Research Article

Minimum 5-Year Outcomes of Robotic-assisted Primary Total Hip Arthroplasty With a Nested Comparison Against Manual Primary Total Hip Arthroplasty: A Propensity Score–Matched Study

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Abstract

Background: Robotic-assisted technology has been a reliable tool in enhancing precision and accuracy of cup placement in total hip arthroplasty (THA). Still, questions remain on the clinical benefit of this technology.

Methods: The purposes of the ongoing study were (1) to report on minimum 5-year outcomes in patients who underwent robotic-assisted primary THA (rTHA), (2) to compare those outcomes to a propensity score–matched manual primary THA (mTHA) control group, and (3) to compare radiographic measures between the groups regarding acetabular cup placement. Prospectively collected patient data were retrospectively reviewed for primary THA recipients during June 2008 to July 2013. Patients with minimum 5-year follow-up for Harris Hip Score, Forgotten Joint Score-12, Veterans RAND-12 Mental, Veterans RAND-12 Physical, 12-Item Short Form Survey Mental, 12-Item Short Form Survey Physical, visual analog scale, and satisfaction were included. Patient-reported outcomes, cup placement, and revision rate of the rTHA group were compared with those of a propensity score–matched mTHA control group.

Results: Sixty-six rTHAs were matched to 66 mTHAs. The rTHA group reported significantly higher Harris Hip Score, Forgotten Joint Score-12, Veterans RAND-12 Physical, and 12-Item Short Form Survey Physical ($P < 0.001$, $P = 0.002$, $P = 0.002$, $P = 0.001$). The acetabular implant placement by rTHA had a 9 and 4.7-fold reduced risk of placement outside the Lewinnek and Callanan safe zones, respectively (relative risk, 0.11 [95% confidence interval, 0.03 to 0.46]; $P = 0.002$; relative risk, 0.21 [95% confidence interval, 0.01 to 0.47]; $P = 0.001$). In addition, rTHA recipients had lesser absolute values of leg length discrepancy and global offset ($P = 0.091$, $P = 0.001$).

Conclusions: Patients who received rTHA reported favorable outcomes at minimum 5-year follow-up. Furthermore, in comparison to a propensity score pair–matched mTHA group, rTHAs reported higher patient-reported outcome scores and had 89% reduced risk of acetabular implant placement beyond the Lewinnek safe zone and 79% reduced risk of placement beyond the Callanan safe zone.

Level of Evidence: Level III

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Total hip arthroplasty (THA) is one of the most successful orthopaedic procedures.[1] The longevity of arthroplasty components, however, has always been a concern. This concern has led to the design of better and more robust implants.[2,3] It has also led to investing in robotic systems to increase the accuracy of implant placement.[4-9]

Although robotic-assisted placement of implants may extend THA survivorship, this does not necessarily translate to increased clinical benefit.[10] As a result, validated patient-reported outcomes (PROs) are essential in evaluating the utility of robotic surgery.[10,11]

The purpose of the current study was threefold: (1) to report on minimum 5-year outcomes in patients who underwent robotic-assisted primary THA (rTHA), (2) to compare those outcomes to a propensity score–matched manual primary THA (mTHA) control group,[12] and (3) to compare radiographic measures between the groups regarding acetabular cup placement.

It was hypothesized that rTHA recipients (1) would achieve favorable PROs at minimum 5-year follow-up, (2) would have higher PROs compared with matched mTHAs, and (3) would have more accurate acetabular cup placement regarding the defined safe zones.

Methods

Participation in the American Hip Institute's Hip Replacement Registry

Although the present study represents novel findings, data on some patients in this study may have been reported in other studies. All data collection received the institutional review board approval.

Patient Selection Criteria and Reported Outcomes

Prospectively collected patient data were retrospectively reviewed for primary THA recipients during June 2008 to July 2013. All procedures were performed by a single, fellowship-trained orthopaedic surgeon (B.G.D.) either by direct anterior (DAA) or posterior approach (PA). The time-frame period of the study included the transition from PA to DAA for the senior author. Currently, indications for the PA approach are body mass index (BMI) $\geq$ 40 kg/m^2, associated full-thickness gluteus medius tear, or concomitant removal of lateral hardware. Patients were considered eligible for this study if they were minimum 5 years out from their THA. Included patients, however, had minimum 5-year follow-up, defined as documented Harris Hip Score (HHS), Forgotten Joint Score-12 (FJS-12), 12-Item Short Form Health Survey, Veterans RAND 12-item health survey, and the 0 to 10 visual analog scale (VAS) for pain. The HHS was used to define outcomes as "excellent" (100 to 90), "good" (89 to 80), "fair" (79 to 70), and "poor" (<70).[13]

Group Matching

For further comparison, rTHA recipients were propensity score–matched to mTHA counterparts based on age at surgery, sex, laterality, approach, and BMI. A nearest neighbor, greedy-matching algorithm was implemented using logit propensity scores.[14] Matching was performed without replacement and with a caliper of 0.5 times the SD of the logit propensity score.

