stryker

The clinical and economic value of **Mako SmartRobotics™**

Mako clinical evidence

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About this document

This document is intended to provide useful information to payers, healthcare facilities and healthcare providers to assess the clinical and economic value of Mako SmartRobotics™. The studies explored in this document are of varying design, ranging from large controlled clinical studies to single-surgeon studies and cadaver studies. As a result of variations in study design, the robustness of the data arising from different studies may vary. The document includes descriptions of studies relied upon, and published sources are cited throughout. We encourage you to consult the cited publications.

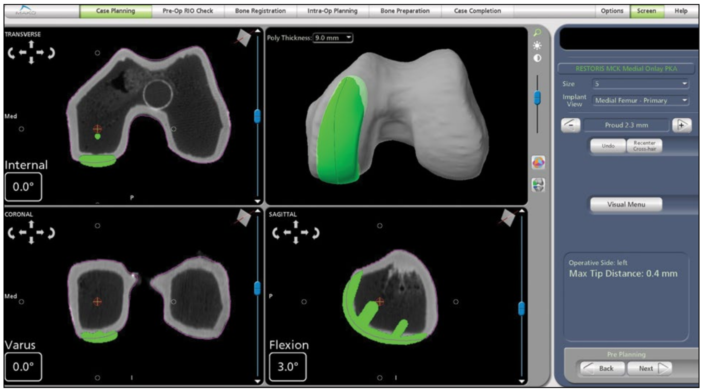
Mako SmartRobotics™ – an introduction

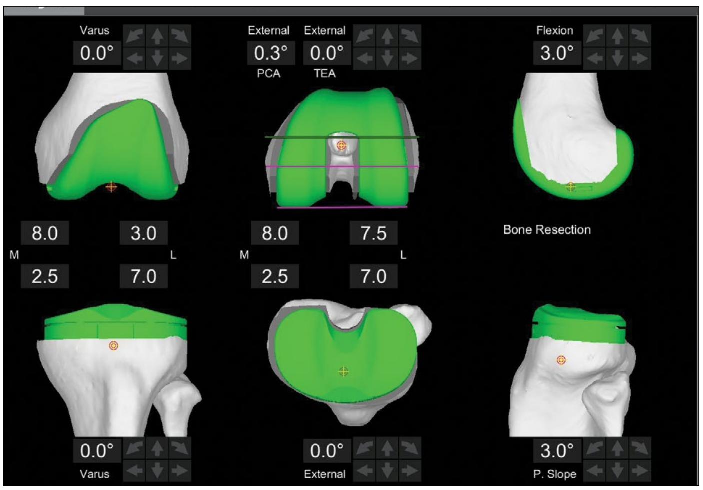
Mako SmartRobotics™ offers a transformational shift in orthopaedic practice, and ultimately in patient care, through its potential to deliver value to patients, payers and surgeons. Mako can help surgeons address the challenges of today's changing orthopaedic landscape and healthcare environment.

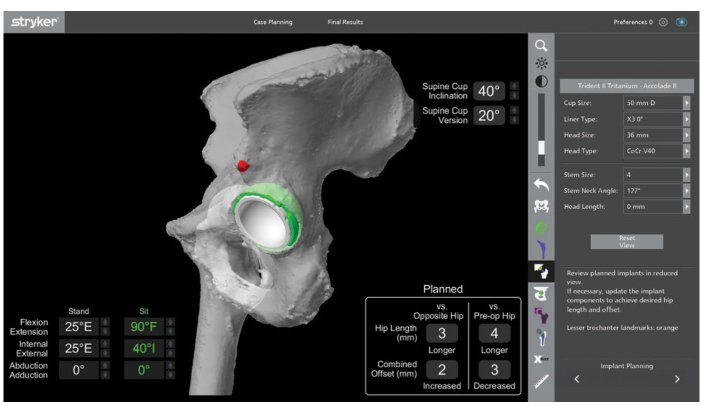
Mako SmartRobotics™ combines 3D CT-based planning and AccuStop™ haptic technology into one platform which has shown better outcomes for total hip, total knee and partial knee patients compared to manual.[1,2,3]

Figure 1. The Mako System

Know more.

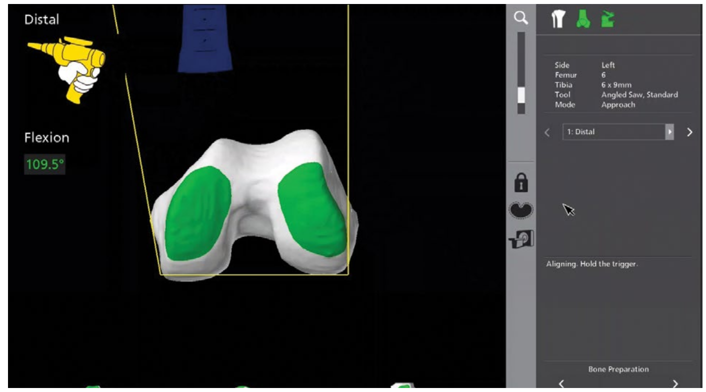


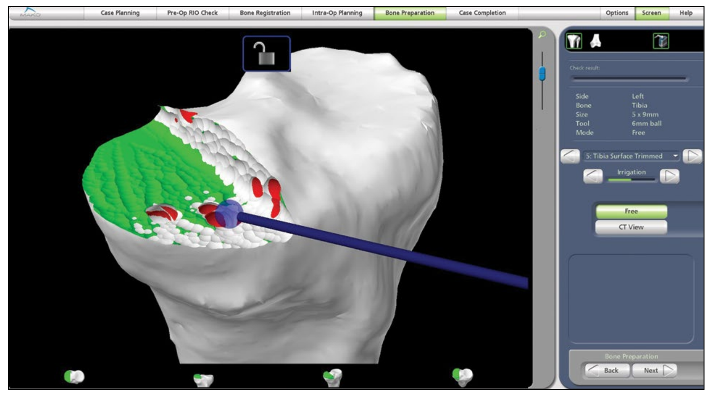


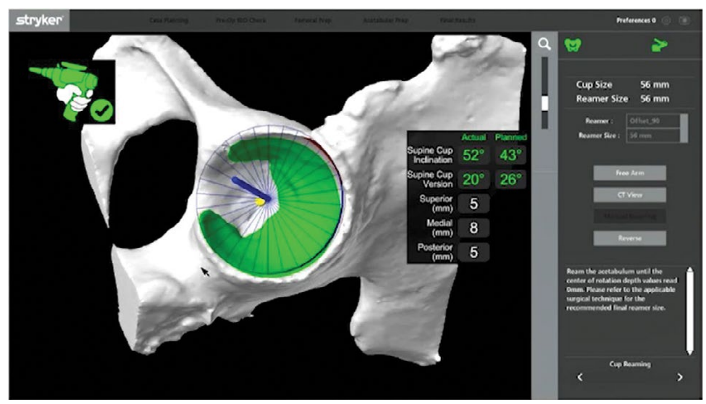


It all starts with a CT scan that creates a 3D image of the patient's unique anatomy. This information allows surgeons to create their patient's plan and assess and balance the joint.

Cut less.







Using everything the CT scan allows the surgeon to know about their patient, Mako's AccuStop™ haptic technology guides the surgeon to cut what they've planned...precisely for each patient and to cut less.[1,4,5] For some patients, that means preserving soft tissue; for others, that means saving healthy bone.[6-10]

Throughout the procedure, surgeons and their surgical staff receive real-time data, allowing them to continually assess ligament tension throughout range of motion and implant articulation and helping them to avoid inadvertent transection of vital structures. Surgeons can refine the surgical plan intraoperatively for enhanced soft tissue balance.

Changing orthopaedic landscape and the future of healthcare reform

Demand for knee and hip procedures is on the rise. According to a study evaluating historical procedure rates and population projections using the National Inpatient Sample, primary total hip arthroplasty (THA) in the U.S. is projected to increase 71%, to 635,000 procedures, by 2030 and primary total knee arthroplasty (TKA) in the U.S. is projected to increase 85%, to 1.26 million procedures, by 2030.[11] These dramatic increases will have a considerable impact on healthcare utilization, demand for orthopaedic surgeons and the desire for technological advancements to enhance patient outcomes.

