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Original article

Feasibility and efficacy of knee extension training using a single-joint hybrid assistive limb, versus conventional rehabilitation during the early postoperative period after total knee arthroplasty

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Abstract

Objectives: To evaluate the feasibility and efficacy of treatment for the recovery of knee joint function after total knee arthroplasty (TKA) using a robotic suit.

Patients and Methods: Knee joint extension exercise sessions were started with a robotic suit (single-joint hybrid assistive limb [HAL-SJ, Cyberdyne, Inc., Tsukuba, Japan]) in one group of patients after TKA. Patients who underwent standard rehabilitation were enrolled in the control group. To evaluate feasibility and safety, we assessed the adverse events, the number of training sessions, and training time. We compared the changes in knee joint pain and extension lag (°) between the groups.

Results: The average age was 71.3 ± 6.2 years in the HAL-SJ group and 74.9 ± 8.7 years in the control group. There were no severe adverse events. In the HAL-SJ group, training was performed 2.9 times, on average, and lasted 18.8 min. In the HAL-SJ group, there was a reduction in the visual analog scale (VAS) for pain after training, which was not significant. In the control group, the VAS score worsened after the sessions. The extension lag significantly improved in the HAL-SJ group after the 2nd and 3rd sessions, and this was more due to improvements in their active extension range of motion than their passive extension range of motion.

Conclusions: HAL-SJ-based training is safe and effective, and leads to instantaneous improvement of extension lag, without worsening knee joint pain. HAL-SJ-based knee extension training could represent a viable novel post-TKA rehabilitation modality.

Key words: total knee arthroplasty, rehabilitation, osteoarthritis of the knee, extension lag, hybrid assistive limb

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Introduction

In total knee arthroplasty (TKA) for knee osteoarthritis, obtaining a good range of motion (ROM) affects clinical results[1–3]. When TKA is compared to total hip arthroplasty, although the pain improvements are similar, improvements in joint function, ROM, and quality of life are inferior[4]. Knee flexion and extension ROM are temporarily lowered for 1 month after TKA, and recover after 12 months. Reduced extension ROM is possibly caused by quadriceps femoris muscle dysfunction and postoperative pain due to surgical invasion into the knee joint extension mechanism[3]. Reduced knee joint extension ROM is also strongly correlated with reduced joint function and patient satisfaction due to the increased load on the quadriceps femoris muscle, reduced walking speed, and gait abnormalities due to leg-length discrepancies[5, 6]. Continuous passive motion (CPM) is used for training knee joint ROM, but its effectiveness is controversial[7–9]. At present, there is no method to maintain knee joint passive extension obtained during surgery without pain (an extension angle of 0°), even with active extension. The invasiveness of TKA impairs the knee joint extension mechanism, causing knee pain and restricted extension

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ROM. A new treatment strategy that does not prolong post-TKA knee joint extension lag (EL) is needed. EL causes a number of issues that negatively affect patient satisfaction[10].

We studied the feasibility and safety of knee joint extension exercises with the assistance of a robotic suit and compared the efficacy of this method versus that of conventional rehabilitation.

Patients and Methods

This study was approved by the institutional review board of our hospital, and written informed consent was obtained from each participant. We prospectively studied patients who underwent TKA under the diagnosis of knee osteoarthritis. The selection and exclusion criteria were as follows: selection criteria included those who visited our department in the hospital and those who underwent surgery on one side only. Around 5–7 days after surgery, they also had a maximum active knee extension angle that did not achieve the maximum passive knee extension angle, as measured under anesthesia at the end of their knee joint surgery. Other factors included weight (40–100 kg), height (150–190 cm), and the ability to wear the single-joint hybrid assistive limb (HAL-SJ); moreover, the observation had to be possible for the entire research period. The exclusion criteria were: significant skeletal deformations, such as osteoarthrosis, spondylosis, or scoliosis outside the surgical area making training, including joint exercise or wearing the HAL-SJ, difficult or unsafe; underlying diseases or perioperative complications that would make it difficult to wear the HAL-SJ; complications such as a bleeding tendency or osteoporosis that would cause problems during training; failure to attach bioelectrodes due to skin diseases, participation in other research studies within 12 months of this study, and the physician's decision.

