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The Effects of The ReWalk™ Robotic System on Walking Capability in Paraplegic Spinal Cord Injury Patients in Taiwan

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Background: The ReWalk™ system is an exoskeleton robotic device developed for ambulation assistance in patients with paraplegic spinal cord injury (SCI). The purpose of this study is to evaluate the safety and walking capability of the ReWalk™ system for patients with paraplegic spinal cord injury in Taiwan.

Methods: Eight patients with SCI and paraplegia were recruited for the study in a period from April 2015 to April 2016. The level of injuries ranged from T4 to T11. Assessments included the continuous walking time, the continuous walking distance, 6-minute walking test and 10-meter walking test after training for forty hours.

Results: Among eight patients, five patients completing both basic and advanced courses, with minimum of forty hours. The average walking distance was 2937.6 meters in a single walk, and the maximal continuous walking time was 1.6 hours. The average and maximal walking speeds for 10-meter walking test were 0.4 meter/second and 0.68 meter/second, respectively. The average and maximal walking distance for 6-minute walking test were 132.48 meters and 144 meters. There was no adverse event observed during the test.

Conclusion: The ReWalk™ system is a novel robotic system, and most of the patients performed well after receiving proper training of its usage. This system may be suitable for paraplegic patients with SCI in Taiwan. (Tw J Phys Med Rehabil 2020; 48(1): 35-41)

Key Words: spinal cord injury, exoskeletal robotic system, the ReWalk™ system, walking capability

INTRODUCTION

According to the data collected by the Spinal Cord Injury Foundation, there are currently more than 40,000 patients with SCI in Taiwan.¹ With the advancement in
medical technologies, the survival rate of patients with SCI has increased. However, most patients experienced low quality of life after injury. Sequelae such as numbness, paresthesia, decreased cardiopulmonary function, incontinence, loss of bone density, abnormal muscle tone, and pressure point pain have caused severe problems in these patients.[2] Factors diminishing quality of life include limited mobility and failure to perform daily life activities independently, which further hindered social participation. Limited mobility is one of the most serious complications of SCI and is the most crucial part of the rehabilitation process.[3]

Ambulation after SCI

Manual or electric wheelchair is the method of choice for locomotion for patients with SCIs. However, the application of wheelchair is often limited by environmental factors and requires modifications to perform functional daily activities.[4] Keeping on a wheelchair for a long time can easily cause the patient to develop pressure sores.[5] The overuse of shoulders concomitant with shoulder injury is another complication when the patient pushes up from the wheelchair.[6] On the other hand, clinical gait training is mainly based on the applications of knee-ankle-foot orthosis. However, this orthosis is very heavy and difficult to don and doff. It only provided a certain degree of exercise effect. Reciprocal gait orthosis has further improved the shortcomings of traditional knee-ankle-foot orthosis, but the patients still required excessive energy consumption during walking.[7]

Effects of ReWalk training for SCI patients

The ReWalk™ system is a lower limb powered exoskeleton robotic device developed for ambulation assistance in patients with thoracolumbar complete SCI. [7] This external and bipedal lower limb frame consists of built-in actuator motors that are located near the hip and knee joints. The patient is strapped into the device by using soft straps, rechargeable battery and computer unit are carried in a backpack. The exoskeleton is controlled wirelessly by a computer, and it can be easily used for eight hours after a single charge.

In Fineberg’s study, seven patients with complete thoracic SCI were enrolled. They received standing and walking training with the ReWalk™ device three times a week. Each training session was three to four hours. The total training course lasted 6 months. The results of this study indicated that after receiving training with the ReWalk™ system, all the tested patients were able to walk a long distance to achieve a more efficient walking style. The study also suggested that the results of vertical ground reaction force-based analysis of six patients with complete SCI after walking with a dynamic exoskeleton of the ReWalk™ system were similar to those of normal humans.[8]

In Esquenazi’s study, 12 patients with complete cervical and lumbar SCI were recruited for walking training with the ReWalk™ system for two months. They received training about 75–90 minutes for each session, three times a week. Their activities were measured by a six-minute walk test, ten-meter walk test. After training, they could walk 50–100 meters continuously and were able to walk for at least 5–10 minutes at a speed of 0.03–0.45 m/s, and successfully achieved functional walking (0.71 m/s).[7]

Purpose

Taiwan was the first country in Asia to launch this system. Therefore, the purpose of this study is to evaluate its safety and efficacy for SCI patients with paraplegia to regain walking capability in Taiwan.

