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ORIGINAL ARTICLE

Single-joint Hybrid Assistive Limb in Knee Rehabilitation after ACL Reconstruction: An Open-label Feasibility and Safety Trial

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Objectives: To achieve better outcomes, neuromuscular and biomechanical factors should be considered in rehabilitation after anterior cruciate ligament reconstruction. In this study, we investigated the feasibility and safety of a wearable exoskeleton robot suit [known as the single-joint hybrid assistive limb (HAL-SJ)] and whether knee training using this device could improve functional outcomes after anterior cruciate ligament reconstruction. **Methods:** HAL-SJ-assisted knee extension and flexion exercises were commenced in 11 patients 18 weeks after reconstruction; exercises were performed once a week for three weeks at a frequency of five sets of ten repetitions. Patients were monitored for HAL-SJ-related adverse events. Physical evaluations were conducted before and after HAL-SJ training. Surface electromyography of the quadriceps and hamstring muscles was performed in 4 of the 11 patients during each session and the muscle co-contraction index was calculated. **Results:** The peak muscle torque was higher at all velocities after HAL-SJ training. The active range of motion significantly increased in both extension and flexion, and the range of motion in passive flexion significantly increased. The Tegner Activity Scale and Lysholm Knee Questionnaire scores also significantly increased after knee HAL training. The muscle co-contraction index during extension tended to be lower after HAL-SJ training. No adverse events were observed. **Conclusions:** The findings of this study indicate the feasibility and safety of HAL-SJ training as a neuromuscular rehabilitation tool after anterior cruciate ligament reconstruction. The knee HAL-SJ training may have contributed to these results from a neurophysiological perspective by lowering the co-contraction of knee muscles, which would correct impairment of the antagonistic or synergistic muscles.

Key Words: co-contraction index; limb symmetry index; neuromuscular rehabilitation tool

INTRODUCTION

One of the most important goals of the rehabilitation process after anterior cruciate ligament (ACL) reconstruction is to reduce the risk of a second ACL injury. Numerous factors affect the likelihood of a second ACL injury, including surgical technique, choice of graft, and the effectiveness of postoperative rehabilitation and patient education. One study also reported that age and sports activity level are key factors in the occurrence of a second ACL injury after ACL reconstruction.[1)] Physical therapists can use several treatment

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modalities during postoperative rehabilitation. Some studies have suggested that postoperative rehabilitation should include neuromuscular training to improve outcomes after surgery.[2,3] Research on the prevention of ACL reinjury has focused on identifying the relevant risk factors, including neuromuscular and biomechanical factors.[4] Modifiable neuromuscular and biomechanical risk factors have been found to contribute to increased risk of a second ACL injury.[5] Addressing these factors in athletes after ACL reconstruction using targeted rehabilitation may significantly reduce the incidence of second ACL injury and subsequent functional disability.[6]

The hybrid assistive limb (HAL) is a wearable exoskeleton robot suit that provides real-time assistance to an individual for walking and limb movements through actuators mounted on the hip and knee joints bilaterally.[7] A single-joint hybrid assistive limb (HAL-SJ) has been developed for use in rehabilitation training. Studies have shown that knee rehabilitation training using an HAL-SJ improves functional outcomes in patients after total knee arthroplasty or opening wedge high tibial osteotomy.[8,9] In a case report of a patient who had undergone ACL reconstruction, HAL was applied to the knee and showed efficacy improvement in some of the most commonly used clinical scores, in particular, the limb symmetry index (LSI) for peak extension and flexion torque.[10] HAL training has the potential to be effective in patients with neuromuscular impairment. The HAL-SJ has a bioelectric signal-balancing capability that can adjust the balance of the detected flexion and extension signals by means of computer processing. Knee rehabilitation training using the HAL-SJ could provide useful biofeedback to avoid erroneous motor learning. Therefore, we hypothesized that knee rehabilitation training using the HAL-SJ could be a novel rehabilitation treatment modality for patients after ACL reconstruction. To our knowledge, there has been no clinical trial on the application of the HAL-SJ in patients who have undergone ACL reconstruction. In this study, we investigated the feasibility and safety of knee training with the HAL-SJ after ACL reconstruction and whether use of this device can improve functional outcomes.

