

Are we there yet? A review of current medical lower-limb

exoskeleton

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Abstract

Functional disability is one of the prevalent sequelae for patients with nerve or muscular impairment. The exoskeleton therapy is a novel training method which could help eliminate those functional disabilities. In this review, we introduce the growth of medical lower-limb exoskeletons and the current clinical classifications. The clinical usages of therapeutic lower-limb exoskeletons (TLLE) with different medical conditions are presented afterwards. A TLLE case, ExoMotus M4, would be analyzed to identify to what extent the existing commercial TLLE satisfies the clinical needs. Finally,

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a research and market trend of TLLE is discussed.

1. Background

Functional disability is often reported among patients with nerve or muscular impairment [1]. For example, stroke has a lifetime risk is about 25% globally from 25 years [2]. Patients with this high-risk disease often report lower limb functional disability as one main symptom [3]. Other neurological diseases, such as spinal cord injury (SCI) [4] and multiple sclerosis (MS) [5], are also reported with lower-limb disorders. These sequelae are strongly and negatively impacting those patients' quality of life. Early mobilization [6] and very early mobilization [7] are recommended for post-

neurological rehabilitation as soon as the medical condition is stabilized [8]. These opportune interventions strategy would help benefit the patient's medical condition by minimizing deficits and stimulating neuron recovery. However, traditional early mobilization requires a heavy workload [9]. For example, therapists are advised to spend 45 minutes on early physical and occupational therapy [10]. This workload would be too heavy for therapists to keep presenting effective treatment during the whole day. Furthermore, output quality might vary with therapists individually.

Therapeutic exoskeletons, or training method for patients exoskeletons for rehabilitation, requiring early mobilization. would be an alternative strategy.

Therapeutic lower-limb exoskeletons (TLLE) are a series of robots with power units attached to the lower limbs of the users. These units could output force to help support the user's body and move the hip, knee and ankle joints synchronized following the gait trajectory [11].

The advantages of TLLE are firm weight-support structures, robust gait-correction trajectory, and high tolerance to workload [12]. Under a high volume of those passive or assistive gait training, the patients' gait trajectory and quality of life would be improved. These make the exoskeleton become a novel

2. The history of medical lower-limb exoskeleton

The first medical exoskeleton, named 'active exoskeleton for rehabilitation', was designed at Mihailo Pupin Institute (1969) in Serbia [13]. This exoskeleton was powered by a pneumatic system and controlled partly by a kinematical program. The Rudimentary technology was the legged locomotion system [14]. This is believed as the first exoskeleton for handicapped individuals' rehabilitation. The predecessor of the electrically powered exoskeleton, i.e. pilot study using the electric motor as

an actuator, would be the one designed five years later [15].

The first accessible research for clinical exoskeleton experiments is defined as the HAL in 2009 [16].

The Japanese group applied this single-leg version of HAL to one individual with hemiplegia. This case study discovers that HAL working as an assistive exoskeleton would improve the walking speed and distance of the user. In 2011, another exoskeleton research group called 'Vanderbilt Exoskeleton' [17] started to present their design for the disabled cohort. Then a growing amount of attention is absorbed in this exoskeleton field. Several new brands of commercial exoskeletons have been gradually

allowed to enter the world market afterwards.

3. The applications of medical lower-limb exoskeleton

This review divides exoskeletons into two different medical applications: exoskeletons for assistance, and therapy purposes.

Assistive exoskeletons are mainly orthosis-like size robots. Users are those who could provide voluntary muscle strength. Those individuals might also have reached the bottleneck of rehabilitation generally. The aims of these exoskeletons are mainly for daily gait assistance and supporting activities of daily living (ADL). A large frame for guaranteeing patients' safety is not required. Instead, whether the exoskeleton is

comfortable, wearable and less occupied for room-walk would be key point for the users.

Instead, exoskeletons for therapy mainly help improve lower limb recovery of the users. High repetitions of gait guidance powered by the exoskeleton would stimulate neuron recovery and other circulating systems such as the metabolic and cardiovascular systems [18]. However, the

medical conditions of these TLLE individuals might challenge the robustness of the exoskeleton. For example, spasticity is often reported among post-stroke patients. The high muscle tone and little voluntary lower-limb muscle strength (Medical Research Council MRC grade 0-2) might prevent the power units from

repeating the correct gait trajectory which could be easily provided among healthy users [19]. For better gait correction, the main requirement of those exoskeletons would be the robustness of the providing gait trajectory and body-weight support. Solid but large external structures are often one typical feature of these therapeutic exoskeletons.