MATERIALS AND METHODS

Subjects

This study was approved by The Institutional Review Board of Chang-Gung Memorial Hospital. Written informed consent was obtained from each patient. The inclusion criteria of subjects are as follows: injury level below T3, normal physical conditions of bilateral upper extremities (strength, range of motion, and flexibility), normal range of motion of lower extremities (The knee joint extension contracture less than 10 degrees), lower extremities Modified Ashworth Scale for spasticity of score less than 2. Eight patients with SCI and paraplegia were recruited for the study in a period from April 2015 to 2016. The level of injuries ranged from T4 to T11. The average onset time was 8.25 years, ranging from 1 year to more
than 20 years.

**Equipment: The ReWalk™ System**

The ReWalk™ system is a powered motorized exoskeleton with a battery unit accompanied with a computer-based controller contained in a backpack, a wireless communicator, and a tilt sensor that can detect the center of gravity of the user if there is an anterior movement. There is a built-in backup system for both the battery and the main computer. The exoskeleton has bilateral lateral uprights for the thigh, leg, and hinged knee joints. It is articulated to foot plates distally and to a sacral band proximally. (Figure 1)

There are drivers at bilateral hip and knee joints, but the ankles have mechanical joints with spring-assisted dorsiflexion. In the ‘walk’ mode, the tilt sensor detects the forward tilt of the upper body and triggers a step. The regular gait is a three-point pattern with forearm crutches, which advances one step at a time. There are four additional modes: sit to stand, stand to sit, ascending stairs, and descending stairs. The maximal walking velocity provided by the machine is 2.3 km/h. A watch-like communicator was placed around the wrist to set different mode.

Because the activation of movements is under the voluntary control and initiation of the user, the device is inherently safer than a pure robotically driven control. The system is equipped with a special software and gear system in the joints for prevention of rapid hip and knee flexion as it may result in a fall. The software enables to control speed for sit-to-stand and stand-to-sit to avoid buckling. A manual mode allows the adjustment of the position of the lower limbs. User's stability and safety during standing and ambulation are achieved by the concurrent use of walking aids such as crutches and walkers.

**Training**

All the patients recruited in this study received 20-hour basic course for indoor activity training. After that, the patient received another 20-hour advanced course for outdoor activity training. The training time for each session was 60 to 90 minutes, and the frequency of training was 2 to 3 sessions per week. It took about 6 to 8 weeks to complete the 20-hour basic course training. Basic course included the following skills: transfer, manual joint adjustment, donning/offing, standing balance, sit to stand and stand to sit, communicator use, turning(left, right), walking through doorway, stopping, graceful collapse, bypass mode, skin check, general equipment knowledge, and wall rest. In this stage, balance training was the main concern and was started with the ReWalk™ system in the standing mode. The balance training contained weight shift in the ReWalk™, forward and reverse movement of crutches, correction of body after disturbance from the external force, horizontal and reverse lifting of one crutch, and turning to the right and left around. “Graceful collapse” happens if the system is powerless. The exoskeletal hips and knees will not automatically collapse but gradually lose the tension of the joints as there are specially designed gear system, which provide adequate time for rescuing. “Bypass mode” is a special mode when the communicator malfunctions and the user could operate the system by controlling the button over the sidebar directly. When patients completed balance training, the program progressed to ambulation training with the goal to gain average walking speed>0.15m/s in 10-meter walking test.

The advanced course included the following skills: advanced walking skills-conversing, advanced walking skills-noisy environment, reaching-counter & shelf, doorway navigation, timed door navigation, timed walking, sitting on / standing from bench, ramps, side angle walking, multiple surface, fall recovery. The main goal was to gain average walking speed >0.4 m/s in 10-meter walking test and average walking distance >110 meter in 6-minute walking test.