MATERIALS AND METHODS

Patients

We performed an open-label prospective trial in our institution between April 2019 and October 2020 with a postoperative follow-up period of 6 months. Within that time period, all patients who had undergone arthroscopic ACL reconstruction were assessed for eligibility. The inclusion criteria for the current study were as follows: a primary ACL injury, unilateral ACL reconstruction, ability to understand an explanation of the study and provide informed consent, and availability for observation throughout the study. Patients with multiple knee ligament injuries, those for whom wearing and training using the HAL-SJ was expected to be difficult because of underlying disease, and those with perioperative complications were excluded. During the study period, a total of 38 patients underwent arthroscopic ACL reconstruction and 27 of these were excluded. Consequently, this study included 11 patients (six men, five women; mean age, 25 ± 8.4 years; height, 167.6 ± 8.4 cm; weight, 68.4 ± 11.0 kg) who had undergone arthroscopic ACL reconstruction with soft tissue graft materials (anatomic single-bundle, n=9; anatomic double-bundle, n=2). The semitendinosus tendon alone or both the semitendinosus and gracilis tendons were harvested and used as multi-stranded grafts. The tendon graft was hooked to the Ultrabutton adjustable-loop device (Smith & Nephew Endoscopy, Andover, MA, USA) on the femoral side. The tibial end of the graft was sutured using a double-spike plate and screw (Smith & Nephew Endoscopy) with an initial tension of 20 N or 30 N using a tension meter at 20° or 30° of knee flexion. The femoral and tibial bone tunnels were anatomically created at the tibial and femoral insertions of the ACL using the outside-in tunnel technique. Three of the 11 patients had a concomitant meniscus injury that was partially removed or repaired; consequently, ACL reconstruction only was performed in eight patients, and lateral meniscus repair, medial meniscus repair, and partial lateral meniscectomy were performed in one patient each. Three patients played soccer, two played handball, one played basketball, one was a skier, one played tennis, one was a javelin thrower, and two played only recreational sports. After surgery, all patients underwent rehabilitation training by a physical therapist starting on postoperative day 1. Range of motion (ROM) and weight-bearing exercises were started on postoperative day 5. If patients had partially repaired menisci, ROM and weight-bearing exercises were not started until 1 week after surgery. Post-discharge, a physical therapist or an athletic trainer administered the rehabilitation program once a week, comprising closed and open kinetic chain exercises, hip and knee muscle strength training, neuromuscular training, neuromuscular electrical stimulation, and cryotherapy for the ACL-reconstructed leg. After 3 months follow-up postoperatively, patients who participated in competitive sports continued to receive the rehabilitation program two or three times per month. In contrast,

Table 1. Clinical characteristics of the eleven patients

Patient no.	Age (years)	Sex	Height (cm)	Weight (kg)	Surgical procedure	Sports level
1	33	Male	177	81.1	ACLR + MMR	Recreational
2	21	Male	165.6	74.9	ACLR	Recreational
3	23	Male	172	82	ACLR	Competitive
4	21	Female	157.5	55	ACLR	Recreational
5	19	Female	160.6	54.6	ACLR	Recreational
6	26	Male	175.2	79	ACLR	Competitive
7	20	Female	162	56.6	ACLR	Competitive
8	25	Male	176.3	77.4	ACLR + PLM	Competitive
9	21	Male	178.3	68	ACLR	Recreational
10	47	Female	164.5	65	ACLR + LMR	Recreational
11	19	Female	155	58.4	ACLR	Competitive

ACLR, anterior cruciate ligament reconstruction; MMR, medial meniscus repair; LMR, lateral meniscus repair; PLM, partial lateral meniscectomy.

patients who participated in recreational sports received the rehabilitation program once a month. In an effort to increase the external validity of the findings, we did not control the rehabilitation program. **Table 1** summarizes the patients' clinical characteristics.

The study was conducted with the approval of the ethics committees of Tsukuba University Faculty of Medicine (approval number TCRB18-077) and Ibaraki Prefectural University of Health Sciences (approval code: e119) and was performed in accordance with the Declaration of Helsinki. All patients provided written informed consent before enrollment in the study.

