schematic illustration, respectively, the DGO during locomotor training with a patient. In order to allow training of patients with gait disorders on a treadmill (“LOKO spezial,” Woodway GmbH, Germany), several considerations must be taken into account.

Adjustability of the DGO to Different Patients

The DGO has to be applied differently for the training of different patients. Therefore, it must be adjustable to the anatomy of each subject, and several parameters have to be kept variable in order to allow an optimal fitting of the orthosis to the individual patient (Figure 3). The width of the hip orthosis (Figure 3, index 1) can be adjusted by a spindle, which moves the two legs apart. The band that is fixed around the breast of the patient is mounted to a back pad, which again can be positioned vertically and horizontally (Figure 3, indices 2 and 3). The length of the thigh and the shank of the orthosis can be changed as well. Both limbs consist of rectangular tubes pushed into one another that can be fixed in different positions by a bolt (Figure 3, indices 4 and 5). Finally, the position of the leg braces (Figure 3, indices 6 and 7) and the size of the leg braces (Figure 3, index 8) can also
be adapted to individual requirements. The braces are connected to a right-angled tube that is fixed to the leg orthosis. The tube can be moved in an anterior-posterior direction on the leg orthosis and tightened in the correct position by a small lever. In the same way, the brace becomes fixed at the right position medio-laterally on the other side of the tube. If one brace does not fit with the individual leg, it can easily be replaced by a bigger or smaller brace.

In order to prevent skin pressure sores, all straps around the patient are wide and soft. At all sites of contact between patient and orthosis, i.e., where the straps are fixed to the DGO, a soft pad is mounted to reduce the possibility of a skin sore.

Figure 1.
Photograph of an incomplete paraplegic patient fixed within the DGO during treadmill training.

Figure 2.
Schematic drawing of a patient fixed within the DGO during treadmill training. The patient is partially unloaded by a harness via the suspension system.

Figure 3.
Adjustments of the DGO to individual needs. 1: width of the hip, 2: vertical position of the back pad, 3: horizontal position of the back pad, 4: length of the thigh, 5: length of the shank, 6: medial-lateral position of the leg brace, 7: anterior-posterior position of the leg brace, 8: size of the leg brace.
Control of Balance

Because some patients do not have trunk stability, the upper body has to be stabilized in the vertical direction during training. This is achieved by fixing the DGO to the railing of the treadmill by a rotatable parallelogram (Figures 2 and 4). This approach enables the DGO to move only in a vertical direction and prevents tilting to one side. The parallelogram also keeps the DGO in a fixed position over the treadmill and prevents backward movement induced by the moving treadmill belt. Nevertheless, this setup allows the upward and downward movements of the body that occur during walking.

Figure 4.
The parallelogram and its fixation.

The setup with the parallelogram has several advantages. First, it makes the control of the DGO simple, because the movements of the legs have to be controlled only in a sagittal plane. It also allows the therapist to perform training with tetraplegic patients because with this setup, these patients do not have to keep their upper body in a vertical position themselves. In addition, there is a gas spring mounted at the parallelogram (Figure 4) that compensates for the total weight of the orthosis by holding up the parallelogram. In this way the patient does not have to carry the weight (21 kg) of the orthosis and it is possible to reduce slipping down of the orthosis.

Driving Power

In order to generate an optimal afferent input to the spinal cord, the gait movements applied by the DGO should be as similar to normal walking as possible. To be able to move the legs of the patient in such a way, the drives at the knee and hip joints have to be strong enough to move the limbs even if spastic muscle hypertonia is present. At the same time, the orthosis should be easy to handle and the drives should therefore not be too big or too heavy.

As already reported for other powered orthoses (12), the torque that is necessary to move the ankle joint is greater than the one needed at hip and knee joints, if an orthosis is designed to provide a forward propulsion of the body. Therefore, we omitted an active drive at the ankle and took advantage of the moving treadmill. The treadmill controls the movement of the feet during stance phase, while dorsiflexion of the ankle joint during swing phase is achieved by the introduction of a passive foot lifter (Figures 1 and 2).

