Early Postoperative Clinical Outcomes of Robotic Arm-Assisted Vs. Image-Based Navigated Total Hip Arthroplasty

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Abstract

**Background** The purpose of this study was to compare the clinical outcomes of total hip arthroplasty (THA) using computer navigation systems (nTHA) and those of robotic arm-assisted THA (rTHA).

**Methods** Thirty prospective subjects who underwent rTHA were clinically compared with 30 subjects who underwent nTHA. Clinical data (the surgical time, intraoperative blood loss, length of hospital stay, pain severity, number of days to independent walking, and Harris Hip Score (HHS) at discharge) and radiographic parameters (the inclination and anteversion angles) were statistically compared between the two groups.

**Results** The surgical time, number of days to independent walking, and postoperative pain were significantly reduced in the rTHA group than in the nTHA group. The rTHA group showed a significantly higher postoperative HHS than did the nTHA group. No statistically significant difference was observed in radiographic parameters between the groups.

**Conclusion** The surgical time, postoperative pain, and number of days to independent walking were significantly shorter, and the HHS at discharge was significantly higher in the rTHA group than in the nTHA group. Thus, as compared to nTHA, rTHA improved early clinical outcomes.

Background

Although total hip arthroplasty (THA) is a generally successful procedure [1], several factors, including patient demographics, surgical technique, and implant features, may affect its short- and long-term outcomes [2–4]. One of the most important surgeon-controlled factors is component positioning [5]. Inadequate component positioning during THA may lead to an increased risk of postoperative complications such as bony/implant impingement, limited range of motion, dislocation, polyethylene wear, and loosening [6, 7]. Furthermore, malposition may also lead to leg-length discrepancy and muscle weakness due to a lack of offset, ultimately leading to patient dissatisfaction. Therefore, a precise and appropriate implant position is essential for good outcomes [6–8]. Several studies have assessed optimal acetabular cup alignment, with Lewinnek et al. defining the “safe zone” of cup alignment as 40° ± 10° inclination and 15° ± 10° anteversion [6]. However, consistently accurate component placement is difficult and high outliers from the “safe zone” are reported in 59–78% conventional THA cases [6, 9, 10]. With the goal of achieving more accurate implant positioning during THA, computer-assisted orthopedic surgery (CAOS) has been developed [11], with good implant accuracy reported in THA using computer navigation systems (nTHA) [12, 13]. More recently, robotic arm-assisted THA (rTHA) has been introduced and is expected to enhance the accuracy of implantation and has been shown to improve the accuracy of component positioning compared to manual THA [14]. Although both rTHA and nTHA are CAOS systems to achieve more accurate implant positioning during THA, they have crucial differences. Navigation systems are typically passive systems that only provide patient-specific anatomical data with recommendations for bone resection and optimal implant positioning; thus, the computer system does
not actively control or restrain the motor function of the operating surgeon [15]. In contrast, rTHA uses computer software to convert anatomical information to a virtual patient-specific three-dimensional (3D) reconstruction of the pelvis that the operating surgeon uses to calculate and plan optimal implant positioning. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy, as reaming and acetabular component impaction are controlled by a haptic boundary while the surgeon physically moves the robot arm [11, 16, 17]. However, no studies have compared the clinical benefits, including surgical time and clinical outcomes, between rTHA and nTHA.

The purpose of this study is to compare clinical outcomes, including 1) surgical time, 2) days to independent walking, 3) intraoperative blood loss, 4) length of stay in hospital (LOS), 5) post-surgical pain severity, and 6) Harris Hip Score (HHS), between rTHA and nTHA. The primary outcome was the surgical time and early clinical outcomes such as postoperative pain, functional recovery to independent walking, and HHS at discharge. The secondary outcomes were intraoperative blood loss and LOS.

Methods

Subjects

This prospective comparative study was approved by the institutional review board of our institution and informed consent was obtained from each patient. This study utilized data from a prospective total joint arthroplasty database containing demographic, clinical, and radiographic data on all primary THA procedures performed at our institution from February 2018 to January 2020. The clinical and radiographic results of a single senior surgeon at our institution following primary THA were reviewed. After robotic arm-assisted systems (Stryker Mako, Ft. Lauderdale, FL) was covered by insurance in Japan, the surgeon switched from nTHA (Computed Tomography [CT]-based Hip Navigation version 1.1, Stryker Navigation, Freiburg, Germany) to rTHA (Stryker Mako) for all primary THA in June 2019. Among the 70 consecutive THA cases, female patients were selected to exclude the influence of sex on clinical outcome variance. Therefore, this study included 30 cases each of nTHA and rTHA.

