

Original Article

Effects of Supplemental Robot-Assisted Knee Flexion Exercise After Total Knee Arthroplasty: A Randomized Controlled Clinical Study

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Abstract

Objectives: This study aimed to investigate the beneficial effects of single-joint hybrid assistive limb (HAL-SJ)-assisted rehabilitation after total knee arthroplasty (TKA), with a focus on the early postoperative period. **Methods:** This single-anonymized randomized controlled trial assigned 72 participants who underwent primary TKA for knee osteoarthritis to the HAL-SJ ($n=35$) and control groups ($n=37$). The passive knee range of motion (ROM; i.e., the primary outcome) was evaluated preoperatively and at 1 week, 2 weeks, and 3 months postoperatively. Extension lag and knee pain intensity scores were evaluated preoperatively and at 1 and 2 weeks postoperatively. Quadriceps and hamstring isometric knee strength and walking speed were evaluated preoperatively and at 2 weeks postoperatively. The Knee Injury and Osteoarthritis Outcome Score (KOOS) was evaluated preoperatively and at 3 months postoperatively. **Results:** Compared with the control group, the HAL-SJ group showed significantly improved knee extension ROM ($p=0.001$) and greater KOOS Activities of Daily Living subscale score ($p=0.005$) at 3 months postoperatively, with a significantly early improvement in extension lag ($p=0.001$) and hamstring strength ($p=0.012$) at 2 weeks postoperatively. **Conclusions:** HAL-SJ effectively supports postoperative rehabilitation, showing clinical advantages for improving daily activities by 3 months after TKA. **Clinical Trial Registration:** University Hospital Medical Information Network (UMIN000053675).

Keywords: Knee Osteoarthritis, Rehabilitation Therapy, Total Knee Arthroplasty

Introduction

Total knee arthroplasty (TKA) is a common surgical procedure for treating knee osteoarthritis (OA)¹. The increasing global prevalence of OA has led to a rise in the prevalence of TKA and the associated medical expense

burden². Rapid recovery of muscle function and early mobilization are important for successful rehabilitation following TKA. Perioperative care programs, such as “enhanced recovery after surgery” protocols, emphasize early mobilization³ to minimize the length of hospital stays, complications, and overall cost⁴. However, new rehabilitation methods are required to further improve the early recovery of knee joint function following TKA.

Recently, rehabilitation robots have emerged as digital aids for musculoskeletal rehabilitation⁵. The single-joint hybrid assistive limb (HAL-SJ, Cyberdyne Inc.; Tsukuba, Japan) is a new device designed for post-TKA rehabilitation^{6,7}. The HAL-SJ is a neurologically controlled therapy device that supports knee joint flexion and extension triggered by a patient’s bioelectrical signals (BEs)^{8,9}. Knee joint extension training using the HAL-SJ after TKA improves knee range

The authors have no conflict of interest.