Hip and knee joints are driven by custom-designed drives with a precision ball screw (KGT 1234, Steinmeyer GmbH & Co., Germany). The nut on the ball screw is driven via a toothed belt by a DC motor (Maxon™ RE40, Interelectric AG, Switzerland), which delivers a nominal mechanical power of 150 W. The motor allows long-time usage at a maximum torque of approximately 180 mNm. For short but repetitive peaks, a torque of up to 1 Nm can be achieved.

Converted to the knee and hip joints of the orthosis (different geometry), an average torque of approximately 30 Nm and 50 Nm, respectively, can be achieved. Peaks of 160 Nm for the knee joint and 280 Nm for the hip joint are possible. The mechanical layout of the orthosis has been designed to optimally profit from the recommended speed characteristics of the motor at walking speeds up to 3 km/h (cadence of 90). The bandwidth (with PD controller) is at least 1 Hz, which is sufficient for normal gait.

With their experimental device, Ruthenberg and coworkers (13) have determined the hip torque that is required to move the legs of a patient. From their results it can be estimated that a moment of 1 Nm per kilogram of body weight is maximally required at the hip joint. An average moment was not indicated in this study but it can be presumed to be in the range of 35 Nm. The applied drives in our DGO were designed to be strong enough to generate a gait pattern that is suitable for most patients.

Control Setup of the DGO

The control setup of the DGO is shown in Figure 5. It consists of three main hardware parts: the host personal computer (PC), the target PC, and the current controller. The therapist responsible for the training controls
the DGO via a user interface that is programmed in LabView (and runs on the host PC). It consists of a database and an interface to the DGO. The user interface is described in detail below.

![Control setup of the DGO.](image)

To be able to train the patient with different gait patterns, all four driven joints of the DGO can be controlled separately. Therefore, an individual position-controller loop has been implemented for each drive. This loop is built out of a commercially available current controller, which again is fed by the output of a position controller. The position controller is implemented in a real-time system (RealLink™) that runs on a second PC (target PC). The actual angles of each joint are measured by potentiometers and the corresponding values are transferred via an analog to digital converter into the real-time system. Host PC and target PC communicate with each other by the serial bus (RS232). The therapist can change the speed of the DGO at the user interface. The intended speed is transferred to the target PC that adjusts the gait pattern accordingly and also sets the desired speed of the treadmill by a second serial port.

**User Interface**

The DGO has to be operated by physiotherapists. Therefore, the user interface must be easy to manage. Also, the handling of the DGO may be rather complicated, and errors in affixing it to the patient can lead to injury of the patient’s legs. We have programmed the user interface in such a way that every step of the procedure is specified in a separate sequence of the program and the therapist has to confirm each step before proceeding.

An important part of the user interface is the database that is implemented. It is used to store personal data about the patient, as well as the settings for the different adjustments. The latter is important to save time with the handling of the DGO during the daily training and to improve the performance with each patient. The adjustment of the DGO to a new patient usually takes about 15 minutes. It must be confirmed that the joints of the patient and the orthosis are in line with each other and that there is no part of the DGO pressing too hard on the patient’s skin. When the patient comes to the next therapy session, the settings of the adjustments can be reloaded from the database and the orthosis can be preset to the patient’s personal values. By this procedure the patient is ready for training within three to five minutes. If additional corrections have to be made, the new values can be stored in the database at the end of each training session.

**Application of a Physiological Gait Pattern**

The DGO has been developed to perform locomotor training of paraplegic patients. Therefore, the main focus was to generate an appropriate afferent input to the spinal cord. This can be achieved only by moving the legs in a physiological way, i.e., by imposing joint movements known from recordings in healthy subjects.

