

stryker



Mako Total Hip

Clinical summary

Volume 9

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1. Introduction

Total hip arthroplasty (THA) has been one of the most successful procedures within the field of orthopaedics since the late 1960s.¹ Despite its high success, mechanical failure, aseptic loosening and component malpositioning leading to dislocations are some of the most common reasons for revision THA.² These complications can be mitigated adequate preoperative planning that can help surgeons better understand a patient's specific anatomy, thus helping the surgeon to more accurately position the component to plan. The Mako System was introduced with a goal of providing more accurate implant positioning while leveraging the benefits of computed tomography (CT) imaging to help restore anatomy, reduce the risk of postoperative complications, enhance patient outcomes, provide an efficient user experience, and lower costs in comparison to manual techniques. This document summarizes the evidence to date that supports the use of the Mako System for primary total hip arthroplasty and Direct Anterior (DA) total hip arthroplasty.



2. What is Mako Total Hip?

Mako Total Hip is a robotic-assisted (RA) system that uses segmented, CT scans to generate a 3D model reconstruction of the pelvis and proximal femora to aid in the creation of a patient-specific preoperative plan

(Figure 1).³ With Mako Total Hip, surgeons have the ability to dynamically balance the joint and tailor implant position based on each patient's unique anatomy and spinopelvic characteristics. The system also provides real-time intraoperative feedback through AccuStop™ haptic technology, which is designed to aid the accurate execution of the surgical plan.³ Mako Total Hip is designed to minimize the margin of error associated with restoring native hip biomechanics while incorporating patient-specific anatomy, regardless of the surgical approach used.⁴



Figure 1. Preoperative planning screen with 3D reconstruction of pelvis and femur depicting leg length and combined offset.

2.1 Accuracy with restoring native biomechanics

In a multicenter clinical trial including 110 patients, acetabular cup positioning was compared between preoperative plan, assessment, and achieved radiographic measure.⁵ Results showed that intraoperative robotic-assisted THA (RA-THA) achieved greater accuracy in preparation and position of the (Table 1).

	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.⁵

Gou et al. conducted a study aimed at evaluating accuracy of Mako Total Hip cup positioning using the posterolateral approach.⁶ This study showed that the planned inclination and anteversion of the acetabular cup were correlated with the actual postoperative measurements.⁶ The difference between planned and actual measurement was $1.43 \pm 0.15^\circ$ and $1.47 \pm 0.11^\circ$, respectively, therefore this study demonstrated it is possible to achieve accurate cup position of Mako Total Hip to plan.⁶

When utilizing a direct anterior (DA) approach in THA, most surgeons use fluoroscopic guidance to confirm the acetabular component position.⁷ Literature has proposed that RA-THA using DA approach may offer improved implant placement.⁷ A clinical study compared the accuracy of acetabular component position between DA and posterior approach (PA) using Mako Total Hip, in the absence of fluoroscopic guidance.⁷ The DA cohort conferred significantly higher accuracy with respect to inclination ($p=0.001$) and better accuracy for cup anteversion than PA cohort.⁷ This study also concluded that the acetabular component position using Mako Total Hip is both accurate and precise in most cases, regardless of surgical approach.⁷

In addition to cup position, studies have found that restoring native hip biomechanics such as hip center of rotation (COR) and leg lengths are important for reducing the risk of dislocation.⁸ In a prospective randomized control trial (RCT) conducted by Fontalis et al., they looked to compare the reproducibility of planned hip COR between manual THA (M-THA) and RA-THA, as well as other technical objectives.⁹ The use of RA-THA was associated with statistically significant superior accuracy in restoring native horizontal and vertical COR ($p < 0.001$).⁹ In addition, the RA-THA cohort demonstrated statistically significant improved accuracy in achieving acetabular component positioning ($p < 0.001$) and reduction of leg length discrepancy ($p < 0.001$).⁹

Clinical studies have also shown that Mako Total Hip has been associated with more precise reaming, which can not only influence recreation of COR, but also impact preservation of bone stock.¹⁰ Suarez-Ahedo et al. (2017) studied bone preservation during primary THA in a matched pair control study of M-THA ($n = 57$) and RA-THA ($n = 57$).¹⁰ When comparing these matched cohorts, the RA-THA allowed for more precise reaming and lead to the use of smaller acetabular cups in relation to the patient's femoral head size.¹⁰ Using acetabular cup size relative to femoral head size as surrogate measure of acetabular bone resection, these results suggest that greater preservation of bone stock using Mako Total Hip compared to M-THA.¹⁰ This may reflect increased translational precision during the reaming process (**Figure 2**).¹⁰