Knee HAL-SJ Training

The HAL-SJ is a wearable exoskeleton-type robot that provides voluntary assistive training using an actuator on the lateral side of the knee joint and using muscle action potentials detected from the middle fibers of the quadriceps and hamstrings.[8,9] Surface electrodes were attached to the quadriceps and hamstring muscles (vastus medialis [VM], rectus femoris, vastus lateralis [VL], and biceps femoris [BF], and the medial hamstrings) to evaluate the bioelectrical activity from the long axis (along the belly) of each muscle. Knee HAL-SJ training commenced 18 weeks after ACL reconstruction to avoid the risk of laxity of graft tension, partial graft tear, and poor synovial coverage.[11,12] HAL-SJ training was performed once a week for a total of three sessions. Prior to setup, the physical therapist measured the patient's femoral and lower limb length, hip and ankle width, and ACL-reconstructed leg maximum active flexion and extension ROM. With the patient seated, the therapist fitted the leg attachments and ankle support (fitting time, 3–5 min). After measuring maximum active flexion and extension angles prior to the intervention, the physical therapist set the knee HAL-SJ assist angle to prevent over-assisting. During knee extension training, the patient was seated at the end of a bed. For knee flexion training, the patient remained in the prone position on the bed (**Fig. 1**). Five sets of HAL-training-assisted knee extension and flexion exercises were performed (10 exercises/set, a total of 50 exercises).[10] Each weekly session lasted approximately 50 min, including fitting and evaluation. Patients underwent conventional knee rehabilitation on the non-HAL training days. Details of the knee HAL-SJ training setup are shown in **Fig. 1.**

Adverse Events

Adverse events were defined as any undesirable symptom after ACL reconstruction, such as severe pain, fracture, infection, arthritis, skin problems, and a tear or sprain of the ACL graft that was not specifically related to knee HAL training.

Measurements

Physical evaluations were conducted at postoperative week 17 (pre-HAL) and at postoperative week 21 (post-HAL).[10] Isokinetic assessment was performed at 60°/s, 180°/s, and 300°/s using an isokinetic dynamometer (Biodex System III; Biodex Medical Systems, Sakai, Tokyo, Japan), and strength during knee extension and flexion was measured bilaterally. The LSI was calculated to determine whether the side-to-side difference could be classified as normal or abnormal.[13] The LSI was defined as the ratio of the injured side to the

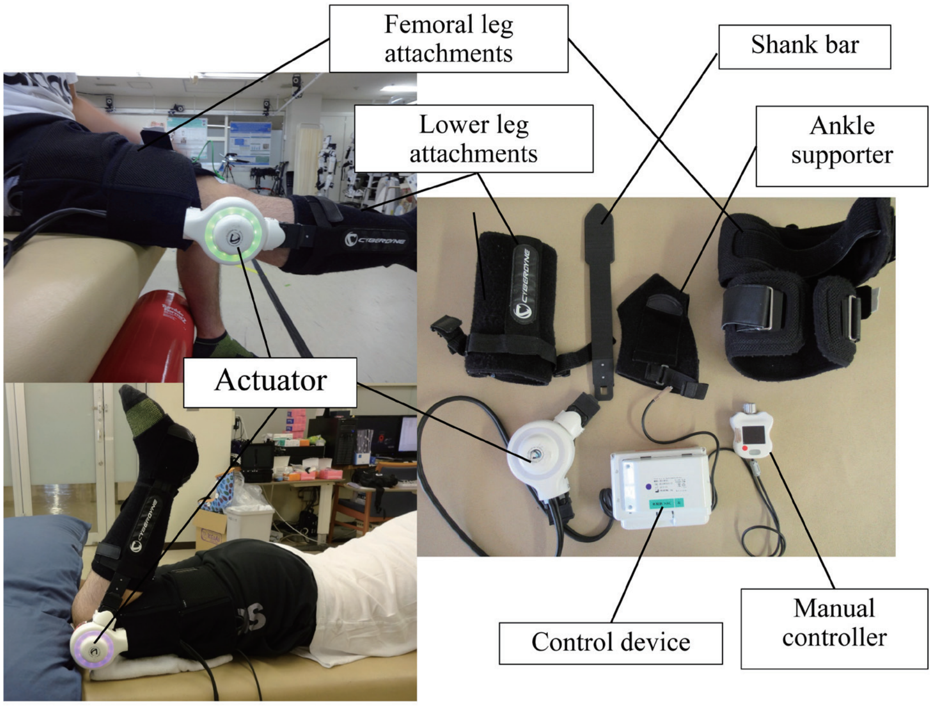

Fig. 1. Components of the single-joint hybrid assistive limb (HAL-SJ) and images of knee extension and flexion training with assistance of the HAL-SJ.

non-injured side and expressed as a percentage (injured/non-injured×100%).