Overview of osteoarthritis

During 2016-2018, an estimated 23.7% (58.5 million) of adults (aged 18 years and older) have been diagnosed with arthritis in the U.S.[12] About 43.9% (25.7 million) of these 58.5 million adults have limitations in their usual activities due to their arthritis, representing 10.4% of the total U.S. adult population.[12] Osteoarthritis (OA), the most common form of arthritis, is a major cause of pain and disability among adults in the U.S.[13] From 2008 to 2014, 32.5 million U.S. adults, or one in seven persons (14%), reported osteoarthritis and allied disorders, including joint pain with other specified or unspecified arthropathy, annually.[14] Among adults 65 years and older in the U.S., an estimated 43% are living with osteoarthritis.[14]

As the U.S. population ages, the number of adults affected by osteoarthritis is expected to increase substantially.[15] By the year 2040, an estimated 78.4 million (25.9% of the projected total adult population) adults will have doctor-diagnosed arthritis, and an estimated 34.6 million adults (43.2% of adults with arthritis or 11.4% of all U.S. adults) will report arthritis-attributable activity limitations.[13]

Burden of disease

The Global Burden of Disease study ranked hip and knee osteoarthritis as the 11th highest contributor to global disability.[16] In the U.S., 1 in 3 adults with arthritis reports arthritis-attributable activity limitations, and the prevalence of age-adjusted arthritis-attributable social participation restriction ranges from about 1 in 8 to more than 1 in 4 adults with arthritis across states nationwide.[13] Arthritis-attributable severe joint pain is reported by at least 1 in 5 adults with arthritis in every state in the U.S.[13]

OA was the second most costly health condition treated at U.S. hospitals in 2013.[13] In that year, it accounted for $16.5 billion, or 4.3%, of the combined costs for all hospitalizations. OA was also the most expensive condition for which privately insured patients were hospitalized, accounting for over $6.2 billion in hospital costs.[13]

Nearly 3 million hospital stays in 2013 in the U.S. had an OA diagnosis, and it was the leading cause (46%) of hospitalization among all arthritis diagnoses. Osteoarthritis accounted for 45% of total hospital charges for arthritis diagnoses (cost charged but not necessarily paid), presumably in part because OA is the principal diagnosis associated with hip and knee joint replacements.[14] Fewer than half (43%) of patients with an OA diagnosis were discharged to home or self-care, the lowest share of all arthritis-diagnosed hospitalized patients. This is probably due to discharges to assisted living facilities or skilled nursing facilities for rehabilitation following hip or knee joint replacement.[14]

Osteoarthritis was diagnosed in 20.8 million outpatient visits in 2013 and accounted for 1 in 5 (21%) ambulatory care visits with any arthritis diagnosis. During that time, 1 in 12 (8.4%) outpatient visits included an OA diagnosis.[14]

Combining direct and indirect costs, average annual all-cause costs for OA in the U.S. and allied disorders for the years 2008 to 2014 were $486.4 billion. Total incremental costs (direct and indirect costs associated with osteoarthritis) were $136.8 billion.[14]

Approaches to treatment

Joint replacement surgery is a treatment consideration for patients who are non-responsive to initial therapy and who continue to experience continuing joint symptoms and pain.[17]

For patients who are candidates for joint arthroplasty procedures, several surgical approaches are available, including total joint replacement and partial joint arthroplasty, as well as a variety of surgical techniques including manual (traditional), navigation-assisted and robotic-assisted techniques. While total joint replacement procedures may offer pain reduction and function recovery for many, the potential for complications still exists.[18]

Knee and hip arthroplasty are associated with a recovery period that may include postoperative pain, frequent physical therapy, the use of assistive devices for ambulation in the near-term and narcotic analgesics to manage pain in the months following the procedure.[18]

Procedure	Common challenges
Partial knee arthroplasty[19-24]	• Demanding procedure, with restricted visual field • Potential for technical errors • Poorly implanted PKA may fail earlier
Total knee arthroplasty[26]	• Instability • Infection • Aseptic loosening • Malalignment
Hip arthroplasty[27]	• Early mechanical failures • Dislocation • Prosthetic failures (periprosthetic fracture, leg length discrepancy)

Figure 2. Challenges associated with hip and knee arthroplasty procedures that may contribute to failure or need for revision surgery

In some cases, patients may be hesitant to undergo these procedures. Although many factors have been shown to influence the prevalence of knee and hip arthroplasties, patient preferences play a role in these surgeries as well. A qualitative focus-group study of ethnically and age-diverse patients with knee osteoarthritis explored factors that patients considered to be important in their decision to undergo TKA. Among these patients, personal experience (positive and negative), fear of lengthy recovery and complications, and interactions with physicians were all important decision-making factors.[25]

Enhancing hip and knee arthroplasty

The comprehensive research on Mako has demonstrated the potential clinical, functional and economic value of the Mako System and the corresponding partial knee, total knee and total hip implant systems, and has laid a scientific foundation for the support and development of future products and applications. Studies have shown enhanced patient outcomes, reductions in health resources utilization and episode-of-care (EOC) cost-savings in PKA, TKA and THA.

The potential benefits of Mako SmartRobotics™ in total knee arthroplasty

Total knee arthroplasty is an established and successful procedure for the treatment of end-stage knee arthritis.[28] Survivorship at 10 years is commonly reported in the 90th percentile,[29] while outcomes reported using patient-reported outcome measures (PROMs) demonstrate that TKA also delivers a functional benefit to patients.[30]

Despite the demonstrable benefits of TKA, satisfaction rates are known to be lower than for total hip arthroplasty.[31] Reported dissatisfaction rates for TKA are around 20%.[32,33] TKA is also known to be sensitive to surgical factors such as implant positioning and soft tissue balance.[34,35] Inaccuracies in positioning and soft tissue balance have the potential to reduce implant survivorship and impact negatively on patient outcomes.[34-36]

The Mako Total Knee application, in comparison to manual techniques, has been shown in cadaveric and clinical settings to have increased accuracy and precision of component placement to plan.[37-39] Features of Mako SmartRobotics™ that may have contributed to these outcomes include preoperative 3D planning, which takes into account each patient's specific anatomy, and AccuStop™ haptic technology, which enables the surgeon to execute their plan. This plan can be virtually modified intraoperatively to address implant alignment, soft tissue balancing and flexion contractures. Additional features include intraoperative visual, auditory and tactile feedback provided to the user.

Outcomes for total knee arthroplasty

Mako Total Knee was launched in 2016. As the initial Mako Total Knee patients have reached various postoperative time points, improvements in both short- and midterm outcomes have been shown. In a prospective, consecutive series, single-surgeon study, Kayani et al. demonstrated statistically significant early postoperative results for 40 patients who received Mako Total Knee surgery as compared to 40 patients who received conventional jig-based TKA.[2] The Mako Total Knee group had less postoperative pain ($p < 0.001$), less need for analgesics ($p < 0.001$), less postoperative blood loss ($p < 0.001$), less time to achieve straight leg raise ($p < 0.001$), less time to hospital discharge (Mako Total Knee resulted in 26% reduction in length of stay (LOS)) and improved maximum flexion at discharge.[2]

In a retrospective matched cohort analysis of a multihospital database, RA-TKA was associated with fewer revisits (p=0.027) and readmissions with >23 hours of observation (p=0.003) through 90 days post-operative compared to M-TKA.[40] More specifically, RA-TKA had fewer revisits due to joint stiffness (p=0.002) and chronic pain (p=0.039), fewer 90-day readmissions due to lower extremity muscle/tendon strain (p=0.021), and fewer ED visits due to joint stiffness (p=0.001) and hematoma (p=0.016) compared to M-TKA.[40]

In summary, these studies demonstrated that Mako Total Knee was associated with decreased pain, improved early function recovery, and reduced time to hospital discharge and fewer revisits compared with conventional jig-based TKA.[2,40]

Outcome	Conventional (n=40)	Robotic (n=40)	P-value
Mean operating time (mins)	61.2 (54.6 to 83.1)	70.4 (59.2 to 91.7)	0.34*
Mean fall in Hb (g/L)	26.1 (5.1 to 49.6)	18.4 (8.0 to 37.2)	<0.001*
Mean postoperative Hb (g/L)	106.7 (77.3 to 138.4)	114.7 (86.4 to 139.1)	0.01*
Mean pain score (NRS) – Day 0	5.4 (3.0 to 7.0)	3.1 (2.0 to 5.0)	<0.001*
Mean pain score (NRS) – Day 1	6.3 (4.0 to 8.0)	3.6 (2.0 to 6.0)	<0.001*
Mean pain score (NRS) – Day 2	6.1 (3.0 to 8.0)	3.3 (1.0 to 5.0)	<0.001*
Mean pain score (NRS) – Day 3	4.5 (2.0 to 7.0)	2.6 (1.0 to 5.0)	<0.001*
Median analgesia (mg) – Day 0	36.0 (IQR 29 to 51.3)	20.0 (IQR 16.0 to 28.5)	<0.001†
Median analgesia (mg) – Day 1	10.0 (IQR 10.0 to 20.0)	10.0 (IQR 0.0 to 10.0)	<0.001†
Median analgesia (mg) – Day 2	10.0 (IQR 10.0 to 20.0)	10.0 (IQR 0.0 to 10.0)	<0.001†
Median analgesia (mg) – Day 3	10.0 (IQR 0.0 to 10.0)	0.0 (IQR 0.0 to 5.0)	<0.001†