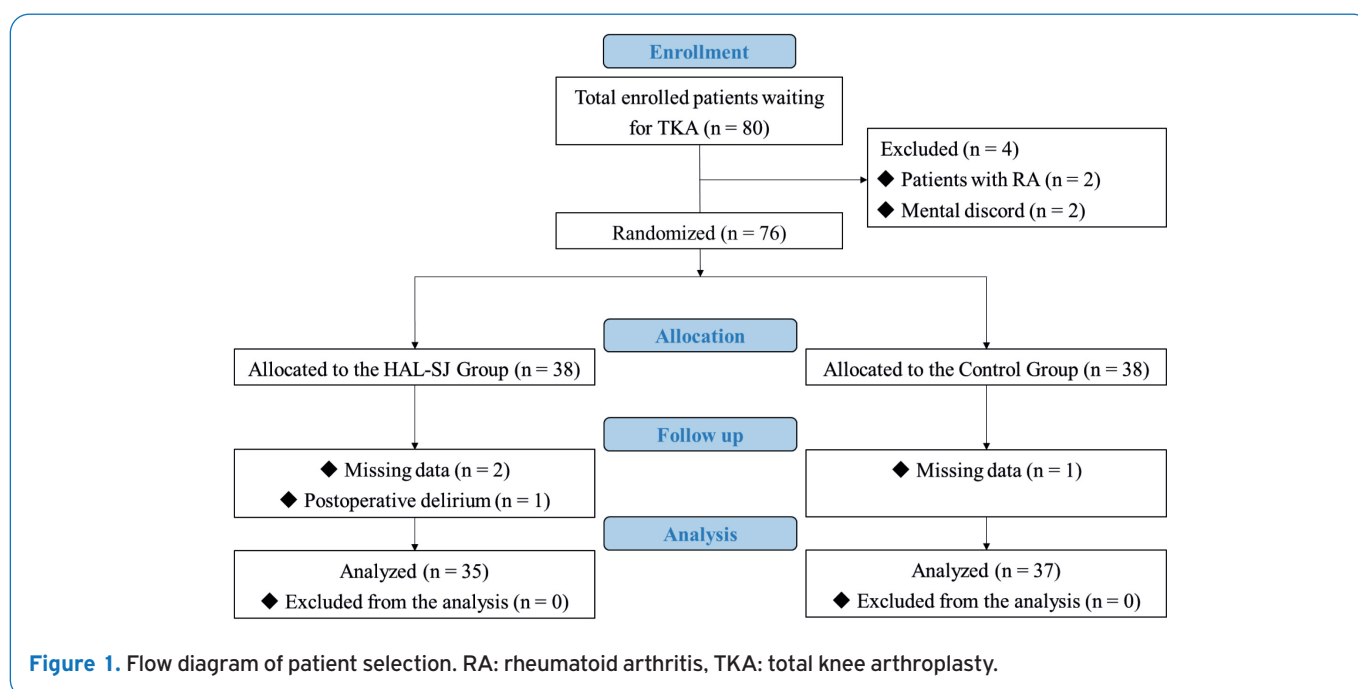
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of motion (ROM), extension lag, and gait function without increasing knee pain^{6,10,11}. In addition, patient-reported outcomes are significantly better with HAL-SJ therapy than with conventional physical and continuous passive motion therapies^{7,12}. However, most previous studies have been limited to pilot studies or case reports with small sample sizes; therefore, the effects of HAL-SJ-assisted rehabilitation after TKA remain unclear.

This single-anonymized randomized controlled trial (RCT) aimed to evaluate the effects of HAL-SJ for orthopedic rehabilitation in the early postoperative period after TKA. We hypothesized that knee exercises using the HAL-SJ would enhance the early recovery of knee joint function and patient satisfaction.

Materials and Methods

Study Design

This single-anonymized RCT conformed to the Consolidated Standards of Reporting Trials 2010 statement: Extension for pilot/feasibility studies¹³. Eligible participants underwent a baseline assessment conducted by a blinded assessor and were randomized into two intervention groups. The randomization sequence was generated using Excel (Microsoft Inc., Redmond, WA, USA). Participants were blinded to the group allocation to prevent it from influencing their adherence, the use of other treatments, or increasing dropout rates. All participants provided written informed consent to participate in the project.

Patient Recruitment

This prospective RCT recruited patients with primary end-stage OA scheduled for primary TKA from a single university hospital between October 2021 and August 2023. Overall, our study included 80 Japanese patients with knee OA who underwent cruciate-retaining type TKA using the Robotic Surgical Assistant Knee system (Zimmer Biomet; Warsaw, IN, USA) through a subvastus approach (Figure 1). The exclusion criteria were the presence of rheumatoid arthritis, a severe cognitive deficit, mental disorder, Kellgren–Lawrence score <2, lower extremity paralysis, history of tibial osteotomy or revision arthroplasty, body mass index >35 kg/m², pain that renders conventional rehabilitation impractical, history of non-device-related revision surgery, and treatment rejection by the patient. Four patients who met one or more of these criteria were excluded. The 76 patients who satisfied the inclusion criteria were assigned to either the HAL-SJ group (HAL-SJ administered 7 days after TKA) or the control group.

Measurements

The primary outcomes were passive ROM at 3 months postoperatively. Passive ROM was measured using a goniometer (Toudaisiki-Goniometer, OG Wellness Co., Ltd.; Okayama, Japan).

The secondary outcomes were the disappearance of extension lag, quadriceps and hamstring isometric knee strength, and knee pain intensity, measured using the



Figure 2. Patients in the HAL-SJ group sit in bed and perform extension and flexion exercises with the affected knee joint using the single-joint hybrid assistive limb (HAL-SJ).

