Robot-assisted total hip arthroplasty: Clinical outcomes and complication rate

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Abstract

Background: The purpose of this study was to report minimum 2-year outcomes and complications for robotic-arm-assisted total hip arthroplasty (THA).

Methods: Data were prospectively collected and retrospectively reviewed between June 2011 and April 2014. Inclusion criteria were primary robotic-arm-assisted THAs treating idiopathic osteoarthritis with ≥ 2-year follow-up. Demographics, operating time, complications, 2-year outcome scores and satisfaction, and subsequent surgeries were recorded.

Results: There were 181 cases eligible for inclusion, of which 162 (89.5%) had minimum 2-year follow-up. At the latest follow-up, the mean visual analogue scale was 0.7, satisfaction was 9.3, Harris hip score was 91.1 and forgotten joint score was 83.1. Six (3.7%) intraoperative complications and six (3.7%) postoperative complications were reported. No leg length discrepancies (LLDs) or dislocations were reported.

Conclusions: Robotic-arm-assisted THA demonstrates favourable short-term outcomes and does not result in a higher complication rate compared to non-robotic THA as reported by the literature.

KEYWORDS
clinical outcomes, complications, forgotten joint score, robotic-arm assisted, total hip arthroplasty

1 | INTRODUCTION

Total hip arthroplasty (THA) has been one of the most successful surgeries in orthopaedics since its popularization in the late 1960s. The short- and long-term outcomes may be influenced by numerous factors: patient demographics, which are inherent characteristics and cannot be altered by the surgeon, and surgical technique and implant features, which can be altered in the operating room (OR). One of the most important surgeon-controlled factors is component positioning. Component malposition has been linked to higher rates of hip dislocations, poor biomechanics, accelerated wear, leg length discrepancy (LLD) and revision surgeries. Component malposition is directly associated with dislocations and mechanical loosening, which account for 40% of THA revisions.

In the attempt to define the ideal component position, anteverision and inclination are the two most commonly examined parameters. Lewinnek et al. defined the acetabular safe zone, based on hip stability, as 15° ± 10° of anteversion and 40° ± 10° of inclination. However, inclination greater than 45° demonstrated a higher rate of wear of the bearing surface. This finding led Callanan et al. to decrease the inclination safe zone to 30°–45°. Amuwa and Dorr defined a combined safe zone for femur and acetabulum anteversion of 25°–50°. In a recent study, Nakashima et al. demonstrated that if the combined anteversion is outside 40°–60°, the likelihood of dislocation is 5.8 times higher. Additionally, misplacing the femoral component may lead to LLD, change in offset and instability. LLD is a major source of patient dissatisfaction and is the second most common cause for litigations in joint replacement surgeries.

Two large studies have demonstrated significant percentages of acetabular malpositioning using conventional THA methods. When
the safe zone was 30°–45° of inclination and 5°–25° of anteversion. 38%–50% of the reported implants fell within this safe zone. In the last two decades, several methods have been developed to improve component positioning, including intraoperative fluoroscopy, mechanical navigation, computer navigation and robotic-arm-assisted guidance. Most of these methods have been shown to improve component positioning; however, they have also introduced intraoperative fluoroscopy, mechanical challenges and increased OR time. Robotic-arm-assisted THA is a novel technology that has been shown to enhance the accuracy of cup positioning according to plan compared to traditional techniques. The technique is based upon a computed tomography (CT) navigation and a robotic arm that helps to direct the reaming and component implantation.

The purpose of this study was to report minimum 2-year outcomes and complications for robotic-arm-assisted total hip arthroplasty. We hypothesized that robotic-arm-assisted THA will yield favourable outcomes and will not show a higher complication rate compared to non-robotic THA as reported by the literature.