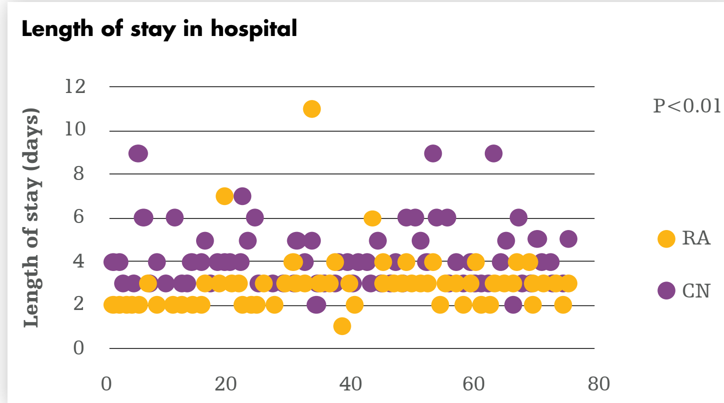
Figure 3. Study outcomes for patients who underwent conventional jig-based TKA and robotic-arm assisted TKA[2]

***Unpaired t-test**
†Mann-Whitney U test
NRS, numerical rating scale; IQR, interquartile range

Bhimani and colleagues published a comparison of 140 robotic-arm assisted TKA (RATKA) patients and 127 manual TKA (MTKA) patients. Consistent with Kayani et al., Bhimani et al. observed reductions in early postoperative pain, opioid usage and length of stay for patients who underwent RATKA. Patients undergoing RATKA had statistically significantly lower average visual analog scores (VAS) for pain, both at rest and with activity, at two and six weeks following the index procedure. At the six-week interval, the RATKA group required 3.2 mg less morphine equivalents per day relative to the conventional group ($p < 0.001$), and a significantly greater number of patients in the RATKA group were free of opioid use compared to the conventional TKA group (70.7% vs. 57.0% ($p = 0.02$)). Patients in the RATKA group had a shorter LOS (1.9 days vs. 2.3 days ($p < 0.001$)), and a greater percentage of RATKA patients were discharged on postoperative day one (41.3% vs. 20.5% ($p < 0.001$)).[41]

Clark et al. published a study that compared clinical outcomes in patients who received either a haptically guided RATKA or a computer-navigated TKA (CN TKA). Compared to those who received CN TKA, patients who received RATKA had significantly improved postoperative pain, reduced total morphine consumption and a reduced length of stay. The mean LOS was 3.05 days for the RATKA group compared to 4.1 days for the CN TKA group ($p < 0.001$). There was no significant difference found between the groups in Oxford Score, Forgotten Joint Score (FJS) or EQ5D VAS at 10 weeks or one year. The authors reported a statistically significant difference in inpatient total morphine equivalent consumption, with the RATKA group at 173 units and CN TKA group at 262 units ($p = 0.001$). In addition, a positive relationship was found between morphine equivalence usage (MEU) and increase in length of stay.[42]

Longer-term studies also report reduced pain and improvements in outcome scores for RATKA patients. Marchand et al. published a single-surgeon study that was performed on consecutive cemented robotic-arm assisted TKA patients matched with consecutive cemented manual TKA patients.[43,44] In a cohort followed to six months postoperative, a WOMAC survey including pain, stiffness, and physical function subcategories was administered to patients. At six months, the RATKA cohort had significantly reduced total pain scores when compared to the MTKA cohort and also demonstrated significantly improved mean total satisfaction and physical function scores when compared to the manual cohort.[43] In another cohort followed to one year postoperative, significant improvements in mean total



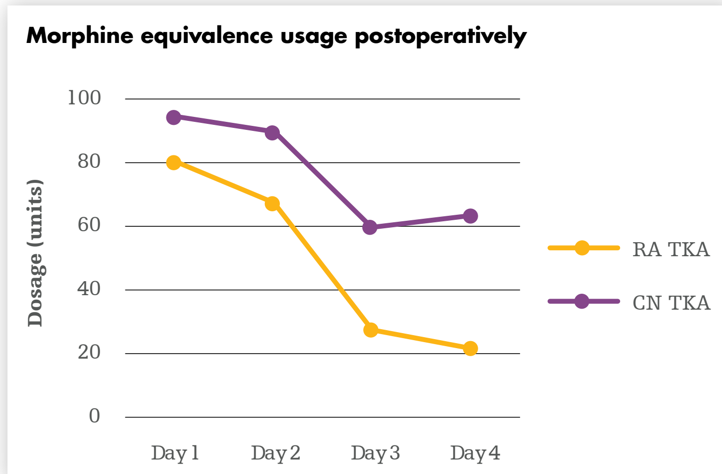


Figure 4. Results showed significant reduction in LOS and less MEU required for the RATKA group[42]

satisfaction and physical function scores were seen when compared to the manual cohort at six months and at one year.[44] These results indicate the potential of this surgical tool to improve short-term pain, physical function and total satisfaction scores. Although they involved limited cohorts, these studies showed promising outcomes for up to one year for RATKA patients when compared to the MTKA control group.[43,44]

Marchand et al. continued follow-up of 196 patients longitudinally and collected two-year postoperative WOMAC, FJS and Patient Joint Perception (PJP) scores.[45] Patient-reported mean pain, physical function and total satisfaction scores statistically significantly improved as patients progressed from preoperative to two-year follow-up ($p < 0.05$, Figure 5). RATKA patients reported a median FJS of 65.8 ± 31.1 at two-year follow-up with 36% of patients having an FJS > 80. The median FJS was comparable to the normative value, 66.8 ± 34.0, reported for a U.S. general population with a similar age range.[45] Based on the PJP score, 83% of patients reported their knee feeling like a "natural joint" or an artificial joint with minimal or no restrictions.

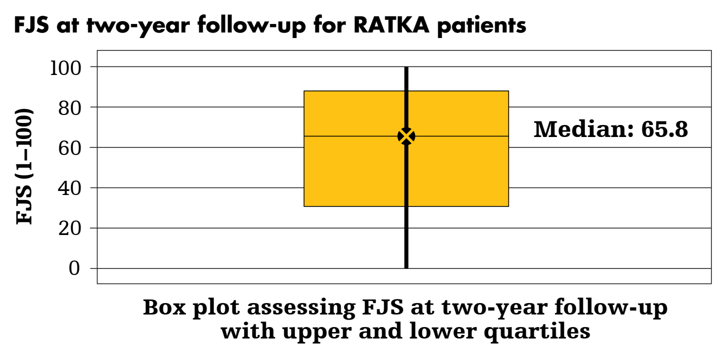


Figure 5. FJS at two-year follow-up for RATKA patients[45]

Wang et al.[46] performed a retrospective review in which a single high-volume surgeon performed 148 RATKA cases and 159 MTKA cases with matched demographics. The RATKA cohort experienced a significantly longer tourniquet time when the learning curve phase was included (96.8 min vs. 91.6 min); however, a significant difference was not observed when the last 20 RATKA cases were compared to the MTKA cases (93.8 min vs. 91.6 min, $p = 0.506$). Postoperatively, the RATKA cohort was more often discharged to home care (95.95% vs. 83.65%, $p < 0.001$) compared to acute rehabilitation, had a reduced number of physical therapy appointments (11.0 vs. 13.3, $p = 0.004$) and a lower number of 30-day readmissions (1 vs. 5, $p = 0.014$). This trend in enhanced outcomes followed through to one year, with the RATKA group demonstrating enhanced Knee Injury and Osteoarthritis Outcome Scores for Joint Replacement (KOOS-JR) ($p = 0.034$) and FJS ($p = 0.021$). These favorable results for the RATKA indicate patient outcomes continued to improve when compared to MTKA out to one year postoperative.

As more robotic-arm assisted TKA patients reach longer term follow-up, additional studies are beginning to report on these outcomes. Malkani et al. reported on the longer term outcomes of 188 RATKAs performed at five centers. They found that RATKA patients had excellent outcomes in multiple PROMs. The mean postoperative Short Form-12 Questionnaire (SF-12) mental composite score (MCS) and physical composite score (PCS) were both 57 points, with 50 as the threshold for norm-based scoring. The mean FJS was 75 points. The mean Knee Society Score (KSS) Functional Score was 84 points and the mean Knee Score was 92 points. Malkani et al. also found that the aseptic revision rates were low at 1.06% and that there were few other postoperative complications (3.7%).[47] A separate analysis on the manipulation under anesthesia (MUA) rates of these patients compared with a consecutive equal number of control patients by each of the specific surgeons found that patients who underwent robotic-assisted TKA experienced a significant 4.5-fold decrease in rates of manipulation under anesthesia ($p = 0.032$). Given that MUAs can be a marker of knee stiffness following total knee arthroplasty, the lower rate indicates that study cohort patients had less knee stiffness and, therefore, greater initial postoperative range of motion than the control cohort.[48]

Most recently, the Australian Orthopedic Association Registry has shown a 2.1% revision rate for robotic-arm assisted TKA, compared to 2.5% for computer-navigated and 2.6% for manual TKA at six-year follow-up.

