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Case Report Open Access

Case Report on Long-Term, Continuous Improvement of Walking Ability as a Result of Botulinum Toxin Injection Therapy and Low-Frequency Rehabilitation with HAL

Toyoko Asami*, Masaki Kitajima, Yusuke Nanri, Kazuki Murata and Taketo Sato

Department of Rehabilitation Medicine, Saga University Hospital, Japan

*__Corresponding author:__ Toyoko Asami, Clinical Professor, Department of Rehabilitation Medicine, Saga University Hospital, Japan, Tel: +81-952-34-3285; Fax: +81-952-34-2026; E-mail: asamit@cc.saga-u.ac.jp

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Introduction

Previously, robots in Japan have been mainly used in industry. However, in recent years, rehabilitation robots designed to improve walking ability and support and assist activities of daily living (ADL) immediately after the onset of disorders have been developed, put into clinical use, and have become more and more widespread in the fields of medical care and nursing care [1,2]. In 2015, the HAL robot suit was the first wearable medical robot to receive manufacture and marketing approval as a medical device, and in 2016 it received approval for coverage by Japan's national health insurance system. As the situation continues to develop, it is important to consider how to use robots in rehabilitation medicine.

At our hospital, the first rehabilitation robotic device that we used was the Ottobock myoelectric arm prosthesis known as the "Myoelectric Arm Prosthesis System Myobock (myoelectric arm prosthesis)," which we began using in 2001. Subsequently, we added the Cyberdyn "HAL Robot Suit," the Honda "Walking Assist" device, the Francebed "H200 Hand Rehabilitation System (NESS H200)" and "Foot Drop System NESS L300 (NESS L300)," and the Teijin WalkAid device. We have been engaged in an on-going investigation of how to utilize these robotic devices in our rehabilitation program. In one of our investigations, we conducted combination therapy with robot-assisted rehabilitation, magnetic stimulation therapy, and botulinum toxin injection therapy. In addition, in 2014 we advocated "robot-assisted rehabilitation" and started outpatient rehabilitation in order to provide robot-assisted rehabilitation to larger numbers of patients [2]. Currently, we utilize a total of 9 types of robots, including Toyota's "Walking Training Assist (GEAR)," Teijin Pharma's "Upper Arm Exercise Training Device (ReoGo-J)," and the "ITRI-EXO" of the Industrial Technology Research Institute (ITRI) of Taiwan [3-9]. We conduct robot-assisted rehabilitation with all of the robotic devices at our hospital, and as we do this, we concurrently investigate the indications of each device through clinical studies.

Here, we report on a case we experienced in which long-term, continuous walking ability improvement was obtained through the use of botulinum toxin injection therapy and HAL on a cerebrovascular disease (CVD) patient.

Case

This case was a man in his 30s who had suffered head trauma approximately 5 years prior. He had left hemiplegia, his leg was Brunnstrom stage III, and his MAS grade was 2. He was able to walk indoors under observation with the use of an ankle foot orthosis and a T-shaped handle walking cane.

Methods

HAL robot suit (HAL)

When the wearer intends to make a physical movement, HAL detects the weak myoelectric signals transmitted to the wearer's muscles from the brain via motor neurons through sensors affixed to the skin. In reaction to these signals, the robot then moves the wearer's hip and knee joints, which in turn serves to assist and augment voluntary movements, which improves physical functioning. The robot also helps complete the feedback mechanism that transmits afferent signals from the neuromuscular spindles to the central nervous system (Figure 1) [3,4]. During training, the wearer's center of gravity and trajectory of the center of gravity during walking are displayed on a specialized computer screen, which allows the wearer's progress to be monitored.

Figure 1: HAL.