2 | METHODS

2.1 | Patient selection

Between June 2011 and April 2014, data were prospectively collected on all patients undergoing primary THA by the senior surgeon (B.G.D.). The inclusion criteria for this study were all patients who underwent robotic-arm-assisted THA for the treatment of idiopathic osteoarthritis with a minimum follow-up of 2 years. Demographic data such as age, body mass index (BMI) and gender were collected, along with prior hip conditions. Surgical data collected included approach, operating time and complications. The Institutional Review Board (IRB: 5276) approved this study and all subjects provided informed consent to participate in it.

Diagnosis of osteoarthritis was determined by patient history, physical examination and imaging findings. Prior to scheduling surgery, patients attempted conservative measures before consenting to THA, such as modification of activity, physical therapy, pain medication and intra-articular injections.

2.2 | Data collection

Intraoperative data, including operating time and intraoperative complications, and postoperative patient-reported outcome (PRO) scores were prospectively collected and retrospectively reviewed. Postoperative complications were recorded at all re-check appointments. Patients were assessed using Harris hip score (HHS), forgotten joint score (FJS-12), visual analogue scale (VAS) for pain and patient satisfaction. Scores were recorded postoperatively at 3 months and annually from the operation, following our institution’s standard protocol. Data on pain were collected using VAS, 0 being no pain at all and 10 being worst pain possible. Patients were asked to rate their level of satisfaction with the surgery: 0 being not satisfied at all and 10 being extremely satisfied. Patients who did not follow-up in clinic after 2 years were contacted via email or telephone. A subgroup analysis was also performed, comparing anterior and posterior approach cases for demographic factors, PRO scores and complications.

2.3 | Surgical technique

Preoperative planning required a pelvic and ipsilateral knee CT scan. A 3-dimensional model was built by the treatment planning team from the CT space for use with the MAKO™ robotic-arm-assisted total hip system (Stryker Orthopaedics, Mahwah, NJ). This preoperative plan includes measurements of acetabular version, acetabular inclination, leg length and offset. The computer system uses intraoperative patient-specific landmarks to determine pelvic and proximal femur positions such as LLD and offset difference between the legs (Figure 1). In addition, we templated all THAs in a standard radiographic way to determine component size and position.

2.4 | Surgical procedure

At our institution, all robotic-arm-assisted THAs are performed via a standardized mini-anterior or mini-posterior approach. The anterior approach utilized in this study followed that previously described by Matta et al. and the posterior approach was performed as described previously. All patients received intravenous tranexamic acid (10 mg/kg) and general anaesthesia. Conventional preparation and draping of the patient was undertaken prior to incision.

2.5 | Pelvic array placement

The pelvic array allowed the robotic-arm camera to visualize the topography of the pelvis. The array was attached to three pelvic pins.
that were positioned within the anterior part of the iliac crest. The pins were inserted into the contralateral iliac crest during the anterior approach and the ipsilateral iliac crest during the posterior approach (Figure 2).

2.6 | Femoral registration

Femoral registration was used to verify anatomic orientation embedded in the software, defined by preoperative CT scan. The femur was registered using a femoral array and a checkpoint. The femoral array, attached to a large screw, was inserted into the greater trochanter at the intersection of the gluteus medius and vastus lateralis. The checkpoint, which is a small screw inserted just proximal to the array, was used as a redundant point to verify the accuracy of registration. To register the femur, a probe was used to touch the proximal femur at 32 points, as defined by the software. Verification points were used to align anatomic geometry, defined by CT, with a reconstructed geometry, built by the software, enhanced with topographic inputs from a surgical field array. Following proper femoral registration, femoral neck osteotomy was performed with robotic-arm assistance and software guidance (Figure 3).

2.7 | Acetabulum registration and reaming

The acetabulum was exposed for registration. A checkpoint was registered at the 12 o'clock position on the acetabulum. The probe was touched to the pelvic checkpoint to confirm registration and location. The software defines 32 points to be probed to confirm the spatial location of the acetabulum and robotic arm. Once both had been registered within the surgical field, acetabular reaming was initiated. The system provided visual, auditory and haptic feedback to the surgeon during reaming. Software created a 3D model, using information from CT and registration procedures, to plan and visualize bony resection. The acetabular model created by the software would change colours from green to white to confirm the progress of reaming (Figure 4). The model would turn red if more than 0.5 mm of bone was resected beyond the planned resection.

