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ORIGINAL ARTICLE

Development of a Gait Rehabilitation Robot Using an Exoskeleton and Functional Electrical Stimulation: Validation in a Pseudo-paraplegic Model

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Objective: We have developed a robot for gait rehabilitation of paraplegics for use in combination with functional electrical stimulation (FES). The purpose of this study was to verify whether the robot-derived torque can be reduced by using FES in a healthy-person pseudo-paraplegic model. **Methods:** Nine healthy participants (22–36 years old) participated in this study. The robot exoskeleton was designed based on the hip–knee–ankle–foot orthosis for paraplegia. Participants walked on a treadmill using a rehabilitation lift to support their weight. The bilateral quadriceps femoris and hamstrings were stimulated using FES. The participants walked both with and without FES, and two walking speeds, 0.8 and 1.2 km/h, were used. Participants walked for 1 min in each of the four conditions: (a) 0.8 km/h without FES, (b) 0.8 km/h with FES, (c) 1.2 km/h without FES, and (d) 1.2 km/h with FES. The required robot torques in these conditions were compared for each hip and knee joint. The maximum torque was compared using one-way analysis of variance to determine whether there was a difference in the amount of assist torque for each gait cycle. **Results:** Walking with the exoskeleton robot in combination with FES significantly reduced the torque in hip and knee joints, except for the right hip during extension. **Conclusions:** In the healthy-participant pseudo-paraplegic model, walking with FES showed a reduction in the robot-derived torque at both the hip and knee joints. Our rehabilitation robot combined with FES has the potential to assist paraplegics with various degrees of muscle weakness and thereby provide effective rehabilitation.

Key Words: functional electrical stimulation; paraplegia; robotic therapy

INTRODUCTION

According to a 2018 survey, 4603 traumatic spinal cord injuries occur annually in Japan. The average age of such patients is 70.0 years, and the number of incomplete spinal cord injuries resulting from low-energy trauma, such as falls on level ground, is increasing.[1)] With the aging of society, the number of patients with incomplete spinal cord injuries is likely to increase. Consequently, it is necessary to establish effective rehabilitation methods for these patients.

Gait training using lower-limb orthoses has been widely used to treat hemiplegia and paraplegia caused by central nervous system diseases such as stroke and spinal cord injury. However, the amount of training provided is usually insuf-

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ficient because of the extensive therapist assistance required. Paraplegics with spinal cord injury, especially those who are elderly, generally require a large amount of assistance. Evidently, this is an issue that needs to be addressed.

In recent years, rehabilitation involving gait training with robots has become available for clinical use and is reportedly effective.[2,3] However, one problem with gait training with robots is that movements are determined by the output of the robot. To treat paralysis, training with muscle contraction that is independent of the motor torque of the robot may be useful, but it is difficult to achieve in rehabilitation using a robot alone. By stimulating muscles with functional electrical stimulation (FES), it is possible to elicit muscle contraction that does not depend on the motor torque of the robot. FES induces muscle activity by providing electrical stimulation to the paralyzed muscles and nervous system and is useful for the rehabilitation of patients with stroke and spinal cord injury.[4] However, even though FES alone is expected to improve the range of motion and muscle activity, gait training is often difficult to execute with FES alone when muscle weakness is severe. Therefore, rehabilitation using robots and FES in combination has been attempted in recent years. The ankle joint range of motion was improved by using FES in combination with gait training with a gait rehabilitation robot in patients with hemiplegia caused by central nervous system disorders, mainly traumatic brain injury.[5]

We are currently developing a new gait rehabilitation robot for hemiplegic lower limbs using a hybrid FES system that combines FES and robotics. By feeding back the movements of a healthy lower limb to specify the movements of the robot to exercise the paralyzed lower limb, hemiplegic patients are expected to acquire a more natural and personalized gait.[6] The system we have developed combines FES and an exoskeleton robot to improve gait rehabilitation for hemiplegia.

In this study, we used the amount of torque assistance provided by the robot as an indicator of the success of muscle activation by FES. We theorized that if the muscle contraction caused by FES could produce joint movement, the torque generated by the motor unit could be reduced to the minimum necessary level of assistance when used in combination with FES. The purpose of this study was to verify whether the combined use of FES and an exoskeleton-type robot could reduce the robot-derived torque in a pseudo-paraplegic model provided by a healthy person.