Table KT60 **Cumulative percent revision of primary total knee replacement since 2016 by robotic assistance (primary diagnosis OA)**

Technology assistance	N revised	N total	1 year	2 years	3 years	4 years	5 years	6 years
Robotically assisted	886	71505	0.9 (0.8, 0.9)	1.4 (1.3, 1.6)	1.9 (1.7, 2.0)	2.2 (2.0, 2.3)	2.3 (2.1, 2.5)	2.4 (2.1, 2.7)
Not technology-assisted	4058	174394	0.9 (0.9, 1.0)	1.7 (1.6, 1.7)	2.2 (2.1, 2.3)	2.5 (2.5, 2.6)	2.8 (2.8, 2.9)	3.1 (3.0, 3.2)
Total	**4944**	**245899**						

Note: Restricted to modern prostheses. Restricted to procedures with known ASA, BMI, bearing surface, patella usage and stability

Table KT66 **Cumulative percent revision of Triathlon CR/Triathlon Primary Total Knee replacement using XLPE since 2016 by technology assistance (primary diagnosis OA)**

Technology assistance	N revised	N total	1 year	2 years	3 years	4 years	5 years	6 years	7 years
Robotically assisted	486	42692	0.8 (0.7, 0.9)	1.3 (1.1, 1.4)	1.6 (1.5, 1.8)	1.8 (1.6, 2.0)	1.9 (1.7, 2.1)	2.1 (1.7, 2.5)	
Computer-navigated	812	43193	0.8 (0.8, 0.9)	1.4 (1.3, 1.5)	1.8 (1.7, 2.0)	2.1 (1.9, 2.2)	2.3 (2.2, 2.5)	2.5 (2.4, 2.7)	2.7 (2.5, 2.9)
Not technology-assisted	464	23121	0.8 (0.7, 1.0)	1.4 (1.2, 1.6)	1.8 (1.6, 2.0)	2.1 (1.9, 2.3)	2.4 (2.2, 2.7)	2.6 (2.3, 2.8)	2.9 (2.6, 3.2)
Total	**1762**	**109006**							

Note: Restricted to modern prostheses
Only procedures with known ASA, BMI are included
Excludes 33 procedures using IDI

Figure 6a and 6b. AOANJRR 2024 Annual Report cumulative percent revision of primary total knee since 2016 by robotic assistance (a) and cumulative percent revision of Triathlon CR/Triathlon Primary Total Knee replacement using XLPE since 2016 by technology assistance (b).[20]

Mako Total Knee health economics

Mako Total Knee provides surgeons with preoperative planning and real-time data, allowing for continuous assessment of ligamentous tension and range of motion. Using this technology, soft tissue protection,[8,49] reduced early postoperative pain,[2] improved patient satisfaction,[44] reduced complications such as MUAs,[48] reduced revisions,[20] reduced LOS[41] and reduced revisits[40] have been shown. These advances have the potential to enhance surgical outcomes and may also reduce episode-of-care costs for patients, payers and hospitals. As Mako SmartRobotics™ continues to be adopted, it is also be important to understand whether Mako Total Knee is associated with reduced EOC costs.

Cool et al. performed a retrospective review of a U.S.-based Medicare database for TKA surgeries between January 2016 and March 2017.[50] After propensity score matching, 519 RATKA and 2,595 MTKA cases were assessed to compare EOC cost, index cost, LOS, discharge disposition and readmission rates. Results found overall 90-day EOC costs were $2,391 less for RATKA patients ($p < 0.0001$).[50] Index facility cost and LOS were less for RATKA patients by $640 ($p = 0.0001$) and 0.7 days ($p < 0.0001$), respectively.[50] Additionally, robotic-arm assisted patients were discharged to self-care more frequently (56.65% vs. 46.67%, $p < 0.0001$) and to skilled nursing facilities (SNF) less frequently (12.52% vs. 21.70%, $p < 0.0001$), and had a 90-day readmission reduction of 33% ($p = 0.04$) compared to MTKA patients.[50] This evidence demonstrated a cost-savings to Medicare when comparing RATKA to MTKA. This 90-day EOC savings for the RATKA group was driven by reduced facility costs, LOS and readmissions, and an economically beneficial discharge destination.[50]

Mont et al. performed a healthcare utilization analysis that compared RATKA and MTKA techniques.[51] They specifically compared (1) index costs and (2) discharge dispositions, as well as (3) 30-day (4) 60-day and (5) 90-day (a) episode-of-care costs, (b) readmission, and (c) postoperative healthcare utilization. The same propensity matched group from Cool et al. was used in this study to assess trends in total episode payments, healthcare utilization and readmissions at 30-, 60- and 90-day time points. The RATKA cohort had consistently lower average total episode payment than the MTKA cohort when compared at 30, 60, and 90 days (Figure 7). At 30 days, 47% fewer RATKA patients utilized SNF services (13.5 vs. 25.4%, $p < 0.0001$, Figure 7) and RATKA patients had lower SNF costs at 30, 60, and 90 days. Robotic-arm assisted TKA patients also utilized fewer home health visits and incurred fewer costs at each time point ($p < 0.05$). Additionally, 31.3% fewer RATKA patients utilized emergency room services at 30 days postoperatively, and the RATKA cohort had fewer

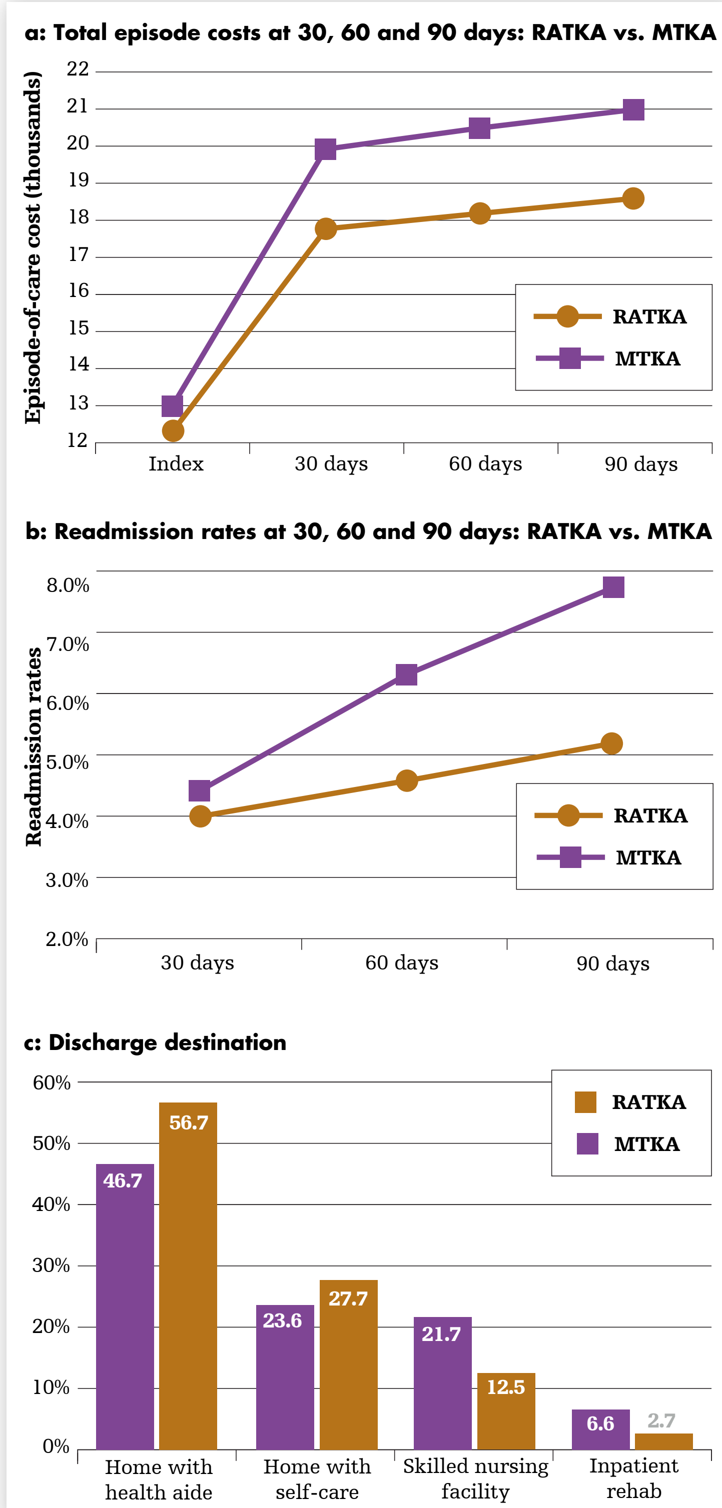


Figure 7. Medicare 100% Standard Analytical Files were queried for RATKA and MTKA cases. Based on propensity-matched cohorts, RATKA had (a) reduced episode-of-care cost at 30, 60, and 90 days postoperative as well as (b) reduced rate of readmission at those time points. Mont et al. also observed that (c) RATKA patients were more likely to be sent home postoperatively with a health aide or self-care than sent to a skilled nursing facility or inpatient rehab compared to manual[51]