Surgical technique

All THAs were performed using the posterolateral approach, with patients in the lateral decubitus position. All hips were implanted with a cementless cup (Trident Acetabular Shell, Stryker Orthopedics, NJ, USA), a cemented stem (Exeter V40 Femoral Stem, Stryker Orthopedics, NJ, USA), ceramic 32-mm head (BIOLOX Delta V40 Ceramic Head, Stryker Orthopedics, NJ, USA), and non-elevated ultra-high-molecular-weight polyethylene liner (Trident X3 insert, Stryker Orthopaedics, NJ, USA). Preoperative CT was performed in all subjects for navigation and robotic arm-assisted systems. The slice thicknesses were 2.5mm for navigation and 0.625 mm for robotic arm-assisted systems. The surgical procedures, including acetabular reaming and cup placement, differed between nTHA and rTHA, as described below.

nTHA
After placement of a 4.0 mm tracker pin and acetabular exposure, surface mapping registration was performed to match the patients’ bony surface to the preoperative CT. Based on the instructions, the inner parts of the acetabulum were avoided for surface mapping. If a difference of $>1.0$ mm was found between the surface mapping and the preoperative CT, re-registration was performed until the difference met the safe criteria. Thereafter, the surgeons performed acetabular reaming, during which the surgeons could see both anteversion and lateral inclination angles within the navigation monitor and control these angles manually. As the navigation could not visualize the reaming depth, step-by-step reaming of one mm was performed up to one mm smaller than the preoperative plan, from six mm smaller. The anterior, posterior, and medial wall thicknesses were checked in a timely manner to maintain an adequate reaming center and prevent wall collapse. After the reaming, the surgeon determined the target anteversion and lateral inclination angle using navigation and placed the component manually until the rigid fixations were achieved.

rTHA

After placement of a 4.0 mm tracker pin and acetabular exposure, surface mapping registration was performed to match the patients’ bony surface to the preoperative CT. Robotic systems require pointing within the inner parts of the acetabular space. The difference between registration and preoperative CT was 0.5 mm in the rTHA. Single-step reaming a reamer one mm smaller in size was performed with robotic arm-assistance. The MAKO system also guided the component placement angle and depth. If protrusions $>3$ mm were found, same-size reaming was repeated to achieve an adequate depth of fixation. The target inclination and anteversion angles in both groups were 40° and 20°, respectively.

The Mako Total Hip system does not track the stem itself during stem insertion. Thus, in all THAs (nTHA and rTHA), a cemented stem was inserted at the target angle in the femoral canal using a navigation system. The stem anteversion was adjusted to match the anatomical neck anteversion.

The preoperative assessment, patient education program, pain management protocol, and postoperative rehabilitation protocol were the same for both groups throughout the study period.

Evaluations

Patient demographics (age, sex, diagnosis, height, and weight) and clinical data (surgical time, intraoperative blood loss, length of stay in hospital [LOS], pain severity, and the number of days to independent walking) were recorded for both groups. In addition, Harris Hip Score (HHS) was determined preoperatively within one week before surgery and at the discharge. These data were statistically compared between the two groups.

Pain severity

Post-surgical pain severity was evaluated using a numeric rating scale (NRS) for pain, with zero and ten indicating no and worst imaginable pain, respectively. The NRS during motion was evaluated on postoperative days (PODs) one, three, seven, ten, and 14.
Physical function

The number of days to independent walking was defined as the period required for the patient to achieve a defined standard of independent walking using a T-cane. The following conditions had to be met with physical therapists observing the walking: walking for >50 m with a T-cane, patient confidence in their ability to walk with the T-cane, and a timed up and go (TUG) result of <13.5 seconds. The TUG is used to measure the time required to walk a 3.0 m distance, starting and ending with a sitting position. The LOS was recorded as the number of postoperative hospitalization days.

Acetabular component placement, including version and inclination, was assessed radiographically using postoperative anteroposterior (AP) supine X-rays, as previously described [18]. Briefly, the software (Advanced Case Plan Ver2.2; Stryker) created a horizontal reference line along the inferior aspect of the pelvic inter-ischial line as well as a complex of lines comprising a sphere, a concentric ellipse, and a bisecting line bisecting the ellipse along its long axis. While the lines comprising this complex could be manipulated individually, their relationships to each other remained unchanged. The sphere was then manipulated to fit the circumference of the acetabular cup and the ellipse to fit the opening of the cup. The relative ratio of the axes of the ellipse corresponded to the cup version angle. The angle formed by the bisecting line and the inter-ischial reference line indicated the cup inclination angle.

