

Mako Total Hip arthroplasty: clinical summary



Mako clinical evidence

1. Introduction

Total hip arthroplasty (THA) has been one of the most successful procedures within the field of orthopaedics since the late 1960s.¹ The short- and long-term outcomes of THA may be influenced by several factors, including patient demographics, surgical technique and implant features.² One of the most important surgeon-controlled factors is component positioning.² Component malposition has been linked to poor biomechanics, accelerated wear, leg length discrepancy (LLD), and revision surgeries.² In addition, component malposition is directly associated with dislocations and mechanical loosening, which account for approximately 40% of THA revisions.³ The Mako System was introduced with a goal of providing more accurate implant positioning and alignment to plan, to help restore anatomy and enhance patient outcomes. This document summarizes the evidence to date that supports the use of Robotic-Arm Assisted Surgery for total hip arthroplasty.

2. What is the evidence that supports the use of Mako Total Hip?

Successful clinical outcomes following total joint replacement are dependent on component placement and on restoring the natural joint anatomy of the hip.² Instability, early mechanical failures and dislocation in hip arthroplasty continue to be primary reasons for revision.³ The Mako System is designed to minimize the margin of error associated with component placement and to enhance the accuracy and reproducibility of THA.

2.1 Accuracy and reproducibility in THA

In a multicenter clinical trial including 110 patients, acetabular cup position was compared between preoperative plan, intraoperative assessment and achieved radiographic measure.⁴ Results confirmed that intraoperative robotic-arm assistance achieved greater accuracy in preparation and position of the acetabular cup during THA (Table 1).⁴

	Preoperative plan	Intraoperative robotic-arm measurements	Martell radiographic measurement
Inclination	40.0°±1.2°	39.9°±2.0°	40.0°±4.1°
Version	18.7°±3.1°	18.6°±3.9°	21.5°±6.1°
Count (n)	119	119	110

Table 1. The average inclination and anteversion values of the acetabular components in the study, showing the preoperative plan, measures recorded intraoperatively and those measured from plan radiographs using the Martell method.²

Figure 1a

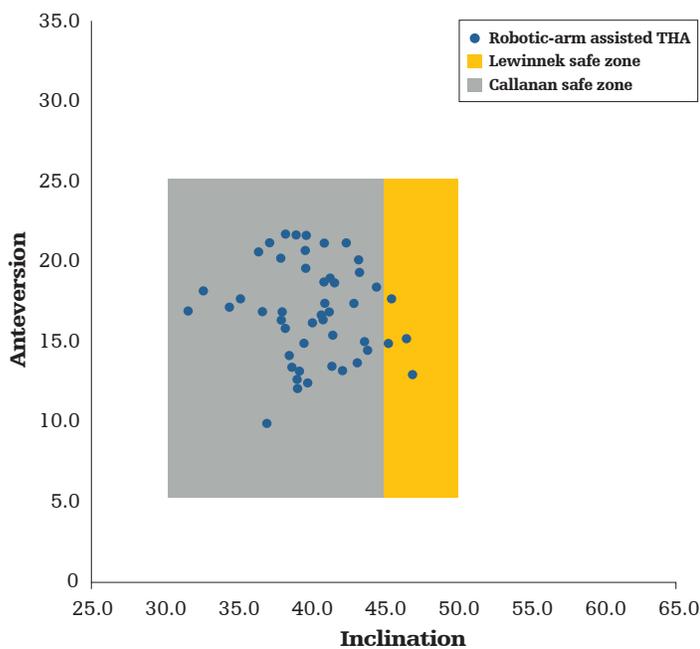
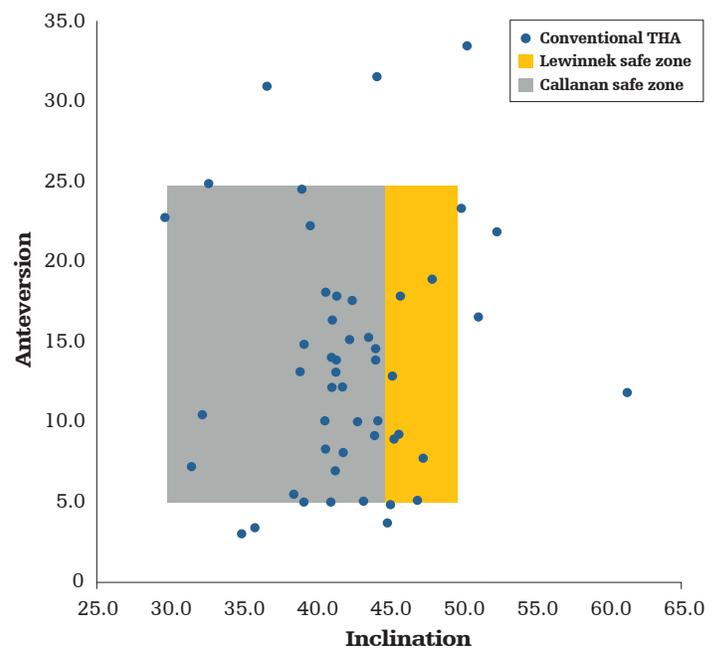