2.8 | Acetabular cup placement

The acetabular cup was loaded onto the robotic arm, which was confined by a stereotactic tunnel in order to maintain cup inclination and...
anteversion within 5° of the plan. After implantation of the cup, the plastic liner was inserted. Final cup placement could be measured using the probe to ensure proper placement. The probe could be touched at 5 designated points to confirm final placement.

2.9 Femoral stem placement and final reduction

The femur was prepared and broached for an uncemented implant. A hybrid of CT and software-generated topography was used to gauge the alignment of the femoral broach in relation to the patient’s registered anatomy. After implantation of the final implants, software was able to calculate cup placement, stem version, leg length and global offset (Figure 5). Feedback from the robotic system enabled quantitative comparisons of the final reconstruction compared to the planned reconstruction.

A deep drain was inserted and local anaesthetic was injected into the superficial wound and deep tissues. To confirm proper alignment of implants, a single radiograph was taken prior to wound closure. Intraoperative fractures could be identified at this point.

2.10 Rehabilitation and follow-up

To conform to the standard of care at our institution, arrangements for postoperative home physical therapy and home nursing care were made according to protocol. Patients participated in home care for 1–2 weeks followed by outpatient physical therapy for an additional 6–8 weeks in order to improve strength and range of motion. Clinical and radiographic follow-up occurred at 2 weeks, at 3 months and annually thereafter.

2.11 Statistical analysis

All statistical analysis was performed in Microsoft Excel (Microsoft Corporation, Redmond, WA). The chi-squared test was used to compare categorical variables between the anterior and posterior approaches for the sub-analysis. The Shapiro–Wilk test was applied to all continuous variable distributions. Based on these results, the Student’s t-test was used to compare normally distributed (p ≥ 0.05) variables, and the Mann–Whitney U-test was used to compare non-parametric distributions (p < 0.05). Mean values with standard deviations were calculated and are reported below.

3 RESULTS

There were 181 surgical cases identified as eligible for inclusion, of which 162 (89.5%) had minimum 2-year follow-up. The remaining cases met all inclusion criteria but were lost to follow-up data collection and were therefore excluded. There were 73 males and 89 females. The average patient age was 61.2 (± 8.9) and the average patient BMI was 29.8 (± 5.2). There were no statistically significant differences between anterior and posterior approach patients for age (p = 0.328) or sex (p = 0.950). However, the patients who underwent posterior approach had significantly higher mean BMI of 30.4 (± 5.4) compared to 28.4 (± 4.4) for the anterior approach patients (p = 0.022). Patient demographic information is detailed in Table 1. The mean operating time was 76.7 min (± 20.1 min).

At the latest follow-up, mean VAS for pain was 0.7 (± 1.6), patient satisfaction was 9.3 (± 1.8), HHS was 91.1 (± 12.5) and FJS-12 was 83.1 (± 21.2) (Table 2). There were no significant differences between the anterior and posterior subgroups for HHS (p = 0.429), VAS (p = 0.170) or patient satisfaction (p = 0.338). The FJS-12 scores of the anterior approach patients were significantly (p = 0.021) higher than those of the posterior approach patients, with means of 87.3 (± 19.7)

![Figure 5](image)