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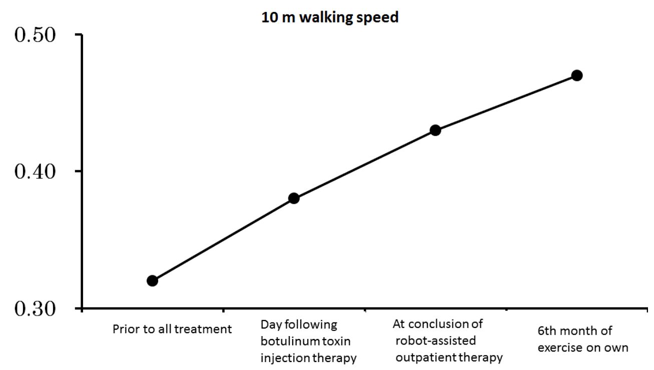

Figure 2: 10-meter Walking Speed.

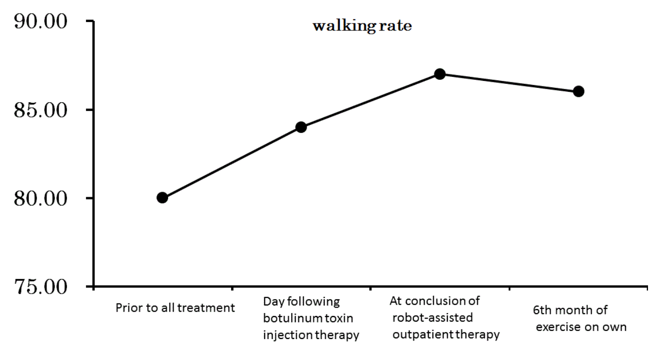

Figure 3: Walking Rate.

Pretreatment

Before rehabilitation began, we improved the spasticity of the patient's upper and lower limbs through botulinum toxin injection therapy. The dose used was 300 units in the patient's leg muscles (75 units each in the femoral biceps, medial head of gastrocnemius muscle, lateral head of gastrocnemius muscle, soleus muscle) and 50 units in the patient's affected arm (biceps brachii muscle).

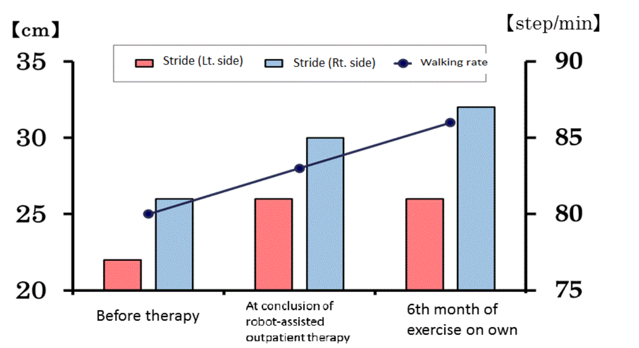

Figure 4: Stride and Walking Rate by 3D gait analysis (VICON).

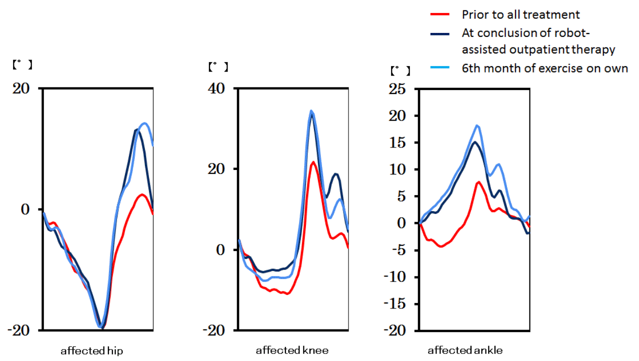

Figure 5: Angle of flexion and extension by 3D gait analysis (VICON).

Assessment methods

The following assessments were performed: Patient medical history, range of motion, muscle strength, Brunnstrom stage, Modified Ashworth Scale (MAS), Barthel Index, and walking assessment (10-meter walking speed, walking rate, three-dimensional (3D) gait analysis:VICON).

Risk management

Rehabilitation was conducted in accordance with the exercise termination criteria for CVD. During training, we inquired if the patient became tired due to the training, we checked vital signs, and we took sufficient precautions against falling.