Figure 1b



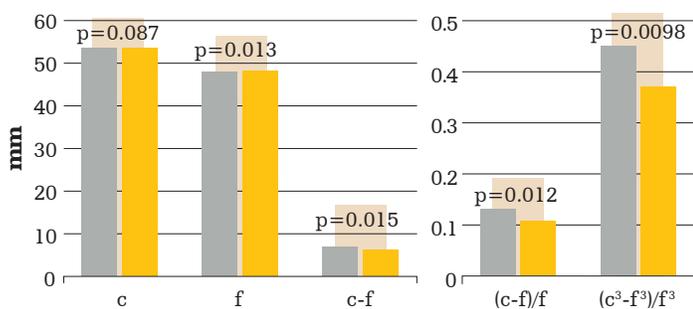
Figures 1a and 1b. Scatterplots of the (a) robotic-assisted and (b) conventional cups in the safe zones of Lewinnek et al. and Callanan et al. are shown.⁶

Domb et al. conducted a study involving six surgeons at a single institution, in which 1,980 THA surgeries were evaluated.⁵ The aim of this study was to understand the influence of surgical approaches and modes of guidance on accuracy of acetabular component placement.⁵ Robotic-arm assisted surgery resulted in a significantly greater percentage of components placed in the Callanan safe zone (30°-45° inclination and 5°-25° version) than all other modalities, including navigation- and fluoroscopy-guided approaches ($p < 0.05$).⁵ This study highlighted the consistency of the robotic-arm assisted technology, based on a large patient series.⁵

In another clinical study that compared robotic-arm assisted THA to manual THA, 100% of robotic-arm assisted THAs were within the Lewinnek safe zone (30°-45° inclination and 5°-25° version), compared with 80% of the conventional THAs ($p = 0.001$).⁶ A total of 92% of robotic-arm assisted THAs were in the Callanan modified safe zone, compared with 62% of conventional THAs ($p = 0.001$).⁶ Use of the Mako System allowed for more consistent placement of the cup in both safe zones (Figure 1a-b).⁶

Clinical evidence continues to build on the potential benefits of robotic-arm assisted THA. Investigations have demonstrated robotic-arm assisted surgery is accurate to 1.0 ± 0.7 mm for leg length/offset.⁷ Compared to manual THA, robotic-arm assisted THA was five times more accurate to plan in cup inclination and 3.4 times more accurate to plan in cup anteversion.⁷ A recent publication highlighted the influence of head center of rotation (COR) on the risk of hip dislocation.⁸ A potential benefit of robotic-arm assisted THA is that it has been shown to be significantly more accurate in reproducing COR when compared to manual implantation, which may result in reduced incidence of hip dislocation.⁷

Results: Bone stock



■ Conventional THA
 ■ Robotic-arm assisted THA

c-f = bone thickness lost over course of surgery

(c-f)/f = bone thickness lost through surgery per width of the femoral head

(c³-f³)/f³ = volume of bone lost through surgery

Figure 2. Illustrates the Mako System's single reaming technique preserves bone as compared to conventional THA's sequential reaming technique.⁹