**Assessments**

Assessments included required training time for continuous walking more than 100 meters, the continuous walking time, the ability of indoor and outdoor walking, 6-minute walking test and 10-meter walking test were performed after training for forty hours.
Table 1. Characteristics of the study participants

<table>
<thead>
<tr>
<th>Code</th>
<th>Gender</th>
<th>Age (Y)</th>
<th>Neurologic level of Injury (complete)</th>
<th>Onset Time (Y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>36</td>
<td>T10-T11</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>48</td>
<td>T4</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>23</td>
<td>T4</td>
<td>5</td>
</tr>
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<td>4</td>
<td>M</td>
<td>33</td>
<td>T4</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>22</td>
<td>T4</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>45</td>
<td>T4</td>
<td>&gt;20</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>29</td>
<td>T10-T11</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>26</td>
<td>T8</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 2. Five patients completed both indoor and outdoor training with the ReWalk™ system; another two patients only accomplished indoor basic training and the other one patient did not complete the ReWalk™ basic training. “V” means completing the test. “X” means failing the test.

<table>
<thead>
<tr>
<th>Code</th>
<th>Total Training Time (Hr)</th>
<th>Course 1: indoor walking</th>
<th>Course 2: indoor walking</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&gt;60</td>
<td>V</td>
<td>V</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>V</td>
<td>X</td>
</tr>
<tr>
<td>3</td>
<td>&gt;150</td>
<td>V</td>
<td>V</td>
</tr>
<tr>
<td>4</td>
<td>40</td>
<td>V</td>
<td>V</td>
</tr>
<tr>
<td>5</td>
<td>40</td>
<td>V</td>
<td>V</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>7</td>
<td>22</td>
<td>V</td>
<td>X</td>
</tr>
<tr>
<td>8</td>
<td>70</td>
<td>V</td>
<td>V</td>
</tr>
</tbody>
</table>

Table 3. Five patients who completed both indoor and outdoor walking training were recorded for required training time for walking>100m, continued walking time, continued walking distance, 10-meter walking test and 6-minute walking test, respectively. “X” means failing the test.

<table>
<thead>
<tr>
<th>Code</th>
<th>Required Training Time for walking &gt;100m (Hr)</th>
<th>Continued walking time (Hr)</th>
<th>Continued walking distance (m)</th>
<th>10-meter walking test (m/s)</th>
<th>6-minute walking test (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20</td>
<td>1.1</td>
<td>2692.8</td>
<td>0.68</td>
<td>126</td>
</tr>
<tr>
<td>2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>3</td>
<td>32</td>
<td>1.6</td>
<td>3916.8</td>
<td>0.68</td>
<td>111.6</td>
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<tr>
<td>4</td>
<td>32</td>
<td>1.1</td>
<td>2692.8</td>
<td>0.41</td>
<td>144</td>
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<td>33</td>
<td>1.1</td>
<td>2692.8</td>
<td>0.42</td>
<td>144</td>
</tr>
<tr>
<td>6</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
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<td>7</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>8</td>
<td>56</td>
<td>1.1</td>
<td>2692.8</td>
<td>0.41</td>
<td>136.8</td>
</tr>
</tbody>
</table>

RESULTS

The ReWalk™ system was applied to eight patients with SCI and paraplegia from April 2015 to April 2016. Among them, there were five males and two females, with the average age of 31 years. The average body height was 168.14 cm ranging from 155 to 180 cm, with a standard deviation of 8.19 cm. The average body weight was 62.57 kg ranging from 50 to 79 kg, with a standard deviation of 10.78 kg. Those patients with body height less than 155 cm were excluded due to poor application of the ReWalk systems. The level of injuries ranged from T4 to T11. (Table 1)

Among these eight patients, one patient who failed to complete basic training had structural leg length discrepancy, which made it difficult for him to perform weight shifting and forward steps. Another two patients did not complete advanced course because of personal reasons such as need to get back to work, and poor motivation.

