Early Recovery of Walking Ability in Patients After Total Knee Arthroplasty Using a Hip-Wearable Exoskeleton Robot: A Case-Controlled Clinical Trial

Kazunori Koseki, PT, MSc1, Hirotaka Mutsuzaki, MD, PhD2, Kenichi Yoshikawa, PT, PhD1, Koichi Iwai, PhD3, Yuko Hashizume, PT, MSc1, Ryo Nakazawa, PT1, and Yutaka Kohno, MD, PhD2

Abstract
Introduction: The Honda Walking Assist (HWA) is a hip-wearable exoskeleton robot for gait training that assists in hip flexion and extension movements to guide hip joint movements during gait. This study aimed to evaluate the effects of walking exercises with HWA in patients who underwent total knee arthroplasty (TKA). Materials and Methods: This study involved 10 patients (11 knees) in the HWA group and 11 patients (11 knees) in the control group who underwent conventional physical therapy. The patients assigned to the HWA group underwent a total of 17-20 gait training sessions, each lasting approximately 20 min from week 1 to 5 following TKA. Self-selected walking speed (SWS), maximum walking speed (MWS), range of motion (ROM), knee extension and flexion torque, and Western Ontario and McMaster Universities Osteoarthritis Index subscales of pain (WOMAC-p) and physical function (WOMAC-f) scores were measured preoperatively, at 2, 4, and 8 weeks following TKA. Results: Interventions were successfully completed in all patients, with no severe adverse events. A significant difference was noted in the time × group interaction effect between preoperative and week 2 SWS and MWS. Regarding knee function, there was a significant difference in the time × group interaction between preoperative and week 2 active ROM extension; however, no significant difference in knee torque, WOMAC-p, and WOMAC-f scores were observed. In the between-group post hoc analysis, WOMAC-f in the HWA group was higher than that in the control group at week 8. Discussion: Although the control group showed a temporary reduction in SWS and MWS 2 weeks after TKA, the HWA group did not. These results suggest that HWA intervention promotes early improvement in walking ability after TKA. Conclusions: The gait training using HWA was safe and feasible and could be effective for the early improvement of walking ability in TKA patients.

Keywords
total knee arthroplasty, walking exercise, walking ability, exoskeleton robot, early recovery

Submitted April 20, 2021. Revised May 27, 2021. Accepted June 06, 2021.
their walking ability and knee function. Therefore, early postoperative improvements in walking ability and activities of daily living (ADL) are necessary, and they are important goals of postoperative rehabilitation.

In general, physical therapy interventions, such as lower extremity strength training, ROM exercises, balance exercises, and ADL training, are provided to patients after TKA to minimize postoperative functional decline. Recently, the effects of using robotics for walking exercises have been examined, and exoskeletal robotic exercises have been proposed for patients who have undergone TKA to improve postoperative knee function and walking ability. However, several of these devices are heavy and have a strong exoskeleton mechanism to provide lower leg support because they are intended to be used during repetitive walking exercises for severely paralyzed patients. As patients after TKA surgery do not have severe paralysis, these exoskeleton-type robotic devices may not be efficient in clinical settings because of the large scale of the devices and time it takes to fit them. Therefore, we focused on the Honda Walking Assist (HWA) device, which is a light and simple wearable robotic device for gait training.

The HWA has actuators placed at the hip joint to assist with hip flexion and extension and to guide left-right symmetry of gait (e.g., temporal and spatial parameters including symmetry of stride length and symmetry of stance time) by adjusting the timing and intensity of the assist. Angular and torque sensors placed at the hip joint monitor the hip joint angle, and the “assist torque” assists hip joints based on an algorithm for regulating and correcting gait (Figure 1A). We previously used the HWA for gait training and observed improved lower limb kinematic parameters (e.g., stiff knee gait pattern), as well as early improvement of walking ability after surgery in a patient who underwent TKA. In addition to the aforementioned improvement of gait symmetry, we hypothesized that walking practice using a hip-driven exoskeleton-type robot can promote early recovery of walking and knee function in patients with knee joint diseases, since hip assist with the HWA can influence lower extremity kinematics during gait (Figure 1B). For this reason, we conducted a comparative study with a control group that received conventional physical therapy.

The purpose of this study was to verify safety, feasibility, and effectiveness of the walking exercise with HWA in postoperative TKA patients would result in early improvement of walking ability and knee function.

**Method**

**Participants**

Between March 2015 and April 2020, 23 subjects (24 knees), excluding those who participated in other clinical trials and with a central nervous system disease such as cervical myelopathy, who underwent TKA at our hospital participated in this study. These patients were divided into 2 groups before surgery (HWA and control groups). Two patients were unable to continue the study, 1 due to postoperative delirium and the other due to wound infection. Finally, 10 patients (11 knees) in the HWA group and 11 patients (11 knees) in the control group completed the intervention period. Four patients in the control group were lost to follow-up at week 8 because they did not visit the hospital at the time of measurement (Figure 2).

The surgical procedure was similar to that described in previous reports. With the patients under general anesthesia, we made a midline skin incision and reached the joint using a medial parapatellar approach. The patella was not replaced, and the posterior cruciate ligament was retained. We used a Persona® (Zimmer Biomet, Warsaw, IN, USA) implant for the
femoral component and a NexGen® Trabecular Metal™ Monoblock Tibia (Zimmer Biomet) implant for the tibial component.