Robotic-arm assisted THA has also been associated with more precise reaming, which can not only influence recreation of COR, but also impact preservation of bone stock.⁹

Suarez-Ahedo et al. studied bone preservation during primary THA and performed a matched pair control study which demonstrated that when compared to conventional THA (n=57), robotic-arm assisted THA (n=57) allowed for more precise reaming.⁹ This led to the use of smaller acetabular cups in relation to the patient's femoral head size.⁹ Using acetabular cup size relative to femoral head size as a surrogate measure of acetabular bone resection, these results suggested greater preservation of bone stock using robotic-arm assisted THA compared to conventional THA.⁹ This may reflect increased translational precision during the reaming process (Figure 2).⁹

The potential benefits of using CT-based robotic technology such as Mako to assess the influence of native femoral version on final stem version (SV) and combined anteversion when using a straight, uncemented stem were researched by Marcovigi et al.¹⁰ A total number of 362 patients who underwent Mako Total Hip were enrolled from three different orthopaedic centers.¹⁰ All patients underwent CT planning with measurement of femoral neck version (FNV) and intraoperative measurement of SV, acetabular component version, and combined version (CV) using robotic instrumentation.¹⁰ Results showed that the mean FNV was $5.0^\circ \pm 9.6^\circ$, and SV was $6.4^\circ \pm 9.7^\circ$.¹⁰ A strong correlation was found between SV and CV ($R = 0.89$, $P < .001$) and a significant difference in SV was found between the three centers ($P < .001$). CV was $< 25^\circ$ in 109 patients (30.1%) with relative risk of CV $< 25^\circ$ being 8.6 times greater with SV $< 5^\circ$ ($P < .001$) (Figure 3).¹⁰

From this data, it is important to note that when using an uncemented, single-wedge straight stem, SV is highly variable.¹⁰ The greater variability of FNV in patients with osteoarthritis is confirmed.¹⁰ Despite being moderately correlated with native FNV, SV can be partially influenced by the surgeon.¹⁰ The authors concluded that knowledge of preoperative and intraoperative stem version is fundamental to avoid abnormal combined version and therefore to reduce the risk of impingement, dislocation or acetabular uncoverage.¹⁰ They also emphasized that CT-based planning and robotic technology may be useful tools to have in the operating room, combined with stem designs which facilitate the achievement of desired version angles.¹⁰