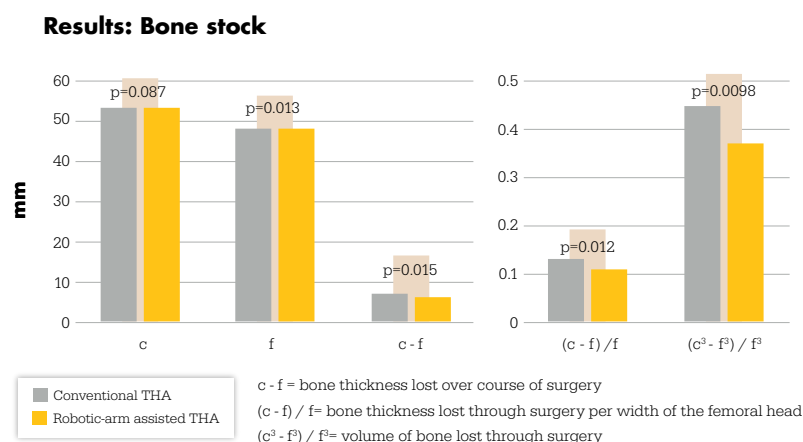


Figure 2. Illustrates that Mako Total Hip's single reaming technique preserves bone as compared to conventional THA's sequential reaming technique.¹⁰

2.2 Incorporating patient anatomy with functional approaches

Surgeons have been using the Lewinnek safe zone as a guide for cup placement for over 40 years.¹¹ However, studies have shown that greater than 50% of THA dislocations have cups placed within the safe zone.^{12,13} One shortcoming of the Lewinnek safe zone is that it generally applies to all patients, and does not consider patient-specific pelvic tilt or dynamic pelvic motion during movement.¹⁴ Mako Total Hip incorporates features that allow surgeons to assess a patient's change in pelvic tilt (PT) in the supine, standing and seated position as well as the ability to visualize range of motion to impingement using a virtual range-of-motion (vROM) tool.¹⁴ (**Figure 3**).

O'Conner et al. found that PT can significantly change the functional orientation of the acetabular component and may differ markedly between patients (**Figure 4**).¹⁵ They then used the vROM tool from the Mako Total Hip application to assess the risk of impingement and investigate changes to implant position to reduce that risk.¹⁵

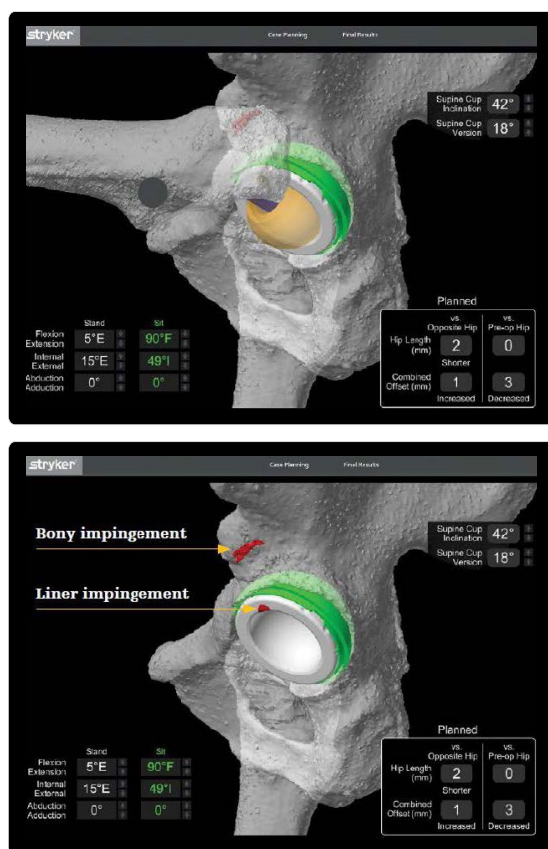


Figure 3. Mako Total Hip has a virtual range-of-motion (vROM) tool indicating risk of impingement (highlighted in red). The surgeon can change implant position and/or implant systems to help address impingement.

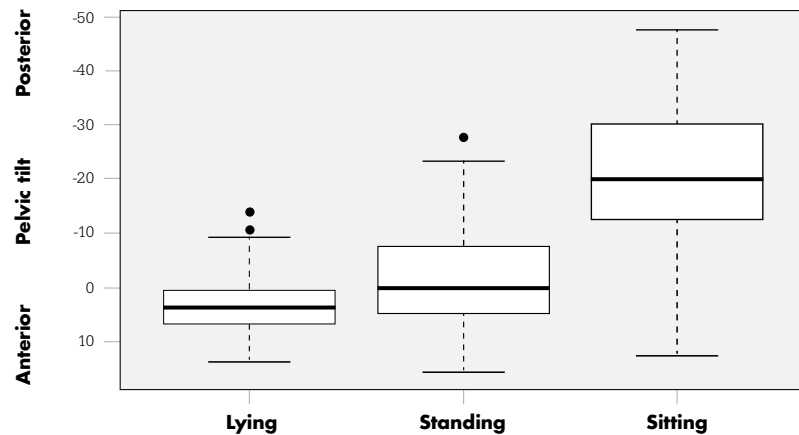


Figure 4. O’Conner et al. found high variability in preoperative lying, standing, and sitting pelvic tilt (PT) in patients undergoing total hip arthroplasty.¹⁵