**FIGURE 5** Final screen after reduction showing all values for positioning compared to preoperative and planned values

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<th>TABLE 1 Demographics</th>
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<td>Hips eligible</td>
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<th>TABLE 2 Patient-reported outcomes (PROs) and future surgery information</th>
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<td><strong>Outcomes</strong></td>
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<td>Revision THA</td>
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and 81.4 (± 21.6) respectively. Complications are summarized in Table 3. Three (1.9%) greater trochanteric fractures and three (1.9%) calcar fractures were noted. All fractures were diagnosed and treated intraoperatively using standard methods. There were two (1.3%) reports of deep vein thrombosis (DVT) following surgery, one (0.6%) report of femoral stem loosening, one (0.6%) report of infection and one (0.6%) report of aseptic haematoma. There was one (0.6%) report of drop foot that was treated using ankle–foot orthotics (AFO). One (0.6%) hip required a revision surgery after 8.7 months due to loosening of the femoral stem and two (1.3%) hips required 1-stage incision and drainage (I&D). No dislocations were reported. There were no cases with postoperative LLD of 10 mm or greater, and there were no patient complaints or revision surgeries due to LLD. Two greater trochanteric fractures, one calcar fracture, infection and aseptic haematoma occurred in patients who underwent anterior approach. One greater trochanteric fracture, two calcar fractures, both cases of DVT and the femoral stem loosening occurred in the posterior approach subgroup. This did not (p = 0.501) represent a significant difference in complications rate between anterior and posterior approach.

TABLE 3  Complications

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<tr>
<td>Trochanteric fractures</td>
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<tr>
<td>Calcar fractures</td>
<td>3</td>
<td>1.9%</td>
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<tr>
<td>Deep vein thrombosis</td>
<td>2</td>
<td>1.3%</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
<td>0.6%</td>
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<tr>
<td>Aseptic haematoma</td>
<td>1</td>
<td>0.6%</td>
</tr>
<tr>
<td>Drop foot</td>
<td>1</td>
<td>0.6%</td>
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<tr>
<td>Femoral stem loosening</td>
<td>1</td>
<td>0.6%</td>
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unfavourable long-term pain outcome ranged from 7% to 23%.18 Hence, as clinicians, it is our duty to look for improvements even in a highly favourable procedure.

Robotics in surgery in general and in orthopaedics in particular is a new technology that shows promising accuracy, reproducibility and precision of component placement.9,19 In theory, if placement is more accurate, this may help in reducing LLD, reducing dislocation rate and reducing wear and tear of the components. However, because of the very good short-, medium-, and long-term outcomes of THA, the long-term outcomes may be the only metrics that will show the major clinical differences between the robotic and the non-robotic systems.

As outcomes for total joints in general and total hip in particular are improved, new assessment tools are needed. The FJS-12 is a 12-item questionnaire that can be used as a tool to assess the occurrence of forgetting that the joint has been replaced in everyday life. This score ranges from 0 to 100, with 100 being the best score possible. In a validation study done on 243 patients by Behrend et al., the FJS-12 was shown to have high internal consistency (Cronbach α = 0.95) and a low ceiling effect (9.2%) compared to WOMAC – Western Ontario and McMaster Universities (16.7%).20 The FJS was highly discriminative, not only between ‘good’ and ‘bad’ but also between ‘very good’, ‘very good’ and ‘excellent’ outcomes. Hamilton et al. reviewed 193 THAs for the assessment of the responsiveness and ceiling effect of the FJS-12 compared to the Oxford hip score (OHS).21 The mean FJS-12 was 56.8 at 6 months and 62.1 at 12 months. They found the FJS-12 to be more responsive than OHS to changes between 6 and 12 months after THA. The measured ceiling effect of the OHS was twice that of the FJS-12. The effect size (Cohen’s d) was d = 0.10 for the OHS and d = 0.17 for the FJS-12; if PROs are going to be used as the primary outcome measurement, this difference has an important implication. Thiennpont et al. reviewed the 1-year results of FJS-12 for 75 patients who underwent THA. The mean FJS-12 was 80.22 In a recent study, Homma et al. evaluated the lateral femoral cutaneous nerve (LFCN) injury in 122 hips after direct anterior THA with a mean follow-up of 12.8 months. They demonstrated a mean FJS-12 of 50.9 for hips with LFCN injury vs. 64.3 without. Taking into consideration the fact that THA is known to have very good results and that FJS-12 is known to have a low ceiling effect, we decided to evaluate patients with FJS-12 along with other PROs. The mean FJS in our study was 83.1, and according to our literature search, this is the highest FJS-12 after THA. In addition, the FJS-12 scores of patients who underwent anterior approach THA were significantly higher than those of posterior approach patients in this study. However, we cannot conclude that the anterior approach results in superior outcomes, because the significantly higher BMI of the posterior approach patients constitutes a potential confounding factor. A controlled comparison of the anterior and posterior approaches in the context of robotic-arm-assisted THA is left for future study when more data on outcomes are available.

