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Effectiveness of an innovative hip energy storage walking orthosis for improving paraplegic walking: A pilot randomized controlled study

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ABSTRACT

Background: The high energy cost of paraplegic walking using a reciprocating gait orthosis (RGO) is attributed to limited hip motion and excessive upper limb loading for support. To address the limitation, we designed the hip energy storage walking orthosis (HESWO) which uses a spring assembly on the pelvic shell to store energy from the movements of the healthy upper limbs and flexion-extension of the lumbar spine and hip and returns this energy to lift the pelvis and lower limb to assist with the swing and stance components of a stride. Our aim was to evaluate gait and energy cost indices for the HESWO compared to the RGO in patients with paraplegia.
Methods: The cross-over design was used in the pilot study. Twelve patients with a complete T4-L5 chronic spinal cord injury underwent gait training using the HESWO and RGO. Gait performance (continuous walking distance, as well as the maximum and comfortable walking speeds) and energy expenditure (at a walking speed of 3.3 m/min on a treadmill) were measured at the end of the 4-week training session.
Results: Compared to the RGO, the HESWO increased continuous walking distance by 24.7% ($P < 0.05$), maximum walking speed by 20.4% ($P < 0.05$) and the comfortable walking speed by 15.3% ($P < 0.05$), as well as decreasing energy expenditure by 13.9% ($P < 0.05$).
Conclusion: Our preliminary results provide support for the use of the HESWO as an alternative support for paraplegic walking.

1. Introduction

In 1983, Douglas et al. developed a reciprocating gait orthosis (RGO) to assist paraplegic patients with walking [1]. The basic mechanism of the RGO is a functional linkage between the right and left hip joints, activated by forward motion of the trunk, which allows the non-stance leg to swing forward. In this way, the RGO enables a smoother gait pattern that greatly reduces the effort required to walk for paraplegic patients. Although the RGO has been considered to be revolutionary in enabling individuals with neurological lesions from T4 to L2 spinal levels, the functional use of the RGO is limited by a slow walking speed and high-energy consumption, as well as the difficulty of the donning and doffing process [2,3]. Because of these limitations, the majority of patients abandon the use of their RGO within 6 months [4,5].

Kawashima et al. attributed the slow walking speed and high energy cost of RGOs to limited hip motion and excessive upper limb loading required to support the body [6]. Therefore, we assume that an orthosis that would store energy generated by the movement of the upper limbs and flexion-extension of the lumbar spine and hips and return this energy to partially simulate the function of hip flexor and extensor muscles would significantly improve the walking capacity of individuals with paraplegia. Based on this concept, we designed the hip energy storage walking orthosis (HESWO) which utilizes a set of springs, assembled on the pelvis shell, to store energy from upper limb and lumbopelvic movement, and to subsequently release this energy to lift the pelvis and assist with both the swing and stance components of a stride. This energy storage system is uniquely different from the basic design concept of the RGO. We therefore predicted that, compared to the RGO, the HESWO would increase the speed of walking while

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reducing the energy cost. Therefore, the purpose of our pilot study was to assess the effectiveness of the HESWO in terms of speed and energy expenditure of walking among patients with paraplegia.

2. Materials and methods

2.1. Inclusion and exclusion criteria

The study included participants aged 18–60 years who met the following criteria: a chronic (> 6 months) complete spinal cord injury at the level of T4–L2; normal passive hip mobility; and at least 3 months of experience using a walking orthosis (other than the HESWO), such as a hip-knee-ankle-foot orthosis and knee-ankle-foot orthosis, prior to being enrolled in the study. Participants were screened based on the following exclusion criteria: spinal instability; a hypertonia score > 2 on the Modified Ashworth Scale; and chronic cardiopulmonary diseases. Twelve patients with a complete thoracic-lumbar spinal cord injury were recruited and completed the full study protocol. After obtaining written informed consent, participants were provided with one custom HESWO and one RGO and underwent gait training with each of the orthoses.