Average post-index 90-day pay amounts

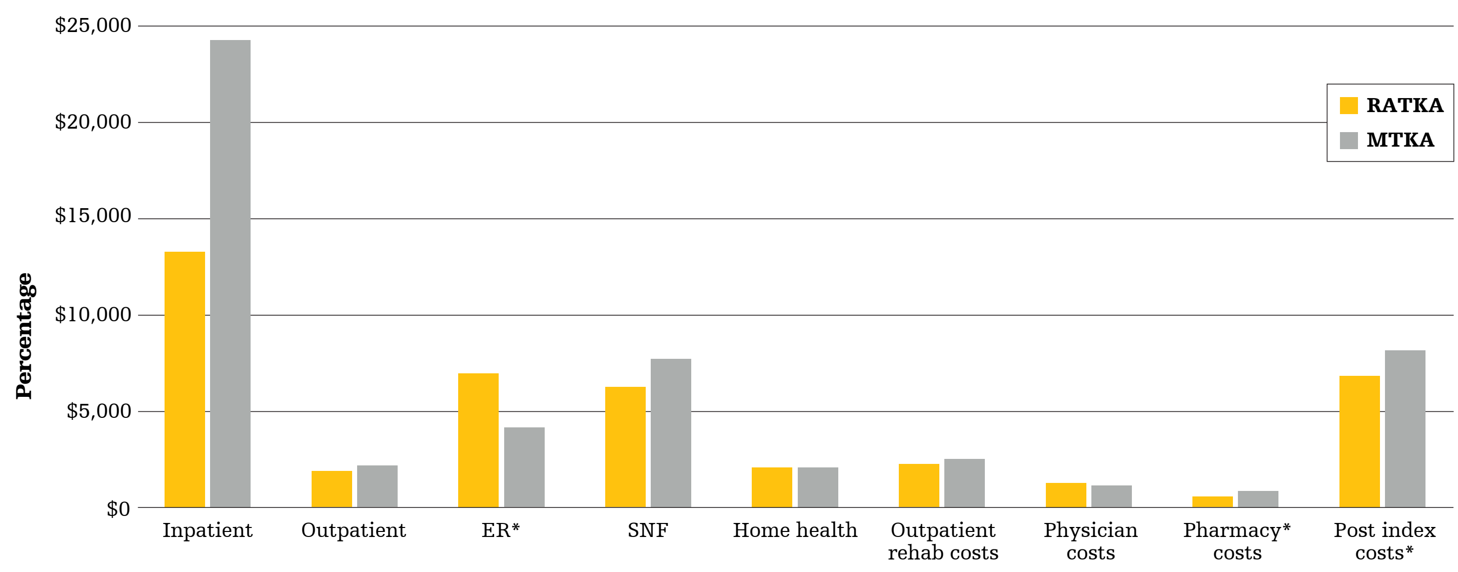


Figure 8. Average post-index 90-day pay amounts for patients who underwent RATKA vs. MTKA[53]

***indicates statistically significant difference**

90-day readmissions (5.2 vs. 7.75%, p = 0.0423, Figure 7). Mont et al. concluded that RATKA was associated with lower 30-, 60- and 90-day postoperative costs and healthcare utilization. These results are of marked importance given the emphasis to contain and reduce healthcare costs, and this study provides promising initial economic insights into RATKA.

While total joint arthroplasties account for more Medicare expense than any other inpatient procedure as of 2017,[52] studies have reported the growth of TKA procedures in commercially insured patients under 65. Pierce and colleagues[53] evaluated 90-day EOC costs in a commercially insured population. TKA procedures were identified using the Optum Insights Inc. database. The procedures were stratified into two groups, the RATKA cohort or the MTKA cohort. Following 1:5 propensity score matching, 357 RATKAs and 1785 MTKAs were included in the analysis. Utilization and associated costs were analyzed for 90 days following the index procedure. The authors observed that the overall length of stay was significantly lower for those in the RATKA arm (1.80 vs. 2.72 days; p < 0.0001). Within the 90 days following the index stay, patients who underwent robotic-arm assisted TKA were less likely to utilize inpatient services (2.24 vs. 4.37%; p = 0.0444) or SNF (1.68 vs. 6.05%; p < 0.0001) than those in the MTKA cohort. Patients who utilized home health in the RATKA arm used significantly fewer days of home health than MTKA patients (5.33 vs. 6.36 days; p = 0.0037). Cost associated with the utilization of services was substantially lower in the RATKA arm; the overall post-index cost was $1,332 less per case in the RATKA arm ($6,857 vs. $8,189; p = 0.0018). Cost was also significantly less in the RATKA cohort for those patients who utilized outpatient rehab ($2,272 vs. $2,494; p = 0.0194) and pharmacy ($588 vs. $843; p = 0.0057). The 90-day EOC cost was $4,049 less per case in the RATKA arm ($28,204 vs. $32,253; p < 0.0001).[53]

Gregory et al. evaluated the 90-day episode of care for 4,135 RATKAs matched to 4,135 MTKA from a U.S. commercial payer database. They found that index costs to the payer for RATKA patients were less than those for MTKA patients ($29,984 vs. $31,280, p <0.0001), even when including the cost of pre-operative CT scans. Post-discharge costs were less for in the inpatient and outpatient services as well as for the use of skilled nursing facilities, pharmacies, or other services. Overall, 90-day EOC costs for RATKA patients were found to be $1,834 less than that for MTKA patients. RATKA patients also had lower average LOS for the index procedure and have a higher percentage of one day stays (47 vs 36% p<0.001) compared to MTKA.[54]

Ong et al. compared not only the 90-day episode of care, but also the 12-month episode of care for 742 RATKA matched to 4452 MTKAs from the MarketScan database. Their study found that RATKA patients had shorter LOS (mean 1.56 versus 1.91 days; p < 0.001), lower index costs by $1762 ($32,747 versus $34,509; p = 0.003), and higher discharges to home rates (51.8 versus 47.8%; p = 0.049) than MTKA patients. RATKA patients had less 90-day (68.5 versus 72.0%; p = 0.048) and one-year (70.8 versus 75.0%; p = 0.016) home health utilizations. The RATKA cohort had lower 90-day ($39,260 versus $41,458; p = 0.001) and one-year ($51,462 versus $54,171; p = 0.011) EOC costs.[55]

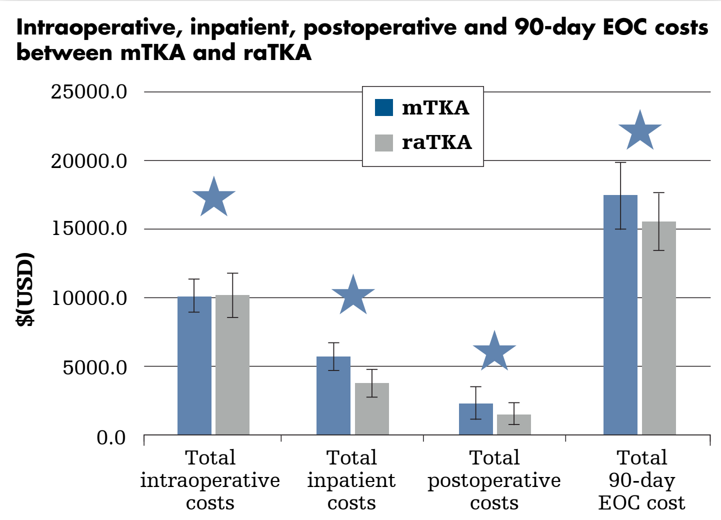


Figure 9. Graphical representation of the intraoperative, inpatient, postoperative, and 90-day episode of care costs between manual total knee arthroplasty and robotic-assisted total knee arthroplasty groups. Error bars represent standard deviation. The star symbol signifies statistical significance p<0.05. EOC, episode-of-care; MTKA, manual total knee arthroplasty; RATKA, robotic-assisted total knee arthroplasty[54]

In a U.S. study, Cotter and colleagues evaluated costs to their hospital comparing 147 Mako and 139 manual TKAs over the 90-day EOC. In their analysis they found, length of stay (LOS) was reduced 25% (1.2 vs. 1.6 days, $p < 0.0001$) and prescribed opioids were reduced 57% (984.2 versus 2240.4 morphine milligram equivalents, $p < 0.0001$) when comparing RATKA with MTKA. Robotic-specific intraoperative costs were offset by cost reductions associated with reduced instrument reprocessing and reduced costs for the inpatient stay. The rate of discharge to postacute care facilities was 52% lower with RATKA compared with MTKA (4.1% RATKA vs. 8.6% MTKA, $p = 0.118$), although not statistically significant due to the small number of occurrences. Patients who underwent MTKA called the physician's clinic office approximately twice as frequently compared with RATKA patients (average 8.9 calls vs. 4.3 calls, respectively, $p < 0.0001$). The majority of phone calls in both groups were related to pain control. Overall, ninety-day EOC costs were $2,090.70 lower for RATKA compared with MTKA ($15,629.94 vs. 17,720.64, respectively; $p < 0.001$).[56]