The ethics committee of Ibaraki Prefectural University of Health Sciences approved the study (no. e98 and e204). We explained the purpose of the study to the patients verbally and obtained written consent.

**Intervention**

The patients allocated to the HWA group underwent gait training using the HWA from week 1 to 5 following TKA. Training was conducted at the hospital and consisted of 4-5 sessions, each lasting ~20 min (excluding resting time) per week, for a total of 17-20 sessions. Moreover, the patients in both groups underwent conventional rehabilitation during the intervention period, such as ROM exercises; stretching; muscle strengthening; balance training; ADL training such as toileting, bathing, and bedside tasks; gait training; and stair climbing training. Each HWA training session was integrated with the walking exercises during physical therapy sessions. The patients allocated to the control group underwent conventional rehabilitation only during the intervention period. In order to compare the amount of intervention, the total physical therapy time during the intervention period was investigated in both groups.

Adverse events such as exacerbation of knee pain and skin problems involving wounds were carefully observed during and after the HWA training. In addition, knee pain was assessed using the visual analog scale (VAS) during each HWA training session and compared to that of walking without HWA on the same day.

**Methods of Assessment**

Figure 3 summarizes the parameters and timing of measurements related to knee function and walking ability.

Knee function measurements included ROM in terms of knee flexion and extension during passive and active movement of the operated knee; knee extension and flexion torque (representing quadriceps and hamstring strength); and Western Ontario and McMaster Universities Osteoarthritis Index subscales of pain (WOMAC-p) and physical function (WOMAC-f) scores, modified for the Japanese context. Isometric knee torque was measured using a Biodex System 4 dynamometer (Biodex Medical Systems, Inc., NY, USA), with the knee fixed at 60° of flexion. Each torque was measured 3 times for 5 s at a time, and the peak torque value was divided by the body weight for further analysis.

Measurements related to walking ability included self-selected walking speed (SWS), maximum walking speed (MWS), mean step length at SWS and MWS, and cadence at SWS and MWS. SWS and MWS tests were conducted without the HWA on a walking path with an extra path of 3 m before and after the 10 m measurement section. Steps were counted during these tests to calculate the step length and cadence. These measurements were performed before TKA and at 2, 4, and 8 weeks following TKA.

**Statistical Analysis**

A few missing values were included in the data. Multiple imputation is commonly practiced under the assumption that data are missing at random (MAR). Imputation was conducted using a fully conditional specification approach using PROC MI in SAS 6.4 (SAS Institute Cary, NC, USA). Student’s t-test was used to confirm the differences between the 2 groups at each time point. The effect size was calculated using Cohen’s d. The changes in the 8-week training after surgery in the control and HWA intervention groups were examined using generalized linear mixed models (GLMM), using the SPSS 26.0 (GENLINMIXED procedure; IBM Corp., Armonk, NY, USA). The main effects of treatment group and time, as well as the treatment group × time interaction effect, were examined using the mixed-effect models. Statistical significance was measured at the 5% level.

**Results**

Interventions were successfully completed in all patients, with no severe adverse events. No patient experienced skin trouble during gait training with HWA. In the initial phase of the intervention, 1 patient complained of mild pressure pain at the femoral cuff attachment site; however, this improved by changing to a larger attachment. Comparing knee pain during walking exercise with and without HWA, knee pain worsened in 1 case and decreased in 6 cases.

Table 1 summarizes the preoperative characteristics of patients, namely, age, sex, weight, height, body mass index (BMI), disease, TKA-operated side, contralateral side TKA, WOMAC-p score, and WOMAC-f score. The differences in patient characteristics between the 2 groups were not significant.
Walking Ability

The results of walking ability are summarized in Tables 2 and 3. The main effect of time was significant between pre-operation and week 2 for all measurements, although the differences between pre-operation and week 4 or pre-operation and week 8 were not significant. The main effect of the group was not significant. Regarding the time × group interaction effect, there were significant differences in SWS, MWS, and SL-SWS between pre-operation and week 2. SWS in the control group decreased significantly from 1.09 m/s (95% CI, 0.96-1.23) to 0.70 m/s (95% CI, 0.51-0.90), whereas in the HWA group, it decreased only minimally from 1.04 m/s (95% CI, 0.89-1.19) to 0.96 m/s (95% CI, 0.84-1.07). Similarly, MWS in the control group decreased significantly from 1.36 m/s (95% CI, 1.22-1.49) to 0.90 m/s (95% CI, 0.67-1.14), whereas in the HWA group, it decreased only slightly from 1.30 m/s (95% CI, 1.08-1.51) to 1.20 m/s (95% CI, 1.06-1.35). In the between-group post hoc analysis, the SWS (p = .022, Cohen’s d = 1.09), MWS (p = .025, Cohen’s d = 1.04), SL at SWS (p = .032, Cohen’s d = 0.94), and SL at MWS (p = .036, Cohen’s d = 1.02) were greater in the HWA group than in the control group at week 2.