2.2. Walking orthoses

The HESWO and the isocentric RGO (an improved RGO with greater reliability in mechanical design, Fillauer Companies, Inc.) were customized for each participant. Additional information on the HESWO is provided as follows. The HESWO consists of three parts: a plastic pelvis shell (Fig. 1A), hip energy storage device (Fig. 1B) and modified knee-ankle-foot orthosis (Fig. 1C). The plastic pelvis shell is comprised of two hemipelvis shells connected with flexible straps. Two inverted triangular metal brackets are attached to the side of each hemipelvis shell and the hip joint below. Slides along the upper and rear bevel sides of the triangular metal bracket regulate the tension within the springs. The hip energy storage device includes two springs, one located anterior to the hip joint and the other posterior to the joint. The spring at the front of the hip extends from the sliding fixed device located inside the front slide of the triangular bracket to the upper anterior surface of the support strip of the modified knee-ankle-foot orthosis, simulating the action of the hip flexors. The rear spring, conversely, extends from the sliding fixed device located inside the rear slide of the triangular bracket to the upper posterior surface of the support strip of the modified knee-ankle-foot orthosis, simulating the action of the hip extensors. The springs used in the hip energy storage device have a spring constant 'k' of 0.75 N/mm. The initial tension and torque in springs can be adjusted by moving the sliding fixed device. The modified knee-ankle-foot orthosis in the HESWO is similar to that in a standard RGO. We reused the lower portion of the RGO with a small change, which was to add a plastic assembly to fix the lower limbs from the front of the thigh (see Fig. 1A).

2.3. Pre-orthosis rehabilitation program

Participants completed a comprehensive, 4-week, rehabilitation program prior to training with the RGO and HESWO. The general program included strengthening of the upper body and remnant abdominal and back muscles; stretching to maintain full lower limb joint mobility, and training of sitting and standing.

2.4. Gait training with the orthoses

The 12 participants enrolled in our study were randomly allocated to two gait training protocols (Fig. 2). In protocol A, participants trained with the RGO followed by the HESWO, while in protocol B, training was completed first with the HESWO and subsequently with the RGO. For randomization, group allocation was placed in a sealed envelope (6 envelopes for each protocol), with one envelope randomly given to each participant.

In protocol A, patients first completed a 1-week program of standing in their RGO, using a walker (5-in wheels, Drive Medical Two Button Folding Universal Walker), for 30–60 min per day. This was followed by gait training for 30–60 min per day, 5 days per week for 3 weeks. Gait performance and cardiopulmonary function were evaluated on week 5. Prior to training, all participants received an explanation functioning of the RGO and were provided with instructions for the correct use of the orthosis. Incorrect posture during gait training was corrected as necessary. After completion of the evaluation of the RGO, participants received the HESWO. Again, prior to training, participants received information regarding the functioning of the HESWO and were provided with instruction for correct use. The basic components of walking with the HESWO are as follows: while sustaining weight support on the upper limbs, straighten the spine; move the center of gravity of trunk toward the stance leg; raise the hip and leg on the non-support side and swing the leg forward by releasing the elastic energy stored in the moving hip. The torque in the spring hip energy storage device was adjusted on a case-by-case basis, using feedback from participants during the gait training to obtain the best walking performance possible. In protocol B, participants were provided with

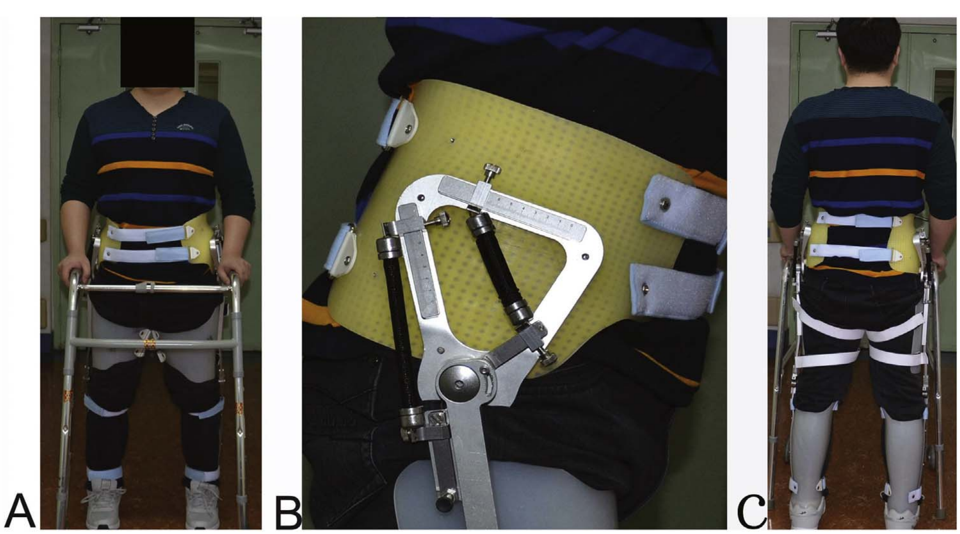

Fig. 1. A patient wearing the hip energy storage walking orthosis (HESWO).