This was a prospective, case-control study comparing knee function between robot-assisted and conventional rehabilitation groups. We included patients who underwent TKA at our institution between April 2015 and February 2017. Each doctor consecutively and alternatively assigned subjects into two groups: the control group (conventional rehabilitation [ROM training, muscle power training, wheelchair operation training, standing operation training, and walking training, which included the use of a walker or T cane and stair training]), and the HAL-SJ group (conventional rehabilitation plus HAL-SJ-based training).

HAL-SJ robotic suit

The robot suit "HAL" (Hybrid Assistive Limb®, Cyberdyne Inc., Tsukuba, Japan) is a wearable motion assistance robot developed at the System Information Department of Tsukuba University. The HAL controls a power unit while analyzing the bioelectrical signals (BES) that are detected by electrodes attached to the skin and assists the wearer's motion as necessary[11]. The HAL-SJ (knee type) is worn on the knee, and assists with joint extension and flexion while analyzing the BES from the front and the rear of the thigh as well as the information from the angle sensors[12]. It has a power unit located outside the knee joint, which connects an attachment and a supporter that is worn on the thigh and lower leg, respectively (Figure 1). The power unit is connected to a convenient controller (Figure 2A) that adjusts

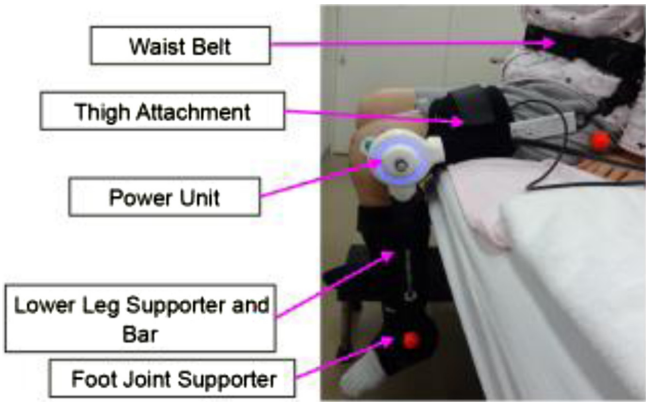

Figure 1 The robotic single-joint hybrid assistive limb (knee type).

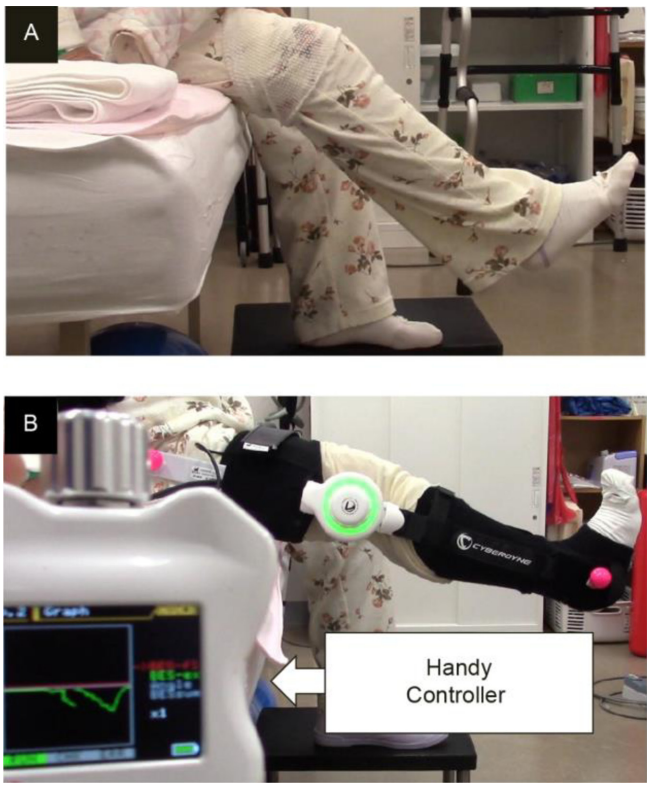

Figure 2 Postoperative day 10. A: Knee joint active extension motion. B: Knee joint extension motion using the single-joint hybrid assistive limb.

the settings and displays information via a wired control box. The assist torque output by the HAL-SJ's power unit is determined by the BES obtained from the front and the rear of the thigh, the extension/flexion signal balance (0–100%) of the BES, the assist gain (adjustment of assist torque relative to the generated amount of BES: 0–100, where 100 is the maximum), and the torque limit (maximum torque = 100%). The parameters that the operator can adjust with the controller are the extension/flexion signal balance, the assist gain, and the torque limit.

