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Exoskeletons in MS rehabilitation are ready for widespread use in clinical practice: Yes

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People with multiple sclerosis (MS) show several motor, sensory, and cognitive dysfunctions, which need to be dealt with specific neurorehabilitation approaches. Walk recovery still is the primary goal for these patients, because achieving independent ambulation is a major contributing factor to their quality of life. Although physiotherapy treatments have proven effective in improving gait and balance, conventional overground walking training may result very difficult or even impossible for patients with severe gait problems.[1]

This commentary focuses on whether robotic interventions, aimed at improving functional outcomes in people with MS, are effective and may be widely used in clinical practice. Robot-assisted rehabilitation is definitely the technology that has shown the greatest advances in the last two decades, especially in the rehabilitation field. Generally speaking, the robotic rehabilitation devices are typically based on motor learning, resulting from intensive, repetitive, and task-oriented motor activities that require the patient's effort, attention, and engagement.[1,2] Robotic rehabilitation systems can be divided into end-effector and exoskeleton devices. In the end-effector systems, movements are generated by the most distal segment of the extremity and no alignment between patient–robot joints is required, whereas the exoskeleton systems have a one-to-one correspondence between robots and human joints, and each single joint is guided along a pre-programmed trajectory. Exoskeletons therefore offer higher levels of safety and better training in patients who are severely impaired.[1] Moreover, gait robotic rehabilitation systems can be classified into stationary (such as the Lokomat, consisting of a powered gait orthosis with integrated computer-controlled linear actuators at each hip and knee joint, a body weight support, and a treadmill) and overground walking systems (also known as powered exoskeletons).[1,2]

The use of robotic-assisted gait training (RAGT) has proven effective in potentiating gait parameters, as well as spasticity and other non-motor symptoms, in different neurological disorders, including MS.[3–5] In particular, RAGT using stationary exoskeletons can be feasible and efficacious in MS patients with severe disability (Expanded Disability Status Scale (EDSS) 6.5–7.5), as these devices can improve gait speed and resistance, as well as increase muscular strength. Positive outcomes after RAGT have also been found in patients affected by progressive MS, which is known to have a worse prognosis.[6]

Powered exoskeleton treatment has instead been tested on patients with moderate gait impairment (EDSS <6), who showed an improvement in gait resistance and in the ability to climb up stairs.[2,6] Notably, RAGT is often administered in addition to other conventional treatments, such as physiotherapy, occupational therapy, hydrotherapy, and/or neuropsychological treatments. Then, we may think about this novel approach as an add-on treatment able to further increase functional outcomes, especially in severely affected patients.

In the last few years, different authors have attempted to demonstrate the clinical efficacy of robotics in patients with MS, mainly focusing on motor outcomes.[7–9]

In their recent systematic review, Bowman et al. found that RAGT, provided with exoskeleton devices, improves balance and gait outcomes in a clinically meaningful way, thanks to their several advantages in terms of safety, motor assistance, and intensity of training. Then, the authors concluded that RAGT should be used in patients with MS and severe disability in a multimodal rehabilitation context as an opportunity to maximize their functional recovery.[7]

Although the review by Yeah et al. demonstrated that RAGT is comparable to conventional treatments in improving walking performance, pain, and quality of life, robotics is significantly superior in improving perceived fatigue and spasticity. Given that these latter symptoms are predominant and RAGT is safe and well tolerated by people with MS, this should be considered as a potential treatment also in clinical settings.[8]

A recent review by the “CICERONE” group has comprehensively investigated all of the main functional outcomes related to the lower limbs after treatment with RAGT in patients suffering from MS.[9] This work demonstrates that training with robotic devices, such as Lokomat or Reha-Stim, is feasible and significantly effective in MS patients, due to their potential for improving gait speed, gait resistance, and balance. Moreover, patients affected by spasticity may benefit from this type of training, especially when robotics is coupled with drugs, such as nabiximols, acting as neuromodulators.[10] Finally, an improvement in several types of other non-motor outcomes including pain, fatigue, depression, and quality of life following RAGT has been found. These data support the idea that RAGT could be used in clinical practice, also considering their effects not only on motor but also (and especially) on non-motor outcomes that negatively affect MS people’s quality of life. Unfortunately, to date, no clear clinical indications on the use of RAGT in individuals with MS have been provided. Based on the available literature data, in order to overcome this important issue, the authors suggest that different training with different approaches and kinds of devices should be used in the different stages of the disease, taking into consideration the patients’ EDSS level. More in detail, patients with an EDSS score of 5.5 to 7.5 would benefit more from stationary exoskeletons, those with a moderate disability (EDSS 3.5–5) should be treated with either end-effectors or powered exoskeletons, whereas patients with mild gait impairment do not need RAGT.[9] Specific protocols on RAGT treatment frequency, duration, and intensity are, however, needed to maximize the effect of this training in clinical settings.