A prospective, multi-center clinical study was conducted on patients who received Mako Total Hip with software that incorporates patient’s PT and vROM.¹⁶ The purpose of this study was to quantify the percentage of cases where the surgical plan deviates from a 40° inclination and 20° anteversion target after incorporating spinopelvic motion and intraoperative vROM impingement modeling.¹⁶ Cases were separated into groups based on their preoperative spinopelvic mobility: 64% of cases were considered normal (change $\geq 10^\circ$ and $\leq 30^\circ$), 27% of cases were considered stiff (change $< 10^\circ$) and 9% of cases were hypermobile (change $> 30^\circ$).¹⁶ For all groups, the majority of cases (normal: 76%, stiff: 79%, hypermobile: 90%) deviated from the 40° inclination and 20° anteversion target.¹⁶ In summary, Mako Total Hip and the incorporation of spinopelvic motion and vROM impingement modeling changed the preoperative plan 78% of the time, allowing surgeons to plan and execute functional hip positioning based on a patient’s native anatomy.¹⁶

2.3 Soft-tissue protection

A cadaver study was performed to assess soft-tissue protection in DA THA by examining nine structures including the gluteus medius, gluteus minimus, quadratus femoris, tensor fascia lata, sartorius, superior and inferior gemellus muscles, the vastus lateralis, as well as the ilio-tibial band.¹⁷ A total of 6 paired cadaveric hips (3 RA-THA and 3 M-THA) were performed by two surgeons. An additional surgeon, blinded to the method of preparation, graded structure damage using a 1 to 4 grading scale.¹⁷ The grading of soft tissue damage postoperatively determined that utilizing RA-THA may lead to enhanced soft-tissue protection compared with M-THA for the DA approach.¹⁷ The authors suggest this may be due to the enhanced preoperative planning with the Mako Total Hip software, real time intraoperative feedback, haptically-bounded reamer usage, reduced surgical steps, as well as ease of use with reaming.¹⁷

In another study, Kayani et al. developed the bone trauma and soft-tissue injury (BOSTI) Hip classification system for assessing iatrogenic soft-tissue injury during THA.¹⁸ The BOSTI Hip classification system provides a reproducible grading system for stratifying soft-tissue injury during THA.¹⁸ Using intraoperative photographs, the study compared soft-tissues of 30 M-THA and 30 RA-THA's.¹⁸ Mako Total Hip was associated with significantly higher BOSTI scores ($p=0.002$), more pristine osseous acetabular surfaces, and reduced muscle injury compared to M-THA.¹⁸

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

Clinical benefits resulting from a patient-specific plan afforded by Mako Total Hip have been shown to reduce the rate of dislocation, enhance postoperative patient outcomes, and improve patient recovery and satisfaction. Results of studies in this area are promising.

3.1 Reduction of dislocations

Dislocations following primary total hip arthroplasty (THA) is a well-known complication, and instability is a leading cause of revision THA in many national joint registries.¹⁹ The treatment of recurrent instability is revision THA, which is associated with high cost of hospitalization, prolonged length of stay, and continuing increased risk of further instability compared with primary THA.¹⁹ Clinicians and researchers have emphasized the importance of patient-specific preoperative planning and intraoperative strategies to achieve targets that may reduce the risk of dislocation.¹⁹

In a retrospective, single-surgeon review of 300 THAs, the rate of dislocation at one year follow up was studied in three groups of patients: 1. The surgeon's first 100 M-THA cases (2000-2001); 2. The surgeon's last 100 M-THA cases (2010-2011) and 3. The surgeon's first 100 robotic-assisted THA (RA-THA) cases (2011-2012).²⁰ Dislocation rates between the three groups were significantly different and dislocation was more frequent in group one (5/100, 5%) and group two (3/100, 3%) than group three (0/100, 0%) at one year follow up.²⁰

Multiple studies report the impact of RA-THA on dislocation rates following THA. Bendich et al. conducted a retrospective review of 13,802 THAs: 1,700 RA-THA, 3,155 computer navigated THA (CN-THA) and 8,877 M-THA. This study concluded that the odds ratio of reoperation for dislocation was 0.3 for RA-THA compared to M-THA ($p=0.046$).²¹ Similarly, Di Gangie et al. analyzed 11,740 THAs, 1,293 RA-THA, 4,574 CN-THA and 5,873 M-THA, and found that the use of RA-THA was found to be associated with a significantly reduced dislocation risk compared to M-THA, with an odds ratio of 0.3 ($p=0.007$).²² Additionally, at one year follow up, there was a statistically significant decreased risk of reoperation due to dislocation with RA-THA and a lower rate of dislocation requiring reoperation compared to M-THA.²¹