MATERIALS AND METHODS

Nine healthy men (aged 22–36 years) participated in this investigation. The exoskeleton was originally designed by us based on the hip–knee–ankle–foot orthosis for paraplegia. The participants were lifted and their weight was supported by a rehabilitation lift (SP-1000, Moritoh, Aichi, Japan), and in this condition, they then walked on a treadmill (8.1T, Johnson Health Tech Japan, Tokyo, Japan) (**Fig. 1**). FES (Dynamid, DM2500, Minato Medical Science, Japan, Osaka) was used to stimulate the bilateral quadriceps and hamstrings (**Fig. 2**). The quadriceps, mainly the rectus femoris, was stimulated from mid-swing to mid-stance, and the stimulation point was located on the motor point identified by palpation of the anterior superior iliac spine and lateral femoral condyle. The hamstrings, mainly on the lateral side, were stimulated from pre-swing to mid-stance, and the stimulation point was located on the motor point identified by palpation of the sciatic tuberosity and the head of the fibula. The exoskeleton system was preprogrammed with gait data of the joint angles of a healthy person. The system performed the walking motion by changing the positions of the hip, knee, and ankle joints according to the gait data. FES stimulation was performed according to the phase. The stimulus was set at 25 Hz and 15–25 mA. The resting motor threshold for the quadriceps was set as the minimum stimulus required to cause knee extension; for the hamstrings, it was set as the minimum stimulus required to cause knee flexion. The participants walked with the exoskeleton robot both with and without FES. Two walking speeds, 0.8 and 1.2 km/h, were used. The subjects walked for 1 min in each of the four conditions: (a) 0.8 km/h without FES, (b) 0.8 km/h with FES, (c) 1.2 km/h without FES, and (d) 1.2 km/h with FES. The four conditions were executed in the order a, b, c, and d. We compared the robot torque supplied to the hip and knee joints in the four conditions.

Participants were instructed to walk with their full weight supported by a rehabilitation lift and with both lower limbs completely relaxed. To achieve this, participants were lifted to support their full body weight in a rehabilitation lift and then instructed to avoid voluntary muscle contractions in both lower limbs. Participants focused on not making any voluntary muscle contractions during the gait test. In other words, joint movements were caused solely by the sum of the muscle contraction caused by FES stimulation and the robot-derived torque. The required torque was automatically and continuously calculated by the exoskeleton system to achieve the required joint angles. The maximum amount of torque applied to each joint on each gait cycle was compared using one-way analysis of variance. All statistical analyses were conducted using EZR (Saitama Medical Center, Jichi Medi-

Fig. 1. Gait rehabilitation robot for paraplegia. The robot contains a functional electrical stimulation system for quadriceps femoris muscle and hamstrings of both sides, a treadmill, and a safety rehabilitation lift for unloading.

cal University, Saitama, Japan).[7] Statistical significance was set at P <0.05.

This study was approved by our institution's Ethics Committee (Akita University Graduate School of Medicine, approval number 1966). All individuals participated voluntarily and provided written informed consent.

RESULTS

Figures 3–6 show comparisons of the torque applied to the hip and knee joints in conditions a–d for both extension and flexion. In a healthy-person pseudo-paraplegic model, walking with FES resulted in a reduction of flexion and extension torques provided by the rehabilitation robot to the hip and knee joints. The combination of FES and the robot significantly decreased the torque in all joints except in the right hip joint during extension. There were no significant differences in joint torque when comparing walking at 0.8 and 1.2 km/h. No adverse events occurred in this study.

DISCUSSION

In this study, we developed a gait rehabilitation robot for paraplegic patients for use in combination with FES. Although rehabilitation robots using FES and robots for hemiplegic patients have been reported, there are currently few reports of robots for lower limb paralysis patients, and we believe that our approach is novel.

We showed that the amount of robot-derived torque can be reduced in both lower limbs by combining the robot with FES in a model of muscle weakness using healthy subjects. Stimulation of the quadriceps femoris by FES induced hip flexion and knee extension, whereas stimulation of the hamstrings induced hip extension and knee flexion. These FES-induced movements are thought to have reduced the torque assist required of the robot.