Comparison of Patient-reported Outcomes

Hypothesis testing was used to compare outcomes between groups. The Shapiro-Wilk test assessed normality. An F-test or Bartlett test determined the

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equality of variances between groups. A two-sided Student *t*-test or a non-parametric equivalent evaluated the difference in means. A chi-squared analysis was used for categorical variables. The number of patients who achieved the HHS within the "excellent" range within each group was compared with a chi-squared test. A statistical analysis was performed with Python (Python Software Foundation. Python Language Reference, version 3.7). An a priori power analysis on using a minimal clinically important difference of six and SD of eight for HHS, indicated that 28 patients were needed to show 80% power and alpha at 0.05.[15]

Radiographic Assessment of Acetabular Implant Placement

Component placement was assessed radiographically. Acetabular cup inclination and version, leg length discrepancy, and global offset were measured using TraumaCad software (Brainlab) from postoperative AP supine x-rays. The safe zones of acetabular cup placement previously defined by Callanan et al and Lewinnek et al were used.[4,16] Relative risk (RR) and 95% confidence intervals (CIs) were calculated for acetabular implant placement outside the safe zones. The means of continuous radiographical measurements were compared by Student *t*-test or a non-parametric equivalent test.

Survivorship With Kaplan-Meier

A Kaplan-Meier curve was used to compare the rates of revision surgery. A logrank test was used to detect statistical differences between curves.

Indications for Hip Arthroplasty

The indications for THA were advanced osteoarthritis that caused significant pain and hindered daily activities for pain, and failure to improve with conservative treatment for at least 3 months.

Preoperative planning for all mTHAs was performed with TraumaCad software.17 TraumaCad assisted in planning implant sizes and measuring leg length discrepancies and hip offset.

After the technique for rTHA was introduced at our institution in 2011, all THAs were performed using this technology unless requested otherwise by the patient. For all rTHAs, preoperative planning was based on 3D CT scans.[9,18-20]

Surgical Technique

All DAA THA patients were in the supine position, whereas all PA THA patients were in the lateral position.[21-24] In rTHA, pelvic and femoral arrays registered the acetabulum and femur based on preoperative CT scans to generate a real-time 3D anatomical model of each patient's hip during surgery. Acetabular reaming, cutting, and component placement were guided with the Mako Robotic-Arm (MAKO Surgical Corp. [Stryker]). Once implants were all in place, the surgeon used the system to calculate leg length discrepancy and offset.[18,25]

The present study used robotic-assisted acetabular reaming and cup placement, and manual femoral preparation and stem placement. The native femoral version, however, is given by the software as a guide before broaching. Once the femoral implant is in place, the final femoral version of the implant can be assessed and compared with the native version.[26-28] Specifically, the robotic technology used to perform THA in this study allowed the surgeon to manually operate while reaming but constrained the range of possible motion during acetabular preparation.[9,18,20,25,29]

For DAA mTHA, fluoroscopic guidance was used for acetabular reaming and cup component positioning.[30,31]

Postoperative Rehabilitation

After their surgery, patients were instructed to follow a rehabilitation protocol which included physical therapy and home care for 1 to 2 weeks. Patients then progressed to outpatient physical therapy for an additional 6 to 8 weeks where they improved their range of motion and strength. Furthermore, patients were seen for the postoperative follow-up appointments with radiographic evaluation at the 2-week, 3-month, and annual time points.