A cohort study from Michigan Arthroplasty Registry Collaborative Quality Initiative. (MARCOI) of 2,247 consecutive patients (1,724 M-THA and 523 RA-THA) compared dislocation rates and related revisions between M-THA and RA-THA.²³ When compared to the M-THA, the RA-THA cases reported lower periprosthetic dislocation rate without mechanical failure (0.57% vs. 2.49%, $p=0.007$).²³ All RA-THA dislocations were successful with conservative treatment without recurrence, whereas 46% of traditional dislocations were ultimately revised for recurrent instability.²³

These studies add to the evidence that the CT-based Mako System showed reduced rates of dislocation compared to M-THA. The use of preoperative CT imaging allows surgeons to create patient-specific implant plans and use Mako Total Hip to help accurately execute the preoperative plan.

3.2 Enhanced clinical outcomes

In the research conducted by Bukowski et al., outcomes for three groups of 100 consecutive THAs (first 100 M-THA; last 100 M-THAs; and first 100 Mako Total Hips), were reviewed.²⁴ Mako Total Hip resulted in significantly higher modified Harris Hip Scores (HHS) (92.1 ± 10.5 vs. 86.1 ± 16.2 , $p=0.002$) and University of California Los Angeles (UCLA) activity levels (6.3 ± 1.8 vs. 5.8 ± 1.7 , $p=0.033$) than M-THA at minimum one-year follow-up (**Figure 5 and Figure 6, Table 2**).²⁴

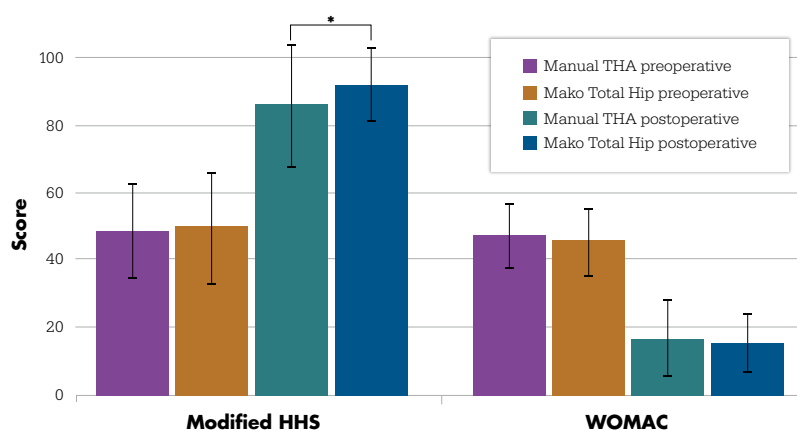


Figure 5. Statistically higher modified HHS were shown for Mako Total Hip patients.²⁴

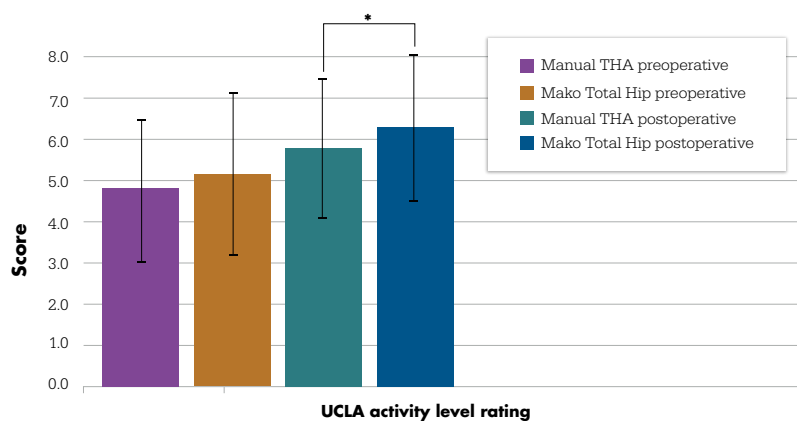


Figure 6. Statistically higher modified UCLA were shown for Mako Total Hip patients.²⁴

Patient-reported outcomes (PROMs) comparing rTHA and mTHA patient groups					
	Group (RATHA n=100, MTHA n = 100)	Preoperative	Postoperative	PROMs (postoperative - preoperative)	p-value
mHHS (means 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
10-79	6.0% (6)		5.0% (5)		0.756
<70	6.0% (6)		19.0% (19)		0.005

