Technical Developments for Rehabilitation of Mobility

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ABSTRACT

Technically assisted rehabilitation of mobility after stroke has been well established for several years. There is good evidence for the use of end-effector devices, exoskeletons and treadmill training with and without body weight support. New developments provide the possibility for functional training during mobilization, even in intensive care units. Mobile exoskeleton devices have been developed, but their clinical effects need still to be evaluated. All devices should not only focus on increasing the number of repetitions, but also include motivational aspects such as virtual reality environments. Hygienic aspects impose a special challenge. All devices should be integrated into a rational and clearly-defined therapy concept.

Introduction

Technicallyassisted rehabilitation of mobility after stroke has been well established for several years [1]. The premise “if you want to learn to walk, you have to walk” is of primary importance. In 1995, the working group led by Stefan Hesse showed that repetitive training of walking movements using a treadmill leads to greater improvement of walking ability in stroke patients compared to conventional physiotherapy [2].

Since using a treadmill for severely affected patients is not an optimal approach, alternative solutions have been sought [3]. Almost simultaneously two technical solutions were developed. By developing the electromechanical Gangtrainer GT1®, the Berlin group created a so-called end-effector device in which the trajectory of the gait cycle is predefined and the body’s center of gravity is controlled by a belt system in the vertical and horizontal direction. An alternative technical solution, the Lokomat®, was developed by a Zürich working group as an exoskeleton which uses motors to control the knee and hip joints, so that the patient can perform gait exercises even in the case of complete paraplegia.

These approaches can now be classified as clearly evidence-based. Within the framework of the guideline initiative of the German Society for Neurorehabilitation, the guideline “Rehabilitation of Motor Function after Stroke” (ReMos) was published in 2015. Based on a systematic literature search, a total of 188 randomized clinical trials and 11 systematic reviews were identified that met stipulated quality criteria [4]. This literature was grouped not only according to interventions, but also according to the target criteria and thus the severity of the patients’ disability. Based on available evidence, different recommendations were made for gaining and improving mobility, improving walking speed, walking distance and balance [5].

However, during the last few years the rehabilitation landscape in Germany has been particularly characterized by earlier admissions of patients who are still quite disabled when leaving the primary care hospitals. This is demonstrated by massive increases in early rehabilitation treatment capacity, including those with possibilities of mechanical ventilation [6]. For patients, this development offers the advantage of being transferred early in structured

▶ **Fig. 1** Verticalization in conjunction with initiation of walking movements (Erigo®, image rights: Hocoma, Zürich, Switzerland).

rehabilitative environments where new solutions are being developed. The current state of the art as well as new developments will be discussed below.

Mobilization in the ICU

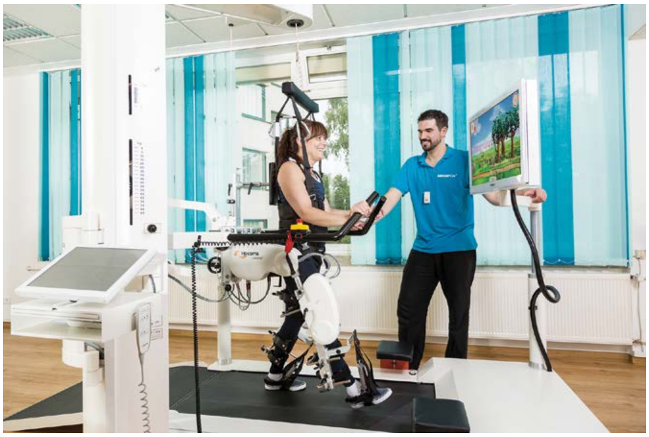
Systematic verticalization and mobilization play a particular role during weaning and rehabilitation of ventilated patients [7]; these are initial steps in the restoration of mobility which also serve to develop cardiovascular resilience. Often, questions arise regarding practical solutions for the mobilization of vegetatively unstable patients who tolerate only brief verticalization times. Simple-to-implement solutions include mobilization wheelchairs (Tina®, Thekla®) in which patients are transferred in a lying position and then brought upright into a sitting position.