4. Clinical usability

Recent research has demonstrated the possibility of exoskeleton therapy for several neuromuscular recoveries, such as post-stroke [20], and post SCI [21]. Additionally, the positive result could be seen not only in the walking phase but also in cardiovascular health, muscle tone

and many other aspects. Therefore, to present thoroughly, the following paragraphs explain the general benefits of TLLE therapy.

4.1 general usability

Exoskeleton therapy is used for much more than motor recovery. Through guided walking, patients would regain motor learning [22], stop muscular atrophy [23] and improve cardiovascular health [24]. In addition, since the exoskeleton supports the user to stand vertically, the body weight would also vertically pressure the organs and skeletal system [25], which then could re-promote the organs' function [26] and facilitate the bones to cease potential fracture [27]. Furthermore, clinicians have discovered the obviously positive result when applying this therapy

for declining muscle tone and reducing the degree of spasticity [28].

4.2 typical illness

4.2.1 Stroke

Individuals who suffer from stroke would have neurological deficits, which lead to motor coordination dysfunction. Abnormal gait performance is basically due to this neurological disorder [29].

One current study reveals that exoskeleton therapy would have 'a significant immediate impact on stroke subjects' lower-limb muscle synergy pattern' [30]. Researchers tested the intervention with an exoskeleton on ten post-stroke patients. Results indicated that exoskeleton therapy would benefit lower limb muscular coordination

by changing the previous muscle synergy pattern. This finding, predicted by the academic group, might help patients to regain mobility.

4.2.2 Spinal Cord Injury (SCI)

SCI, normally caused by traumatic damage, is another neurological impairment leading to functional disability. Two types of SCI are divided by their degree of injury: incomplete SCI which the damage of the Spinal Cord is not completely blocking the neuromuscular transmission, and complete SCI which the transmission is blocked by the lesion [31]. Both two SCI groups would present a sedentary or bed life-style, similar to post-stroke survivors, which subsequently causes several complications, such

as bone mineral density loss [32], organ dysfunction [33] and so on. These circumstances help to absorb the researcher attention on exoskeleton therapy outcome.

For complete SCI recovery, researchers test the effects of exoskeleton therapy for an 8-week gait training, with an intensity of 2 sessions (1 hour/session) per week. The result shows that patients can not only have better performance (faster speed, lower energy cost, no injury case) than traditional lower-limb orthosis during walking. Furthermore, bone mineral density is also increased [34].

For incomplete SCI rehabilitation, the exoskeleton would enhance the motor function for further recovery. One study [35]

indicates that the passive training mode would facilitate the proprioception in a 2-day training. The promoted outcome would then positively impact motor function.

Exoskeleton therapy would also regain the function of organs. Researchers found that the incomplete SCI patients under this therapy would have improved bowel function after a 12-week training. Providing vertical gravity and increasing bowel transit time [36] would be the reasons [37]. A recent study [38] reproduces a similar improvement of bowel function in both incomplete and complete SCI patients with a 12-week training with an intensity of 30 minutes*5 times/week. The research group also discovered that this training mode could

enhance bladder function. These outcomes would upgrade the quality of SCI patient's life.

4.2.3 Cerebral palsy

According to Freeman Miller, cerebral palsy (CP) is a motor disorder caused by lesions in the cerebral brain [39]. This disease would last for a life-long time and gradually influence the patient's motor function till the total loss of mobility if no intervention could be given [40]. The gradual dysfunction in motor, with muscular spasticity on one side and hyper-extension on the other side, is definitely influencing the patient's quality of life, especially for daily walking [41].

Exoskeleton could not only reduce overwhelming energy costs. Reduction of disordered soleus

activity and increase in walking speed could also be achieved. Overwhelming Energy costs limit the training duration. A study utilized exoskeleton among six individuals with different severities of CP. The result shows that obvious ameliorations are detected in more severe individuals [40]. Furthermore, one research group successfully discovered that the exoskeleton could help correct the crouch gait [42].

4.2.4 Multiple sclerosis

Multiple sclerosis (MS) is also known as one type of neurological illness. Its manifestations could be discovered in both motor aspects, such as motor deficits, and mental aspects: such as fatigue, and negative feelings [43]. These

syndromes strongly influence the patient's quality of life. However, exoskeleton therapy would manage these MS manifestations. One case study reports a positive outcome after the patient experienced the exoskeleton therapy for 15 sessions (1 hour per session twice weekly). Not only her quality of life score (The 5-level EuroQol 5-dimensions) is raised, but her cardiovascular manifestation also presents an improving trend [44]. Another trial indicates that the exoskeleton would benefit motor relearning. This pilot experiment applies exoskeleton training (2 times/week times 4weeks) for 7 MS individuals and finds that exoskeleton could improve

functional mobility and cognitive processing speed [45]

5. One therapeutic lower-limb exoskeleton case analysis

Plenty of studies have indicated the TLLE application. However, whether the existing TLLE could satisfy the clinical requirement and market is still under discussion. Thus in this part, we choose ExoMotus M4 (see figure.1). This exoskeleton could be found on the market for a TLLE case to analyze its suitability in real-world.