ACL graft tears and anterior knee laxity were assessed using the pivot shift and Lachman's test. The active and passive ROM, the Tegner Activity Scale score (where work and sport activities are graded numerically),[14] the Lysholm Knee Questionnaire score (a 100-point scoring system for examining a patient's knee-specific symptoms),[14] and the International Knee Documentation Committee subjective knee form score (a scoring system to quantify the disability caused by ACL injury)[15] were also measured. All patients were observed for adverse events during the study period.

Collection and Analysis of Surface Electromyography Signals

We measured the surface electromyography (EMG) signals from the quadriceps and hamstring muscle groups to evaluate neuromuscular impairment and whether it was affected by HAL. Surface EMG measurements were obtained for patients 7, 8, 9, and 11. The measuring system comprised a four-channel MyoSystem EMG unit (Noraxon, Scottsdale, AZ, USA) and bipolar Ag–AgCl surface electrodes, each measuring 1 cm in diameter with a center-to-center distance of 2.5 cm.

The skin was wiped with alcohol before applying the surface electrodes to reduce skin impedance. Pairs of surface electrodes with a diameter of 1 cm and center-to-center spacing of 2.5 cm were applied to the dominant limb. The EMG electrodes were placed on the VL and VM muscles of the quadriceps femoris and the BF and semitendinosus (ST) muscles representing the lateral and medial hamstring muscle groups, respectively. Electrode placement on the examined muscles was based on the SENIAM recommendations.[16]

Evaluations were conducted during each weekly knee HAL training session. During each session, ten repetitions of open-chain knee extension and flexion with EMG evaluations were conducted and recorded before and after knee HAL training. All EMG signals were filtered with a band-pass filter (50–500 Hz) and then rectified and smoothed using a symmetrical moving root mean square (RMS) filter of 100 ms. The RMS EMG amplitude was normalized to the peak EMG signal from the isometric maximal voluntary contraction (MVC). All contractions were completed while seated in the Biodex System III according to the MVC protocol.[17] Before data analysis, all results were normalized by calculating them as percentages of their MVC, after which the EMG of each evaluation was time-normalized to

100 points. The normalized open-chain knee extension and flexion EMGs were analyzed at each point. The muscle co-contraction index (CCI) was calculated using the average muscle amplitude and the following formula:

$$CCI = \frac{LEMG}{HEMG}(LEMG + HEMG)$$ [18]

where LEMG is the normalized magnitude of the RMS EMG amplitude for the less active muscle and HEMG is the normalized magnitude of the RMS EMG amplitude for the more active muscle. The CCI was calculated at each point of the evaluation, and the mean CCI was calculated for the medial hamstring and quadriceps muscles (ST–VM) and for the lateral hamstring and quadriceps muscles (BF–VL) during each trial.

Statistical Analysis

The normality of the data was tested using the Shapiro–Wilk test. The *t*-test or Wilcoxon signed-rank test was then used to evaluate differences between pre-HAL and post-HAL physical evaluations and CCI. The ROM, Tegner Activity Scale and Lysholm Knee Questionnaire scores, and CCI values were calculated as effect sizes in terms of Cohen's d. Statistical analyses were performed using IBM SPSS Statistics 24 software (IBM, Armonk, NY, USA). The alpha level was set at 5%.

RESULTS

All patients completed the three weekly sessions of knee HAL training without adverse events. None of the patients developed pain, clinical signs of inflammation, or functional instability.