Numerical Rating Scale (NRS) score preoperatively and 1 and 2 weeks postoperatively. The NRS rates pain on a 0–10 scale, with 0 indicating no pain and 10 indicating the worst pain. The intraclass correlation coefficient (ICC) of the NRS was 0.95¹⁴. Walking speed was measured preoperatively and 2 weeks postoperatively. The Knee Injury and Osteoarthritis Outcome Score (KOOS) was used to evaluate knee function and patient-reported outcomes preoperatively and 3 months postoperatively. The KOOS is a validated score for TKA that evaluates short-term effects and physical therapy (ICC: 0.85)¹⁵. Extension lag (the difference between the active and passive ranges of knee extension) was measured by licensed physical therapists (ICC: 0.90)¹⁶. Quadriceps and hamstring strengths were measured using a handheld dynamometer (HHD; #Tas F-1, ANIMA; Japan) and performed using a technique validated for measuring quadriceps and hamstring strength after TKA^{17,18}. Isometric knee force was measured as follows: (1) the patient was seated with the hip flexed at 90° and the knee flexed at 90°, with hands resting on their lap; (2) The physical therapist fixed an HHD approximately 5 cm proximal to the medial malleolus; and (3) The patient exerted a maximal isometric knee force while the physical therapist matched the patient's force with the HHD. HHD force values were measured in newtons and normalized as a percentage of the patient's body weight (newton/body weight). The HHD force was typically measured twice within each assessment period, and the maximum value was used for the analyses. The interrater ICC scores are good, and range from 0.90 to 0.96 for quadriceps and hamstring strengths measures¹⁹. The 10-m walking speed was measured along a 14-m straight walking path with 2-m front and rear runways. The time required for patients to finish the 10-m walk comfortably was measured using a

stopwatch²⁰. The 10-m walking speed measurements have been shown to have excellent test reliability (ICC: 0.96–0.98)²¹.

Rehabilitation Protocol and Interventions

All patients underwent a similar rehabilitation treatment protocol. HAL-SJ was administered instead of knee flexion–extension exercises 7 days postoperatively in the HAL-SJ group. All patients received 40 min/day rehabilitation 5 times per week during hospitalization. On day 1, treatment was initiated in both groups in the in-bed sitting posture, followed by transfer to wheelchairs, standing and short-distance walking on flat ground, flexion–extension exercises, and isotonic muscle contraction while seated. From day 2 until hospital discharge, the following exercises were performed: active-resisted quadriceps exercises, gradual exercise intensification while using walking aids, increased distance walking, re-education on walking patterns, and adaptation to daily life activities. From day 7 until hospital discharge, patients in the HAL-SJ group sat in bed and performed extension and flexion of the knee joint in the affected knee, undergoing primarily active-assisted mobilization using HAL-SJ (Figure 2). The BEs of the vastus medialis and biceps femoris muscles were detected using electrodes placed according to the SENIAM guidelines²². In the cybernic voluntary control mode (CVC-AutoEXT/AutoFlx), the patient was supported by BEs triggered by knee joint extension and flexion. In this mode, the knee flexion signal remains constant, allowing the robot to flex as needed. When the force is removed from the knee extension, an assistive torque toward flexion is generated, enabling operational assistance adapted to knee extension in a sitting position, as the robot returns automatically to the limb training's start position. The settings were as follows: extension/flexion signal balance with flexion

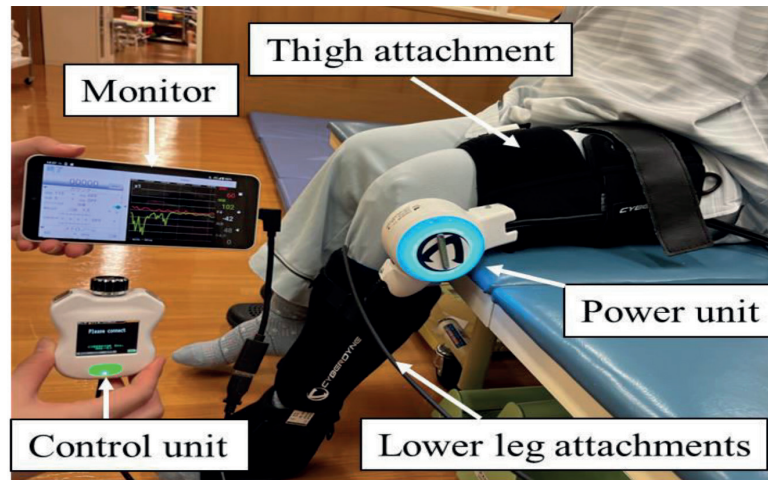


Figure 3. Components of the single-joint hybrid assistive limb.