Component position is highly important and malpositioning may lead to instability, increased wear and early failure of THA.24 Several articles have shown that traditional techniques may be inaccurate regarding the implant position. When reviewing 1549 THA procedures, when the abduction range was 30°–45° and anteversion 5°–25°, Barrack et al. showed that 43% met the abduction target, 86% met the anteversion target and 38% met both targets.8 On the
same acceptable ranges, Callanan et al. evaluated 1823 THAs for cup position and found that 63% were within the abduction range, 79% were within the version range and 50% were within both ranges.1 In an effort to minimize human error in accuracy of component position, surgeons have used navigation systems and robotics. A study by Redmond et al. evaluated the accuracy of component placement in robotic-arm-assisted THA.13 Intraoperative, pre- and postoperative radiographs were evaluated in 146 patients for acetabular inclination, anteversion, change in leg length and change in offset. The robotic measurements for component position were compared to the radiographic ones and the correlation between them was within 10° for 95.9% of THAs for inclination and within 10° for 99.3% of THAs for anteversion. They concluded that the robotic intraoperative data correlate well with the radiographic data on component position.

One of the early complications in THA is dislocations. Weeden et al. reviewed 945 posterior approach THAs and found an early (within first postoperative year) dislocation rate of 0.85%.25 They concluded that with appropriate soft tissue repair and correct orientation of the components, a low early dislocation rate using the posterior approach can be achieved. In another study that reviewed 336 ceramic-on-ceramic THAs, Mai et al. demonstrated an early dislocation rate of 0.6%.26 In a multi-centre study by Barnett et al. a total of 5090 primary THAs were performed in an anterior approach.27 They showed a dislocation rate in the first 90 days after surgery of 0.2%. Homma et al. retrospectively reviewed 60 patients who underwent a primary THA with dual mobility cup via direct anterior approach.28 They showed an early dislocation rate of 1.7%. In our cohort we had no dislocations in a minimum 2-year follow-up.

LLD is the second most common cause for litigations in joint replacement surgeries and a major source of patient dissatisfaction.7 A review by Aravind et al. found the rate of LLD following THA to range from 1% to 27%, with discrepancies varying from 3 mm to 70 mm.29 El Bitar et al. compared LLD after primary THA between 67 robotic-arm-assisted posterior approach, 29 fluoroscopy-guided anterior approach and 59 conventional posterior approach procedures.30 There were no statistically significant differences between the approaches when LLD of more than 3 mm and 5 mm were set as outliers. No patient in any group had LLD more than 10 mm. Proper cup placement in an obese population may be a challenge. On the other hand, two studies have shown no difference in cup placement between obese and non-obese patients; however, the power of these studies is not strong enough to provide an answer to this question.31,32 Gupta et al. reviewed the cup placement in 105 patients who underwent robotic-arm-assisted posterior approach.33 They divided them into three BMI (kg m⁻²) groups of < 30 (n = 59), 30–35 (n = 34) and > 35 (n = 12). There were no statistical differences between the groups regarding acetabular inclination or version. In a prospective study by Elmallah et al., 224 radiographs of robotic-arm-assisted primary THAs were assessed after pre-determining the anteversion to be 15° and the inclination to be 40°.34 The mean inclination was 40°, the mean anteversion was 16° and 99% of the patients remained in the safe zone. In a multi-surgeon study, Domb et al. aimed to compare and assess the accuracy of acetabular component placement, LLD and global offset difference (GOD) between six different surgical modes and techniques of guidance.35 They reviewed 1980 primary THAs and demonstrated that robotic-arm-assisted (P < 0.005) and navigation-guided (P > 0.05) techniques were more consistent than other techniques in placing cup placement into Lewinnek’s safe zone (30°–50° inclination and 5°–25° version), and robotic-arm-assisted was more consistent than other techniques in placing the cup into Callanan’s safe zone (30°–45° inclination and 5°–25° version). No statistically significant differences were noticed in LLD and GOD between the techniques. In our study, there were no patients with LLD above 10 mm.