In this study, the HAL-SJ was used in the CVC-AutoFlx mode. In this mode, the knee flexion signal is constant so that the robot flexes when needed; when the force is removed from the knee extension, an assistive torque toward flexion is generated. This makes it possible to have operational assistance adapted to knee extension in a sitting position, because the robot automatically returns to the limb position at the start of training (knee flexion 90°). The settings were as follows: extension/flexion signal balance of flexion at 40%, extension at 100%; assist gain adjusted between 20 and 50 to minimize the patient's EL; and torque limit at 50%.

Surgical procedure and rehabilitation protocol[12]

For TKA, the knee surgeon was T.Y. and the implant was a VANGUARD (Zimmer Biomet, Inc., Warsaw, IN, USA) in the HAL-SJ group. In the control group, the knee surgeon was either A.K. or T.Y. and the implant was a LEGION (Smith & Nephew, Inc., Memphis, TN, USA). Three knee surgeons were enrolled in our department at the time, and because the study aimed to assess safety and feasibility, we assigned the patients of T.Y. (a research representative) to the HAL-SJ group and the patients of the other knee surgeons to the control group. Both groups used the same surgical techniques, which included longitudinal skin incisions, the medial parapatellar approach, the modified gap technique, posterior-stabilized type, femur and tibia components fixed with cement, and no patella exchange.

For the rehabilitation program, in the control group, conventional rehabilitation therapy that allowed full weight bearing from the day following surgery was used, with therapy performed by a physical therapist, including patella mobilization, sitting, standing, and walking training, ROM training, and muscle power maintenance and strengthening training, for 40 min, 5 days per week (Monday–Friday) until discharge. After the drain within the joint was removed 2 days after surgery, CPM training was started for 1 h per day and continued until discharge. The HAL-SJ group followed the same conventional rehabilitation program on the day following surgery. From the 8th day after surgery, knee joint extension training was started with the HAL-SJ in a sitting position (10 extensions per set, five sets, twice per week) (Figure 2A and 2B).

Measurement of ROM and outcomes

To assess feasibility, we evaluated the training time, including the time required to put on the HAL-SJ, the number of training sessions, and knee joint pain (visual analog scale [VAS])[13] before and after the HAL-SJ intervention, and compared these values with those of the control group. Patients in the control group rated pain according to the VAS immediately before and after conventional rehabilitation.

To evaluate the functional recovery of the operated knee, we measured EL, defined as the difference between active and passive ROM of knee extension on postoperative day (POD) 8, 10, and 15, before and after the HAL-SJ intervention. The HAL-SJ intervention was performed three times (mean, 2.9) on POD 8, 10, and 15. POD 8 was the first time point because the HAL-SJ intervention was initiated on POD 8. The protocol involved twice-weekly sessions thereafter, performed on PODs 10 and 15. We compared the EL values to evaluate any immediate changes and whether the HAL-SJ-based intervention caused adverse events. In the control group, EL was measured before and after rehabilitation. To evaluate whether the change in EL was primarily due to active motion or passive motion of the knee joint extension angle, we measured the angular improvement during active motion and passive motion, both before and after the intervention. We used a goniometer (Tokyo University type, 450 mm) to measure the ROM according to the Japanese Orthopedic Association and the Japanese Association of Rehabilitation Medicine. Patients' ROM was measured with the patient sitting with their legs hanging down, with the greater trochanter, external condyle of the knee joint, and external condyle of the ankle joint as indicators[14].

Statistics

We used SPSS version 21.0 (IBM Corp., Armonk, NY, USA) to analyze the data using two-group comparisons (comparative t-test) with a significance level <0.05. Values are presented as means ± standard deviations.

Ethical considerations

The present study was approved by the institutional review board at University of Tsukuba Hospital (H26-219, UMIN000017012).