Table 1. Patient demographics data.

Variable	HAL-SJ group (n=35)	Control group (n=37)	p-value
Sex (males: females)	14: 21	13: 24	0.808
Age at time of surgery (years)	74.3 (5.7)	75.4 (6.8)	0.465
Affected side (left: right)	14: 21	18: 19	0.460
Height (cm)	154.7 (6.4)	155.2 (10.9)	0.818
Weight (kg)	61.5 (9.6)	61.6 (10.4)	0.973
BMI (kg/m ²)	25.6 (2.8)	25.6 (4.2)	0.933
Kellgren-Lawrence grade	III: 9, IV: 26	III: 12, IV: 25	0.531

Values are reported as mean (standard deviation). BMI, Body mass index.

at 80% and extension at 100%, using the BEs obtained from the anterior and posterior of the thigh; 20–40% assist gain (0–100 assist torque adjustment relative to the generated BEs, where 100 is the maximum); and a torque limit of 50% of the maximum (Figure 3). The knee joint was moved with assistance, and the amount of movement for flexion started at 90°. The flexion was increased to 120° as soon as the patient could perform more exercises. Five sets of 10 repetitions were performed three times weekly (1 min rest between sets; 10–15 min total duration per unit). The control group performed active knee extension exercises without HAL-SJ. The physical therapist did not assist with joint movement but only provided verbal instructions. Five sets of 10 repetitions were performed three times weekly. The routine treatment administered to both groups included intermittent pneumatic calf compression and self-administered ankle dorsiflexion–plantar flexion exercises to prevent deep vein thrombosis.

Postoperative analgesic management was similar

between the groups. Patients were administered an adductor canal block using 20 mL of ropivacaine (7.5 mg/mL) by the anesthesiologist at the time of surgery. Opioid analgesics were administered intravenously as needed in the postoperative period. Celecoxib (200 mg/day) was administered orally for a week starting the next day.

Statistical Analysis

The sample size was calculated using the G-Power 3.1.9.6 (Franz Paul; Kiel, Germany). A 10° of passive ROM difference between groups was deemed clinically significant and potentially sufficient to warrant an increase in treatment frequency. The sample size required to detect a significant difference (2-sided, $\alpha < 0.05$) of at least 10° ROM between groups (primary outcome) with an assumed standard deviation of 15° and a power of 0.80 was 37 individuals per

Table 2. Preoperative and postoperative clinical results in the groups.

Clinical results	HAL-SJ group	Control group	p-value	Cohen's d
Hospitalization duration (days)	17.8 (3.2)	18.3 (3.3)	0.521	0.152
Inpatient rehabilitation (days)	12.1 (2.1)	12.9 (2.5)	0.168	0.329
Extension lag (days)	10.7 (3.7)	13.6 (3.4)	0.001	0.810
Pre-TKA				
Flexion ROM (°)	112.2 (16.9)	112.0 (16.1)	0.836	—
Extension ROM (°)	-10.4 (8.3)	-8.0 (6.2)	0.159	—
Quadriceps strength (N/kg)	3.0 (0.8)	3.4 (1.3)	0.127	—
Hamstring strength (N/kg)	1.7 (0.5)	1.7 (0.5)	0.878	—
Resting pain NRS	4.2 (1.5)	3.7 (1.6)	0.199	—
Walking speed (m/sec)	0.9 (0.1)	0.9 (0.1)	0.673	—
Week 1 after TKA				
Flexion ROM (°)	95.1 (10.3)	94.1 (9.1)	0.636	0.128
Extension ROM (°)	-4.4 (3.7)	-5.0 (3.9)	0.531	0.113
Resting pain NRS	1.9 (1.7)	2.2 (1.3)	0.395	0.204
Walking pain NRS	4.0 (1.4)	4.0 (1.4)	0.867	0.040
Week 2 after TKA				
Flexion ROM (°)	112.0 (8.2)	110.0 (9.5)	0.314	0.223
Extension ROM (°)	-1.8 (3.0)	-2.7 (2.8)	0.219	0.270
Quadriceps strength (N/kg)	2.2 (0.8)	2.1 (0.7)	0.702	0.172
Hamstring strength (N/kg)	1.2 (0.4)	1.0 (0.4)	0.012	0.753
Resting pain NRS	1.0 (1.2)	0.9 (1.3)	0.926	0.023
Walking pain NRS	2.5 (1.4)	2.7 (1.4)	0.624	0.109
Walking speed (m/sec)	0.8 (0.1)	0.8 (0.1)	0.432	0.187
Month 3 after TKA				
Flexion ROM (°)	115.1 (8.8)	114.0 (8.0)	0.587	0.129
Extension ROM (°)	-0.5 (2.0)	-3.4 (4.1)	0.001	0.863