Tilting table solutions combined with different stimulation methods are especially suitable for patients who are at least vegetatively stable when supine and do not have other contraindications, e. g., unstable brain pressure or unstable fractures. One solution directed toward restoration of mobility is the Erigo® produced by Hocoma which has a mechanism to perform cyclical leg movements that mimics walking (▶ **Fig. 1**). This allows simultaneous verticalization and initiation of gait movements for patients who could not perform gait training because of insufficient cardiovascular capacity [8]. There are also approaches using vibration plates to promote vigilance [9]. The common underlying concept of all these approaches is that verticalization is not an isolated goal, but that this phase of rehabilitation with improving cardiovascular situation should also be used for motor or cognitive stimulation. In addition, such devices are used directly in the wards, which minimizes transport and set-up times. However, problematic is often their size, or the necessity of patient transfers out of the intensive care bed which sometimes inhibits daily use directly at the bed.

▶ **Fig. 2** End-effector device (electromechanical Gangtrainer GT1®, image rights: RehaStim, Berlin, Germany).

Initiation of Walking Movements

The initiation of gait movements should take place as early as possible after the patient achieves sufficient cardiovascular stability. Various developments have been implemented in this regard. The electromechanical Gangtrainer GT1® developed by the group of Stefan Hesse [10] is a so-called end-effector device in which the trajectory of the gait cycle is predetermined (▶ **Fig. 2**). This device has been a major clinical and commercial success and has now been installed in over 100 facilities worldwide. In recent years, numerous new machines have been introduced to the market, varying the basic therapeutic principle as well as offering stimulation and feedback procedures. The G-EO® not only simulates walking on a even plane, but also has simulation algorithms that allow the patient to practice stair climbing and descent [11]. The Lyra® produced by the Swiss company Ability has been particularly optimized with respect to ergonomics. In principile, the effectiveness of



▶ **Fig. 3** Exoskeleton device (Lokomat®, image rights: Hocoma, Zürich, Switzerland).

end-effector-based devices for restoration of walking function in initially non-ambulatory patients is now undisputed [4].

However, this therapeutic approach also has problems. Particularly in the case of very severe paresis with additional knee joint instability, there is still the need for therapeutic guidance during movement execution. Thus, based on preliminary work with paraplegic patients, the Lokomat® exoskeleton device was developed at the Balgrist University Hospital in Switzerland [12]. In contrast to end-effector devices, the exoskeleton approach guides not only the foot position, but also controls hip and knee flexion (▶ **Fig. 3**). This method achieves a significantly higher degree of reproducibility of individual movements. In practice, this approach means that even seriously neurologically affected patients can be treated without greater staff involvement. The problem, however, are the considerably extended set-up times, since the exoskelets must be adapted to the individual body size of the patient. In practice, this requires approximately 20 minutes per patient before the therapy can start.

There is clear evidence for the effectiveness of both therapeutic approaches. For the end-effector principle with the Gangtrainer GT1®, the greatest body of data is availablefor. A total of 8 studies with more than 400 participants were conducted in a randomized controlled design, which clearly demonstrate the superiority of end-effector therapy compared to conventional training of same duration [4]. There are fewer studies for the exoskeletal principle, but they likewise prove its effectiveness. However, it must be noted that mechanicallyassisted gait training does not offer an advantage in itself, but enables the implementation of a higher repetition rate than could be realized by using only hands-on staff in daily clinical practice. If comparable exercise intensity is realized conventionally, device-assisted therapy demonstrates no superiority [13].