Table 2. Summary of patient-reported outcomes comparing RA-THA to M-THA.²⁴

Marchand et al. have reported on early outcomes out to 1-year complications for a single surgeon's first 100 patients who underwent a Mako Total Hip procedure with functional implant planning.²⁵ Between preoperative to 6 weeks postoperative, the Mako Total Hip cohort achieved a statistically significant improvement ($p < 0.05$) in their Hip Disability and Osteoarthritis Outcome Score, Joint Replacement (HOOS, JR) where this delta was also considered to be a substantial clinical benefit.²⁵ At three- six-months, and one-year follow-up, patients continued to have statistically significant improvement in HOOS Jr which represented a minimal clinically important difference.²⁵

Perets et al. have compared minimum two-year outcomes and complications for patients who underwent a Mako Total Hip procedure to patients where he performed M- THA.²⁶ Eighty-five Mako Total Hip patients were pair-matched to manual controls based on patient demographics. The patients prospectively reported on HHS, Forgotten Joint Score-12 (FJS-12), Visual analog scale for pain (VAS), and satisfaction (scale ranging 0-10).²⁶

The FJS-12 questionnaire has evidence of low-ceiling effects and is suitable for assessing longer term outcomes in well-performing groups after THA.²⁷ The literature has reported an FJS-12 ranging from 50.9 ± 25.3 to 80 ± 24 for patients who received M-THA.^{26, 27} Perets et al. reported an FJS-12 for the Mako Total Hip patients of 80.2, which was significantly greater ($p = 0.003$) than an FJS-12 of 68.6 reported by the M-THA control group.²⁶ The Mako Total Hip group had a significantly higher HSS ($p < 0.001$) and a trend towards having lower VAS scores ($p = 0.120$) when compared to the control group. Additionally, at two years, the Mako Total Hip group had less Leg Length Discrepancy (LLD) (1.0mm, $p = 0.013$), less global offset (0.9mm, $p = 0.31$) and no dislocations reported.²⁶ Postoperatively, one Mako Total Hip patient required a revision at 8.7 months after primary THA due to femoral stem loosening and three M-THA patients required revision at a mean 25.1 months postoperatively, all for femoral stem loosening.²⁶

This same group of patients continued to be followed, and Domb et al. published on minimum five-year outcomes of this patient cohort.²⁸ When compared to a M-THA control group, the Mako Total Hip cases reported significantly higher HHS ($p < 0.001$), 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).²⁸ 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.²⁸

Patient-reported outcomes	Preoperative plan	Intraoperative robotic-arm measurements	p-value
HHS	90.57 ± 13.46	84.62 ± 14.45	<.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
VE-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 Mako Total Hip and M-THA cohort.²⁸

A similar trend was observed in a prospective study of 40 patients undergoing Mako Total Hip that were propensity matched to 80 patients undergoing M-THA.²⁹ Groups were matched based on age, sex, and preoperative function. At 12-month follow-up, the Mako Total Hip group had improved Oxford Hip Score (OHS, $p=0.038$), FJS ($p<0.001$), and fewer dissatisfied patients (Mako Total Hip 0 vs M-THA 6).²⁹ The FJS in the Mako Total Hip group was 21.2 points higher than the M-THA group, which is greater than the minimal clinically important difference.²⁹ Based on radiographic analysis, the M-THA group had a decrease in the horizontal center of rotation (COR), which was also associated with a decrease in acetabular offset.²⁹ This shift of COR was not found in the Mako Total Hip group. The authors hypothesized that this difference in restoration of hip COR and leg length could have impacted the differences in clinical outcomes between the two groups.²⁹

3.3 Early patient recovery and satisfaction

When exploring a patient's road to recovery, their length of stay in hospital after surgery is a key factor to consider. Shaw et al. retrospectively compared the length of stay (LOS) of 523 RA-THA patients against those who received M-THA (n=1724).²³ They reported the RA-THA patients were found to have significantly shorter average postoperative hospital LOS ($p<0.001$) than M-THA.²³ Additionally, 29.64% of RA-THA had a LOS less than 1 day compared to 3.65% of M-THA patients.²³

A retrospective review of a multi-hospital database was conducted by Rajesh et al. and compared matched RA-THA to M-THA cases, resulting in 8,536 patients per cohort.³⁰ The study found that RA-THA was associated with significantly shorter hospital LOS compared to M-THA (1.39 days vs 1.48 days ($p<0.001$)), and significantly more patients were discharged on or before postoperative day 1 (68.2% vs 61.7% ($p<0.001$)).³⁰ Additionally, RA-THA patients were more likely to be discharged home without home healthcare ($p=0.001$) and less likely to be discharged to a skilled nursing facility ($p=0.001$). Both patient populations had similar all-cause 90-day readmission rates, which provides reassurance that the superior discharge outcomes associated with RA-THA cases are not associated with unsafe, premature discharge for patients.³⁰