This system could not differentiate between anteversion and retroversion. For version measurement, the cross-table lateral radiographs of all patients were reviewed using the Woo and Morrey [19] technique to ensure that they were anteverted. The radiographic measurements were performed by two observers blinded to the treatment, with the average used for assessment. The accuracy of the MAKO and navigation measurement were 0.1° and 0.1mm, and 0.5° and 1.0mm, respectively. The accuracy of radiographic measurements was 0.1°. The test-retest reliability of the measurements was excellent (interclass and intraclass correlation coefficients, 0.85 – 0.94)

Statistical analysis

Data analyses were performed using a statistical software package (IBM SPSS Statistics for Windows, version 21.0, Armonk, NY, USA). Shapiro–Wilk tests were used to analyze normally distributed data. As the data were normally distributed, the data were expressed as means ± standard deviation (SD). Comparisons between the two independent groups were performed using dependent t-tests. A statistical a priori power analysis was performed using the G*Power software (version 3.1.9.2; Heinrich Heine Universität Düsseldorf, DE) to determine the sample size based on the difference of the days to independent walking between the two groups, using a prespecified significance level of \( \alpha < 0.05 \), a power level of 80%, and an effect size based on the results of the pilot study with ten cases (effect size \( d = 0.70 \)). The estimated sample size was 26 patients in each group, and the post hoc power analysis further confirmed that the power was 0.99. A \( p \)-value < 0.05 was set as the level of significance.

Results
The patient demographic data are shown in Table 1. No significant differences were observed in age, body mass index, and preoperative TUG between the nTHA and rTHA groups. No acute intraoperative or postoperative complications were noted, including dislocation, infection, nerve palsies, or pin site-related such as fracture. A significantly shorter surgical time was observed in the rTHA group than that in the nTHA group (p = 0.002, Fig. 1(a)). Intraoperative blood losses were comparable between the two groups (p = 0.69, Fig. 1(b)). The LOS tended to be shorter in the rTHA group than that in the nTHA group, although the difference was not statistically significant (24.3 ± 6.0 days vs. 27.0 ± 7.0 days, p = 0.178). The number of days to independent walking was significantly shorter in the rTHA group than that in the nTHA group (p < 0.001, Fig. 2(a)). The NRS scores on PODs seven, ten, and 14 were significantly lower in the rTHA group than those in the nTHA group (p < 0.01, Fig. 2(b)). Although no significant difference in preoperative HHS was observed between the rTHA and nTHA groups (44.1 ± 4.4 vs. 44.2 ± 4.2, p = 0.813), rTHA showed a significantly higher postoperative HHS compared to that in the nTHA group (85.3 ± 3.2 vs. 81.0 ± 8.5, p = 0.014).

The radiographic inclination and anteversion angles in the rTHA group were 42.2 ± 2.2 (range 38–47) and 20.3 ± 1.6 (range, 16–24), respectively, whereas those in the nTHA group were 40.5 ± 4.5 (range, 32–44) and 19.9 ± 3.6 (range, 14–33), respectively. No statistically significant difference was observed between the groups.

Discussion

The most important finding of the present study was that rTHA reduced surgical time and postoperative pain and improved functional recovery to independent walking compared to those in nTHA. Furthermore, rTHA improved the HHS at discharge compared to that in nTHA. These results suggest that rTHA is beneficial to postoperative clinical outcomes compared to nTHA.

Previous studies have investigated the clinical benefits resulting from increased accuracy and precision afforded by rTHA, including functional outcomes and levels of patient satisfaction. Bukowski et al. reported the outcomes for three groups of 100 consecutive THAs (first and last 100 manual THAs and first 100 Mako Total Hips), including significantly higher modified HHS and University of California, Los Angeles activity level in Mako THA than those for manual THA, at a minimum of one-year follow-up [20]. Perets et al. followed 162 patients undergoing rTHA and reported reduced pain, increased patient satisfaction, and improved functional outcomes as assessed using HHS and Forgotten Joint Score at a minimum two years follow-up [21]. To our knowledge, the present study is one of few to compare outcomes between rTHA and nTHA. Because of the very good outcomes of nTHA, the short-term outcomes may be the metrics showing the major clinical differences between robotic and the navigated systems.

