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Robotic rehabilitation therapy using Hybrid Assistive Limb (HAL) for patients with spinal cord lesions: a narrative review



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ABSTRACT

Background: The Hybrid Assistive Limb (HAL) is a rehabilitation device that utilizes the “interactive biofeedback” hypothesis to facilitate the motion of the device according to the user’s motion intention and appropriate sensory input evoked by HAL-supported motion. HAL has been studied extensively for its potential to promote walking function in patients with spinal cord lesions, including spinal cord injury.

Methods: We performed a narrative review of HAL rehabilitation for spinal cord lesions.

Results: Several reports have shown the effectiveness of HAL rehabilitation in the recovery of walking ability in patients with gait disturbance caused by compressive myelopathy. Clinical studies have also demonstrated potential mechanisms of action leading to clinical findings, including normalization of cortical excitability, improvement of muscle synergy, attenuation of difficulties in voluntarily initiating joint movement, and gait coordination changes.

Conclusions: However, further investigation with more sophisticated study designs is necessary to prove the true efficacy of HAL walking rehabilitation. HAL remains one of the most promising rehabilitation devices for promoting walking function in patients with spinal cord lesions.

Introduction

From the late 1990s, robot-assisted gait training for patients with spinal cord lesions was introduced with Lokomat (Hokoma) in combination with a body-weight support harness and treadmill. More recently, several types of wearable exoskeleton robots for gait training have been developed. Wearable exoskeletons are designed to support patients with spinal cord lesions to relearn standing, weight shifting, and stepping patterns for walking. Moreover, they can use various environments for training and performing activities of daily living. Wearable exoskeleton-assisted walking is an overground walking system that employs a rigid external frame to hold the lower extremities and trunk and provides power for hip and knee joint movement. Wearable exoskeletons have FDA approval or a CE mark and are commercially available, namely, Ekso, HAL, Indego, REX, and ReWalk (Table 1). The superiority of wearable exoskeleton-assisted walking training was reported by Zhang et al.,

[1] whose report showed better walking speed recovery compared with that by Lokomat.

Control mode of exoskeletons

To date, several types of wearable exoskeletons have been introduced to rehabilitate patients with spinal cord lesions [2]. The available exoskeletons can be classified according to their control mode into joystick, program and electromyogram (EMG) controlled. Various applications are possible depending on the control mode of operation. Joystick- and program-controlled exoskeletons enable the patient to regain mobility while wearing the device to compensate for the functional loss of the lower limbs. By contrast, EMG-controlled devices are triggered by surface EMG generated by motion intention and support intended motion, resulting in the integration of the patient’s voluntary drive and mechanical support. Several authors have described that the Hybrid Assistive

FDA device/drug status: Approved for this indication (Lokomat); approved for this indication (Ekso); not approved for this indication (HAL); approved for this indication (Indego); not approved for this indication (REX); approved for this indication (ReWalk).

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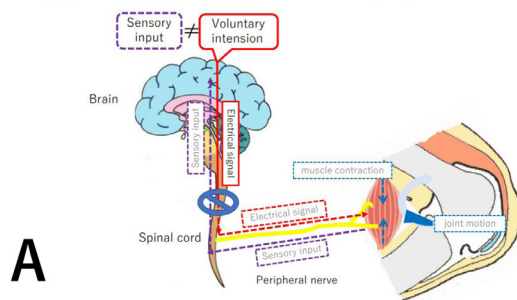
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Table 1
Characteristics of various types of wearable exoskeleton.

	Control mode	Manufacturer	Application
Ekso	Joystick/program	Ekso bionics (CA)	Rehabilitation
HAL	EMG	Cyberdine (Tsukuba, Japan)	Rehabilitation
Indego	Joystick	Ekso bionics (CA)	Community
REX	Joystick	REX bionics (Auckland, New Zealand)	Rehabilitation
ReWalk	Joystick/program	Rewalk robotics (Yokneam, Isreal)	Rehabilitation/community