Knee Range of Motion

The results of the knee ROM are summarized in Tables 4 and 5. The main effect of time between pre-operation and week 2 was

---

Table 1. Preoperative Baseline Characteristics of the Patients.

| Characteristics | Honda group, 10 patients (11 knees) | Control group, 11 patients (11 knees) | P value |
|-----------------|-----------------------------------|-------------------------------------|---------|
| Age             | 71.8 ± 6.2                        | 75.9 ± 6.9                          | .467    |
| Sex             | Male/Female                       | 0/10                                | 1/10    |
| Weight (kg)     | 64.9 ± 10.3                       | 59.5 ± 10.3                         | .988    |
| Height (cm)     | 148.7 ± 7.2                       | 147.4 ± 7.8                         | .855    |
| BMI (kg/m²)     | 29.4 ± 5.0                        | 27.4 ± 4.6                          | .785    |
| Disease         | OA/RA                             | 9/1                                 | 10/1    |
| TKA operated side | Right/Left                      | 6/5                                 | 4/7     |
| Contra lateral side TKA | 3                          | 3                                   | 1.000   |
| WOMAC-p score   | 45.9 ± 19.3                       | 60.9 ± 21.9                         | .631    |
| WOMAC-f score   | 65.5 ± 22.2                       | 69.4 ± 12.9                         | .064    |
| Physical therapy time during intervention (h) | 34.1 ± 6.5                         | 35.5 ± 8.9                          | .674    |

Abbreviations: BMI, body mass index; OA, osteoarthritis; RA, rheumatoid arthritis; TKA, total knee arthroplasty; WOMAC-P, Western Ontario and McMaster Universities Osteoarthritis Index subscales of pain scores; WOMAC-f, Western Ontario and McMaster Universities Osteoarthritis Index subscales of physical function scores.

*Values are expressed as numbers or as mean ± SD.
Table 2. Changes in the Walking Speed, Step Length, Cadence, and Time × Group Interaction Effect.

| Assessment period, mean (95%CI) | Time | Group | Group × time interaction |
|----------------------------------|------|-------|--------------------------|
|                                  | 2W vs Pre | 4W vs Pre | 8W vs Pre | 2W vs Pre | 4W vs Pre | 8W vs Pre |
| SWS (m/sec)                      |       |       |                         |       |       |                        |
| Honda (n = 11)                   | 1.04 (0.89-1.19) | 0.96 (0.84-1.07) | 1.13 (0.96-1.30) | 1.19 (1.04-1.35) | p < .001 | .393 | .618 | .845 | .033 | .230 | .132 |
| Control (n = 11)                 | 1.09 (0.96-1.23) | 0.70 (0.51-0.90) | 1.00 (0.83-1.18) | 1.04 (0.92-1.17) |           |     |     |     |     |     |     |
| MWS (m/sec)                      |       |       |                         |       |       |                        |
| Honda (n = 11)                   | 1.30 (1.08-1.51) | 1.20 (1.06-1.35) | 1.40 (1.17-1.62) | 1.46 (1.27-1.66) | .001     | .284 | .471 | .839 | .041 | .186 | .606 |
| Control (n = 11)                 | 1.36 (1.22-1.49) | 0.90 (0.67-1.14) | 1.23 (1.05-1.40) | 1.44 (1.30-1.58) |           |     |     |     |     |     |     |
| SL-SWS (m)                       |       |       |                         |       |       |                        |
| Honda (n = 11)                   | 0.55 (0.50-0.61) | 0.55 (0.50-0.61) | 0.58 (0.53-0.63) | 0.60 (0.55-0.65) | .003     | .187 | .975 | .771 | .034 | .148 | .364 |
| Control (n = 11)                 | 0.58 (0.52-0.64) | 0.46 (0.39-0.53) | 0.54 (0.48-0.59) | 0.58 (0.52-0.64) |           |     |     |     |     |     |     |
| SL-MWS (m)                       |       |       |                         |       |       |                        |
| Honda (n = 11)                   | 0.61 (0.56-0.66) | 0.59 (0.55-0.63) | 0.65 (0.60-0.69) | 0.67 (0.63-0.71) | .002     | .219 | .155 | 1.000 | .055 | .103 | .313 |
| Control (n = 11)                 | 0.63 (0.56-0.69) | 0.50 (0.43-0.57) | 0.58 (0.52-0.64) | 0.65 (0.58-0.72) |           |     |     |     |     |     |     |
| CAD-SWS (steps/min)              |       |       |                         |       |       |                        |
| Honda (n = 11)                   | 112.10 (102.66-121.54) | 104.10 (98.41-109.79) | 117.72 (108.02-127.43) | 119.10 (109.81-128.38) | .001     | .944 | .824 | .989 | .083 | .517 | .430 |
| Control (n = 11)                 | 112.34 (105.88-118.80) | 87.53 (71.41-103.64) | 111.87 (98.17-125.57) | 113.50 (107.82-119.17) |           |     |     |     |     |     |     |
| CAD-MWS (steps/min)              |       |       |                         |       |       |                        |
| Honda (n = 11)                   | 127.50 (112.46-142.53) | 122.70 (113.87-131.54) | 128.55 (113.26-143.84) | 131.02 (117.59-144.45) | .021     | .643 | .826 | .885 | .201 | .678 | .866 |
Table 3. Walking Ability in the HWA and Control Groups.