Results

Patient-reported Outcomes of All Robotic-assisted Arthroplasty at Minimum 5-Year Follow-up

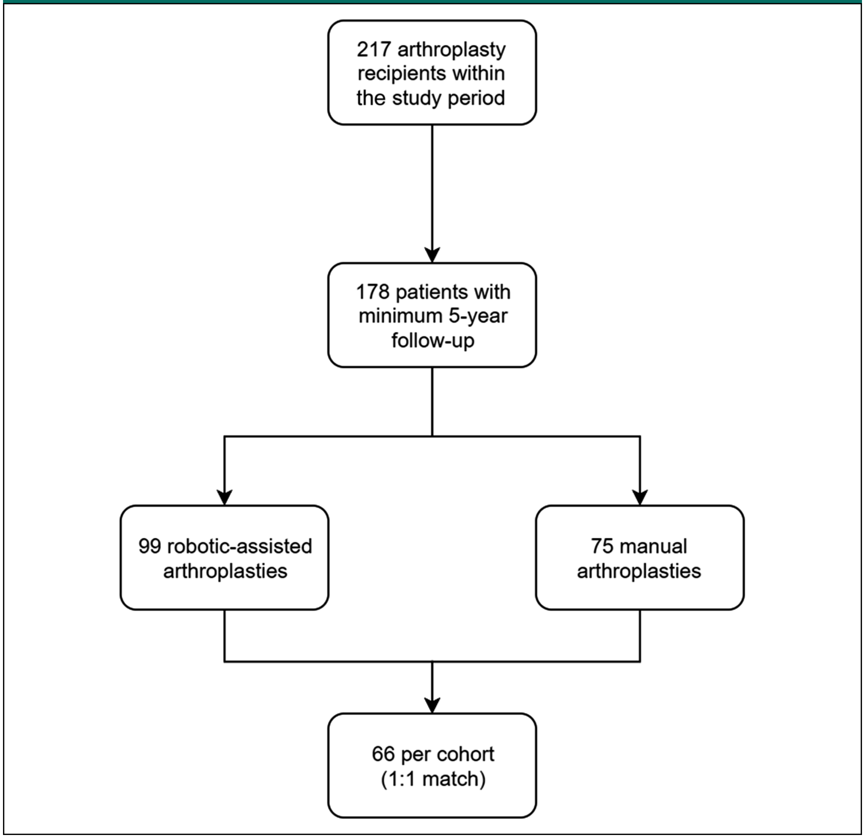
There were 217 THA recipients within the study period, 174 (80.1%) of whom had minimum 5-year follow-up, Figure 1. Of the 174 patients, 99 rTHA had PROs, documented in Table 1. Overall, PROs were favorable for HHS, and FJS-12. Patients reported HHS of 90.92 ± 12.36, FJS-12 of 84.50 ± 19.97, Veterans RAND-12 Mental of 60.52 ± 7.17, Veterans RAND-12 Physical (VR-12 Physical) of 50.51 ± 8.58, 12-Item Short Form Survey Mental of 56.67 ± 5.57, 12-Item Short Form Survey Physical (SF-12 Physical) of 49.35 ± 8.81, VAS of 1.13 ± 1.98, and satisfaction of 9.07 ± 1.74.

Matched Group Demographics

Sixty-six rTHA patients were propensity score matched to 66 mTHA patients, Figure 1. Prematched and postmatched demographic characteristics were shown in Table 2, and Figure 2.

Of the matched groups, the ages of the rTHA and mTHA were 59.01 ± 8.14 and 57.77 ± 10.50 years,

Figure 1



Flowchart showing the patient selection.

Table 1

Minimum 5-Year PROs, VAS, and Patient Satisfaction for All Robotic-assisted THAs

PROs	Robotic-assisted THA (n = 99 Hips)
HHS	90.92 ± 12.36
FJS-12	84.50 ± 19.97
VAS	1.13 ± 1.98
Satisfaction	9.07 ± 1.74
VR-12 Mental	60.52 ± 7.17
VR-12 Physical	50.51 ± 8.58
SF-12 Mental	56.67 ± 5.57
SF-12 Physical	49.35 ± 8.81

FJS-12 = Forgotten Joint Score-12, HHS = Harris Hip Score, PRO = patient-reported outcome, SF-12 Mental = 12-Item Short Form Survey Mental, SF-12 Physical = 12-Item Short Form Survey Physical, THA = total hip arthroplasty, VAS = visual analog scale, VR-12 Mental = Veterans RAND-12 Mental, VR-12 Physical = Veteran RAND-12 Physical

respectively (P = 0.45). The mean BMI was 29.24 ± 4.52 and 28.73 ± 5.91 kg/m^2, respectively (P = 0.57). There were 42 women and 24 men in the rTHA group, and 41 woman and 25 men in the mTHA group.