A reduction in hospital LOS with Mako Total Hip is also being observed in countries such as the United Kingdom. According to a study conducted by Wilson et al. the mean length of stay following THA in the United Kingdom is 5.4 days.³¹ Fontalis et al. conducted a large single-institution study based in the United Kingdom analyzing 1,732 primary THAs to identify factors associated with reduced LOS following RA-THA and M-THA.³² The study found that RA-THA was significantly associated with a shorter median LOS (54 hours vs 60 hours ($p<0.001$)) compared to M-THA.³² In addition, the use of M-THA was associated with an odds-ratio 2.34 times greater risk of being admitted for greater than two days postoperatively.³² There was no difference in discharge dispositions between the two groups.³²

Rosinsky et al. performed an analysis focused specifically on comparing patients who underwent RA-THA either at an inpatient or outpatient facility.³³ The first 100 consecutive patients who underwent outpatient THA were matched to 100 patients who underwent inpatient THA during the same time period.³³ After exclusions, 91 patients remained in each group and were compared. The study compared perioperative variables including surgical time, blood loss, and length of stay as well as 90-day complication rates and 2-year Patient Reported Outcomes (PRO).³³ The outpatient group had an average length of stay of 6.8 hours compared to 43.2 hours for the inpatient group ($P < 0.001$). There were no significant differences between the groups regarding readmissions, emergency room visits, and unplanned clinic visits.³³ Complications and revision rates were similar in both groups. However, in appropriately selected, younger patients, outpatient RA-THA can achieve improved postoperative 2-year PROs compared to inpatient THA.³³

In a prospective randomized controlled trial of 60 patients, Fontalis et al. found that participants in the RA-THA group required significantly less postoperative physiotherapy sessions (median six (IQR 6-11; $p=0.005$)) compared to the M-THA group (median 8 (IQR 6 to 11)).⁹ These findings suggest that Mako Total Hip was associated with accelerated patient recovery.⁹

Overall, data from these studies suggest that patients who undergo RA-THA may be able to return home sooner after surgery than those who undergo conventional THA. 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.²⁶ For the 162 RA-THA cases considered in this study, mean patient satisfaction was a high 9.3 out of 10.²⁶

3.4 Utilization of Mako Total Hip in complex cases

Mako Total Hip has been shown to be a useful tool for 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.³⁴ In all three cases, Mako Total Hip was used to help accurately implement the surgical plan.³⁴ Since there was an absence of conventional bony landmarks, the preoperative CT scan in these cases was instrumental in planning.³⁴ At three months postoperatively, the hip dysplasia patient reported that they were able to walk without assistance, had no hip pain and were satisfied with their leg lengths.³⁴ At the same time point the patient with ankylosing spondylolysis reported no hip pain and was able to walk with a walking frame.³⁴ The patient with post-traumatic arthritis reported no hip pain and was able to walk without assistance.³⁴ According to this study, the planning and accuracy of execution in Mako Total Hip helped the surgeon to give the patients appropriate reconstruction of their hip joints.³⁴ The authors state Mako Total Hip planning and execution was helpful in reconstructing the joint. They go on to recommend Mako Total Hip for complex THA procedures, especially in the absence of conventional bony landmarks.³⁴

Hayashi et al. analyzed a consecutive series of 69 patients who underwent RA-THA, where 30 of those patients had development dysplasia of the hip (DDH) and were classified according to the Crowe type.³⁵ Using the patients' preoperative plan and comparing to postoperative CT data, accuracy of cup alignment and 3D placement were compared between DDH and non-DDH patients.³⁵ No significant differences were found in cup placement between the two groups and excellent restoration of leg length and combined offset were achieved in both groups.³⁵ This study concluded that RA-THA may achieve accuracy and reproducibility of cup placement in both non-DDH and DDH patients, even those with severe DDH.³⁵

4. What are the potential user benefits of Mako Total Hip?

Mako Total Hip also has the potential to provide surgeons an enhanced intraoperative experience such as eliminating the need for intraoperative fluoroscopy, reducing workload and improving efficiencies, regardless of experience level.

4.1 Intraoperative fluoroscopy

Intraoperative fluoroscopy is routinely used to perform direct anterior (DA) approach total hip arthroplasty (THA) to confirm component position or assess for intraoperative complications.³⁶ However, there are associated health risks related to increased radiation exposure that orthopaedic surgeons should be aware of.³⁴ Studies have shown that exposure to radiation may increase the risk of certain cancers among orthopaedic surgeons, including a higher incidence of breast cancer in female surgeons, thyroid cancer, and cataracts.³⁶