Five patients completed both basic and advanced course with minimum of 40 hours. Their average walking distance was 2937.6 meters, and the maximal continuous walking time was 1.6 hours. Fatigue was the main concern that limited the subjects walking distance. Their average and maximal walking speeds for 10-meter walking test were 0.4 meter/second and 0.68 meter/second,
respectively. Their average walking distance for 6-minute walking test was 132.48 meters, while the maximal walking distance for 6-minute walking test was 144 meters. Three T4 patients could ambulate with the ReWalk™ system both indoors and outdoors for more than one hour. No adverse event was observed during the test. (Table 2 and Table 3)

**DISCUSSION**

In this study, we found that this system could not fit patients with body height less than 155 cm. It suggested that the adjustable foot plate should be modified to be more fit in Asian people. Our study showed promising results. Five patients who completed basic and advanced course could continuously walk in both indoors and outdoors.

Two patients with T4 injury achieved walking velocity of 0.41 m/s and one achieved walking velocity of 0.68 m/s in 10-meter walking test. According to Esquenazi’s study, the maximal walking velocity achieved in T4 injury patients in 10-meter walking test was only 0.18 m/s. [7] This suggested that our patients acquired skillful use of ReWalk™ system in basic and advanced training course. The original setting of the maximal walking velocity of the ReWalk™ system is 0.638 m/s; however, one patient with T4 injury manage to perform walking velocity up to 0.68 m/s. This extraordinary performance attracts attention on the trunk control and muscle activation strategy the patient conducted. In Fineberg et al study, F-scan sensor which detects vertical ground reaction force was applied, and the participants with motor-complete SCI were able to demonstrate mechanical loading magnitude and pattern similar to able-bodied gait. [8] This finding was coherent with our study where heel to toe gait pattern was also observed. The main trunk control strategy might lie on pelvis tilting. Advanced pelvis tilting lead to earlier toe off in the terminal stance phase, resulting in walking velocity exceeding the original ReWalk™ system setting. However, more study was needed to reveal the underlying mechanism. No adverse event such as buckling or accidental falls was observed during the test. Nevertheless, the case number was relatively small and further study about the trunk control and muscle activation when patients ambulate with the ReWalk™ system are needed to enlighten the future application.

**CONCLUSION**

The ReWalk™ system is a novel robotic system, and most of the patients perform well after receiving proper training of its usage. This system can be applied in paraplegic patients with SCI patients in Taiwan.

**CONFLICT OF INTEREST**

There are no conflicts of interest to declare.

**REFERENCE**

外骨骼機器腳立可走系統於台灣脊髓損傷合併下半身癱瘓之病患之步行效益

背景：腳立可走系統為針對雙下肢癱瘓之脊髓損傷患者步行所開發的外骨骼機器腳系統。本研究的目的在探討腳立可走系統用在台灣雙下肢癱瘓之脊髓損傷患者的安全性以及其步行效益。

方法：本研究於2015年4月至2016年4月間收錄8位T4至T11脊髓損傷併雙下肢偏癱病患接受立可走機器腳系統訓練。在完成訓練後接續進行評估測試，評估項目包含最長連續步行時間、最長步行距離、10公尺步行速度及6分鐘步行距離。

結果：8位病人中，共有5位完成室內及室外至少40小時的訓練。他們平均步行距離為2937.6公尺，最長連續步行時間為1.6小時；10公尺步行測試中病人平均速度為0.4公尺/秒且最大速度為0.68公尺/秒；6分鐘步行測試中病人平均行走距離為132.48公尺，最大行走距離則為144公尺。過程當中沒有出現明顯的副作用。

結論：腳立可走系統是一個創新的機器人系統。大多數的病患在經過適當的訓練之後多能改善步行能力，本系統可應用於台灣脊髓損傷合併下半身癱瘓的病人。[台灣復健醫誌2020;48(1):35-41]

關鍵詞：脊髓損傷(spinal cord injury)，外骨骼機器人系統(exoskeletal robotic system)，腳立可走系統(the ReWalk™ system)，步行效益(walking capability)