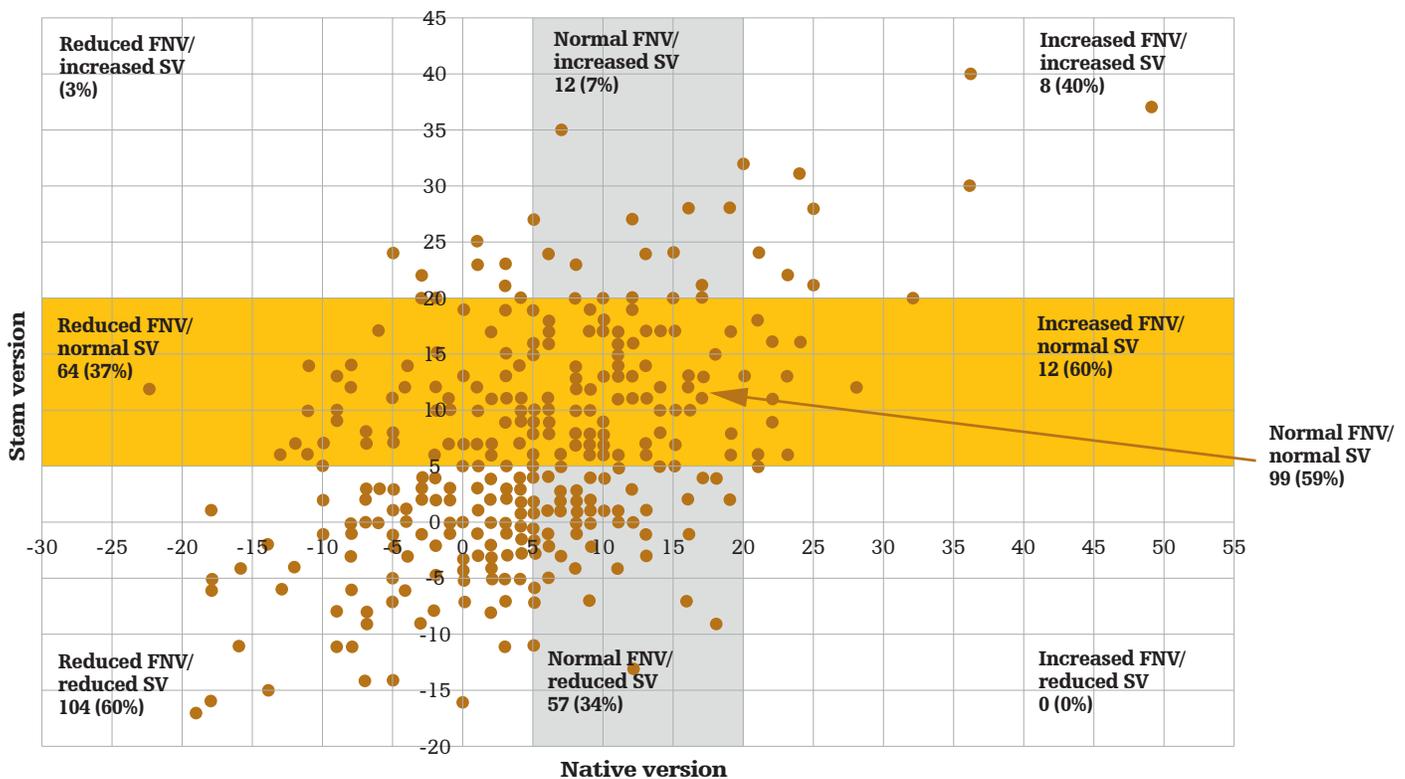


Figure 3. Scatter graph of SV in respect to FNV. The stem “safe zone” was highlighted in green.¹⁰ When FNV was <5°, stem version was “increased” 3% of the time, “normal” 37% of the time, and “reduced” 60% of the time, meaning that the surgeon was not always able to correct femoral retroversion.⁹ Also with a “normal” FNV, the stem was positioned with a SV <5° 34% of the time.¹⁰

2.2 Surgical team learning curve

In a retrospective, single-surgeon review of 100 consecutive Mako Total Hips, Bukowski et al. studied the effects of the learning curve on the outcome of three groups of patients: 1) the surgeon’s first 100 manual THA cases (2000-2001); 2) the surgeon’s last 100 manual THA cases (2010-2011); and 3) the surgeon’s first 100 Mako Total Hip cases (2011-2012).^{11,12} Dislocation was more frequent in group one (5/100, 5%) and group two (3/100, 3%) than in group three (0/100, 0%) (p<0.05) at the one year follow-up interval.¹²

Similarly, Redmond et al. researched the learning curve during the adoption of robotic-arm assisted THA as measured by component position, operative time and complications.¹³

The first 105 robotic-arm assisted THAs performed by a single surgeon were divided into three groups based on the order of surgery: 1) Group A consisted of the first 35 patients who underwent Mako Total Hip by the senior surgeon; 2) Group B consisted of patients 36 to 70; and 3) Group C consisted of patients 71 to 105.¹³ The authors reported a decreased risk of acetabular component malpositioning with Mako experience (P < 0.05).¹³ Operative time appeared to decrease with increasing surgical experience with the Mako System (P < 0.05).¹³ A learning curve of 35 cases was observed, as a decreased incidence of acetabular component outliers

and decreased operative times were noted with increased surgical experience with Mako.¹³