In a laboratory based study comparing the DA approach via fluoroscopic guided THA to robotic-assisted THA (RA-THA), the use of RA-THA eliminated the need for intraoperative fluoroscopy when using the DA approach, therefore removing intraoperative radiation exposure to the surgeon and surgical staff.³⁷ Neitzke et al. conducted a large retrospective study comparing fluoroscopy time and radiation dose for DA THA cases using three techniques: M-THA, computer navigation THA (CN-THA), and RA-THA.³⁸ Among 6,541 cases, RA-THA demonstrated a significant reduction in both fluoroscopy time and radiation dose, specifically a 6.5-fold reduction in radiation dose compared to M-THA.³⁸ The study emphasizes that while overall radiation exposure in arthroplasty can be low, RA-THA offers a meaningful reduction in intraoperative radiation risk to patients and operating room staff.³⁸

In addition to radiation exposure, intraoperative fluoroscopy for the DA approach has been associated with unreliable values for acetabular inclination and anteversion.³⁹ Forty-one hips in 40 patients undergoing DA M-THA with intraoperative fluoroscopy underwent routine postoperative radiographs and CT scans.⁴⁰ The results showed that 39 out of 41 hips were placed with unrecognized excess of anteversion and inclination secondary to imaging the pelvis in extension.⁴⁰ In a study conducted by Foissey et al., 100 M-THA and 50 RA-THAs were both performed via the DA approach.⁴¹ The study found that RA-THA significantly improved accuracy of the acetabular cup orientation ($p=0.0002$) with 98% of cups placed within the defined safe zone, compared to 68% in the M-THA group.⁴¹

4.2 Reduce mental and physical demand during surgery

Mako Total Hip provides a stereotactic boundary that guides the alignment of the robotic-arm during acetabular reaming and cup insertion, helping the surgeon to achieve their desired alignment. Additionally, the system provides a single ream option, potentially 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.⁴² Assistance in performing reaming and cup insertion may enhance the ergonomic health and reduce the workload demand on the surgeon.⁴²

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 M-THA.⁴³ Twelve THAs were performed by two surgeons, with varying RA-THA experience. Each cadaveric specimen received a M-THA on one hip and Mako Total Hip on the contralateral side. During the procedures, each surgeon wore a biometric shirt that allowed the measurement of biometric parameters including caloric expenditure and heart rate.⁴³ Following each surgery, surgeons were asked to perform a modified surgery task load index questionnaire to compare the physical and mental demands for the overall procedure, as well as various individual tasks.⁴³

Mako Total Hip demonstrated reduced surgeon energy expenditure compared with M-THA (83.5kcal vs 100kcal).⁴³ Aside from exposure of the joint space and retractor placement, surgeons reported lower physical demand during Mako Total Hip for all other individual tasks and overall mental demand was lower when compared to M-THA.⁴³ Mental fatigue was significantly reduced during acetabular reaming with Mako Total Hip versus M-THA ($p < 0.05$).⁴³ One potential reason for these results is that during RA-THA surgeons use reamers that are held with a haptic boundary enabling them to ream according to their preoperative plan.⁴³

A cadaveric study by Caba et al. compared surgeons physical and mental demand when performing the DA approach with M-THA and RA-THA.⁴⁴ Using biometric data and surgeon-reported questionnaires, the study found that DA RA-THA significantly reduced both physical and mental demand, particularly during acetabular reaming and preparation.⁴⁴ Metrics such as heart rate, stress levels, caloric expenditure, and sweat loss were generally lower for the Mako Total Hip procedures, and surgeons also reported less fatigue and cognitive strain.⁴⁴

4.3 Efficient user experience

Kong et al. published a retrospective comparative cohort study of an experienced M-THA surgeon's first 100 RA-THA's compared to the surgeon's last 100 M-THA cases.⁴⁵ The average operating time of RA-THA was 95.92 ± 15.64 minutes, ranging from 68 to 145 minutes.⁴⁵ 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.⁴⁵ 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).⁴⁵ Results indicate that there was a 14-case learning curve when considering operative time; however, the authors observed this learning curve did not impact patient outcomes.⁴⁵

Another clinical study looked at a surgeon's learning curve, with over 10 years of experience in hip arthroplasty, based on the duration of the procedure.⁶ The study collected operative time for both M-THA and RA-THA and the operative time was significantly higher in the RA-THA group than the M-THA (91.37 ± 17.34 minutes vs 77.52 ± 6.17 minutes).⁶ However, after 13 cases, the operating time in the RA-THA group decreased significantly and gradually became stable.⁶ Even with the existence of a learning curve of 13 cases, there was no statistical difference between the placement of the acetabular cup for patients in the RA-THA and M-THA.⁶

The study by Masini et al. evaluated the surgeons learning curve for adopting DA RA-THA.⁴⁶ In a series of 89 cases performed by a single surgeon, the RA-THA group initially had longer surgical times, but reached time equivalence with the DA M-THA group after 15 cases.⁴⁶ In addition, the surgeon used fluoroscopy in the first RA-THA cases and then eliminated its use without compromising the implant placement accuracy.⁴⁶ This study concluded that Mako Total Hip via DA approach can be adopted within a short learning curve, while also eliminating the need for intraoperative fluoroscopy.⁴⁶