The first trials with the DGO were done using hip joint and knee joint traces gained from healthy subjects (taken from Winter; reference 14). By this approach, appropriate results were obtained as long as the patient was unloaded by more than 40 percent of his body weight. As soon as the body load on the legs increased
above this level, the swinging leg frequently touched the treadmill belt during the swing phase. Sometimes this even resulted in stumbling. Therefore, the programmed joint angles had to be changed to trajectories that result in greater foot clearance during the swing phase. Such movement trajectories were obtained by measuring the angles of the DGO while healthy subjects were walking with the orthosis. By this approach a gait pattern was obtained that takes into account the restrictions of the orthosis during walking (e.g., no weight shift or hip tilting). The subjects were walking over obstacles with a height of three centimeters. For these recordings, the drives were removed in order to reduce the friction at the joints to a minimum.

Figure 6 shows three averaged joint angle trajectories for hip and knee joints: inter-subject joint angles (normal) from Winter (14), angles of a healthy subject walking normally in the DGO, and angles of a healthy subject walking over the obstacles to get more foot clearance (FC) in the DGO (DGO with FC). In general, all three trajectories look alike. The deviation between the three conditions does not exceed the inter-subject variation. The hip trajectory during gait with more foot clearance shows a greater flexion at the end of the swing phase. With this standardized gait pattern it has been possible to train all patients so far. The deviations for the different angles depended on the amount of unloading, and were small.

Handling of the DGO

The DGO can be lifted on the parallelogram so that the two rotatable bars become positioned in a vertical direction. The parallelogram is connected to a fixation (Figure 4) that can be rotated horizontally to one side. Therefore, the entire system can be swung off the treadmill. To fit the patient into the orthosis, first the harness for treadmill training is applied. After this, the wheelchair, with the patient seated in it, is pushed up a ramp onto the treadmill where the patient is lifted out of the wheelchair by the suspension system. The DGO is moved back on the treadmill and is lowered from behind towards the patient. All braces are open in front and can be closed around the legs by straps. During the adjustment of the braces to the correct positions, the patient is still fully unloaded. After the foot lifters have been applied, the body-weight support is reduced and the training can be started.

At present, four patients have been trained with the DGO. Corrections to the setup had to be made in all four patients after the first trials to ensure individually adapted movements. After the first session the settings were stored in the database. In the following training sessions the stored adjustments could be reproduced and training was usually possible without any readjustments. Three patients were male and one was female. For age, height and weight see Table 1.

The DGO is a strong machine that acts directly on the limbs of the patient. Therefore, a risk analysis was carried out and appropriate precautions were made to ensure that the patients will not be injured. These precautions are not described in detail here.

<table>
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<tr>
<th>Table 1. Patient background data.</th>
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<td><strong>Subject</strong></td>
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<td>Patient 1 male</td>
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<td>Patient 2 male</td>
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<td>Patient 3 male</td>
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<td>Patient 4 female</td>
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RESULTS

Up to now the DGO has been applied to only a few patients, but the results are encouraging. The patients were alternately trained manually and by the DGO. While the manually assisted therapy lasted for only about 10 to 15 minutes, the automated training could be extended up to 60 minutes. The limiting factors for the manual training were the therapists; in the automated training usually the patients became exhausted.

None of the patients reported any serious problem with the automated training. On the contrary, they all expressed positive feedback. The main advantages of the new training were the prolonged training session, the reproducible, physiological gait pattern, and the possibility to walk faster. The only trouble in two patients was skin problems caused by not optimally adjusting the leg braces. This problem was easily rectified in the following training session by correcting the position of the brace. One patient who had been trained was tetraplegic (incomplete lesion at C4). This patient was hard to train manually because of an instability of the trunk. The therapists could only train him with an unloading of 50 percent of his body weight, while the training with the DGO could be carried out with an unloading of 25 percent. An even greater reduction should be possible when the fixation and gait movement can be improved further and can be individually adapted.

During manual training the treadmill speed was around 1.5 km/h. The therapists could not tolerate a higher speed, as the patient had to be fully assisted. With the DGO the speed could easily be increased to 2 km/h from the beginning on. The drives would even allow a speed of 3 km/h. Some small aspects of the DGO still need to be improved. The greatest problem is the fixation of the patient in the orthosis. The DGO could be well adjusted to the four patients and also to several healthy subjects. However, a problem was that the orthosis moved slightly in respect to the patient during training. With the soft straps around the body it is difficult to achieve a fixed placement. During the first trials the patients were moving slightly in the orthosis, i.e., the orthosis was slightly slipping down on the legs about one to two centimeters. This resulted in a change of joint position of the orthosis with respect to the patient. Consequently, the leg movements changed during the therapy with the consequence of stumbling, and in that case the orthosis had to be readjusted. The reason for this slipping of the orthosis is that the foot lifters pull at the upper one of the two shank leg braces. A solution to this problem in the future will be to connect the DGO directly to the treadmill harness. The harness is surrounding the upper part of the body so a better fixation can be achieved.