The Shapiro–Wilk test confirmed that the measurements followed a normal statistical distribution, except for the LSI at a peak flexion torque of 300°/s, the active ROM, the Tegner Activity Scale and Lysholm Knee Questionnaire scores, and the CCIs for BF–VL in extension and ST–VM and BF–VL in flexion. The LSIs at peak torque for all velocities pre-HAL and post-HAL are shown in **Fig. 2**. The LSIs at peak torque at 60°/s were significantly higher post-HAL, i.e., for both the peak extension torque LSI (pre-HAL, 70.2 ± 13.5; post-HAL, 74.8 ± 13.1; P=0.036) (**Fig. 2A**) and the peak flexion torque LSI (pre-HAL, 73.7 ± 10.2; post-HAL, 83.5 ± 17.1; P=0.030) (**Fig. 2B**). The active ROM significantly increased in both extension and flexion [ROM in extension (pre-HAL, −3.3 ± 2.6°; post-HAL, −0.6 ± 0.9°; P=0.013; effect size=1.39), ROM in flexion (pre-HAL, 128.0 ± 5.2°; post-HAL, 132.5 ± 4.1°; P=0.005; effect size=0.96)]. The ROM in passive flexion increased significantly (pre-HAL, 134.3 ± 4.8°; post-HAL, 138.7 ± 4.7°; P=0.016; effect size=0.93). The Tegner Activity Scale and Lysholm Knee Questionnaire scores both significantly increased after knee HAL training [Tegner Activity Scale score (pre-HAL, 4.78 ± 0.9; post-HAL, 5.89 ± 0.6; P=0.014; effect size=1.45), Lysholm Knee Questionnaire score (pre-HAL, 66.8 ± 7.3; post-HAL, 87.89 ± 3.5; P=0.003; effect size=3.68)]. The findings of other physical examinations are shown in **Table 2**. The CCI results are presented in **Table 3**. No significant differences in CCI were detected before and after the HAL-SJ training. Regarding the effect size, the CCI for ST–VM and BF–VL in extension showed small Cohen's d effect size in session 1 (ST–VM; pre-HAL, 3.6 ± 1.9; post-HAL, 4.2 ± 2.4; P=0.245; effect size=0.26; BF–VL; pre-HAL, 7.4 ± 5.6; post-HAL, 9.0 ± 8.6; P=0.400; effect size=0.21). The CCI for ST–VM in extension showed small or medium effect sizes for sessions 2 and 3 (session 2; pre-HAL, 3.4 ± 1.9; post-HAL, 3.0 ± 0.9; P=0.574; effect size=0.24; session 3; pre-HAL, 5.3 ± 2.8; post-HAL, 3.7 ± 1.8; P=0.058; effect size=0.66). The CCI for BF–VL in extension showed a medium effect size in session 2 (pre-HAL, 10.6 ± 5.1; post-HAL, 7.4 ± 3.4; P=0.437; effect size=0.75).

DISCUSSION

All patients successfully underwent knee HAL-SJ training during the study period with no serious adverse events. None of the patients had pain, clinical signs of inflammation, or ACL graft tears, and anterior knee laxity tests were negative. Because the ACL reconstruction procedure involves a graft, which is associated with a risk of laxity of graft tension, partial graft tear, and poor synovial coverage during training, the application of knee HAL training in patients who have undergone ACL reconstruction is different from that in patients who have undergone total knee arthroplasty or high tibial osteotomy.[11,12] However, the absence of serious adverse events in this study supports the notion that knee HAL-SJ training is potentially a safe rehabilitation tool for patients with ACL injury.

Although the LSI for peak torque at 180°/s and 300°/s showed no significant difference post-HAL and pre-HAL, the LSI for peak torque at 60°/s was significantly improved after the HAL training. For strength testing, a previous study focused on the LSI for peak torque at 60°/s in addition to the LSIs at 180°/s and 300°/s.[19] Other physical evaluations, including active ROM, passive flexion ROM, and the Tegner Activity Scale and Lysholm Knee Questionnaire scores, sig-