Caba et al. investigated the surgical efficiency of DA RA-THA without intraoperative fluoroscopy compared to DA M-THA.⁴⁷ Using six matched cadaveric specimen, the study found that DA RA-THA significantly reduced acetabular reaming time ($p < 0.001$) and required fewer reamers to prepare the acetabulum (1 vs 2.67).⁴⁷ Total operative time and femoral broaching time were lower in RA-THA, but not statistically significant.⁴⁷ The study concluded that DA Mako Total Hip enhances surgical efficiency, particularly during acetabular preparation, and may offer broader benefits including reduced radiation exposure, improved component accuracy, and decreased physical and mental demand on surgeon.⁴⁷

4.4 Surgical outcomes across levels of surgeon experience

In a publication by Smith et al., the authors investigated if the accuracy of RA-THA surgery was translatable to newer surgeons in their fellowship.⁴⁸ In a cadaveric study, two adult reconstruction fellows halfway through their training year performed M-THA (n=6) and RA-THA (n=6).⁴⁸ The RA-THA prepared hips demonstrated statistically significant greater accuracy and precision to plan compared to the M-THA prepared hip when considering shell version, shell inclination and LLD.⁴⁸ Error in shell placement was reduced by up to 9mm and error in LLD was reduced by up to 8mm when using RA-THA.⁴⁸ The authors concluded that these findings suggest that CT-based preoperative planning and Mako Total Hip application can allow less experienced surgeons to place implant components more consistently in the desired orientation, with comparable accuracy to what has been reported by experienced surgeons.⁴⁸

In addition to providing accuracy to plan for less experienced surgeons, Shapira et al. studied the use of the Mako Total Hip as a learning tool for fellows training in hip arthroplasty.⁴⁹ The study evaluated the accuracy of fellows' estimation of cup and broach positioning using Mako Total Hip. They found that the mean difference between estimated and actual cup inclination and version was 7.24° (P = 0.060) and 4.81° (P = 0.031), respectively.⁴⁹ Shapira et al. concluded that Mako Total Hip is a useful learning tool for fellows in training to help them understand their own inaccuracies in estimating implant position and hence may help refine their abilities.⁴⁹

5. Is Mako Total Hip cost effective?

In assessing the potential effects of Mako Total Hip on costs to US based private payers and Medicare, Maldonado and colleagues evaluated the long-term cost effectiveness of robotic vs. manual total hip arthroplasty (THA) through a Markov model.⁵⁰ The potential outcomes of THA were categorized into the transition states: infection, dislocation, no major complications, or revision. Cumulative costs and utilities were assessed using a cycle length of one year over a time horizon of five years. They found that robotic-assisted THA (RA-THA) cohort was cost effective relative to manual THA (M-THA) cohort for cumulative Medicare and cumulative private payer insurance costs over the 5-year period.⁵⁰ RA-THA cost saving had an average differential of \$945 for Medicare and \$1,810 for private insurance relative to M-THA while generating slightly more utility (0.04 quality-adjusted life year).⁵⁰ The preferred treatment was sensitive to the utilities generated by successful RA-THA and M-THA. Microsimulations indicated that RA-THA was cost effective in 99.4% of cases.⁵⁰ In these US Medicare and private payer scenarios, RA-THA is more cost effective than M-THA when considering direct medical costs from a US payer's perspective.⁵⁰

A separate US based Medicare analysis propensity matched the 90-day episode of care (EOC) data of 938 RA-THA to 4,670 M-THAs and found that RA-THA 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).⁵¹ RA-THA 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 M-THA.⁵¹ RA-THA 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 M-THA.⁵¹ Overall, RA-THA patients had 12% (\$948) lower average post-index costs compared to M-THA patients ($p = 0.0004$).⁵¹ Total 90-day episode-of-care costs for RA-THA patients were found to be \$785 less than those of M-THA patients (\$19,734 vs. \$20,519, $p = 0.0095$).⁵¹

6. Conclusion

Mako Total Hip offers the potential for surgeons to utilize a patient-specific plan to achieve more accurate implant placement³ and enhance clinical outcomes,²⁴⁻²⁸ compared to manual. Studies have demonstrated that Mako Total Hip led to decreased dislocations,¹⁹⁻²³ decreased length of stay,^{30,32} improved outcomes,²⁴⁻²⁸ improved radiographic accuracy,^{5,29} decreased mental and physical demand,⁴²⁻⁴⁴ efficient user experience⁴⁵⁻⁴⁷ and decreased costs.⁵⁰⁻⁵¹ Ultimately, the benefits of Mako Total Hip may be experienced by all key players – patients, surgeons, and health systems.

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