Values are reported as the mean (standard deviation). ROM, Range of motion; NRS, Numeric rating scale; SD, Standard deviation; TKA, Total knee arthroplasty.

group. Therefore, the target sample size was 80 patients, allowing for potential loss during follow-up.

The Shapiro–Wilk test was used to evaluate the normal distribution of all parameters. After verifying the data distribution's normality, the groups' demographic data, baseline variables, and outcome values were compared using the unpaired t-test, Mann–Whitney U test, and chi-squared test. Cohen's *d* was used to calculate the effect size. Cohen's *d* values of >0.2, >0.5, and >0.8 indicated small, medium, and large effect sizes, respectively²³. All statistical analyses were performed using SPSS Statistics (version 27.0.0.0, SPSS Inc.; Chicago, IL, USA). Statistical significance was set at $p < 0.05$.

Results

The study recruited 76 patients who met the inclusion criteria. Four patients (three in the HAL-SJ group and one in the control group) were excluded because of missing data

or postoperative delirium. The final evaluation included 72 patients, with 35 patients in the HAL-SJ group and 37 in the control group. The demographic characteristics and general data were similar between the two groups (Table 1).

Extension lag was significantly shorter in the HAL-SJ group than in the control group (10.7 ± 3.7 vs. 13.6 ± 3.4 days; $p = 0.001$). Hamstring strength was significantly greater in the HAL-SJ group than in the control group at 2 weeks after TKA (1.2 ± 0.4 vs. 0.9 ± 0.4 N/kg; $p = 0.002$). In addition, knee extension ROM improved more notably in the HAL-SJ group than in the control group ($-0.5 \pm 2.0^\circ$ vs. $-3.3 \pm 4.0^\circ$; $p = 0.001$) 3 months after TKA. The groups exhibited no significant differences in quadriceps isometric knee strength, NRS pain score, walking speed, preoperative and postoperative hospitalization durations, or total days of inpatient rehabilitation (excluding weekends) (Table 2).

The KOOS Activities of Daily Living (ADL) subscale score was significantly better in the HAL-SJ group than in the control group (76.4 ± 12.9 vs. 65.6 ± 18.4 points; $p = 0.005$) 3 months after TKA (Table 3).

Table 3. Preoperative and 3-month postoperative mean KOOS in the HAL-SJ and control groups.

	Pre-TKA			Month 3 after TKA			
	HAL-SJ group	Control group	p-value	HAL-SJ group	Control group	p-value	Cohen's d
KOOS Symptoms	50.8 (16.2)	52.3 (14.9)	0.683	65.3 (13.3)	63.8 (16.2)	0.659	0.105
KOOS Pain	55.3 (18.7)	51.6 (18.8)	0.402	69.5 (13.2)	67.6 (17.6)	0.595	0.126
KOOS ADL	57.6 (18.4)	55.2 (18.3)	0.595	76.5 (12.9)	65.6 (18.4)	0.005	0.676
KOOS QOL	37.9 (24.4)	37.5 (17.9)	0.934	55.8 (17.3)	47.6 (20.2)	0.072	0.431
KOOS Sport/Rec	29.5 (15.8)	24.5 (13.7)	0.150	46.7 (18.0)	42.4 (22.8)	0.390	0.204

Values are reported as the mean (standard deviation). KOOS, Knee Injury and Osteoarthritis Outcome Score; HAL-SJ, single-joint hybrid assistive limb; TKA, Total knee arthroplasty.

Discussion

The most important finding of the present study was that the HAL-SJ group exhibited significantly improved knee extension ROM, extension lag, hamstring strength, and KOOS ADL subscale scores compared to the control group. These results support the hypothesis that knee exercises performed using HAL-SJ enhance the early recovery of knee joint function and patient satisfaction. To the best of our knowledge, the present RCT is the first to demonstrate the efficacy of HAL-SJ in orthopedic rehabilitation in the early postoperative period after TKA.