Of the muscle force required to move the joint to the specified angle, the torque generated by the robot is expected to supplement the force of the joint movement invoked by the FES, thereby enabling the robot-derived torque to be mini-

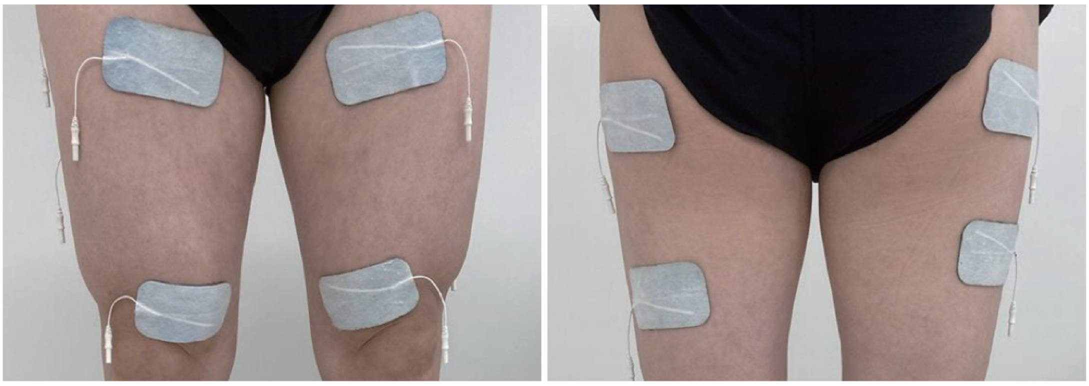

Fig. 2. Functional electrical stimulation pads stimulating bilateral quadriceps and hamstrings.

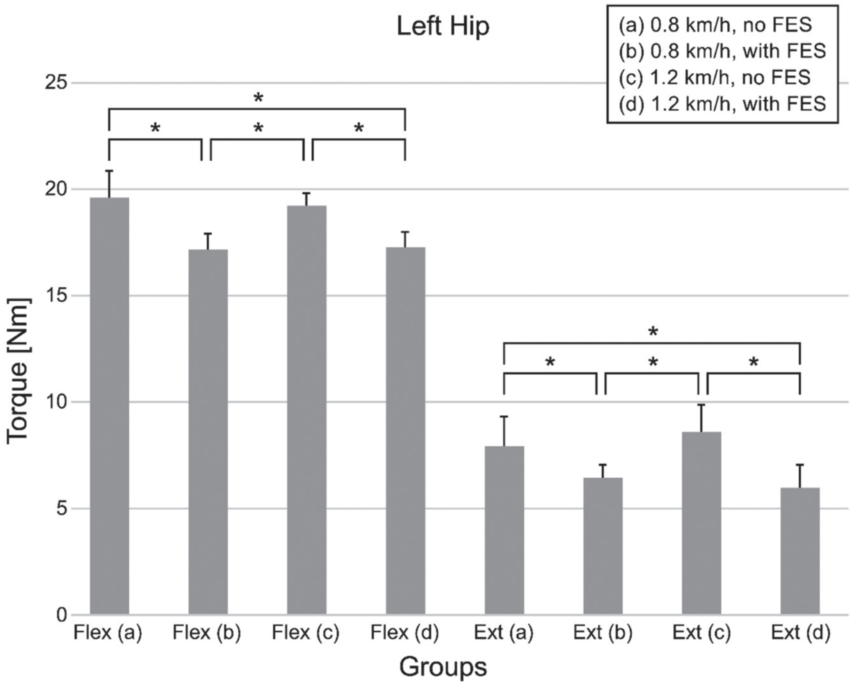

Fig. 3. Left hip torque. In the left hip joint, the torque in (b) and (d) with functional electrical stimulation (FES) was significantly lower than that in (a) and (c) without FES in both flexion and extension. *Significant at P<0.05.