Heng et al. carried out a retrospective comparison of a single surgeon’s last 45 conventional THAs performed prior to changing to the robotic-arm assisted system, and compared them with the first 45 robotic-arm assisted THAs.¹⁴ When comparing surgical times between the two groups, they found that the average surgical time was 96.7 minutes for the robotic-arm assisted group and 84.9 minutes for conventional group.¹⁴ Upon further analysis, the authors determined that each robotic-arm assisted operation was approximately one minute shorter than the previous robotic operation and the average time for the last 10 cases was reduced to 82.9 minutes, which was quicker than the average time of the conventional group.¹⁴ It was concluded that surgical time is comparable with conventional techniques after the initial learning curve of approximately 35 cases.¹⁴

Kong et al. published a retrospective comparative cohort study of an experienced manual surgeon’s first 100 robotic-assisted THAs compared to the surgeon’s last 100 manual cases.¹⁵ The average operating time of robotic-assisted THA was 95.92 ± 15.64 minutes, ranging from 68 to 145 minutes.¹⁵ The learning curve was assessed using a cumulative summation test for learning curve analysis which demonstrated that after the 14th case, a downtrend in the surgeon’s operative time began.¹⁵ There was no statistical difference between the first

14 cases versus cases 15 to 100 when considering cup positioning, postoperative LLD, offset and Harris hip score (HHS).¹⁵ Results indicate that there was a 14-case learning curve when considering operative time; however, the authors observed that this learning curve did not impact patient outcomes.¹⁵

2.3 Impact on surgical team

The Mako System provides a stereotactic boundary that guides the alignment of the robotic arm during acetabular reaming and cup insertion. Additionally, the system provides a single-ream option, eliminating the need for the surgeon to perform multiple reams to achieve final ream size. It has been reported that 66.1% of arthroplasty surgeons have had a workplace-related injury, with 31% requiring surgery.¹⁶ Assistance in performing reaming and cup insertion may enhance the ergonomic health and reduce the workload demand on the surgeon.¹⁶

A cadaveric study was performed to determine how the use of Mako Total Hip can influence a surgeon's energy expenditure as well as mental and physical demand compared to manual THA.^{17,18} Twelve THAs were performed by two surgeons, with varying robotic experience, in their fellowship training. Each cadaveric specimen received a manual THA on one hip and a Mako Total Hip on the contralateral side. The surgeons wore biometric shirts that collected data on caloric expenditure¹⁷ and were administered a modified surgery task load index questionnaire after each procedure to evaluate perceived mental and physical demand.¹⁸ Surgeons who performed Mako Total Hip demonstrated reduced caloric expenditure during acetabular reaming and acetabular implantation.¹⁷ With the Mako System assisting through use of a stereotactic boundary, the surgeons also reported less physical and mental demand during acetabular reaming and acetabular implantation, with statistically significantly less mental demand during acetabular reaming in the Mako Total Hip group.¹⁸

Patient-reported outcomes (PROMs) comparing rTHA and mTHA patient groups ¹¹					
	Group (RATHA n=100, MTHA n=100)	Preoperative	Postoperative	PROMs (postoperative- preoperative)	p-value
mHHS (mean and standard deviation)	RATHA	49.6 (16.3)	92.1 (10.5)	43.0 (18.8)	<0.001
	MTHA	49.2 (14.8)	86.1 (16.2)	37.4 (18.3)	<0.001
	p-value	0.865	0.002	0.035	
SF12-MCS (mean and standard deviation)	RATHA	54.1 (10.4)	54.6 (9.1)	0.4 (9.7)	0.629
	MTHA	53.1 (9.6)	53.0 (10.2)	0.5 (11.5)	0.970
	p-value	0.459	0.245	0.962	
SF12-PCS (mean and standard deviation)	RATHA	33.5 (9.6)	46.0 (10.5)	12.5 (11.8)	<0.001
	MTHA	30.3 (8.0)	44.4 (11.0)	14.0 (11.9)	<0.001
	p-value	0.010	0.282	0.404	
WOMAC (mean and standard deviation)	RATHA	45.6 (18.9)	16.0 (14.9)	-29.6 (21.4)	<0.001
	MTHA	47.1 (14.7)	17.3 (15.5)	-28.5 (18.3)	<0.001
	p-value	0.536	0.538	0.618	
UCLA (mean and standard deviation)	RATHA	5.1 (1.9)	6.3 (1.8)	1.2 (1.7)	<0.001
	MTHA	4.8 (1.8)	5.8 (1.7)	1.0 (1.9)	<0.001
	p-value	0.227	0.033	0.429	
Categorical analysis of modified Harris Hip Score					
	rTHA			mTHA	
90-100	75.0% (75)			61.0% (61)	0.034
80-89	13.0% (13)			15.0% (15)	0.684
70-79	6.0% (6)			5.0% (5)	0.756
<70	6.0% (6)			19.0% (19)	0.005