In conclusion, based on the existing data, RAGT may be considered a valuable tool for the treatment of patients with MS and it is ready for widespread use in clinical practice. In fact, following this innovative approach, MS patients (especially those with severe disability) can improve not only their motor outcomes, such as gait speed and endurance, but also non-motor symptoms, with regard to spasticity and fatigue, with a consequent betterment of their quality of life.

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Exoskeletons in MS rehabilitation are ready for widespread use in clinical practice: No

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The last 15 years there is a strong increase in scientific literature related to the use of rehabilitation robotics and technology for people with multiple sclerosis (MS). Currently, different types of commercial rehabilitation robots are on the market. For upper limb rehabilitation, static exoskeletons (e.g. Armeo Spring) and end-effector devices (e.g. Haptic Master) are mostly used. For lower limb and gait rehabilitation, besides static exoskeletons (e.g. Lokomat system) and end-effectors (e.g. Geo-system) also wearable exoskeletons (e.g. EksoNR system) have made their appearance in recent years.[1,2] Nevertheless, only a limited number of rehabilitation hospitals, and almost no small rehabilitation centers or private clinical practices provide exoskeleton training for people with MS. Reasons for this can be various.

First, despite the growing evidence regarding exoskeletons, firm conclusions on the effectiveness are still missing. This is mainly because clinical studies with exoskeleton training in MS are often pilot or case studies, while large randomized clinical trials with more homogeneous populations are absent. Moreover, the clinical studies in MS with robotic devices show mixed results. In general, in several pilot studies significant improvements on robot-generated measures were reported, but fully statistically powered clinical studies are rare. Besides, the reported changes do not always reflect clinical important differences on the traditional clinical measures.[1] Another important aspect to consider before we start the widespread use of exoskeletons in MS relates to the specific patient subgroup that may benefit. Indeed, it is suggested that clinical effects of robot-assisted gait training are superior to conventional treatment in severely (but not in moderately) affected people with MS.[1,2] These results were implemented in the figure published by Calabro et al.,[3] where patients gait deficits (based on Expanded Disability Status Scale (EDSS) scores) were plotted relative to the type of the therapy and devices (from overground walking training to powered exoskeletons to grounded exoskeletons).

Second, the focus of exoskeleton training needs to be expanded. Besides motor improvements such as walking ability and muscle strength, exoskeletons can also be used to improve cardiorespiratory, psychological, and social outcomes. For example, the use of robot-assistance also affects the level of metabolic and cardiorespiratory load during gait training (i.e. parameters such as oxygen consumption, heart rate and minute ventilation). For severely impaired neurological patients who cannot walk independently, therapists could use exoskeletons to induce low-intensity aerobic exercise. The awareness of these effects by therapists is particularly important since neurological patients are often confronted with impaired cardiorespiratory fitness levels.[4,5] Related to exoskeleton training, fatigue has been poorly investigated, but preliminary data show improvements after robotic treatment.[3] Also noteworthy are the improvements on psychological and social outcomes. For example, in the case study of Wee et al.[6] results after 15 weeks training with a powered exoskeleton showed important improvements on transfer ability, but also on psychological and social outcomes (i.e. meaningful significant change on quality of life and improvements in self-esteem, self-confidence and sleep quality).[7] It is known that adding virtual reality during rehabilitation can be useful to promote neuroplasticity and recovery in persons with MS, increasing subjects' motivation and compliance.[2] Combination of exoskeleton therapy with virtual reality, can increase the impact on motor and non-motor outcomes such as psychological well-being and quality of life.[3,8]

Third, although there is progress related to the usability of exoskeletons there is still a lot of improvement possible. For stationary and mobile exoskeletons, patients and therapists reported high levels of satisfaction. The effectiveness, safety and impact on the patient's gait were highly rated, while comfort, weight, and ease of use of the device were reported as elements that should be improved.[9,10] It is known that for a first training with an exoskeleton donning times of 20 min are needed, and for the subsequent trainings 10 to 15 min. Bearing in mind that a normal physiotherapy session is between 30 min and 1 hr, this means that a significant amount of time is lost on the patient setup only. Consequently, this aspect is an important issue to address in the development and construction of gait rehabilitation robots by engineers. Training and organization must also be considered when using rehabilitation exoskeletons as only certified therapists are allowed to train patients with these systems. Another complexity is that the current exoskeletons are not possible to use without a therapist. In general, donning and doffing is too complex for the patient to do it without assistance of a therapist and patients need help maintaining their balance while walking with a mobile exoskeleton, even in combination with the use of crutches, walkers, or canes. Exceptionally, after a lot of training, a single patient can walk independently with a mobile exoskeleton, but safety and insurance regulations do not allow this.