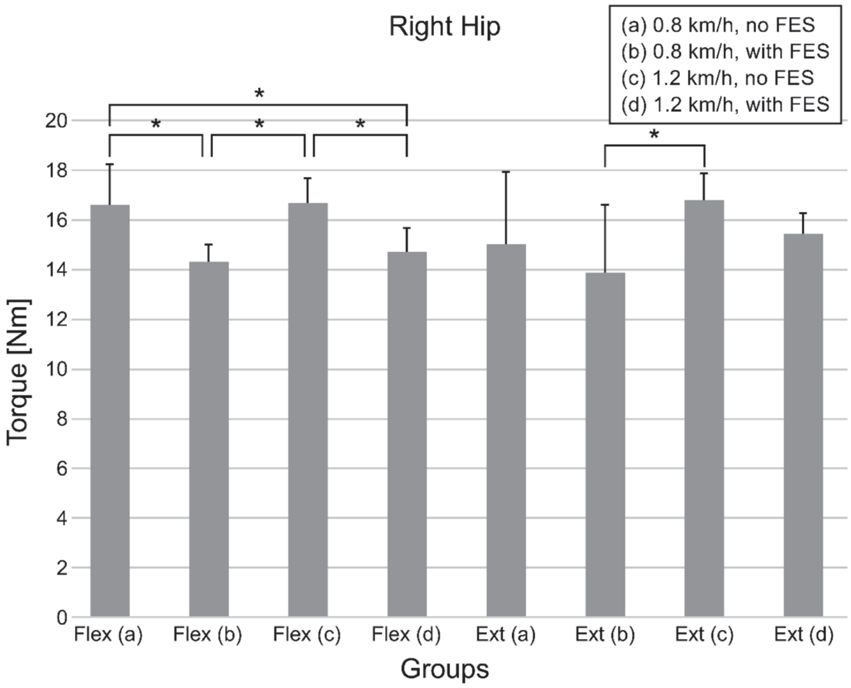

Fig. 4. Right hip torque. In the right hip joint, in flexion, the torque of (b) and (d) with functional electrical stimulation (FES) was significantly lower than that of (a) and (c) without FES. In extension, the torque of (b) and (d) with the FES was lower than that of (a) and (c) without the FES, but the difference was not significant. The torque in (b) was significantly lower than that in (c). *Significant at P<0.05.

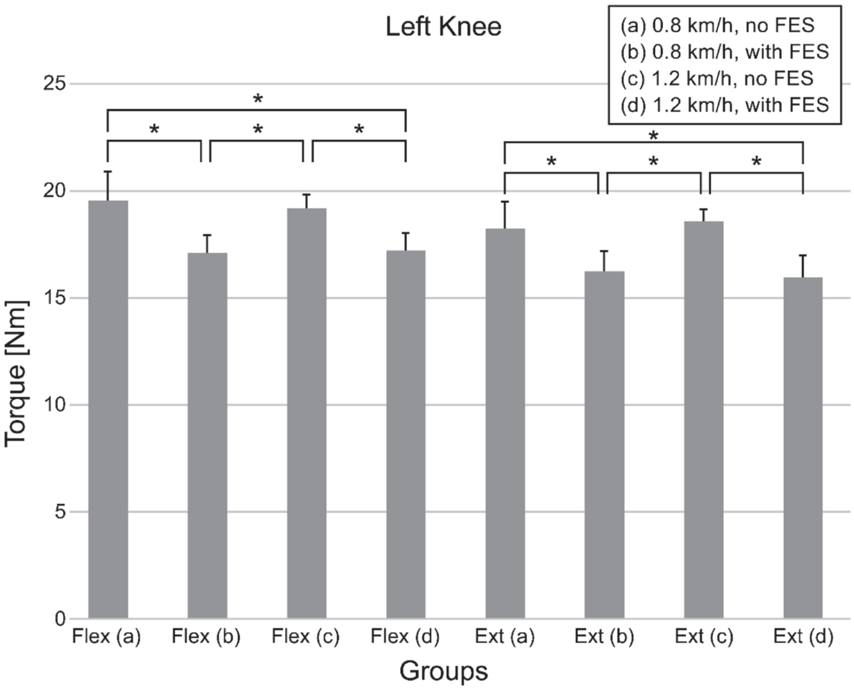

Fig. 5. Left knee torque. In the left knee joint, in both flexion and extension, the torque in (b) and (d) with FES was significantly lower than that in (a) and (c) without FES. *Significant at P<0.05.