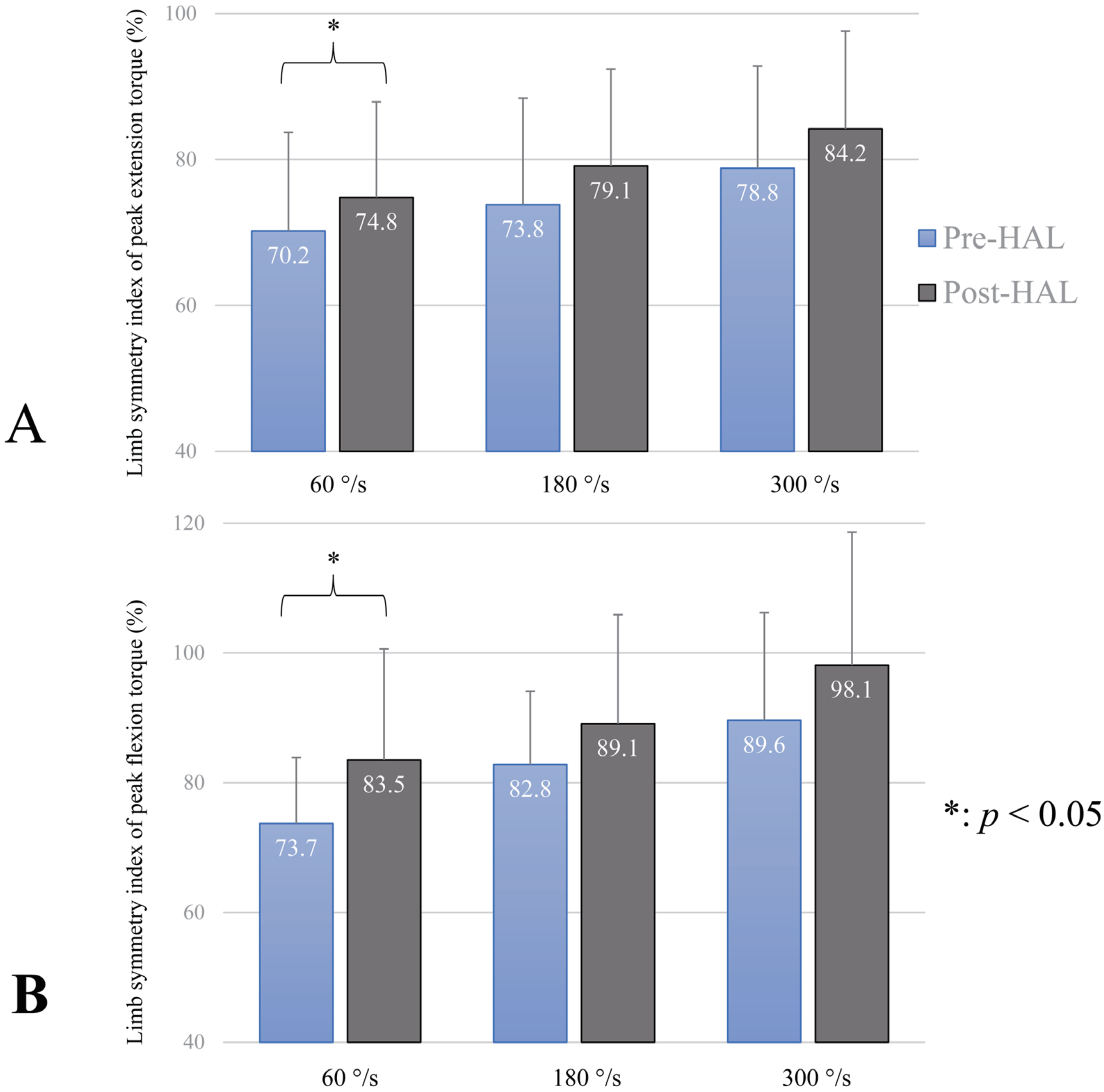

Fig. 2. Limb symmetry index of (A) peak extension torque and (B) peak flexion torque for three angular velocities. Pre-HAL, before HAL-SJ training; Post-HAL, after HAL-SJ training.

nificantly improved in this study. However, these improvements may have resulted from conventional training or the normal recovery from ACL reconstruction, and not from the effect of knee HAL training alone. Regarding neuromuscular function, HAL-SJ has a bioelectric signal-balancing capability that can adjust the balance of detected flexion and extension signals by means of computer processing.[20] In the current study, the CCI for ST-VM and BF-VL in extension was not significantly different post-HAL and pre-HAL; nonetheless, these CCI results showed small or medium Cohen's d effect sizes, which possibly reflect a change in neuromuscular function as a result of HAL-SJ training. Knee HAL-SJ training may have contributed to the results from a neurophysiological perspective by lowering co-contraction of the hamstring and quadriceps muscles, which would correct impairment of the antagonistic or synergistic muscles and help to optimize the efficiency of muscle activity and ROM during movement. Altered neuromuscular function and biomechanics are likely risk factors for a second ACL injury after ACL reconstruction.[21] Moreover, failure of activation of the quadriceps after ACL reconstruction is not simply an isolated local phenomenon related to atrophy caused by neural inhibition.[22] Therefore, it is important to focus on neuromuscular function after ACL reconstruction to prevent a second ACL injury and to improve the efficiency of muscle function.