DISCUSSION

Manual treadmill training with partial body-weight support is a well-accepted approach in rehabilitation to train non-ambulatory patients, and was shown to have several advantages over standard physiotherapy (3). Also, in hemiparetic patients this approach is increasingly applied (8). By the unloading of a part of the body weight (usually up to 50 percent), the patient does not have to balance during walking, but can concentrate on the leg movements. This allows the patient to walk with a higher speed compared to walking on normal ground conditions. The combination of assisted treadmill training and body-weight support allows patients who otherwise could not be mobilized adequately to perform locomotor training. The proportion of patients with incomplete spinal cord lesion is increasing and so is the number of people who have the potential to recover part of their walking abilities.

Until the development of the DGO, one of the limiting factors for locomotor training has been the capacity of therapists. Because the external assistance of leg movements can be exhausting in spastic paretic patients, it must be limited in time. This is why manual training sessions may not last long enough to get an optimal result. With the newly developed DGO, it will be possible to further improve the effect of treadmill training. Furthermore, the workload of the therapists will be reduced. Many therapists suffer from back pain after training because the work has to be done in an unergonomic position. In addition, without the use of the DGO, two therapists are usually needed to perform locomotor training.

The first trials with the DGO show that it is possible to perform automated locomotor training in paraplegic patients. The induced gait pattern is like that of healthy subjects in several aspects. Considering that patients must be trained to gain locomotor experience, training by the DGO seems to hold the promise of success.

Future Plans

The main goal of treadmill training is to "teach" the patient to walk again. The DGO should support weak movements generated by the patient himself (voluntarily
or generated by the central pattern generator). For this, an adaptive controller of the DGO is in development. To recognize the locomotor activity generated by the patient during training, force sensors will be built into the DGO to measure the forces that occur between the DGO and the legs of the patient. With this information, it will be possible to adjust the prescribed gait pattern to some extent to the movement generated by the patient. The physiological gait pattern will be adjusted during training to the individual and actual needs of the patient.

It is planned to improve all mechanical parts of the DGO so that long and secure training with several groups of patients becomes possible. A patent on the DGO is pending and it is planned to commercialize the system on the market (Hocoma GmbH, Medical Engineering, Switzerland).

CONCLUSION

The DGO trains leg movements of patients with paraplegia on a treadmill with a locomotor pattern that is in the range of physiological gait. Therefore, it can be expected that the afferent input generated by the automated training is at least as effective as that produced during manual training. The main advantages of the robotic training are obvious. First, the reproducibility of the movement: It will be possible to test the effects of different gait parameters (speed, step length, amplitude) to optimize the training program. Once these optimal trajectories are found, the DGO can always reproduce them, while therapists usually have to practice for a longer time until they are able to perform optimal training. Nevertheless, therapists still are needed to ensure the effectiveness of the training by monitoring the progress in locomotion and to supervise the training session. Second, the locomotor training sessions can be prolonged and the walking speed can be increased.

It is expected that with more intensive training of paraplegic patients, the effect and outcome of locomotor ability can be enhanced compared to manual training. Furthermore, it seems logical to replace the therapist with a robot to perform locomotor training: monotonous work that has to be done in a well-defined manner for a relatively long time. This seems to be predestined work for a machine, especially as the work for the therapist is neither attractive nor ergonomic. Walking is a rather complex task, and thus the actual version of the DGO cannot reproduce a perfect physiological gait. However, with the foreseen improvements of technology, it will be possible to obtain an optimized approach that would not be possible by manual assistance.

REFERENCES