|                  | Honda Mean ± SD | Control Mean ± SD | p value\(^a\) | d\(^b\) |
|------------------|-----------------|-------------------|---------------|--------|
| **SWS (m/s)**    |                 |                   |               |        |
| Preoperative     | 1.04 ± 0.22     | 1.09 ± 0.20       | .586          | 0.24   |
| Week2            | 0.96 ± 0.17     | 0.70 ± 0.29       | .022          | 1.09   |
| Week4            | 1.13 ± 0.25     | 1.00 ± 0.26       | .260          | 0.51   |
| Week8            | 1.19 ± 0.23     | 1.04 ± 0.19       | .107          | 0.71   |
| **MWS (m/s)**    |                 |                   |               |        |
| Preoperative     | 1.30 ± 0.32     | 1.36 ± 0.20       | .583          | 0.23   |
| Week2            | 1.20 ± 0.21     | 0.90 ± 0.35       | .025          | 1.04   |
| Week4            | 1.40 ± 0.33     | 1.23 ± 0.25       | .403          | 0.58   |
| Week8            | 1.46 ± 0.29     | 1.44 ± 0.21       | .813          | 0.08   |
| **SL at SWS (m)**|                 |                   |               |        |
| Preoperative     | 0.55 ± 0.07     | 0.58 ± 0.09       | .443          | 0.37   |
| Week2            | 0.55 ± 0.08     | 0.46 ± 0.11       | .032          | 0.94   |
| Week4            | 0.58 ± 0.07     | 0.54 ± 0.08       | .194          | 0.53   |
| Week8            | 0.60 ± 0.08     | 0.58 ± 0.09       | .852          | 0.24   |
| **SL at MWS (m)**|                 |                   |               |        |
| Preoperative     | 0.61 ± 0.07     | 0.63 ± 0.09       | .584          | 0.25   |
| Week2            | 0.59 ± 0.06     | 0.50 ± 0.11       | .036          | 1.02   |
| Week4            | 0.65 ± 0.07     | 0.58 ± 0.09       | .071          | 0.87   |
| Week8            | 0.67 ± 0.06     | 0.65 ± 0.10       | .679          | 0.24   |
| **CAD at SWS (steps/min)** | | | | |
| Preoperative     | 112.1 ± 14.05   | 112.34 ± 9.61     | .964          | 0.02   |
| Week2            | 104.10 ± 8.47   | 87.53 ± 23.99     | .501          | 0.92   |
| Week4            | 117.72 ± 14.45  | 111.87 ± 20.39    | .446          | 0.33   |
| Week8            | 119.10 ± 13.82  | 113.50 ± 8.45     | .265          | 0.49   |
| **CAD at MWS (steps/min)** | | | | |
| Preoperative     | 127.50 ± 22.38  | 130.61 ± 11.50    | .686          | 0.18   |
| Week2            | 122.70 ± 13.15  | 110.21 ± 26.62    | .184          | 0.60   |
| Week4            | 128.55 ± 22.76  | 126.68 ± 18.46    | .834          | 0.09   |
| Week8            | 131.02 ± 19.99  | 132.30 ± 13.53    | .863          | 0.08   |

\(^a\)Independent sample t test.
\(^b\)The effect size was calculated using Cohen’s d.

significant for ROM extension active, flexion passive and flexion active, pre-operation and week 4 for ROM flexion passive and flexion active, and pre-operation and week 8 for flexion active. The main effect of the group was not significant. Regarding the time × group interaction effect, there was a significant difference in ROM extension active between pre-operation and week 2. Extension active in the control group decreased significantly from −6.36° (95% CI, −10.07, −2.66) to −12.27° (95% CI, −15.75, −8.79), whereas in the HWA group, it increased from −12.73° (95% CI, −17.56, −7.89) to −11.05° (95% CI, 14.88, −7.22).

In the between-group post hoc analysis, the preoperative measurements of passive extension (p = .027, Cohen’s d = 1.02) and active extension (p = .031, Cohen’s d = 0.99) in the HWA group were lower than those in the control group.

### Knee Torque

The results of the knee torque are summarized in Tables 4 and 5. The main effect of time between pre-operation and week 4 for WOMAC-p and pre-operation and week 8 for WOMAC-p and WOMAC-f was significant. The main effect of group and time × group interaction effect was not significant.

In the between-group post hoc analysis, WOMAC-f (p < 0.001, Cohen’s d = 2.33) in the HWA group was higher than that in the control group at week 8.

### Discussion

The results of this study revealed a time × intervention interaction effect in SWS and MWS between pre-operation and week 2, indicating that the HWA group exhibited a significantly faster improvement from postoperative gait dysfunction. A previous report stated that improvement in walking speed after TKA is slow and inadequate even 3 months postoperatively.23 Moreover, it has been reported that postoperative patients may have residual limitations in walking ability and knee function at least more than 1 year after TKA.7,8 Although there are few reports on walking speed in the early postoperative period, SWS and MWS at 2 weeks19,24 and 4 weeks6 after TKA were decreased than in the preoperative period. In this study, although the control group showed a temporary reduction in SWS and MWS 2 weeks after TKA, the HWA group did not. These results suggest that HWA intervention promotes early improvement in walking ability after TKA.
Table 4. Changes in Knee Range of Motion, Knee Torque, WOMAC-p and WOMAC-f Scores, and Time × Group Interaction Effect.