Sciatic nerve palsy is one of the complications of THA. In a study by Schmalzried et al. that reviewed 3000 THAs, 1.3% were found to have sciatic nerve palsy, and most of these had spontaneous resolution of these symptoms.36 Our study reported one case of drop foot (0.6%), which remained unresolved at 2 years postoperatively and has been treated with AFO.

Fractures may occur during surgery. Brun et al. reviewed 911 THAs, half of which used direct anterior approach and half used anterolateral approach, and found that 3% had greater trochanteric fractures and had worsened outcomes.37 Reviewing 494 direct anterior THAs, Matta et al. found 4 (0.8%) calcar fractures and 3 (0.6%) greater trochanteric fractures.38 In our study we had 3 (1.9%) greater trochanteric fractures and 3 (1.9%) calcar fractures. These rates fall within what is expected in current literature.

Longer operating time was suggested to be one of the obstacles in device-assisted surgery with mechanical navigation.29 However, Redmond et al. reviewed the first 105 robotic-arm-assisted surgeries for one surgeon, divided them into 3 chronological groups: Group A (cases 1–35), Group B (cases 36–70) and Group C (cases 71–105).40 The average operating times for groups A, B and C were 79.8 ± 27 min, 63.2 ± 14.2 min and 69.4 ± 16.3 min respectively (P = 0.02). They concluded that a learning curve was observed for robotic-arm-assisted THA with decreasing operating time and acetabular component outliers. Operating time in our study was measured from first cut to capsular closure, in accordance with Redmond et al. In a recent study that evaluated the influence of BMI on THA, Sang et al. found the mean operating time for direct anterior approach in the BMI range 18.5–25 to be 79.2 min.41 In the same study, the mean operating time for the group with BMI > 25 was 88.5 min. In addition, a different study that compared anterior vs. posterior approach found the mean operating time for primary THA to be 83.0 min for anterior approach and 91.8 min for posterior approach.42 In our cohort, which included the learning curve for the robotic-arm-assisted THAs, the mean operating time was 76.7 ± 20.1 min.

This study has a number of strengths. First, to our knowledge this is the first study in the literature to report clinical outcomes of robotic-arm-assisted THA. Second, we used multiple PROs, with the FJS-12 chosen specifically for its high internal consistency and low ceiling effect.

We also acknowledge several limitations of this study. First, no preoperative scores were collected for comparison with follow-up scores, although most THA patients are in debilitating pain. Second, this study has the inherent limitations of any retrospective case series. However, the prospective collection of data does eliminate recall bias and limit selection bias. Third, there are no postoperative radiographic measurements presented. However, a study by Redmond et al.
evaluating the accuracy of component placement in robotic-arm-assisted THA,\textsuperscript{13} which concluded that robotic intraoperative data correlate well with radiographic data on component position, had approximately the same cohort as our study. Finally, this study does not compare robotic-arm-assisted THA to patients who underwent THA with the conventional manual technique. Thus, it is unknown whether these outcomes represent a significant improvement over THA without robotic assistance.

In conclusion, robotic-arm-assisted THA demonstrates favourable short-term outcomes and does not result in a higher complication rate compared to non-robotic THA as reported in the literature.

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