Rehabilitation program

Walking training using a sling and treadmill (HAL TREAD®) for the purpose of standing balance training, step training, and fall prevention was conducted 60 minutes per session once per week for 6 weeks, for a total of 6 times. Because it is difficult to control adduction and inner rotation patterns as well as ankle flexion and extension of the affected leg using HAL alone, we used the manual assistance of a physical therapist and short leg braces when necessary.

Results

The results of our walking assessment of the case that underwent the rehabilitation program utilized in this study indicated that 10-meter walking speed and walking rate, which were 0.32 m/sec and 80 step/min respectively prior to therapy, improved to 0.38 m/sec and 84 step/min after botulinum toxin injection therapy, and further improved to 0.43 m/sec and 87 step/min after robot-assisted rehabilitation, indicating that botulinum toxin injection therapy led to improvement and that HAL led to further improvement in the case's walking assessment. In addition, although the case continued to exercise on his own after rehabilitation with botulinum toxin injection therapy and HAL therapy, at an additional assessment performed 6 months later, his 10-meter walking speed and walking rate were 0.47 m/sec and 86 step/min respectively, indicating that the combined effect of botulinum toxin injection therapy and HAL therapy had been maintained for 6 months (Figures 2 and 3). These same results were observed in stride length, walking rate, and leg joint angles as measured using 3D walking analysis (Figures 4 and 5). In other words, combined therapy consisting of botulinum toxin injection therapy and HAL therapy as used in this study led to improved walking ability and this improvement was maintained for 6 months.

Discussion

The HAL robot used in the present study provides the same general merits of robot-assistance. Specifically, it provides the appropriate amount of assistance at the appropriate timing, which allows repetitive practice of beneficial exercise patterns. In addition, the wearer's center of gravity trajectory and joint angles can be displayed on a screen when the robot is connected to a computer or tablet device, which allows the monitoring of data in real time. This provides visual feedback that that allows the patient and the staff to observe the patient's walking status during rehabilitation, and this in turn allows them to identify required training tasks and adjust the rehabilitation program accordingly. Because the details of the walking rehabilitation program are recorded, not only the results of each day but also changes in the results as recorded over the entire rehabilitation period can be confirmed. In addition, HAL is also able to detect weak myoelectric signals transmitted from the brain to the muscles via motor neurons and completes the feedback mechanism that transmits the afferent signals from the neuromuscular spindles to the central nervous system. By reacting to the weak myoelectric signals that are detected, even minute voluntary movements can be detected and assisted, which assists in moving the hip, knee, and ankle joints. In other words, we anticipate that it will function as a robot that has a mechanism that improves physical functions themselves [10-12]. We believe that the walking rehabilitation conducted in this study with the use of a HAL robot that has the abovementioned features in addition to botulinum toxin injection therapy was the primary factor that led to improvement of walking ability, in spite of the fact that we used a low-frequency rehabilitation program. Thus, we believe that using robotic features in rehabilitation is highly significant.

However, since we did not investigate whether rehabilitation using HAL once per week for a total of 6 times was the optimum frequency, further research is required to determine the optimum frequency, the optimum time period for each session, and suitable rehabilitation program details.

There are variety of types of robots designed for use in rehabilitation. The selection process of the optimum robot for each patient remains an important issue, and we believe that creating robot evaluation guidelines to be used for this purpose is extremely important.

We believe that rehabilitation in which the optimum robot is selected and in which that robot's features are properly utilized will allow low-frequency but effective rehabilitation, and ultimately will lead to benefits related to health economics.

Conclusion

In this study, we conducted a rehabilitation program consisting of botulinum toxin injection therapy and HAL for a case in the post-discharge phase several years after disease onset. Although the rehabilitation program was low-frequency with a total of 6 sessions, walking ability improved and walking function was maintained for 6 months. This suggests that rehabilitation using botulinum toxin injection therapy and HAL may be an effective rehabilitation program.

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