Table 2

3. What are the clinical benefits of Mako Total Hip?

Clinical benefits resulting from increased accuracy and precision afforded by Mako Total Hip have been investigated, including functional outcomes and levels of patient satisfaction. Results of studies in this area are promising.

3.1 Clinical and functional outcomes in THA

In research conducted by Bukowski et al., outcomes for three groups of 100 consecutive THAs (first 100 manual THAs, last 100 manual THAs and first 100 Mako Total Hips), were reviewed. Mako Total Hip resulted in significantly higher modified HHSs (92.1 ± 10.5 vs. 86.1 ± 16.2 , $p = 0.002$) and UCLA activity levels (6.3 ± 1.8 vs. 5.8 ± 1.7 , $p = 0.033$) than manual THA at minimum one-year follow-up (Figure 4 and 5, Table 2).¹¹

Perets et al. have reported on minimum two-year outcomes and complications for Dr. Benjamin Domb's patients who underwent a Mako Total Hip procedure.²⁰ Dr. Domb is a high-volume, fellowship-trained surgeon. For the 162 Mako Total Hip cases included in their analysis, the average time of surgery was 76.7 minutes, which is comparable to times reported in literature for manual surgeries.^{12,20} Patients reported an average HHS of 91.1.²⁰

The Forgotten Joint Score-12 (FJS-12) questionnaire has evidence of low-ceiling effects and is suitable for assessing longer term outcomes in well-performing groups after THA.²¹ The literature has reported an FJS-12 ranging from 50.9 ± 25.3 to 80 ± 24 for patients who received manual THA.^{20,21} For the 162 cases in this study, Perets et al. reported an FJS-12 for the Mako Total Hip patients of 83.1, which to date is the highest found in literature on THA.²⁰ Additionally, at two years, there were no leg length discrepancies or dislocations reported.²⁰ Postoperatively, six patients reported fractures (greater trochanteric, $n=3$ and calcar, $n=3$) and six had complications such as deep vein thrombosis and infection.²⁰

Dr. Domb's patients continued to be followed, and Maldonado et al. published on minimum five-year outcomes of this patient cohort.²² When compared to a manual THA control group, the Mako Total Hip cases reported significantly higher Harris hip scores ($p<0.001$), FJS-12 ($p=0.002$), Veterans RAND-12 physical component scores ($p=0.002$), and Short Form Health Questionnaire (SF)-12 physical component scores ($p=0.001$) (Table 3).²² While revision rates between these cohorts were similar ($p=0.479$), the acetabular components for the Mako Total Hip cases were more consistently placed within the Lewinnek ($p=0.002$) and Callanan ($p=0.001$) safe zones.²² In addition, Mako Total Hip recipients had lesser absolute values

of leg length discrepancy and global offset ($p = 0.091$, $p = 0.001$). This study used multiple validated functional hip outcome scores to determine that patients who received Mako Total Hip reported favorable outcomes at a minimum five-year follow-up.²²

Patient-reported outcomes	Robotic-assisted THA	Manual THA	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±6.03	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

Table 3. Minimum five-year patient-reported outcomes for a Mako Total Hip and manual THA cohort.²²