Results

Table 1 shows the patient details. No participants dropped out after the start of the HAL-SJ intervention. No severe adverse events occurred due to surgery, such as wound healing failure or infection. The training time was 18.8 ± 6.9 min; HAL-SJ training was performed on average 2.9 times, and the number of days in hospital after surgery was 17.8 ± 1.9 days in the HAL-SJ group.

Figure 3 shows the changes in knee joint pain before

Table 1 Patient demographic data

	HAL-SJ	Control	
Age	71.3 ± 6.2	74.9 ± 8.7	NS
Sex	4 men, 8 women	1 man, 11 women	
BMI	25.1 ± 2.2	26.7 ± 6.1	NS
Operated side	Right 8, left 4	Right 8, left 4	
Preoperative extension angle	−8.1 ± 6.8	−5.5 ± 4.0	NS
Patient registration period	April 2015–January 2017	January 2016–February 2017	

HAL-SJ: hybrid assistive limb-single joint; BMI: body mass index; NS: not significant.

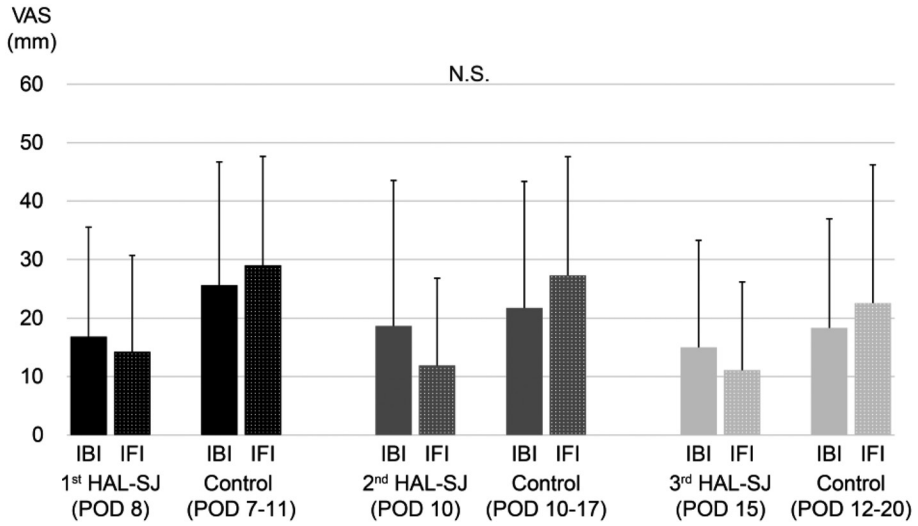

Figure 3 Changes in VAS in the HAL-SJ and control groups before and after intervention.
VAS: visual analogue scale; HAL-SJ: hybrid assistive limb-single joint type; POD: postoperative day; NS: not significant; IBI: immediately before intervention; IFI: immediately following intervention.

and after the HAL-SJ and conventional interventions. Knee joint pain was reduced following the HAL-SJ intervention (not statistically significant). In the control group, pain increased following the intervention (not statistically significant) (Figure 3).

Figure 4 shows the EL before and after the interventions for both groups. In the HAL-SJ group, the EL improved immediately after intervention and after the 2nd and 3rd interventions, it went from 9.1° to 6.3° and from 8.5° to 5.2°, respectively (statistically significant). In the control group, no EL improvements were seen. In the HAL-SJ group, the active extension angle improved more than the passive extension angle, and in the 2nd and 3rd interventions, the active extension angle improved much more than the passive extension angle (Figure 5).

Discussion

Since there were no severe adverse events, no patient dropped out and the average training time per session, including putting on the HAL-SJ, was 18.8 min (equal to the unit of training time [20 min] according to the national insurance system in Japan), HAL-SJ-assisted exercise was found to be feasible and safe.