Patient-reported Outcomes Comparison Between Robotic-assisted and Manual Primary Total Hip Arthroplasty

Comparisons of PROs between rTHA and mTHA patients are shown in Tables 3 and 4 and graphically illustrated in Figures 3 and 4. The rTHA recipients reported significantly higher scores for HHS, FJS-12, VR-12 Physical, and SF-12 Physical (P < 0.001, P = 0.002, P = 0.002, and P = 0.001). Patients who received rTHA reported similar levels of VAS and satisfaction when compared with those of the mTHA group (P = 0.35, P = 0.45). Forty-eight rTHA recipients reported achieving HHS within the "excellent" range compared with 34 mTHA recipients (P = 0.019).

Acetabular Cup Implant Placement

Radiographical measurements indicated that 64 (97.0%) of acetabular components placed by rTHA were within the Lewinnek safe zone and 60 (90.9%) were within the Callanan safe zone (Table 4 and Figure 5). On the other hand, 48 (73.8%) and 37 (56.9%) of acetabular components were within the respective zones in the mTHA group. Patients who underwent rTHA had an 89% reduced risk of acetabular components placed outside the Lewinnek safe zone and 79% reduced risk of placement outside the Callanan safe zone in comparison to mTHA recipients (RR, 0.11 [95% CI, 0.03 to 0.46]; P = 0.002. RR, 0.21 [95% CI, 0.01 to 0.47]; P = 0.001).

Global offset discrepancy was lower for the rTHA group (P = 0.091, P < 0.001). The variations in postoperative radiographic measurements are greater on every count in the mTHA group Table 4.

Table 2

Demographics of Unmatched and Matched Groups at Minimum 5-Year Follow-up

Group	Unmatched rTHA, n = 99	Unmatched mTHA, n = 75	*P* Value	Matched rTHA, n = 66	Matched mTHA, n = 66	*P* Value
Sex			0.70			>0.99
Women	58	47		42	41	
Men	41	28		24	25	
Laterality			0.80			0.38
Left	48	34		31	25	
Right	51	41		35	41	
Approach			0.014			>0.99
Anterior	13	22		14	13	
Posterior	86	53		52	53	
BMI (kg/cm^2) (mean ± SD)	29.01 ± 4.37	28.78 ± 6.13	0.77	29.24 ± 4.52	28.73 ± 5.91	0.57
Age (yrs) (mean ± SD)	59.38 ± 8.45	57.45 ± 10.71	0.19	59.01 ± 8.16	57.77 ± 10.50	0.45

BMI = body mass index, mTHA = manual primary total hip arthroplasty, rTHA = robotic-assisted primary total hip arthroplasty

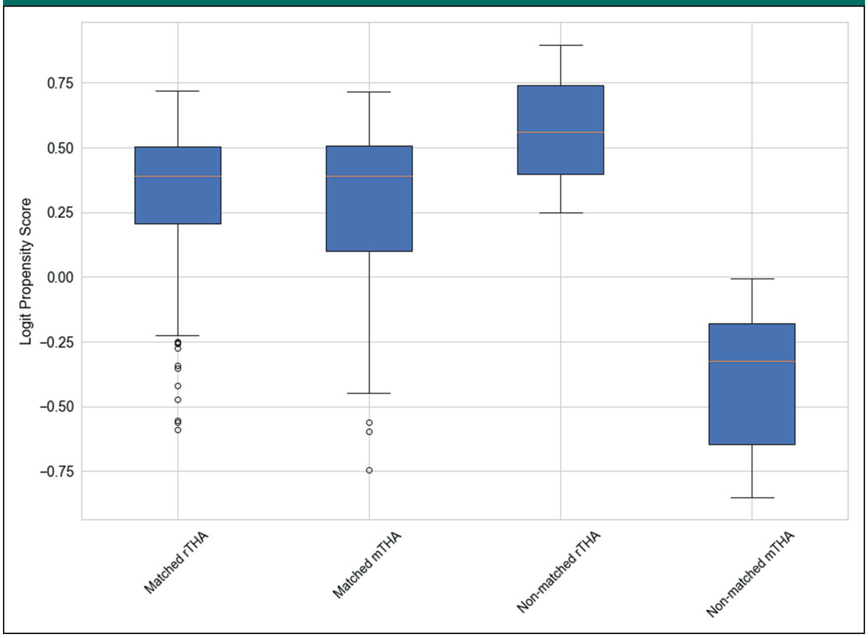
Survivorship for Robotic-assisted and Manual Primary Total Hip Arthroplasty at Minimum 5-Year Follow-up

Kaplan Meier curves for the two groups are presented in Figure 6. There were three and six cases of revision THAs in the rTHA and mTHA groups, respectively. Curves were not significantly different by the logrank test ($P = 0.479$).