| Assessment period, mean (95% CI) | Time | Group | Group × time interaction |
|----------------------------------|------|-------|--------------------------|
|                                  | Preoperative | 2W | 4W | 8W | 2W vs Pre | 4W vs Pre | 8W vs Pre | 2W to Pre | 4W to Pre | 8W to Pre |
| ROM extension passive            | Honda (n = 11) | -11.36 (-16.14, -6.59) | -7.57 (-11.13, -4.01) | -3.64 (-6.28, -1.00) | -2.73 (-5.87, 0.41) | 1.000 | .393 | .253 | .273 | .251 | .055 | .047 |
|                                  | Control (n = 11) | -5.45 (-8.25, -2.66) | -5.45 (-8.25, -2.66) | -3.64 (-5.81, -1.46) | -2.29 (-4.60, -1.38) |       |      |      |      |      |      |      |
| ROM extension active             | Honda (n = 11) | -12.73 (-17.56, -7.89) | -11.05 (14.88, -7.22) | -7.73 (-11.21, -4.25) | -5.00 (-8.36, -1.64) | .028 | .858 | .997 | .331 | .045 | .209 | .045 |
|                                  | Control (n = 11) | -6.36 (-10.07, -2.66) | -12.27 (-15.75, -8.79) | -5.91 (-9.21, -2.61) | -6.37 (-10.64, -2.11) |       |      |      |      |      |      |      |
| ROM flexion passive              | Honda (n = 11) | 116.82 (110.22-123.41) | 95.17 (88.13-102.21) | 109.09 (102.24-115.95) | 115.45 (109.74-121.17) | p < .001 | .017 | .236 | .618 | .968 | .471 | .515 |
|                                  | Control (n = 11) | 123.18 (112.32-134.04) | 101.82 (95.76-107.88) | 110.00 (102.19-117.81) | 117.21 (110.84-123.58) |       |      |      |      |      |      |      |
| ROM flexion active               | Honda (n = 11) | 109.55 (103.27-115.82) | 91.09 (88.88-98.30) | 103.64 (95.53-111.74) | 110.45 (104.74-116.17) | p < .001 | .006 | .311 | .481 | .294 | .187 | .094 |
|                                  | Control (n = 11) | 119.09 (108.49-129.69) | 92.73 (85.01-100.44) | 102.27 (92.27-112.28) | 108.10 (101.58-114.61) |       |      |      |      |      |      |      |
| Torque extension                 | Honda (n = 11) | 0.88 (0.74-1.02) | 0.51 (0.40-0.62) | 0.78 (0.57-0.99) | 0.97 (0.75-1.18) | .009 | .663 | .404 | .812 | .363 | .729 | .960 |
|                                  | Control (n = 11) | 0.82 (0.63-1.00) | 0.56 (0.45-0.68) | 0.77 (0.64-0.90) | 0.91 (0.76-1.04) |       |      |      |      |      |      |      |
| Torque flexion                   | Honda (n = 11) | 0.43 (0.34-0.52) | 0.32 (0.26-0.39) | 0.42 (0.33-0.51) | 0.50 (0.39-0.60) | .057 | .300 | .689 | .871 | .905 | .550 | .711 |
|                                  | Control (n = 11) | 0.46 (0.32-0.60) | 0.34 (0.27-0.40) | 0.39 (0.28-0.49) | 0.49 (0.40-0.57) |       |      |      |      |      |      |      |
| WOMAC-p                          | Honda (n = 11) | 45.91 (32.92-58.90) | 64.66 (52.45-76.86) | 74.55 (62.39-86.70) | 80.00 (70.99-89.01) | .827 | .030 | .003 | .449 | .154 | .365 | .347 |
|                                  | Control (n = 11) | 60.91 (46.20-75.61) | 62.73 (51.86-73.60) | 79.09 (69.49-88.69) | 84.95 (77.09-92.81) |       |      |      |      |      |      |      |
| WOMAC-f                          | Honda (n = 11) | 65.51 (50.57-80.45) | 69.79 (59.59-79.98) | 87.17 (81.37-92.96) | 94.79 (92.35-97.22) | .734 | .053 | .012 | .809 | .522 | .312 | .102 |
|                                  | Control (n = 11) | 69.39 (60.71-78.06) | 66.82 (54.63-79.02) | 81.95 (74.76-89.15) | 84.99 (81.82-88.16) |       |      |      |      |      |      |      |
Although the preoperative knee extension angle in the HWA group was significantly lower, the postoperative knee extension angle improved as much as that of the control group. It is unclear whether HWA intervention plays a role in this result; however, early improvement in walking ability may have had a positive impact.

According to studies that investigated the relationship between knee extension torque and walking ability, the 2 factors were reported to be strongly correlated in patients after TKA.\(^4\)\(^,\)\(^25\)\(^,\)\(^26\) Knee extension and flexion torque at weeks 2, 4, and 8 were not significantly different between the 2 groups in this study, indicating that the improvement in knee strength was not causally related to the improvement in walking speed. In our previous reports, we demonstrated that HWA assistance was not causally related to the improvement in walking speed.\(^2\)\(^1\) This study, indicating that the improvement in knee strength and 8 were not significantly different between the 2 groups in this study, HWA intervention could contribute to the early improvement of walking ability with such a mechanism.