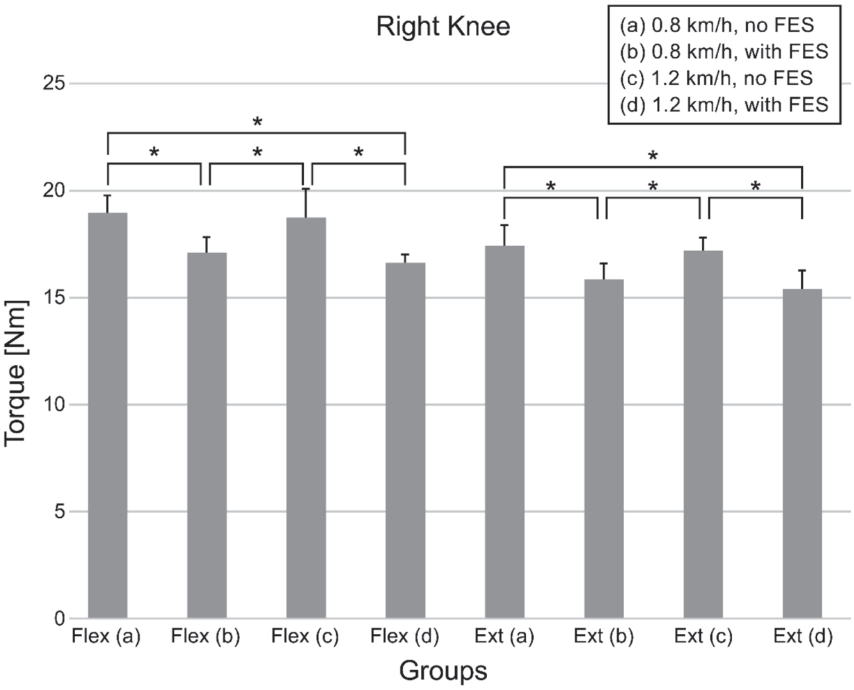

Fig. 6. Right knee torque. In the right knee joint, in both flexion and extension, torque was significantly lower when FES was used (b) and (d) than when FES was not used (a) and (c). *Significant at P<0.05.

mized. Therefore, when paraplegics receive this therapy, the robot can supply the torque required according to the degree of muscle weakness; as a result, effective rehabilitation can be performed with an appropriate amount of load in accordance with learning theory. Furthermore, by stimulating the quadriceps and hamstring muscles at the appropriate times during the gait cycle, we expect the patient to acquire the same gait as before the paralysis.

The use of a gait rehabilitation robot with FES improves joint range of motion, muscle strength, and gait ability.[8,9] However, it is necessary to verify whether rehabilitation using the newly developed robot also improves gait ability compared with conventional training. The muscle fatigue model has reportedly been used to appropriately allocate the respective torque to the FES stimulation and the motor unit.[10] The muscle fatigue model is an important tool for long gait training sessions and multiple sessions. The combined use of FES and robotic rehabilitation has proven more effective in reducing muscle fatigue than rehabilitation using FES alone.[11]

The robot-derived torque could be set to provide assistance with or without inducing muscle fatigue, allowing the user to obtain assistance earlier in the training process and to cope with cases of more severe muscle weakness. In the future, it will be possible to adjust the torque according to the degree of paralysis by introducing an automatic assist adjustment function based on machine learning that is currently under development. Sufficient gait training using a pattern close to the original gait is expected to improve paralysis and gait function. Furthermore, the combined use of FES is expected to reduce the required robot-derived torque, leading to lower power consumption and smaller robots.[10] Miniaturization of the robot is very important for expanding the use of this technique to other facilities. Moreover, because this rehabilitation occurs with the patient's weight supported, falls can be prevented in patients undergoing gait rehabilitation, even for those with paraplegia.

There are several limitations to this study. First, the participants were healthy people acting as pseudo-paraplegic models, and the results may be different from those of real patients with paraplegia. In the future, after confirming the safety of the system, we need to conduct the same experiments with patients with paraplegia to verify the effectiveness of such rehabilitation.

In the present study, FES stimulation reduced the right hip torque in extension, but the difference was not significant. It is possible that in the pseudo-paraplegic model, the left–right difference occurred because the participant could not completely relax. When applying the pseudo-paraplegic model, the harness must be lifted until the legs are unloaded. The lower limbs may have been included in this process. The above limitations must be resolved in future studies to verify the effectiveness of rehabilitation robots in combination with FES for patients with lower body paralysis.

In conclusion, we developed a robot for gait rehabilitation of paraplegics for use in combination with FES. In a healthy-person pseudo-paraplegic model, walking with FES resulted in a reduction in the robot-derived torque for knee and hip joints. Our results suggest that this robot/FES combination has the potential to assist paraplegics with various degrees of muscle weakness and thereby provide effective rehabilitation.

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CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

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