Finally, the business case of exoskeletons is an important barrier for the more widespread use of exoskeletons. Since these wearable robots are still new to the market, their acquisition comes at a high price which makes them unattainable for individuals, but also for small rehabilitation centers. The cost of the devices must become more affordable, and the robotic therapy must be reimbursed in health insurance policies.

To conclude, exoskeletons in MS rehabilitation are not yet ready for widespread use in clinical practice. These systems are more and more used in MS rehabilitation and there is an increased amount of scientific research that show promising results. In general, it can be concluded that the results are more promising in persons with limited mobility (i.e. high EDSS scores) than in patients with minimal physical limitations (i.e. low EDSS scores). Nevertheless, there are still many stumbling blocks related to effectiveness, usability, and financial aspects, before exoskeletons can be widely used for people with MS in clinical practice or even in home situations.

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Exoskeletons in MS rehabilitation are ready for widespread use in clinical practice: Commentary

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Rehabilitation has been recognized as the best, and perhaps only way to restore function in persons with MS.[1] Recently, the application of robotic exoskeletons in MS rehabilitation has garnered much attention, as this approach is associated with a host of advantages relative to manual rehabilitation. Thus, the current controversy addresses whether or not robotic exoskeletons are ready for widespread use in clinical practice settings among persons with MS.

In their arguments, both Calabrò[2] and Swinnen et al.[3] refer to data involving numerous applications of robotics in MS rehabilitation including robot-assisted gait training (RAGT); fixed, upper-extremity exoskeletons; and powered exoskeletons used overground for rehabilitating numerous functions across the MS disability spectrum. It is particularly noteworthy that both positions acknowledge the rapidly growing literature on the promising effects of wearable, powered exoskeletons.

Calabrò[2] presents several review studies supporting the implementation of robotic exoskeletons within clinical rehabilitation; however, these primarily involve RAGT using the Lokomat, which is a passive device without the need for volitional control. Over the years, powered exoskeletons have been developed which address several weaknesses of the Lokomat, particularly the ability to perform robotic-assisted rehabilitation overground, wherein the user has some degree of volitional control of movement. To that end, Calabro articulates that robotic exoskeleton rehabilitation is not a one-size-fits-all endeavor, whereby MS disability status should influence the choice of robotic exoskeleton within clinical settings.[2] This point is echoed by Swinnen et al. with the caveat that such a hypothesis must be directly tested and supported by strong data prior to broad-scale implementation.[3]

Despite promising early-stage evidence supporting the benefits of robotic exoskeleton rehabilitation in MS, we agree with Swinnen et al who call for appropriately powered clinical studies.[3] One such recent RCT reported that 3 months of powered exoskeleton rehabilitation was associated with improved gait speed (10 meter walk) and functional mobility (timed up and go, TUG), whereas physical therapy (control condition) was not associated with such improvements.[4] Interestingly, the pattern of results were observed in the absence of elevated perceived fatigue, an important point identified by Swinnen et al.

Despite arguing the “no” position, Swinnen et al correctly identify that both patients and therapists report high levels of satisfaction, effectiveness, and safety with powered exoskeleton rehabilitation, as well as the need for improvements in comfort, weight and ease of use.[3] Of note, these latter points do not preclude clinical utility of powered exoskeleton rehabilitation in MS.

We agree that the focus of exoskeleton training should be expanded beyond mobility. This indeed has been observed in other populations such as spinal cord injury, showing improved cardiovascular health,[5] bowel/bladder function, psychological outcomes, and decreased secondary complications such as urinary tract infections.[6–8]

Overall, powered exoskeleton rehabilitation can provide intensive practice of high-quality rehabilitation in persons with MS, with the potential to induce significant improvements in functional mobility, and perhaps upper-extremity function. There are now a growing number of studies in clinical settings to support this claim for persons with MS. Thus, there appears to be enough evidence to support a clinical decision that can be utilized by the therapist. However, support for widespread use requires additional clinical studies to examine when such treatment should be used, appropriate dosing information, MS target populations, long term outcomes, and for precisely what clinical outcome. Issues of therapist training, equipment costs, market accessibility, and insurance might further limit its widespread use. Nonetheless, continued development of lighter, easier fitting and more comfortable equipment, coupled with continued outcome research and regulatory approval (already available for some systems in the USA) suggest a bright future for powered exoskeleton rehabilitation in persons with MS.

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