The HWA intervention did not exacerbate knee pain, as WOMAC-p showed comparable improvement to the control group. However, when comparing knee joint pain during the HWA intervention, in 6 out of 10 cases, there was a decrease in joint pain with HWA compared with that without HWA during walking exercises. This result suggests that HWA intervention may be effective in reducing the load on the patients during walking exercise. Although WOMAC-f showed no time \(\times\) intervention interaction effect, in the between-group post hoc analysis, WOMAC-f in the HWA group was higher than that in the control group at week 8. This finding suggests that the HWA intervention improves postoperative physical function.

A review of the literature on walking speed showed that, as highlighted by Montero-Odasso, the low-gait-velocity group had a higher incidence of adverse events, such as predictors of hospitalization, caregiver requirements, and new falls in elderly people, than the high- and median-gait velocity groups.\(^27\) According to Purser, walking speed reduction was associated with poorer health status, poorer physical functioning, more disabilities, additional rehabilitation visits, increased

### Table 5. Knee Function in the HWA and Control Groups.

|                | Honda Mean ± SD | Control Mean ± SD | \(p\) value\(^a\) | \(d\)\(^b\) |
|----------------|-----------------|-------------------|------------------|--------|
| **Passive extension** (degree) | Preoperative | -11.36 ± 7.10 | -5.45 ± 4.16 | .027 | 1.02 |
|                 | Week2          | -7.57 ± 5.29     | -5.45 ± 4.16     | .310 | 0.37 |
|                 | Week4          | -3.64 ± 3.93     | -3.64 ± 3.23     | .999 | 0.00 |
|                 | Week8          | -2.73 ± 4.67     | -2.99 ± 2.40     | .870 | 0.07 |
| **Active extension** (degree) | Preoperative | -12.73 ± 7.20 | -6.36 ± 5.52     | .031 | 0.99 |
|                 | Week2          | -11.05 ± 5.70    | -12.27 ± 5.18    | .605 | 0.23 |
|                 | Week4          | -7.73 ± 5.18     | -5.91 ± 4.91     | .408 | 0.36 |
|                 | Week8          | -5.00 ± 5.00     | -6.37 ± 6.35     | .579 | 0.24 |
| **Passive flexion** (degree) | Preoperative | 116.82 ± 9.82    | 123.18 ± 16.17   | .280 | 0.48 |
|                 | Week2          | 95.17 ± 10.48    | 101.82 ± 9.02    | .126 | 0.68 |
|                 | Week4          | 109.09 ± 10.20   | 110.00 ± 11.62   | .847 | 0.08 |
|                 | Week8          | 115.45 ± 8.50    | 117.21 ± 9.49    | .653 | 0.20 |
| **Active flexion** (degree) | Preoperative | 95.17 ± 9.34     | 92.73 ± 11.48    | .733 | 0.15 |
|                 | Week2          | 91.09 ± 10.73    | 119.09 ± 15.78   | .103 | 0.74 |
|                 | Week4          | 103.64 ± 12.06   | 102.27 ± 14.89   | .816 | 0.10 |
|                 | Week8          | 110.45 ± 8.50    | 108.10 ± 9.70    | .552 | 0.26 |
| **Knee extension torque** (Nm/kg) | Preoperative | 0.88 ± 0.21      | 0.82 ± 0.28      | .543 | 0.24 |
|                 | Week2          | 0.51 ± 0.16      | 0.56 ± 0.17      | .448 | 0.30 |
|                 | Week4          | 0.78 ± 0.31      | 0.77 ± 0.20      | .928 | 0.04 |
|                 | Week8          | 0.97 ± 0.32      | 0.91 ± 0.20      | .629 | 0.23 |
| **Knee flexion torque** (Nm/kg) | Preoperative | 0.43 ± 0.13      | 0.46 ± 0.21      | .721 | 0.17 |
|                 | Week2          | 0.32 ± 0.10      | 0.34 ± 0.09      | .687 | 0.21 |
|                 | Week4          | 0.42 ± 0.14      | 0.39 ± 0.16      | .610 | 0.20 |
|                 | Week8          | 0.50 ± 0.15      | 0.49 ± 0.13      | .879 | 0.07 |
| **WOMAC-p** | Preoperative | 45.91 ± 19.34    | 60.91 ± 21.89    | .104 | 0.73 |
|                 | Week2          | 64.66 ± 18.17    | 62.73 ± 16.18    | .795 | 0.11 |
|                 | Week4          | 74.55 ± 18.09    | 79.09 ± 14.29    | .521 | 0.28 |
|                 | Week8          | 80.00 ± 13.42    | 84.95 ± 11.70    | .367 | 0.39 |
| **WOMAC-f** | Preoperative | 65.51 ± 22.24    | 69.39 ± 12.92    | .623 | 0.21 |
|                 | Week2          | 69.79 ± 15.17    | 66.82 ± 18.15    | .682 | 0.18 |
|                 | Week4          | 87.17 ± 8.63     | 81.95 ± 10.71    | .223 | 0.54 |
|                 | Week8          | 94.79 ± 3.62     | 84.99 ± 4.72     | .001 | 2.33 |