Complications

In the rTHA group, one patient experienced a dislocation that required relocation under sedation without further episodes of instability or need for revision surgery, two experienced superficial infections that resolved with oral antibiotics, and one experienced deep vein thrombosis. In the mTHA group, three patients experienced minor numbness in the thigh, and one experienced a sciatic nerve injury.

Figure 2



Graph illustrating the Box and Whiskers plot of logit propensity scores of groups. mTHA = manual primary total hip arthroplasty, rTHA = robotic-assisted primary total hip arthroplasty

Discussion

Multiple robotic-assisted systems are present, each with its own distinctions,[11,25,32] including both haptic/semiactive and autonomous/active systems.[11,33,34] To our knowledge, the present study represents one of few to assess midterm outcomes specifically for haptic/semiactive rTHA and to compare outcomes against a propensity score pair–matched mTHA group.

In the eligible rTHA study group, patients reported PROs within good and excellent score ranges, Table 1.

Table 3

PROs for Matched Groups

PROs	Robotic-assisted THA (n = 66)	mTHA (n = 66)	*P* Value
HHS	90.57 ± 13.46	84.62 ± 14.45	<0.001
FJS-12	82.69 ± 21.53	70.61 ± 26.74	0.002
VAS	1.27 ± 2.20	1.07 ± 1.87	0.45
Satisfaction	8.91 ± 2.00	8.52 ± 2.62	0.35
VR-12 Mental	60.76 ± 5.94	58.97 ± 6.93	0.17
VR-12 Physical	50.30 ± 8.83	45.92 ± 9.44	0.002
SF-12 Mental	56.59 ± 5.60	56.20 ± 6.62	0.81
SF-12 Physical	48.97 ± 9.21	44.01 ± 10.26	0.001

FJS-12 = Forgotten Joint Score-12, HHS = Harris Hip Score, mTHA = manual primary total hip arthroplasty, PRO = patient-reported outcome, SF-12 Mental = 12-Item Short Form Survey Mental, SF-12 Physical = 12-Item Short Form Survey Physical, THA = total hip arthroplasty, VAS = visual analog scale, VR-12 Mental = Veterans RAND-12 Mental, VR-12 Physical = Veteran RAND-12 Physical

Table 4

Comparison of Acetabular Cup Inclination, Version, LLD, and GO Between Robotic-assisted THA and mTHA

Radiographic Measurement	Robotic-assisted THA	mTHA	*P* Value
Inclination (°)	40.92 ± 3.18	42.95 ± 5.23	0.009
Version (°)	18.39 ± 3.67	16.28 ± 6.64	0.026
Absolute LLD (mm)	4.35 ± 3.53	5.54 ± 4.10	0.091
Absolute GO (mm)	2.96 ± 3.01	4.48 ± 3.04	<0.001

GO = global offset, LLD = leg-length discrepancy, mTHA = manual primary total hip arthroplasty, THA = total hip arthroplasty

The average HHS score of the rTHA group was within the excellent range.

Previously, the senior author published clinical outcomes with minimum 2-year follow-up on 162 rTHA recipients.[25] Excellent results were reported with a mean HHS of 91.1 and FJS-12 of 83.1.

Results after pair matching revealed that rTHA recipients reported significantly higher HHS, FJS-12, VR-12 Physical, and SF-12 Physical scores ($P < 0.001$, $P = 0.002$, $P = 0.002$, and $P = 0.001$). This provides evidence contrary to a recent systematic review by Chen et al[11] that suggested that there are no differences in PROs between rTHA and mTHA. The fact that multiple technologies were included in this systematic review may be the reason behind this finding. We believe that the accuracy in component placement and the ability to objectively "customize" the hip implant to the patient anatomy for offset and leg length may explain these results. Specifically, restoration of the normal spatial relationship between the femur and pelvis may recreate the native muscular vectors and tensions around the hip, allowing it to feel like a normal hip.

Currently, limited data exist in the literature addressing the influence of rTHA on PROs. Illgen et al,[35] published their results at minimum 2-year follow-up with the same robotic-arm system used in the present study. The authors compared 100 consecutives rTHA to their initial 100 mTHA and most recent 100 mTHA and found that the mean estimated blood loss was less in the rTHA group. In addition, the dislocation rate was 0% in the rTHA group in contrast to 5% and 3% in the early and late mTHA, respectively. Nonetheless, no specific PROs were reported.