Alton et al. performed a retrospective review of a large real-world data hospital billing database, including 16,714 RATKA patients matched to 51,199 MTKA patients. In the primary analysis, overall hospital costs of care from index to 90 days post-index were cost-neutral for RATKA and MTKA patients (17,999 vs 17,867, $p \geq 0.05$). Sensitivity analysis found RATKA patients had significantly lower all care costs (18,043 vs 18,243, $p < 0.05$) and cost-neutral knee-related care costs when compared to patients who received MTKA (17,512 vs. 17,632, $p \geq 0.05$). RATKA showed significantly shorter length of stay (0.2 days, $p < 0.05$), 5% higher proportion discharged to home without home health ($p < 0.05$), and 3% fewer patients discharged to skilled nursing facility or other inpatient facility ($p < 0.05$). Within 90 days following discharge, RATKA patients had fewer emergency room visits ($p < 0.05$) with fewer post-operative inpatient readmissions ($p < 0.05$) compared to MTKA.[57]

The potential benefits of Mako SmartRobotics™ in partial knee arthroplasty

Stryker's Mako SmartRobotics™ technology is designed to help enhance the accuracy of component placement, as well as the reproducibility of partial knee arthroplasty.

Partial knee resurfacing for patients with osteoarthritis isolated to only one or two compartments is designed to spare the anterior and posterior cruciate ligaments as well as healthy bone and tissue. Minimizing tissue disruption may enhance patient outcomes and recovery time after TKA procedures, thereby reducing the risk of complications, associated costs and hospital days.[58,59] Manual partial knee replacement can be a demanding procedure with a restricted field of view, and surgeons cannot preoperatively create a patient-specific plan.[4] Patellofemoral arthroplasty is a particularly challenging procedure due to the need to place components properly in multiple planes. This procedure can be sensitive to even one millimeter of abnormality in implant depth, and poorly implanted components may fail earlier.[4] With manual instrumentation, it can be difficult to consistently restore tibial slope,[19] coronal alignment, femoral rotation and limb alignment.[60]

A key clinical paper on Mako accuracy, published by Bell et al., reported on a randomized controlled trial (RCT) involving 120 patients. The study compared patients who received robotic-arm assisted PKA (Restoris MCK n=62) with those who underwent manually implanted PKA (Oxford n=58).[4] Comparisons were made between groups in terms of the preoperative plan of femoral and tibial component positioning against the actual alignment achieved in three different planes (axial, coronal and sagittal). Results showed more accurate component positioning in the robotic-arm assisted group, with lower root mean square errors and significantly lower median errors in all six component parameters ($p < 0.01$).[4] The proportion of patients with tibial slope within 2° of the target position was significantly greater using the robotic-arm assisted technique than the manual technique (80% compared with 22%, $p = 0.0001$). It was concluded that the Mako System helped surgeons to more consistently place the PKA implant in accordance with the preoperative plan.[4]

These results were corroborated by a study performed at University College Hospital in London, England, by Kayani et al.[61] A single surgeon compared implant placement accuracy using radiographs from 60 consecutive conventional PKAs (Oxford) compared to the surgeon's first 60 consecutive Mako Partial Knees (Restoris MCK). The Mako group had significantly ($p < 0.001$) more accurate placement to plan of the femoral and tibial implants, as well as more accurate recreation of the knee's mechanical alignment, posterior tibial slope and joint line height.[61]

Outcomes for partial knee arthroplasty

Achieving desired alignment during surgery may result in enhanced outcomes and patient functioning. In a prospective, randomized, controlled single-center blinded trial (n=139 patients), patients were randomized to receive either a manual PKA or a Mako Partial Knee. An analysis of the RCT patients found that patients who underwent medial Mako Partial Knee experienced less pain during the 90-day postoperative period than those who underwent manual surgery.[62] Median pain scores were 55.4% lower in robotic-arm assisted patients compared to manual patients from day one to day 56 (Figure 10).[62] Furthermore, the robotic-arm assisted patients had better American Knee Society Scores (AKSS) at three months postoperatively and one year postoperatively, and a greater proportion of robotic-arm assisted patients showed improvements in their UCLA Activity Scores.[62]

Additionally, the proportion of patients who achieved an FJS of > 80% at three months postoperatively was almost double in the robotic-arm assisted cohort compared to the manual PKA cohort, although there was no overall statistical difference.[62] The authors also found that inpatient length of stay was shorter in the robotic-arm assisted surgery group, with a difference of 0.54 days ($p = 0.07$), and observed that at three months postoperatively, primary care utilization (calculated from the proportion of the group who visited their general practitioners) was 15% lower ($p = 0.092$) in the robotic-arm group. These patients were followed out to two years postoperative and the Mako Partial Knee patients demonstrated 100% survivorship at two years postoperative, compared to 96.3% in the manual group.[63]

Another study compared a consecutive series of 73 Mako Partial Knee patients with 73 manual PKA patients and found Mako Partial Knee patients to have lower postoperative pain scores at each day of hospitalization following surgery, shorter lengths of stay, reduced usage of postoperative analgesia and fewer physiotherapy (PT) visits required to achieve PT goals.[64]

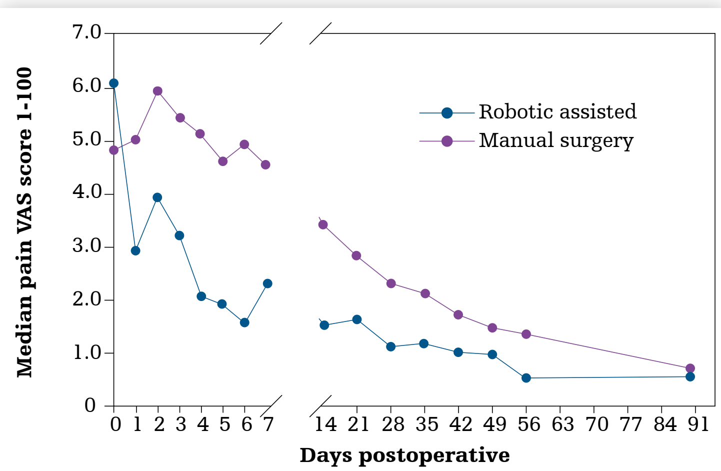


Figure 10. Visual analog scale collected for Mako Partial Knee and manual surgery at 90 days postoperative. Data showed 55.4% lower postoperative pain for Mako Partial Knee patients compared to manual[62]

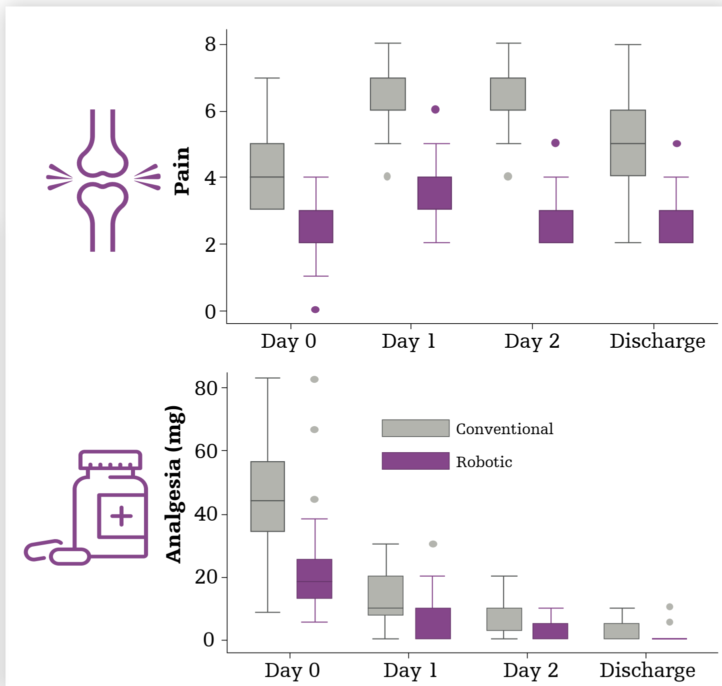


Figure 11. An assessment of early functional outcomes in conventional versus robotic-arm assisted PKA[62]

Mako Partial Knee has also shown improvements in patient satisfaction. In a multicenter, longitudinal clinical trial, the vast majority of patients were "very satisfied" or "satisfied" with their joint replacement (Figure 12).[3,65] This study performed follow-up at 2.5 years (909 knees) and 5.5 years (432 knees) with patients who underwent medial Mako Partial Knee procedures and a total of 92% of patients reported satisfaction with their knee 2.5 years postoperatively, while 91% of patients reported satisfaction at 5.5 years.[3,65]