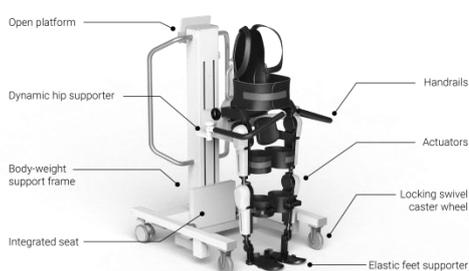


Figure.1 An overview of ExoMotus M4

5.1 Advantages of ExoMotus

M4

The external frame of TLLE for guaranteeing safety is essential.

Patients with neurological impairment are often much more sensitive to the environment than their abled counterparts. If the exoskeleton is unstable, patients could feel unsafe and have high stress. Their muscle tone might increase to prevent these patients from regular training. ExoMotus M4 provides a stable body-weight support frame and handrails to guarantee the safety of those sensitive patients. Additionally, the exoskeleton integrated with external structure is drivable. This design offers cognition rehabilitation with changing visual

input to the brain as ExoMotus M4 moves.

A machine-dominated gait trajectory with four actuators attached to both knees and hips would restrict abnormal cooperation and stimulate the correct neural pathway. This clinically friendly design would be accessible for patients with limited voluntary muscle strength.

The material of the feet supporter is another key pattern of ExoMotus M4. Instead of using materials with high rigidity, a sole-like material is applied for feet supporter. This elastic material would transfer the changing gravity feedback during the stance phase to the user and help promote the sensory organs with proprioception. The neural

pathway would then be rebuilt, according to neural plasticity [46].

Furthermore, a hip supporter with an elastic dynamic adjustment could enhance the simulation of centre of gravity shifting during gait phases. The over-ground frame design, i.e. the moveable external frame, would offer dynamic visual feedback.

The augmented walking simulation might improve neural recovery as well.

For clinical and research target, ExoMotus M4 also provide an open source platform. That is to say, this exoskeleton is accessible for secondary development. For example, one research team drives the ExoMotus M4 with its PD controller. The result shows a

successful simulation of human kinematic and physiology [46].

5.2 Limitations of ExoMotus M4

Although ExoMotus M4 has been applied in clinical and research environments, there are still limitations. One main limitation, not only for ExoMotus M4 but also among other TLLEs, is the duration of preparation. A healthy cohort could finish wearing this exoskeleton in less than one minute. However, the real-world user's medical condition is much more complex. Patients with limited cognition, and muscle strength but high muscle tone could not prepare well in a short time with the help of their therapists. Future

development for an easy-preparation structure is required.

Furthermore, the gait trajectory of the ankle joint is still vacant in ExoMotus M4. Clinically, ankle rehabilitation is much more difficult than hip or knee joint. More degrees of freedom and distal joint characteristics make ankle rehabilitation last for a long duration. The outcome is also worse in recovery results than in other joints. Therefore, ankle early mobilization should be emphasized. The robustness of the TLLE gait trajectory used by patients with a complex medical conditions such as high muscle tone is still questioned [19]. Therefore, the future design of ankle cooperation and test of clinical robustness is required.

6. Researching and marketing trend

Although this literature has indicated a wide clinical range that exoskeletons could intervene, there are still some areas that serious consideration is required before applying exoskeletons. For example, when patients still have difficulties in automatic respiratory, using exoskeleton therapy might disrupt patients' rhythm of the breath. This would then easily cause fatigue or even severe cardiovascular dysfunction. Therefore, for the cases that are not reported, therapists should use exoskeleton after thorough health monitoring. Some medical exoskeleton products might focus on developing advanced control

algorithms or actuators. However, their hardware is not that friendly to patients who use them.

Institutions that possess these exoskeletons report low frequency of usage since the unfriendly design to patients with neurological conditions [47].

As the field of Exoskeleton is increasingly researched and budgeted, reports indicate a market of 200-500 million dollars in 2021 [48,49,50,51]. A huge increase is expected in the near future from compound annual growth rate (CAGR) expectations from 12.5% [51] to 42.1 [50]. Although those 4 institutions presented different CAGRs, they all predict that Exoskeleton for medical purpose is one key market trend. Therefore, high growth of

medical exoskeleton and TLLE is still expected.

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