Two long-term studies have compared PROs between rTHA and mTHA, but both used autonomous/active systems for femoral milling, systems different from the one used in the present study. The authors in these studies reached conflicting conclusions.[10,26] Bargar et al[10] in a 14-year follow-up study compared 40 (45 hips) rTHA patients to 21 (22 hips) mTHA patients and found that patients with rTHA scored higher for HHS and the Western Ontario and McMaster Universities Osteoarthritis Index. On the other hand, Nakamura et al[26] reported on 59 (64 hips) rTHA patients and 56 (64 hips) mTHA patients. They concluded that robotics conferred no benefit. The authors, however, based their conclusion on a single PRO, the Japanese Orthopaedic Association hip score, without inclusion of additional multiple validated functional hip outcome scores to reinforce their findings.

For acetabular implant placement, this study adds to the body of evidence demonstrating increased accuracy and precision of cup positioning for rTHA compared with mTHA.[7,9,27] The present study has shown that acetabular cup placement by rTHA decreased the risk of placement beyond the Lewinnek safe zone by 89% and the Callanan safe zone by 79% (RR, 0.11 [95% CI, 0.033 to 0.46]; $P = 0.002$; RR, 0.21 [95% CI, 0.01 to 0.47]; $P = 0.001$). Multiple studies have supported the assertion that proper THA component placement enhances functionality and extends implant longevity.[4,8,9,28] Proper placement allows for optimal biomechanical interaction between components, and between tissue and implants, thus reducing unnecessary wear and tear.

Acetabular cup placement is one of the key elements affecting THA stability,[29] nevertheless, instability after THA is a multifactorial problem.[36] Almost 50% of dislocations occur within the first three months after the index surgery and over 75% within the first year. Illgen et al[35] reported 0% dislocation rate at minimum 2-year follow-up for rTHA in 100 consecutives patients. Similar results have been obtained by others.[25] In the present study, one dislocation occurred in the rTHA group. Interestingly, the acetabular cup in this particular patient was within Lewinnek and Callanan safe zones limits, which stresses the complexity behind instability after primary THA.[37,38] Furthermore, the sample size on the rTHA and mTHA was not large enough assess impact on the dislocation rate. The rate of dislocation after THA has been reported to be approximately 2%.[39] Thus, a much larger sample cohort would be needed to reduce the risk of a type II error.

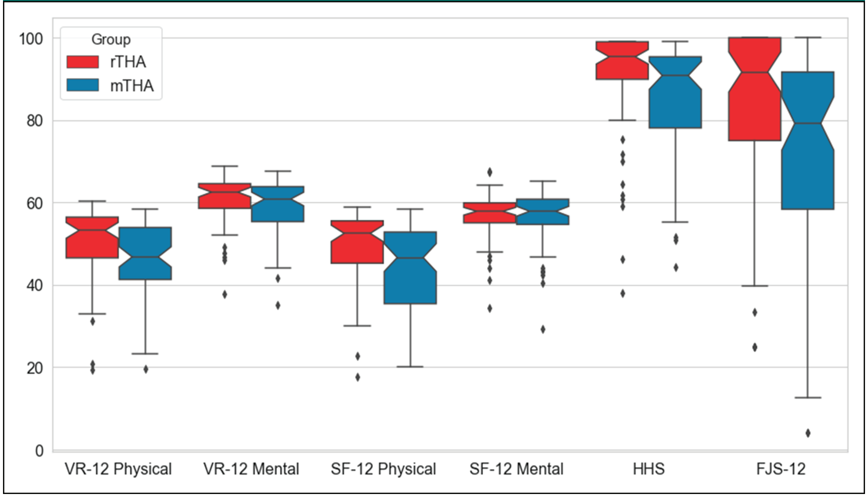
Strengths

The first strength of the current study is its use of multiple validated functional hip outcome scores in combination with pain and satisfaction. Second, this is among the few studies to report PROs in patients who underwent primary rTHA with minimum 5-year follow-up and to compare results with a propensity score matched mTHA group. Third, a single, high-volume, fellowship-trained surgeon (XXX) performed all cases, reducing inconsistencies that may arise when comparing different surgeons or centers.[40,41]