A similar trend was observed in a retrospective review of 45 Mako Total Hips and 45 conventional THA cases as conducted by Heng et al., where complications rates were found to be comparable.¹⁴ The conventional group had three intraoperative complications compared to one in the robotic group.¹⁴ The three intraoperative complications experienced by the conventional group related to acetabular fractures, while the robotic group had none.¹⁴ The authors suggested that this could be due to the single-ream, minimal bone resection technique utilized by the robotic system, which may decrease the risk of acetabular fractures.¹⁴

3.2 Patient satisfaction

THA has been one of the most successful surgeries in medicine, having demonstrated favorable short- and long-term outcomes and resulting in more than 95% survivorship at 10 years.¹ In addition, patient satisfaction post-THA is high, as demonstrated by Perets et al., where patient satisfaction at a minimum of two-year follow-up was assessed.²⁰ For the 162 Mako Total Hip cases considered in this study, mean patient satisfaction was a high 9.3 out of 10.²⁰

3.3 Patient recovery

When exploring a patient's road to recovery, their length of stay in hospital after surgery is a key factor to consider. Heng et al. retrospectively compared the length of stay of 45 patients who underwent Mako Total Hip against those who received conventional THA (n=45).¹⁴ They reported similar results in both groups, however once the patients who required inpatient rehabilitation were excluded, the robotic group had a shorter hospital stay (4.22 days vs. 5.93).¹⁴

This finding was further validated by another study conducted by Banchetti et al., who retrospectively analyzed 107 patients at 24-months follow-up (Mako Total Hip, n= 56; standard technique THA, n=51).²³ They found a significant difference in the length of hospital stay, defined by number of days hospitalized, between the Mako group (M=5.14, SD=1.98) and the standard group (M=8.11, SD=1.64).²³

Overall, early data from these studies suggests that patients who undergo Mako Total Hip may be able, on average, to return home sooner after surgery than those who undergo conventional THA. This may pose a great advantage for the patients' well-being and offer financial benefits to healthcare institutions, since a reduction in length of hospitalization has the potential to reduce economic burden to hospitals.²³ Furthermore, these findings have the potential to offer financial benefits to healthcare institutions since a reduction in the length of stay post-Mako Total Hip surgery potentially reduces the economic burden to hospitals. This is a key area being investigated by various surgeons worldwide.

3.4 Role of Mako in complex cases

Chai et al. carried out a case study that included three complex cases with hip dysplasia, ankylosing spondylolysis and post-traumatic arthritis, respectively.²⁴ In all three cases, the Mako System was utilized to help accurately implement the surgical plan.²⁴ Since there was an absence of conventional bony landmarks, the preoperative CT scan in these cases was instrumental in planning.²⁴ The hip dysplasia patient reported at three months postoperatively that they were able to walk without assistance, had no hip pain and were satisfied with their leg lengths.²⁴ The patient with ankylosing spondylolysis reported no hip pain and was able to walk with a walking frame at three months postoperatively.²⁴ The patient with post-traumatic arthritis reported no hip pain and was able to walk without assistance at three months postoperatively.²⁴ According to this study, the planning and accuracy of execution in Mako Total Hip allowed the surgeon to give the patients excellent reconstruction of their hip joints which substantially enhanced their quality of life. The authors went on to say that Mako Total Hip surgery may be considered

for complex THA cases in order to achieve the desired accuracy of the reconstruction, especially in the absence of conventional bony landmarks.²⁴

4. Cost-effectiveness

4.0 Is Mako Total Hip cost effective?

In assessing the potential effects of Mako Total Hip on costs to private payers and Medicare, Maldonado and colleagues created a Markov model to compare the costs of RATHA and manual THA (MTHA).²⁵ The model considered the cost of postoperative events such as infection, dislocation and revisions.²⁵ Using clinical data from 555 patients and comparing it with literature, the model simulated the outcomes and cumulative costs over five years.²⁵ Cost estimates were taken from the Medicare Standard Analytical Files and a modifier was used to estimate private payer costs.²⁵ The model showed that Mako Total Hip was cost saving compared to manual THA for Medicare (\$14,228 vs. \$15,313) and private pay (\$23,816 vs. \$25,633).²⁵