In the present study, training was performed in the hospital (starting on POD 8). Only 2.9 sessions were performed on average because training was only performed twice weekly during hospitalization. The twice-weekly protocol was chosen because safety and feasibility were the primary outcomes of interest. Another reason was that the staff (physical therapists, doctors) were unfamiliar with how to use the HAL-SJ device. Future studies should explore the optimal number of training sessions for maximum effectiveness. Hypothetically, effectiveness could be improved if sessions were performed earlier and at a higher frequency. By starting earlier, postponing discharge, or increasing the frequency of sessions, the number of training sessions could be increased. However, we believe it is important to develop the most effective and efficient protocol rather than focus purely on the number of sessions. When using the HAL-SJ, the electrodes are attached to the surface of the skin to detect BES. In TKA, the skin incision is close to the patella;

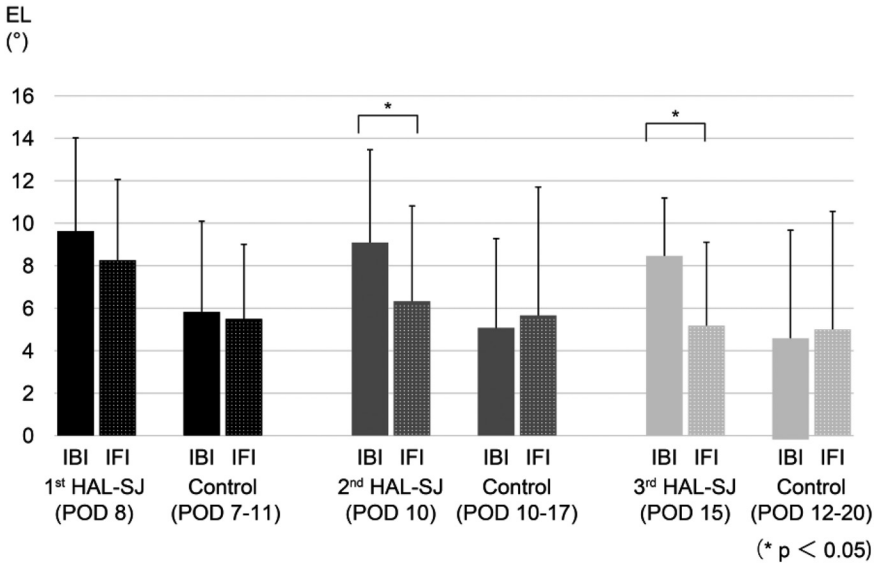

Figure 4 Changes in extension lag in the HAL-SJ and control groups before and after intervention.
EL: extension lag; HAL-SJ: hybrid assistive limb-single joint type; POD: postoperative day

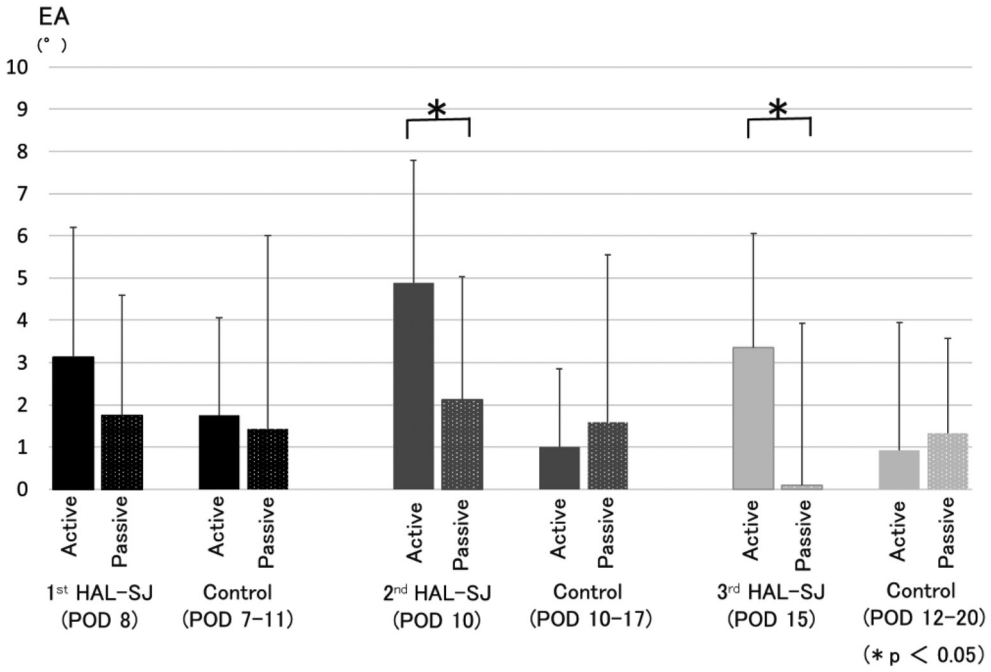

Figure 5 Improvement in knee joint extension angle due to intervention in the HAL-SJ group and control group: comparison of active motion and passive motion.
HAL-SJ: hybrid assistive limb-single joint type; POD: postoperative day; EL: extension lag; EA: extension angle