Limitations

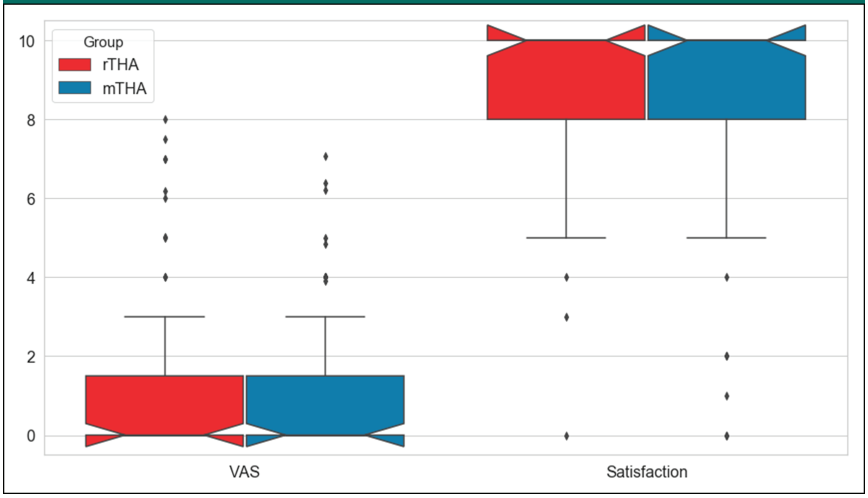
Limitations must be acknowledged. First, as a retrospective group study, findings may not be as unbiased as those in a randomized study. Second, because all procedures were performed by a single surgeon at a single institution, generalizability to other centers is limited. Third, the study uses a single robotic-assisted system. Given the

Figure 3



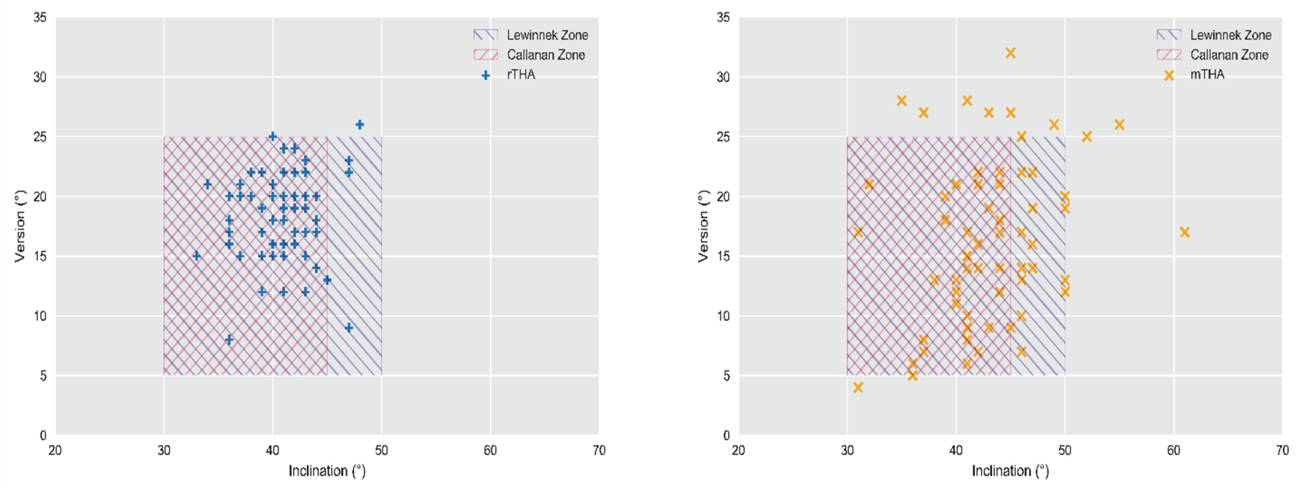
Graph illustrating the Box and Whiskers plot of patient-reported outcomes. The horizontal line within the box indicates the mean. Boundaries of the box indicate the 25th- and 75th-percentile, and the whiskers are set to 1.5 times the interquartile range. The notch indicates the 95% confidence interval around the mean. The nonoverlapping notches offer greater support that there exists a difference in means. FJS-12 = Forgotten Joint Score-12, HHS = Harris Hip Score, mTHA = manual primary total hip arthroplasty, PRO = patient-reported outcome, rTHA = robotic-assisted primary total hip arthroplasty, SF-12 Mental = 12-Item Short Form Survey Mental, SF-12 Physical = 12-Item Short Form Survey Physical, VR-12 Mental = Veterans RAND-12 Mental, and VR-12 Physical = Veterans RAND-12 Physical