Disrupted feedback loop caused by spinal cord lesions



HAL® can compensate disrupted feedback loop

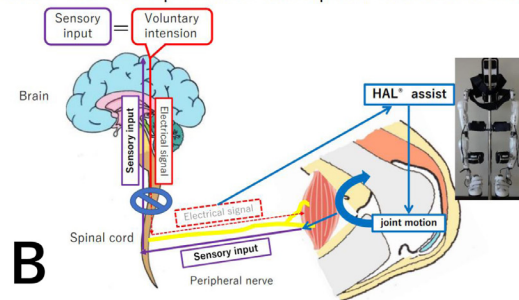


Fig. 1. (A) Disrupted feedback loop in patients with spinal cord lesion. In patients with spinal cord lesions, insufficient joint motion leads to insufficient sensory input, resulting in a discrepancy between motion intention and insufficient sensory input. (B) HAL can compensate for the disrupted feedback loop. Sensory input generated with HAL-supported joint motion, is then sent back to the CNS without discrepancy between motion intention and sensory input activate the impaired neuronal networks.

Limb (HAL), widely known as an EMG-controlled wearable exoskeleton, leads to increased patient mobility when not wearing an EMG-triggered wearable exoskeleton, even in patients with chronic spinal cord injury. Therefore, an EMG-triggered wearable exoskeleton can be used as a rehabilitation device, potentially improving walking patterns after the device is removed [3].

Interactive biofeedback (iBF) hypothesis: theoretical basis of HAL

The “interactive biofeedback (iBF)” hypothesis was first proposed by Sankai et al. [4] to promote functional recovery from neurologic disorders [5]. The motor signals evoked by motion intention are generated in the central nervous system (CNS) and conducted via peripheral nerves to initiate muscle activity, which can be detected as surface EMG signals, triggering the motion of the HAL according to the motion intention (interaction). In patients with spinal cord lesions, insufficient joint motion leads to insufficient sensory input, resulting in a discrepancy between motion intention and sensory input, which is insufficient (Fig. A). Sensory input generated with HAL-supported joint motion is then sent back to the CNS without discrepancy between motion intention and sensory input activating the impaired neuronal networks (biofeedback, Fig. B). The activated CNS, in turn, enhances its motor output. The formation of this closed “errorless” loop might promote neural plasticity and facilitates recovery from spinal cord lesions. Therefore, HAL therapy might be an appropriate approach to overcome the self-perpetuating cycle of maladapted neuronal remodeling related to insufficient motion caused by spinal cord lesions.

HAL walking rehabilitation for patients with spinal cord injury

Several reports describe HAL rehabilitation-mediated recovery of walking ability in patients with spinal cord lesions, including spinal cord injury and spinal lesions [6]. Jensen et al. [7] reported that HAL walking rehabilitation for patients with chronic spinal cord injury promoted functional and ambulatory mobility without the exoskeleton and an increase in the Walking Index for spinal cord injury Scale II (WISCI-II) score along with significant improvements in HAL-associated walking

speed, distance, and time. Brinkemper et al. [8] reported that HAL walking rehabilitation promoted improvement of physiological gait in addition to functional improvement. They showed improvement in physiological parameters such as phases of the gait cycle and significant improvement in all spatiotemporal and gait phase parameters induced by HAL walking rehabilitation. Okawara et al. [9] reported that HAL gait training for patients with chronic spinal cord injury improved results for a 10 m walking test, timed up, and go test, and WISCI-II, and Berg balance scale scores. A recovery in gait and balance function was observed in patients with high walking ability at baseline (WISCI-II score 6–20), but not in patients with low walking ability at baseline (WISCI-II score 0–3). WISCI high score patients showed improved walking speed and increased cadence, although there was no significant change in the severity of the palsy itself (no change in lower extremity motor score). Okawara et al. [10] also reported HAL walking rehabilitation-mediated improved trunk function in patients with chronic spinal cord injury. They measured trunk muscle strength before and after the HAL walking rehabilitation. There was a significant correlation between the improvement of 10 m walking test results (walking speed) and increased trunk muscle strength.