\(^a\) Independent sample t test.
\(^b\) The effect size was calculated using Cohen’s d.
medical-surgical visits, longer hospital stays, and higher costs in hospital inpatients. As walking ability and knee function are associated with postoperative patient satisfaction in TKA patients, early improvement in walking ability is crucial for the benefit of patients. The HWA intervention improves walking ability after the early stage of surgery, which is expected to shorten the hospitalization and rehabilitation period. In addition, the improvement in physical function at week 8 could be expected to hasten the return to daily life and work and prevent falls. This device incurs a rental fee, so which is a potential cost. However, if the number of days spent in the hospital is reduced by encouraging patients to improve quickly, the total cost of medical care could be reduced. In order to make effective use of this device, there is room for consideration on how to make it available to more patients, for example, by giving them the opportunity to self-exercise by wearing the device themselves. The HWA is easy to wear and light-weight, making it ideal for rehabilitation after TKA. Moreover, it was safe to use and expected to be effective for the early recovery of walking ability and physical function after TKA. However, the improvements in muscle strength and ROM were similar to those in the control group. Rehabilitative modalities have been suggested for the recovery of strength and ROM after TKA, with a focus on the early incorporation of exercise therapy, balance training, aquatic therapy, cryopneumatic therapy, neuromuscular electrical stimulation, and transcutaneous electrical nerve stimulation. Further benefits could be expected by combining the HWA training with training focused on the aforementioned parameters. The present study was a pilot study with an insufficient sample size that lacked randomization of patient allocation and a blinded intervention and evaluation. Furthermore, it is also necessary to examine which types of patients are most amenable to walking exercise using the HWA in the future.

Conclusions

Gait training using HWA was safe and feasible and could be used for the early improvement of walking ability in patients who underwent TKA. Further validation is needed to determine those patients in whom the HWA intervention will be most effective and also identify strategies to achieve better results in the long term.

Limitations

This study had a few limitations. First, this was a pilot study, the number of cases was small, and some data were missing and were analyzed by interpolating them using statistical methods. Second, since the main objective of this study was to examine the early postoperative recovery of walking ability and knee function, we only followed the patients up to 8 weeks after TKA, and the long-term effects are unknown. Third, although there was no difference in patient characteristics between the HWA and control groups, the allocation was not randomized. Furthermore, the intervention and evaluation were not blinded; hence, there were various risks of bias. This study was a single-center validation, and future multi-center validations with larger sample sizes are required to increase reliability.

Acknowledgments

We would like to thank the Physical Therapy Department at Ibaraki Prefectural University of Health Sciences Hospital, represented by Kazuhide Tomita, the manager of the Department of Rehabilitation; Tomoyuki Matsuda, the manager of the Department of Physical Therapy; and Keiko Miyamoto, a robotic technical assistant. We would like to thank Editage (www.editage.jp) for English language editing.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Honda Motor Corporation lent us the HWA free of charge for this research.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was partly supported by a Grant-in-Aid for Project Research of the Ibaraki Prefectural University of Health Sciences (1961) and the Japan Society for the Promotion of Science KAKENHI (20H01147).

ORCID iD

Kazunori Koseki @ https://orcid.org/0000-0001-7864-8753

References

1. Gothenos O, Espelhaug B, Havelin L, et al. Survival rates and causes of revision in cemented primary total knee replacement: a report from the Norwegian Arthroplasty Register 1994-2009. Bone Joint J. 2013;95-b(5):636-642. doi:10.1302/0301-620x.95b5.30271
2. Sanna M, Sanna C, Caputo F, Piu G, Salvi M. Surgical approaches in total knee arthroplasty. Joints. 2013;1(2):34-44.
3. Loughead JM, Malhan K, Mitchell SY, et al. Outcome following knee arthroplasty beyond 15 years. Knee. 2008;15(2):85-90. doi:10.1016/j.knee.2007.11.003
4. Pua YH, Seah FJ, Clark RA, Lian-Li Poon C, Tan JW, Chong HC. Factors associated with gait speed recovery after total knee arthroplasty: a longitudinal study. Semin Arthritis Rheum. 2017;46(5):544-551. doi:10.1016/j.semarthrit.2016.10.012
5. Mizner RL, Pettersson SC, Snyder-Mackler L. Quadriceps strength and the time course of functional recovery after total knee arthroplasty. J Orthop Sports Phys Ther. 2005;35(7):424-436. doi:10.2519/jospt.2005.35.7.424
6. Kittelson A, Carmichael J, Stevens-Lapsley J, Bade M. Psychometric properties of the 4-meter walk test after total knee arthroplasty. Disabil Rehabil. 2020;1-7. doi:10.1080/09638288.2020.1852446
7. Walsh M, Woodhouse LJ, Thomas SG, Finch E. Physical impairments and functional limitations: a comparison of individuals 1 year after total knee arthroplasty with control subjects. Phys Ther. 1998;78(3):248-258. doi:10.1093/ptj/78.3.248
8. Maxwell J, Niu J, Singh JA, Nevitt MC, Law LF, Felson D. The influence of the contralateral knee prior to knee arthroplasty on post-arthroplasty function: the multicenter osteoarthritis study. *J Bone Joint Surg Am.* 2013;95(11):989-993. doi:10.2106/jbjs.L.00267

9. Erivan R, Chaput T, Villatte G, Ollivier M, Descamps S, Boisgard S. Ten-year epidemiological study in an orthopaedic and Trauma Surgery Centre: are there risks involved in increased scheduling arthroplasty volume without increasing resources? *Orthop Traumatol Surg Res.* 2018;104(8):1283-1289. doi:10.1016/j.otsr.2018.08.009