The results showed a significantly shortened surgical time for rTHA compared to that for nTHA. As the surgical steps and implant types with the femur are consistent between the two groups, the effect is attributed to the difference in the surgical step on the acetabular side. The rTHA allowed the use of a
single reamer to prepare the acetabulum, followed by immediate component insertion compared to the nTHA technique, which typically involves sequential reaming of the target size with an assessment of bone preparation between each reaming stage [20]. Although the present study did not evaluate the time required for robot preparation and the influence of the difference on registration methods, the reduction in reaming frequency was the most likely reason for the present results.

Several reports have found that rTHA improved acetabular implant accuracy compared to manual THA [17, 22, 23]. Nawabi et al. conducted a cadaveric study to compare conventional manual and rTHAs, in which rTHA reduced the root mean square error values in achieving planned horizontal, anteroposterior, and vertical centers of rotation compared to those for conventional THA (1.5 mm vs. 2.0 mm, 1.2 mm vs. 2.8 mm, and 1.9 mm vs. 2.2 mm, respectively) [17]. Tsai et al. reviewed radiological outcomes, reporting that robotic technology improved the accuracy of achieving the planned vertical center of rotation (0.7 ± 4.4 mm vs. 4.0 ± 4.7 mm) compared to that for conventional manual THA [22]. Only a retrospective review of nearly 2000 THAs showed that both navigated and robotically-placed cups were significantly more likely to be within the safe zone than conventional THA and that neither navigated nor rTHA was superior [18]. In our study, no statistically significant differences were observed in radiographic inclination and anteversion angles between the techniques. These results suggested that both navigation and robotics achieved equally acceptable component alignment. The inaccuracy of the actual cup position after THA is reportedly greatest in the mediolateral direction, in which the position was more lateral compared to the preoperative three-dimensional planning [24]. The study suggested that control of the mediolateral direction is difficult with manual reaming, even with navigation. Although medialization was not evaluated in the present study, our technique using a navigation system might result in insufficient medialization in some cases. In rTHA, acetabular reaming is controlled by the robotic device to ensure that the desired depth is reached for accurate restoration of the hip offset and center of rotation. One possible explanation for the superior results regarding postoperative pain and functional recovery is better medialization in rTHA than that in nTHA. Further studies on the correlations between the amount of medialization and functional recovery are needed to reveal its true contribution. Furthermore, rTHA provides information for adequate depth and position during component impaction. Hasegawa et al. reported that 8.4% of cases experienced periprosthetic occult fractures of the acetabulum in primary THA, which might be ignored during surgery [25]. rTHA might reduce the rate of such occult fractures during impaction, which warrants investigation in future studies.

The present study found that the LOS did not differ significantly between the two groups, although the LOS in the rTHA tended to be shorter than that in the nTHA. The patients’ functional recovery might not directly influence the LOS, as the criteria for discharge in our institution and our country are relatively ambiguous and the timing was mainly dependent on the patients’ request. Different countries with different health systems may show different results.

The limitations of this study include the single-surgeon, and single-institution study design. The sample size was relatively small, although the power analysis found that the sample size was sufficient for the
primary outcomes. Future studies with larger sample sizes and prospective study designs could provide better evidence on robotic hip arthroplasty to build on the findings of this study.

The strength of this study is the homogeneity of the series in terms of technique and implants and the fact that all patients were operated on by the same surgeon.

Conclusions

In summary, the surgical time was shorter; the NRS for postoperative pain on PODs seven, ten, and 14 and the number of days to independent walking were significantly smaller; and the HHS at discharge was significantly higher in the rTHA group than those in the nTHA group. Based on the series of results, rTHA improved the early clinical outcomes compared to those for nTHA.

Abbreviations

3D: three-dimensional
AP: anteroposterior
CAOS: computer-assisted orthopedic surgery
CT: computed tomography
HHS: Harris Hip Score
LOS: length of hospital stay
NRS: numeric rating scale
nTHA: computer-navigated THA
POD: postoperative day
rTHA: robotic arm-assisted THA
SD: standard deviation
THA: total hip arthroplasty
TUG: timed up and go

Declarations

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**Conflicts of interest/Competing interests**

All authors declare they have no conflict of interest.

**Ethics approval and Consent to participate**

Institutional review board at Kobe Kaisei hospital (ethical approval number: 0082) approved this study and all subjects consented to participate the study via verbal, as this comparative study included no subjects selection, nor surgical intervention. The ethics committee approved this procedure.

**Availability of data and material** not applicable

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Not Applicable

**Authors Contributions:**

NS conducted this study, and NS and KI wrote the manuscript. TM, KT, MK, RK, and SH advised the interpretation of data and the constitution of the study. NS and YS analyzed the data. All authors read and approved the final manuscript.

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Tables

Due to technical limitations, table 1 is only available as a download in the Supplemental Files section.