In addition to midterm patient satisfaction, a recent long-term prospective multicenter study found 91% of patients who received a Mako Partial Knee procedure (Restoris MCK) reported being either "very satisfied" or "satisfied" at 10 years follow-up (335 patients).[66]

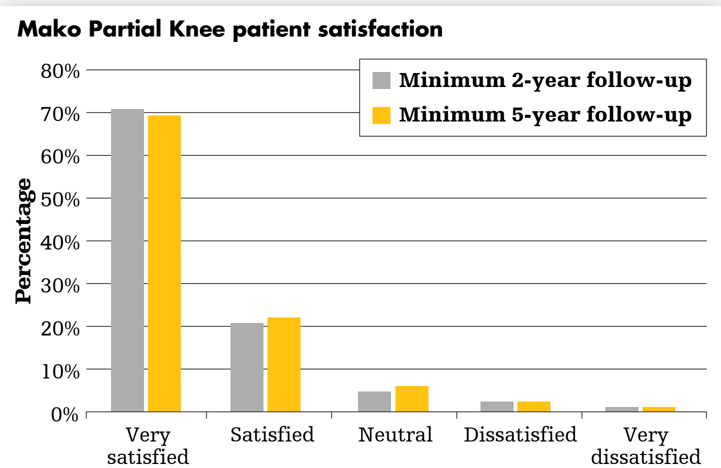


Figure 12. Midterm patient satisfaction with medial Mako Partial Knee procedures[3,65]

In a separate study, Zuiderbaan et al. administered the Forgotten Joint Score questionnaire to medial Mako Partial Knee patients and manually instrumented TKA patients one and two years postoperatively. Scores were compared between 65 patients who underwent medial Mako Partial Knee and 65 patients who underwent manually instrumented TKA.[67] Results demonstrated patients who underwent medial robotic-arm assisted PKA were more likely to forget their artificial joint in daily life.[67]

Survivorship in partial knee arthroplasty

A multitude of studies have shown low revision rates for Mako Partial Knee. A multicenter, longitudinal study evaluating short and midterm survivorship of robotic-arm assisted medial PKA demonstrated 98.8% survivorship (in 909 knees) at 2.5-year follow-up and 97% (in 432 knees) at 5.5-year follow-up.[3,65] Five-year follow-up of 845 patients (1018 knees) has shown survivorship for medial onlay at 97.8%, lateral unicompartmental knee arthroplasty (UKA) at 97.7% and patellofemoral arthroplasty / bicompartmental knee arthroplasty at 93.3%.[121] These survivorship rates were greater than rates derived from high-volume surgeon data and registry data for conventional PKA.[3,65] The study concluded that the favorable survivorship observed resulted from Mako's ability to help enable surgeons to achieve more accurate component positioning when compared to implant placement using manual techniques.[3,65]

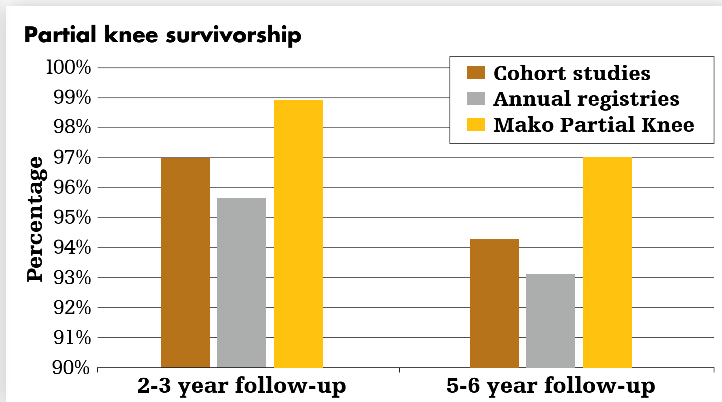


Figure 13. Survivorship data from Pearle et al.[65] and Kleeblad et al.[3] on robotic-arm assisted PKA compared to studies in literature and annual registries reporting 2 to 3 years and 5 to 6 years conventional PKA survivorship data

Similar promising data was published in the 2019 Australian Joint Registry, which reported the cumulative revision rate for the Restoris MCK medial PKA as 1.5% at one year and 2.5% at 3 years, which was significantly lower than non-robotic UKAs in the registry. This compared favorably to the revision rate for all Oxford medial PKA replacements at one year (2.2%) and at three years (5.8%) and is the lowest rate for any PKA implant reported.[20,73] Most recently, evidence has been published to support long-term (ten-year) survivorship and patient satisfaction. Ten-year follow-up of 185 patients from a single surgeon and single institution demonstrated RAUKA had an overall survivorship of 98%. Stratifying patients by satisfaction rates demonstrated majority of the patients were "very satisfied" (80.95%) or satisfied (16.19%) with their procedure.[74] Another prospective, multicenter study found that of the 366 patients (411 knees) included in the analysis, there were 29 revisions reported at 10-year follow-up (91.7% survivorship) and the mean time to revision was 5.2±2.4 years. Of all patients without revision, 91% reported being either very satisfied or satisfied with their procedure.[66] The revision rates for Mako Partial Knee have been published in cohort studies, economic analyses, level I clinical trials (RCTs) and international registries. The evidence supports excellent survivorship of the Restoris MCK implant when used with the Mako System. In summary, Mako has demonstrated positive outcomes through more accurate component positioning[4] and high patient satisfaction.[3,65,66]

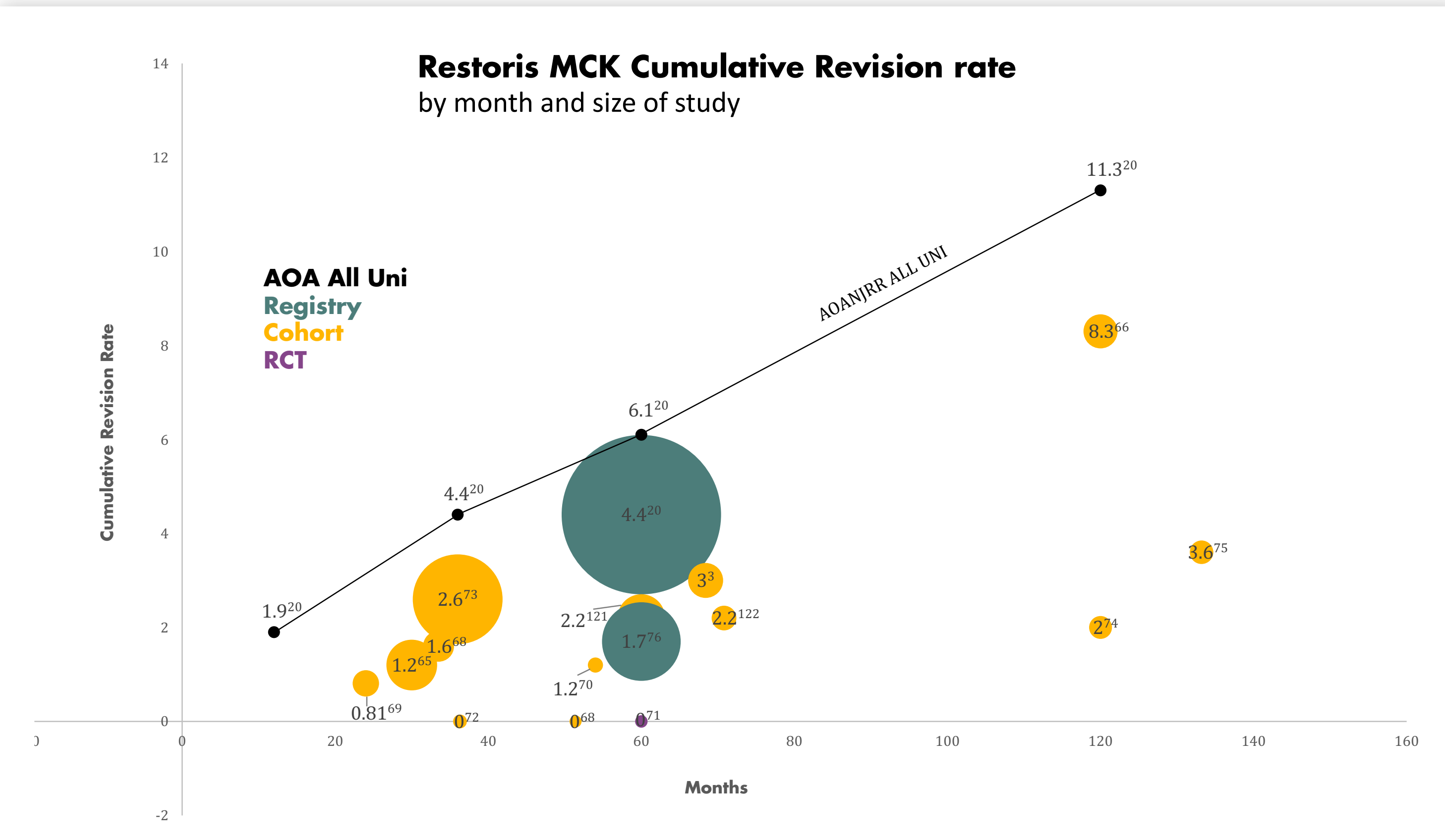


Figure 14. Compiled revision rates demonstrating enhanced results for Mako Partial Knee[3,20,65,66,68-76,121,122]