The comparison of both therapeutic approaches is the subject of heated controversy. It is often argued that optimal reproducibility of "physiological" movements by exoskeletons should have a better therapeutic effect than the higher variability of end-effector devices. However, this is only true if all the axes of motion specified by the exoskeleton correspond exactly to those of human physiological movements; otherwise non-physiological shear forces can occur. In fact, EMG analyses of the leg muscles showed a considerable deviation of the muscular activation pattern between exoskeletal conditions and unrestricted gait movements[14]. This deviation was not noted to the same extent when an end-effector mechanism was used [10]. Likewise, indirect data analyses did not confirm the advantages of the use of an exoskeleton [15], suggesting that physiological training even requires a certain degree of variability among step cycles. Pragmatically, the exoskeleton principle imposes fewer demands on head and trunk control and can therefore be used even earlier in the rehabilitation process. This is offset by the significantly increased set-up time and typically by a difference in acquisition costs.

▶ **Fig. 4** Mobile exoskeleton (ReWalk®, image rights: ReWalk Robotics GmbH, Malborough/Berlin, Germany).

The Lokomat® is a stationary device that virtually can only be used in larger rehabilitation centers. In recent years, advancing miniaturization and improvement of battery technology, however, have resulted in significant development in the form of mobile exoskeletons (▶ **Fig. 4**), which can be individually adapted to the patient. Thus training takes place no longer "on the spot", but in a real environment. Direct comparison of mobile exoskeletons with the Lokomat® is limited, since mobile exoskeletons rely more heavily on torso stability. Training using these devices typically requires additional employment of forearm crutches. Nevertheless, the potential is substantial since this approach can be used practically independently of spatial conditions. Various suppliers are already present on the market. Similar to the Gangtrainer® and Lokomat®, the following devices have been designed primarily as therapy equipment: Ekso GT® by Ekso Bionics [16], the INDEGO® by Parker-Hanifin [17] or ReWalk® by the company of the same name [18]. However, it must be said that, currently, it can only be assumed that the clinical efficacy is similar to that of the stationary exoskeleton devices. There are no separate randomized clinical trials to date [19]. In addition, some products (e. g., ReWalk®, Indego®) also have approval as an electromechanical prosthesis, e. g., for patients with a high degree of paraplegia, as an aid for unassisted movement in everyday life. However, walking with these devices is possible only with crutches. Further clinical experience and studies are required to confirm the optimal use of these different models in everyday practice.

Improvement of Walking Speed and Distance

For patients who are ambulatory (at least with help;FAC ≥ 3), treadmill training is particularly useful. Studies have shown that these patients experience improvement in walking distance and speed [4]. However, this was not confirmed by a recent large treadmill study [20] which is probably due to "conventional" physiotherapy (as control condition) having shifted the focus to intensive and early gait training as well. Exoskeleton devices are less useful for these patients [21].

On closer examination, it becomes clear that treadmill training can basically combine two effective principles. On the one hand, the high number of repetitions of gait movements leads to movement optimization. On the other hand, intensive cardiovascular exercise is exerted, which fulfills the criteria of aerobic endurance training of the American Heart Association [22]. In principle, the first effect can also be achieved by intensive exercise on the ground. In principle, this is also true for the second effect is, but it is much easier to achieve with the aid of the treadmill, in particular when patients are still in a danger of falling. However, it should be noted that cardiovascular training alone, e. g., on a stationary bicycle, has no positive effect on walking distance or walking speed [23]. These parameters are only improved if endurance training is integrated in a functional context.

Thus, treadmill training with or without partial weight support with a speed as high as possible is, without a doubt, a highly effective therapeutic procedure for patients in the subacute as well as in the chronic stage after stroke, even if the contribution of these two different working mechanisms still has to be clarified.