HAL walking rehabilitation for patients with compressive myelopathy

Other than for patients with spinal cord injury, HAL walking rehabilitation for patients with gait disturbance caused by compressive myelopathy had been reported by several authors [11,21]. Kubota et al. [11] reported improved gait parameters with postoperative HAL gait training for patients with thoracic myelopathy caused by ossification of the posterior longitudinal ligament (OPLL) in the thoracic spine. The effects showed superiority compared with historical controls (postoperative patients with severe thoracic OPLL who had undergone conventional rehabilitation programs), especially in patients with severe preoperative gait disturbance. Yatsugi et al. [12] reported that HAL gait training in postoperative patients with various types of spinal lesions promoted improvement of results for a 10 m walking test, and scores for the modified Gait Abnormality Rating Scale, Barthel Index, and the WISCI-II.

Possible mechanism of action of HAL

After clinical studies, several reports indicated a potential mechanism of action led by clinical findings. Sczesny-Kaiser et al. [13] reported that normalization of cortical excitability might be achieved by iBF. By measuring the motor and sensory-evoked potentials of patients receiving HAL rehabilitation, normalization of cortical excitability was proven compared with significantly increased cortical excitability in pre-HAL rehabilitation status. Ezaki et al. [14] reported HAL walking rehabilitation for patients with myelopathy caused by OPLL. HAL walking rehabilitation promoted a faster walking speed, higher cadence, and longer strides with smooth foot clearance and shortened swing time in both acute and chronic phase patients. Three-dimensional walking analyses revealed that a double knee action appeared in both acute and chronic groups after the HAL walking rehabilitation, by contrast with knee hyperextension shown in a common gait impairment in patients with OPLL. These improvements might contribute to a smoother and healthier gait motion. Kadone et al. [15] reported improved muscle synergy promoted by HAL walking rehabilitation in a patient with thoracic myelopathy caused by OPLL in the thoracic spine. In their report, HAL walking rehabilitation enhanced the activity of the extensor muscles for weight-bearing and reduced knee extensor and increased hip extensor activations to achieve larger steps and faster gait, increasing the number of muscle synergies during walking and modulating muscle network properties. The patient acquired a nearly normal joint profile with a greater range of joint motion, faster walking speed, and longer stride. Therefore, it was suggested that HAL promoted the alteration of control of the muscles by the CNS during postoperative walking [15]. Grüneberg et al. [16] reported that HAL walking rehabilitation could attenuate difficulties of voluntarily initiating joint movement. Their article identified 2 cognitive control strategies, shaping and compensation of gait, which can contribute to the attenuation of voluntary initiation of joint motion. Puentes et al. [17] reported gait coordination change caused by HAL walking rehabilitation in postoperative myelopathy patients. Kinematics analysis suggests that HAL improved the gait coordination of acutely affected patients by supporting the relearning process and, therefore, reshaped the gait pattern. These lines of evidence suggest the potential of HAL walking rehabilitation to improve and reconstruct the gait function of patients with spinal cord lesions.

Limitations

To date, studies of HAL gait training rehabilitation for spinal cord injured patients have severe limitations. First, there is no study with high-level evidence for HAL walking rehabilitation in patients with spinal cord lesions. Therefore, the definitive efficacy of HAL walking rehabilitation for spinal cord lesions has yet to be proven. Future well-designed clinical trials with high-level evidence are needed to draw definitive conclusions. Second, the optimal population whose severity and neurologic level of injury can be most benefited remains unknown. In other words, appropriate potential participants with spinal cord lesions for future clinical trials using HAL gait training remain unclear. There is a possibility that most severe palsy cannot be attenuated by HAL walking rehabilitation alone, and a combinatory therapeutic strategy might be needed. Third, an optimal therapeutic time window of HAL for walking rehabilitation for patients with spinal cord lesions remains unknown. Zieriacs et al. [18] compared outcomes of HAL walking rehabilitation between patients with acute and chronic spinal cord injury. Patients with acute and chronic spinal cord injury both showed significant recovery of walking parameters, including results for 10 m and 6 min walking tests, and improvement in WISCI-II score. By contrast, patients

with acute injury showed significantly better improvement. As a result, the accurate therapeutic time window of HAL walking rehabilitation cannot yet be determined.

Conclusion

Robotic rehabilitation, especially for a HAL EMG-triggered wearable exoskeleton, is one of the most promising rehabilitation devices to promote walking function in patients with spinal cord lesions. However, further investigation with a more sophisticated design is needed to prove the true efficacy of HAL walking rehabilitation.

Declarations of competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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