A separate Medicare analysis of the 90-day episode of care (EOC) of 938 RATHAs propensity matched to 4,670 MTHAs found that RATHA patients were less likely to have post-index inpatient rehabilitation (IPR) or skilled nursing facility (SNF) admissions (0.64% vs. 2.68%; $p<0.0001$ and 20.79% vs. 24.99%; $p=0.0041$, respectively).²⁶ RATHA patients used fewer days in post-index inpatient and SNF care (7.15 vs. 7.91; $p=0.8029$ and 17.98 vs. 19.64; $p=0.5080$, respectively) and used fewer home health aide (HHA) visits, (14.06 vs. 15.00; $p=0.0006$) compared to MTHA. RATHA had lower 90-day EOC costs for: IPR (\$11,490 vs. \$14,674; $p=0.0470$), SNF (\$9,184 vs. \$10,408, $p=0.0598$) and HHA (\$3,352 vs. \$3,496; $p=0.0133$) compared to MTHA.²⁶ Overall, RATHA patients had 12% (\$948) lower average post-index costs compared to MTHA patients ($p=0.0004$).²⁶ Total 90-day episode-of-care costs for RATHA patients were found to be \$785 less than those of MTHA patients (\$19,734 vs. \$20,519, $p=0.0095$).²⁶

5. Conclusions

Mako Total Hip offers the potential for surgeons to achieve component placement and alignment accuracy, as well as to enhance clinical outcomes.^{4-14,20-21,23} Patients have reported tangible benefits of Mako Robotic-Arm Assisted Surgery, including treatment satisfaction and return to activities of daily living.^{11,22} Surgeons are

empowered to achieve their target preoperative plans with precision. Ultimately, the benefits of Mako Robotic-Arm Assisted Total Hip arthroplasty may be experienced by all key players – patients, surgeons and health systems.

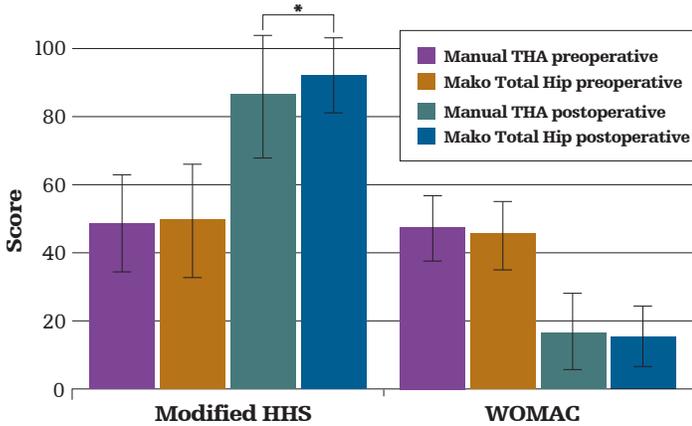


Figure 4. Statistically higher modified HHS were shown for Mako Total Hip patients.¹¹

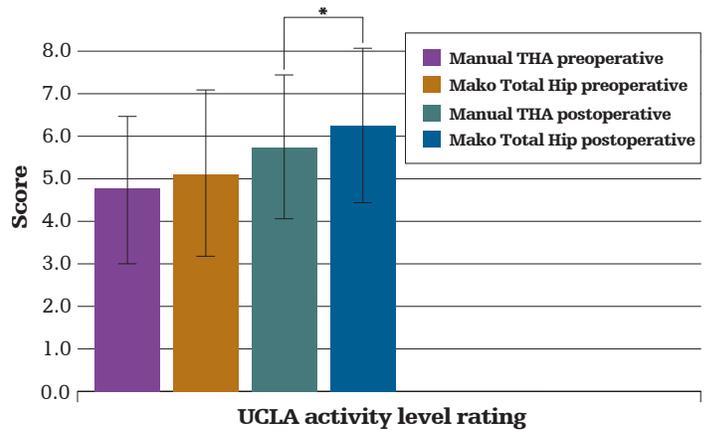


Figure 5. Statistically higher UCLA scores were shown for Mako Total Hip patients.¹¹

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References

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