The present study found knee extension ROM 3 months postoperatively was greater in the HAL-SJ group than in the control group, whereas no differences were observed at 1 or 2 weeks. Active and passive ROM 10 days postoperatively show significant improvements after starting HAL-SJ 5 days postoperatively, with the active ROM at 6-month follow-up being significantly better¹². Our study initiated HAL-SJ 7 days postoperatively, and noticeable improvements in knee ROM were observed only at 3 months postoperatively. This disparity in early improvement with HAL-SJ training may be attributed to the different training points (starting 5 days postoperatively) and follow-up periods. Therefore, future studies should investigate the effects of the initiation timing and training frequency to clarify the precise effects of HAL-SJ training.

HAL-SJ-based training is both safe and effective, demonstrating immediate improvements in extension lag^{10,11,24,25}. Early postoperative muscle weakness is mainly influenced by the supraspinal nervous system level^{24,26}. Recent studies have shown the clinical efficacy of biofeedback on HAL therapy²⁷. In addition, patients who undergo TKA exhibit improved hamstring strength through electromyographic biofeedback^{12,28}. Therefore, the biofeedback effect of HAL-SJ may facilitate early hamstring neuromuscular activation and improve quadriceps femoris function after TKA. The observed reduction in extension lag further underscores the role of HAL-SJ in supporting functional recovery,

indicating its potential as an effective adjunct to conventional rehabilitation practices in patients with TKA. However, as the follow-up period of the present study was short, the results should be interpreted with caution.

The HAL-SJ group exhibited significantly better outcomes on the KOOS ADL subscale score. The Oxford knee and EuroQol 5 dimensions 5-level scores (patient-reported outcomes) significantly improve in patients treated with HAL-SJ^{7,12}. The minimal clinically important difference (MCID), which is the smallest change in an outcome that a patient perceives as clinically remarkable, is commonly used to interpret patient-reported outcome measures²⁹⁻³¹. Previous studies have calculated MCIDs of 10–18 for the KOOS of patients who underwent TKA³²⁻³⁴. In the present study, the HAL-SJ group exhibited an improvement greater than 18 MCID in KOOS ADL. Although robot-assisted rehabilitation in orthopedic settings is currently limited, it holds potential for broader application, particularly for patients with an increased need for support^{5,35}. Therefore, the HAL-SJ is clinically advantageous for improving daily living activities.

This study had some limitations. First, the follow-up period was short; therefore, future studies should investigate the long-term effects of HAL-SJ-assisted rehabilitation to better understand its role in sustained functional improvements after TKA. Second, patients were discharged approximately 18 days after surgery, and only in-hospital rehabilitation using HAL-SJ was feasible. Consequently, the HAL-SJ rehabilitation period was limited to approximately 12 days. Therefore, the optimal timing and number of training sessions remain to be determined. Additionally, future studies should assess varying timings for initiation and frequency of HAL-SJ to optimize outcomes. Finally, the sample size was small because four patients (three in the HAL-SJ group and one in the control group) were excluded because of missing data or postoperative delirium. The smaller sample size and low post-hoc power, such as KOOS, may have resulted in a type II error. These non-significant results may need to be clinically interpreted with caution. However, despite the small size of the sample, we observed sufficient post-hoc

power to detect significant differences between the HAL-SJ and control groups in this study. Expanding the sample size and incorporating multi-center trials may enhance generalizability and address current limitations.

In conclusion, HAL-SJ is effective for postoperative rehabilitation, improving extension lag, hamstring strength, and knee extension ROM. Moreover, it demonstrates a highly significant postoperative improvement in the KOOS ADL subscale score. These findings suggest that HAL-SJ leads to clinically beneficial improvements in daily activities at 3 months after TKA.

Ethics approval

This study was conducted in accordance with the principles embodied in the Declaration of Helsinki. Additionally, this study was approved by the Ethics Review Committee of our institution (approval no. 113786) and was registered with the University Hospital Medical Information Network (UMIN000053675).

Consent to participate

Written informed consent was obtained from all participants.

Authors' contributions

TW, RM, and TS designed this study. TW, RM, and GS collected and analyzed the data. TS, SY, MK, and YA interpreted the data. TW, TS, MK, and YA drafted the manuscript. RM, TS, GS, SY, MK, and YT reviewed the manuscript. All authors have read and approved the final version of the manuscript.

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