Figure 4



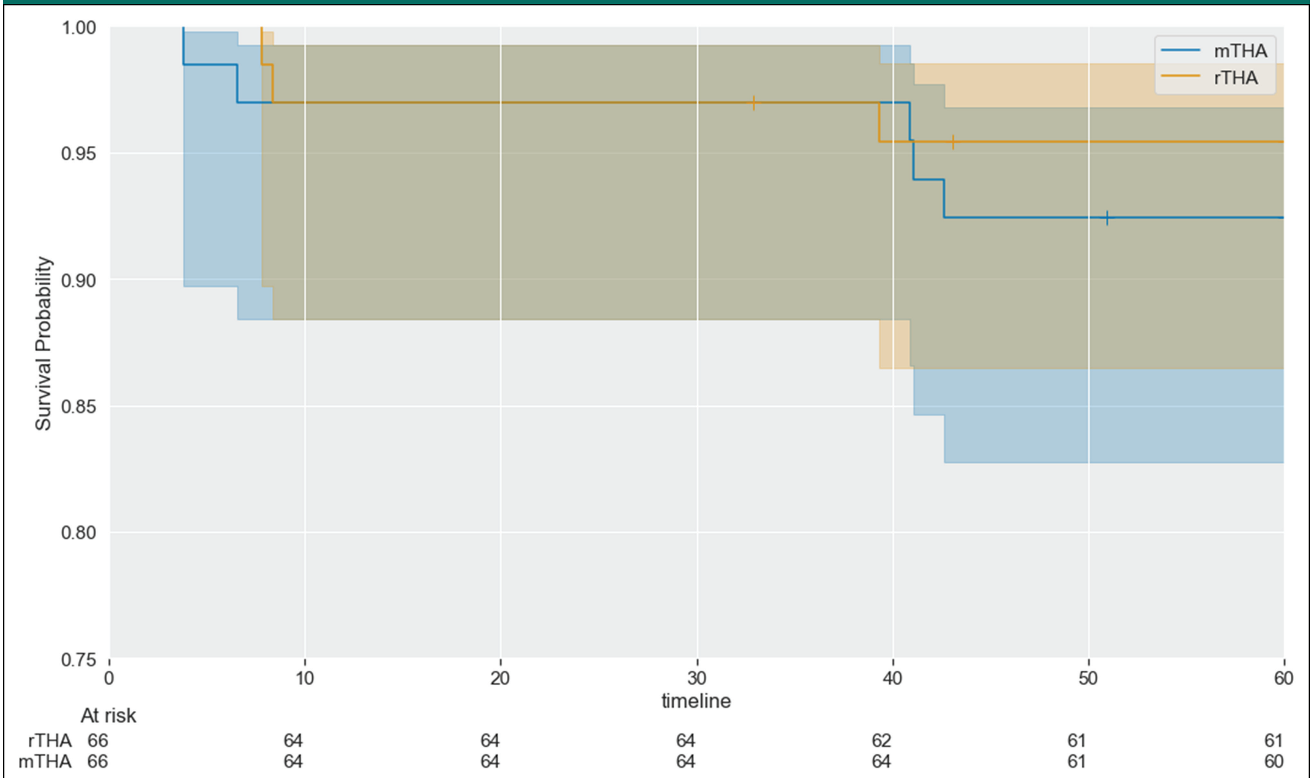
Graph illustrating the Box and Whiskers plot of patient-reported outcomes. The horizontal line within the box indicates the mean. Boundaries of the box indicate the 25th- and 75th-percentile, and the whiskers are set to 1.5 times the inter-quartile range. The notch indicates the 95% confidence interval around the mean. mTHA = manual primary total hip arthroplasty, PRO = patient-reported outcome, rTHA = robotic-assisted primary total hip arthroplasty, and VAS = visual analog scale

Figure 5



Graphs illustrating the Acetabular cup inclination and version. Measurements in degrees (°). mTHA = manual primary total hip arthroplasty, rTHA = robotic-assisted primary total hip arthroplasty

Figure 6



Graph illustrating the patients at risk. Timeline is presented in months. mTHA = manual primary total hip arthroplasty, rTHA = robotic-assisted primary total hip arthroplasty

available technologies, the findings here may not hold true for other systems. Four, although the study was powered for HHS, the sample sizes of both groups were too small to determine statistical differences between the groups regarding the dislocation rate. Five, the statistical significance obtained for HHS, FJS-12, VR-12

Physical, and SF-12 Physical favoring rTHA does not equate to clinical significance, and further research is needed to clarify this point. Finally, as a midterm follow-up study, long-term follow-up will be critical to corroborate these results.

Conclusion

Patients who received rTHA reported favorable outcomes at minimum 5-year follow-up. Furthermore, in comparison to a propensity score pair–matched mTHA group, rTHAs reported higher PRO scores and had 89% reduced risk of acetabular implant placement beyond the Lewinnek safe zone and 79% reduced risk of placement beyond the Callanan safe zone.

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