In an earlier study, a gradual increase in recovery of muscle strength after ACL reconstruction was identified during the

Table 2. Results of physical evaluations before and after HAL-SJ intervention

		Pre-HAL	Post-HAL	P-value	Effect size
Active ROM (°)	Extension	–3.3 ± 2.6	–0.6 ± 0.9	0.013*	1.39
	Flexion	128.0 ± 5.2	132.5 ± 4.1	0.005*	0.96
Passive ROM (°)	Extension	–0.5 ± 1.1	0	0.197	0.64
	Flexion	134.3 ± 4.8	138.7 ± 4.7	0.016*	0.93
Pivot shift test result		0	0		
Lachman's test result		0	0		
Tegner activity scale score		4.78 ± 0.9	5.89 ± 0.6	0.014*	1.45
Lysholm knee questionnaire score		66.8 ± 7.3	87.89 ± 3.5	0.003*	3.68
IKDC subjective knee form score		A	A		

IKDC, International Knee Documentation Committee; Post-HAL, after training; Pre-HAL, before training; ROM, range of motion.

Table 3. Co-contraction index before and after each HAL-SJ intervention

		HAL session 1		HAL session 2		HAL session 3	
		Extension	Flexion	Extension	Flexion	Extension	Flexion
ST–VM	Pre-HAL	3.6 ± 1.9	4.9 ± 7.3	3.4 ± 1.9	6.4 ± 8.6	5.3 ± 2.8	7.9 ± 7.9
	Post-HAL	4.2 ± 2.4	5.4 ± 8.2	3.0 ± 0.9	6.1 ± 6.9	3.7 ± 1.8	8.7 ± 8.4
	P-value	0.245	0.408	0.574	0.721	0.058	0.32
	Effect size	0.26	0.06	0.24	0.05	0.66	0.09
BF–VL	Pre-HAL	7.4 ± 5.6	3.4 ± 4.4	10.6 ± 5.1	5.1 ± 5.3	12.7 ± 9.3	6.4 ± 5.7
	Post-HAL	9.0 ± 8.6	4.2 ± 4.3	7.4 ± 3.4	4.6 ± 4.4	12.3 ± 9.3	6.3 ± 5.6
	P-value	0.400	0.482	0.437	0.572	0.344	0.894
	Effect size	0.21	0.15	0.75	0.09	0.04	0.02

ST, semitendinosus; VM, vastus medialis; BF, biceps femoris; VL, vastus lateralis.

early period of neuromuscular rehabilitation.[23] However, in the current study, knee HAL-SJ training was performed in the late phase and focused on neuromuscular training (starting at 18 weeks after ACL reconstruction in our study and within 1 week following surgery in the previous study). Despite starting in the late phase following ACL reconstruction, the LSI for peak torque at 60°/s significantly improved after HAL training. Reconstructed ligaments recover in patients at a minimum of 18 months after ACL reconstruction,[24] and impaired neuromuscular function around the knee is considered to be responsible for persisting functional deficits in maximal strength and a prolonged muscle reaction time.[25] Rehabilitation training after ACL reconstruction is a long-term process to improve these functional deficits. Therefore, knee HAL-SJ training, as a form of neuromuscular rehabilitation, may contribute to the amelioration of functional deficits or neural inhibition despite not being started until the late phase after ACL reconstruction.

This study had several limitations. Although one of its aims was to determine whether knee HAL-SJ training improved functional outcomes after ACL reconstruction, it was difficult to distinguish recovery as a result of ACL reconstruction itself from the effect of knee HAL training. Therefore, future studies of the efficacy of knee HAL training should include a control group. Furthermore, surface EMG measurements were obtained for only four subjects. Therefore, the mechanism underlying the response in terms of muscle function after knee HAL training from a neurophysiological perspective is unclear, and further investigations are required in a greater number of patients. Another limitation is that assessments of ACL graft tears and anterior knee laxity used only the pivot shift and Lachman's test. However, those assessments depend on subjective factors.[26] Therefore, objective assessment of ACL graft tears and anterior knee laxity such as KT-1000 is desirable. However, the present study is the first to demonstrate that the use of the knee HAL-SJ could be an effective training tool for patients who have undergone ACL reconstruction.

CONCLUSION

We investigated the feasibility and safety of knee HAL-SJ training and whether it can improve functional outcomes after ACL reconstruction. The absence of serious adverse events in this study indicates that knee HAL-SJ training is potentially a safe rehabilitation tool for patients with an ACL injury. Knee HAL-SJ training may have contributed to the efficiency of muscle activity due to lower co-contraction of the knee muscles, which would correct impairment of the antagonistic or synergistic muscles. Our findings show that knee HAL training is a safe and feasible rehabilitation tool after ACL reconstruction.

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CONFLICTS OF INTEREST

The authors report that there are no conflicts of interest.

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