10. Napier RJ, Spence D, Diamond O, O’Brien S, Walsh T, Beverland DE. Modifiable factors delaying early discharge following primary joint arthroplasty. *Eur J Orth Surg Traumatol.* 2013;23(6):665-669. doi:10.1007/s00590-012-1053-5

11. Bandholm T, Kehlet H. Physiotherapy exercise after fast-track total hip and knee arthroplasty: time for reconsideration? *Arch Phys Med Rehabil.* 2012;93(7):1292-1294. doi:10.1016/j.apmr.2012.02.014

12. Mistry JB, Elmallah RD, Bhave A, et al. Rehabilitative guidelines after total knee arthroplasty: a review. *J Knee Surg.* 2016;29(3):201-217. doi:10.1055/s-0036-1579670

13. Zhang X, Yue Z, Wang J. Robotics in lower-limb rehabilitation after stroke. *Behav Neurol.* 2017;2017:3731802. doi:10.1155/2017/3731802.

14. Holanda LJ, Silva PMM, Amorim TC, Lacerda MO, Simao CR, Morya E. Robotic assisted gait as a tool for rehabilitation of individuals with spinal cord injury: a systematic review. *J Neuroeng Rehabil.* 2017;14(1):126. doi:10.1186/s12984-017-0338-7

15. Carvalho I, Pinto SM, Chagas DDV, Praxedes Dos Santos JL, de Sousa Oliveira T, Batista LA. Robotic gait training for individuals with spinal cord injury: a systematic review. *Arch Phys Med Rehabil.* 2017;98(11):2332-2344. doi:10.1016/j.apmr.2017.06.018

16. Yoshiooka T, Kubota S, Sugaya H, et al. 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. *J Rural Med.* 2021;16(1):22-28. doi:10.2185/jrm.2020.024.

17. Fukaya T, Mutsuzaki H, Yoshikawa K, Sano A, Mizukami M, Yamazaki M. The training effect of early intervention with a hybrid assistive limb after total knee arthroplasty. *Case Rep Orthop.* 2017;2017:6912706. doi:10.1155/2017/6912706

18. Tanaka Y, Oka H, Nakayama S, et al. Improvement of walking ability during postoperative rehabilitation with the hybrid assistive limb after total knee arthroplasty: a randomized controlled study. *SAGE Open Med.* 2017;5:2050312117712888. doi:10.1177/2050312117712888

19. Yoshikawa K, Mutsuzaki H, Sano A, et al. Training with hybrid assistive limb for walking function after total knee arthroplasty. *J Orth Surg Res.* 2018;13(1):163. doi:10.1186/s13018-018-0875-1

20. Honda Walking Assist Device. https://global.honda/products/power/walkingassist.html. Accessed March 16, 2021.

21. Koseki K, Mutsuzaki H, Yoshikawa K, et al. Gait training using a hip-wearable robotic exoskeleton after total knee arthroplasty: a case report. *Geriatr Orthop Surg Rehabil.* 2020;11:2151459320966483. doi:10.1177/2151459320966483

22. Hashimoto H, Hanyu T, Sledge CB, Lingard EA. Validation of a Japanese patient-derived outcome scale for assessing total knee arthroplasty: comparison with Western Ontario and McMaster Universities osteoarthritis index (WOMAC). *J Orthop Sci.* 2003;8(3):288-293. doi:10.1016/s1077-5546-02-0629-0

23. Turcot K, Sagawa Y, Fritschy D, Hoffmeyer P, Suvà D, Armand S. How gait and clinical outcomes contribute to patients’ satisfaction three months following a total knee arthroplasty. *J Arthroplasty.* 2013;28(8):1297-1300. doi:10.1016/j.arth.2013.01.031

24. Iwata A, Sano Y, Wanaka H, Yamamoto S, Yano Y, Iwata H. Different improvement trends in gait function and quadriceps strength early after total knee arthroplasty. *J Phys Ther Sci.* 2019;31(1):57-62. doi:10.1589/jpts.31.57

25. Pua YH, Poon CL, Leah FJ, et al. Comparative performance of isometric and isotonic quadriceps strength testing in total knee arthroplasty. *Musculoskelet Sci Pract.* 2018;37:17-19. doi:10.1016/j.msksp.2018.06.008

26. Aalund PK, Larsen K, Hansen TB, Bandholm T. Normalized knee-extension strength or leg-press power after fast-track total knee arthroplasty: which measure is most closely associated with performance-based and self-reported function? *Archives of Physical Medicine and Rehabilitation.* 2013;94(2):384-390. doi:10.1016/j.apmr.2012.09.031

27. Montero-Odasso M, Schapira M, Soriano ER, et al. Gait velocity as a single predictor of adverse events in healthy seniors aged 75 years and older. *J Gerontal A Biol Sci Med Sci.* 2005;60(10):1304-1309. doi:10.1093/gerona/60.10.1304

28. Purser JL, Weinberger M, Cohen HJ, et al. Walking speed predicts health status and hospital costs for frail elderly male veterans. *J Rehabil Res Dev.* 2005;42(4):535-546. doi:10.1682/jrdr.2004.07.0087