Reinforcement through Visualization and Motivation

Both end-effector devices and exoskeletons support non-ambulatory patients while walking. However, assistance offered by external aids can lead to passive behavior during training and reduce effort. Thus, repetitive walking movements by the patient should be supported with motivational techniques. Experienced therapists use verbal instructions to induce increased effort in leg movements through increased muscle activation. Newer approaches to this goal are offered by virtual reality techniques which have been developed by the game industry [24]. Sophisticated solutions have been developed, especially for the Lokomat®, which show the patient's movement, mapped in speed and direction, on a large screen. Additionally, the interaction between the patient in the Lokomat® and virtual objects along the pathway are displayed. Already for safety reasons, externally-driven exoskeletons are equipped with sensors at the hip and knee which detect interacting forces between the patient and the mechanism. Various games have been developed, using this sensor information for an individual game. Children enjoy kicking a football and competing against virtual opponents. Adults, for example, can watch their virtual dog run away if they slow down due to insufficient muscle activity. Initial clinical studies have shown that these additional aspects can increase the patient's effort, thus enhancing the effect of device-based training further [25].

It is worthwhile to differentiate among the various elements that are introduced into this environment. Some studies suggest, for example, that the movement-synchronous representation of a body in a virtual environment (avatar) has additional effects that go beyond the purely motivational aspect of a playful environment. Initial concepts of classifying different environments have been presented [26]. On the whole, it should be noted that "mor colourful" and "more sophisticated" computergraphic environments do not necessarily have to be more effective, especially in cognitively limited patients.

Long-term Effect of Training

It is crucial for the patients that the effects of their training persist. At a first glance, data are heterogeneous. As a rule, patients who have achieved their basic walking ability during the subacute stage after stroke may continue to improve it in subsequent months. Patients who have not achieved this milestone during the first months – or only to a lesser extent – generally only make limited progress during the following weeks and months [13, 27].

On the other hand, this seems to be different for achieved high walking speed and long distance. Both in the subacute and chronic stage after stroke, such gains are even lost if not maintained. On closer examination, however, there is no contradiction between these observations. Those patients who have improved their walking ability at the beginning have been able to practice it afterwards in everyday life. They usually do not practice, however, long distances or high velocities. In summary, as in sports, it is a matter of "use it or lose it". Technical support can help both to acquire these abilities as well as to maintain them.

Hygienic Aspects

In addition to the above-mentioned pathophysiological and pragmatic considerations, it is also necessary to take into account patients with multiresistant germs, which are increasingly common in the rehabilitation environment [28]. It is obvious that a higher degree of external therapeutic guidance places greater demands on hygienic practices. Unfortunately, this aspect has not been sufficiently documented for many devices. For textile components (belts, etc.) separate sets for individual patients are indispensable. In addition, sufficient surface desinfection must be possible. Hollow parts (such as for size adjustment) and open access to the mechanics represent a particular risk. Using such equipment with patients with a high contagion risk must be considered carefully. It remains a clinical dilemma that the patients with the greatest need for elaborate technical assistance also have the highest probability for restrictions for hygienic reasons. For these patients, more uniform and validated procedures are required.

Future Developments

Stationary electromechanical gait training devices, long on the market, are mature products, as evidenced by their broad employment in rehabilitation facilities. In contrast, mobile training devices are still in a phase of rapid development. Software advances will reduce existing problems with maintaining balance and expand training options. Technical durability will improve and more flexible adaptability will further improve usability. It is to be hoped that increasing the number of units produced will allow to reduce the dauntingly high prices. On the horizon, further new technologies are in development which are based on innovative textile materials and require few rigid structures ("soft exosuits").

Finally, however, it should also be pointed out that all these technologies can support individual therapy to increase the intensity of therapy while reducing the physical stress on therapists. In no way, device-supported therapy can completely replace individual therapy. All new technical developments must be integrated into a meaningful clinical therapy concept with clearly-defined inclusion and exclusion criteria. At the same time, the transfer of therapy into everyday life must always be kept in mind.

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Conflicts of Interest

F. Müller was a member of the Medical Advisory Board of Ekso Bionics. C. Dohle and K. M. Stephan declare no conflicts of interest.

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