however, it was possible to avoid the surgical wound and detect BES from the quadriceps femoris muscle. An important assumption for using this method is that, even in the acute period after surgery for knee osteoarthritis in patients with musculoskeletal disorders, it is relatively easy to detect BES on the muscle belly of the quadriceps femoris muscle. This observation is in contrast to that observed in intractable neurological diseases.

The fact that VAS decreased after HAL-SJ intervention suggests that this method is safe in the acute postoperative period. The mechanism for this reduction in VAS is unclear, but the effect probably results from the motion assistance of the HAL-SJ. In contrast to conventional therapy with a physical therapist, the BES generated when the patient tries

to extend the knee joint is detected by the HAL-SJ, synchronizing extension with the intended motion. In contrast, active assisted exercise with a physical therapist involves active extension assistance while talking to or guiding the patient. The HAL-SJ adjusts its assistance by adjusting several parameters as described in the Methods section based on BES, while the physical therapist performs exercise assistance based on experience and knowledge of physiology and anatomy. Currently, conventional rehabilitation involves knee joint ROM training with a physical therapist. This new robotic approach could become more common if it provides significantly better treatment outcomes than conventional therapy. Future comparative studies are planned to determine which method can more effectively produce functional improvements without increasing pain.

A statistically significant improvement in EL was found after the 2nd and 3rd interventions. Figure 5 shows the improvement in knee ROM (°) after HAL-SJ intervention. Active extension ROM significantly improved after the 2nd and 3rd sessions. This suggested that the effect was caused primarily by an improvement in active extension ROM. In the improvement of EL using the HAL-SJ, the active extension ROM approaches the passive extension ROM, suggesting that it is important to obtain complete knee extension during surgery using the appropriate surgical techniques. In the future, the operational mechanism should be studied from a neurophysiological viewpoint. Comparative studies are also needed between HAL-SJ and conventional rehabilitation in order to determine which method provides the best early functional improvement, as well as to elucidate the differences in the mid- and long-term, and clarify the clinically meaningful indicators of efficacy.

In the acute post-TKA period, it is sometimes difficult to perform sufficient knee joint extension due to swelling or pain in the joint[5, 8, 15]. Knee EL is one of the reasons for reduced knee joint function and patient satisfaction after TKA[5, 6]. Until now, due to the Japanese lifestyle (sitting on the knees), many developments have been made with respect to the techniques and types of rehabilitation used to obtain deep flexion. The HAL-SJ, by providing knee active extension assistance in real-time based on BES and patient feedback, represents a new method for recovering knee joint extension function. This is expected to have positive neuromuscular and exercise training effects[12].

A limitation of the present study is the different surgeons and implants were used in the HAL-SJ and control groups. Therefore, it is difficult to clarify the efficacy of HAL-SJ training in this study. It will be necessary for the same surgeon to perform TKA using the same implant and technique in the future. Patient characteristics should also be kept uniform between groups, especially since the maximum passive knee extension angle as measured under anesthesia at the end of surgery was partially decreased in the control group. Furthermore, the HAL-SJ group had various types of evaluations performed before and the after knee joint extension. Meanwhile, in the control group, knee joint extension exercises and several conventionally performed types of rehabilitation were performed. In the future, it will be necessary to perform the same exercise tasks in each group. It is also necessary to clarify the clinical significance of the improvements in EL angles obtained in this study. In the future, the mid- and long-term efficacy should be assessed in more detail.

Conclusion

In conclusion, HAL-SJ-based training can be safely performed in the acute post-TKA period. The HAL-SJ is effective without causing an increase in pain. The operational mechanism should be clarified, and the best usage methods (program settings, frequency, and number of sessions) investigated. Comparative studies of HAL-SJ-based therapy versus conventional rehabilitation are required to assess the reliability of these results.

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