Mako Partial Knee health economics

Clinical findings such as reduced revision rates have the potential to add value in the continuum of care. In a study by Cool et al., reasons for revisions and associated costs were analyzed for robotic-arm assisted partial knee arthroplasty cases. PKA procedures were identified using a U.S. commercial administrative claims database to evaluate hospital admissions for revision surgeries. Robotic-arm assisted PKA (RAPKA) and manual PKA (MPKA) procedures performed between March 1, 2013 and July 31, 2015 were used to calculate the rate of revisions within 24 months of the index procedure. Cases were propensity matched 2:1 based on age, sex, race, geographic division, high-cost comorbidities and concentration of healthcare specialists per 100,000 population to control for outside confounding factors at case index. A total of 738 commercial health plan patients (246 RAPKAs, 492 MPKAs) were selected for inclusion in the analysis. Results indicated fewer revision procedures in RAPKA, 0.81% [2/246] vs. 5.28% [26/492]; ($p = 0.0017$) and RAPKA patients incurred lower mean costs for the index stay plus revision(s), $26,001 vs. $27,977; $p > 0.05$. Lower length of stay at index was also noted in the RAPKA group, 1.77 vs. 2.02 days; $p = 0.0047$. The study concluded that patients who underwent RAPKA had fewer revision procedures, shorter LOS and incurred lower mean costs at 24 months.[69]

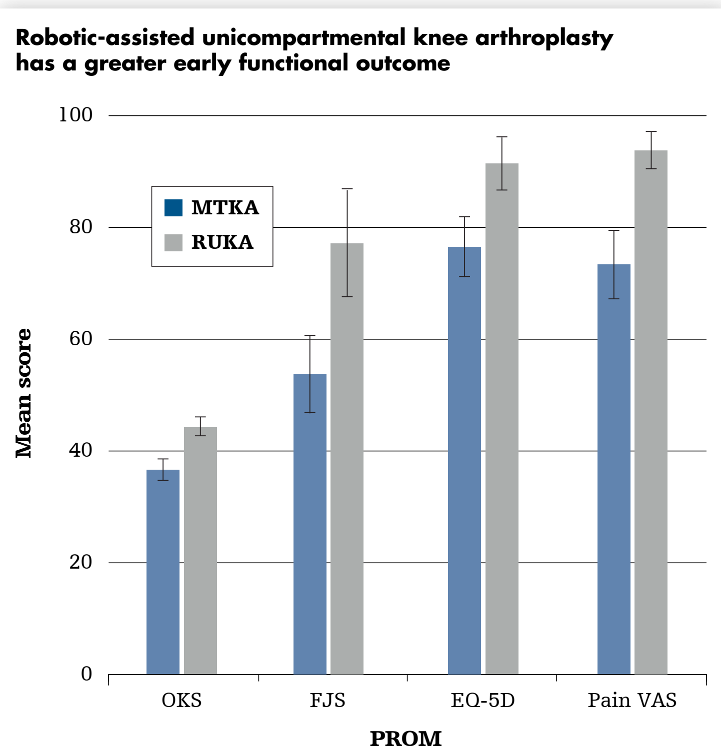


Figure 15. Six-month postoperative patient-reported outcome measures (PROMs) for the robotic unicompartmental knee arthroplasty (RUKA, gray bars) and manual total knee arthroplasty (MTKA, blue bars) groups. Error bars represent 95% confidence intervals. EQ-5D, EuroQol five-dimensional questionnaire; FJS, Forgotten Joint Score; OKS, Oxford Knee Score; VAS, visual analogue scale[78]

Some have tried to evaluate potential clinical and economic differences between PKA and TKA. A prospective study of 30 Mako Partial Knees compared to 90 propensity-matched manual TKAs found that six- month pain VAS scores, Oxford Knee Score (OKS), FJS and EQ5D were significantly better for the Mako Partial Knee group compared to manual TKA. They also found that LOS was significantly shorter in the robotic-arm assisted PKA group compared to manual TKA.[78]

With rising demand for PKA in patients who seek restored function and a quicker recovery time, a study performed by Kazarian et al. evaluated the cost-effectiveness of PKA compared to TKA as well as nonsurgical treatment (NST). Using a Markov decision analytic model, the authors assessed lifetime costs and quality of life years (QALYs) as a function of age at time of initial treatment (ATIT) of patients with end-stage unicompartmental knee osteoarthritis. The analysis included direct medical and indirect costs. Models were run for ATITs at five-year intervals from 40 through 90 years of age. Results indicated unicompartmental knee arthroplasty had the greatest QALY accumulation followed by TKA and NST, and PKA was more cost-effective compared to NST for patients from ages 40 to 86. When surgical treatments were compared, PKA dominated TKA by generating more QALYs than TKA for all ATITs. The authors further concluded that if PKAs were performed as 12% to 20% of the total volume of knee arthroplasties versus the less than 8% observed, it would lead to a lifetime cost-savings of 987 million to 1.5 billion U.S. dollars and increased lifetime QALY accumulation of 124,403 to 217,705 across the U.S. population.[79]

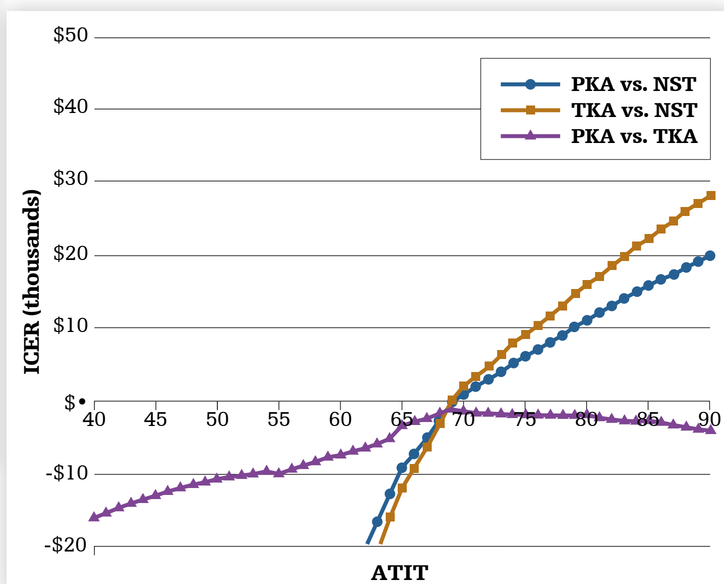


Figure 16. Incremental cost-effectiveness ratio (ICER) values comparing PKA with NST, TKA with NST, and PKA with TKA by age[79]

In a separate U.K.-based study, a Markov decision analysis was performed to assess the cost-effectiveness of robotic-arm assisted unicompartmental knee arthroplasty (RAUKA) relative to manual TKA and PKA for patients with isolated medial compartment OA of the knee with a mean age of 65 years. The study objective was to identify the cost per QALY of RAUKA specifically relative to TKA and PKA. Model inputs included hospital costs, implant survival and mortality rate. Using a model with an annual case volume of 100 patients, the cost per QALY of RAUKA was £1395 and £1170 relative to TKA and PKA, respectively. The cost per QALY was influenced by case volume: a low-volume center performing ten cases per year would achieve a cost per QALY of £7,170 and £8,604 relative to TKA and PKA. For a high-volume center performing 200 RAUKAs per year with a mean two-day length of stay, the cost per QALY would be £648; if performed as day cases, the cost would be reduced to £364 relative to TKA. For a high-volume center performing 200 RAUKAs per year with a shorter length of stay of one day relative to PKA, the cost per QALY would be £574. Furthermore, the cost per QALY of RAUKA decreased with reducing length of hospital stay and with increasing case volume compared with TKA and PKA.[77] The model showed that RAUKA may offer a cost-effective alternative to TKA and PKA for patients with isolated medial compartment OA of the knee. In summary, these models demonstrated that PKA can be more cost-effective than nonsurgical treatment and TKA for the specified age groups modeled and showed that robotic-arm assisted PKA can be cost-effective compared to TKA.

	RAUKA[77]	TKA[77]	MUKA[77]
Total health gain (QALYs)[77]	13.59	11.8	12.2
Health improvement (vs. TKA)[77]	1.8	0	1.39
Cost/QALY (vs. TKA)[77]	£1,395.00	£2,101.00	£1,170.00

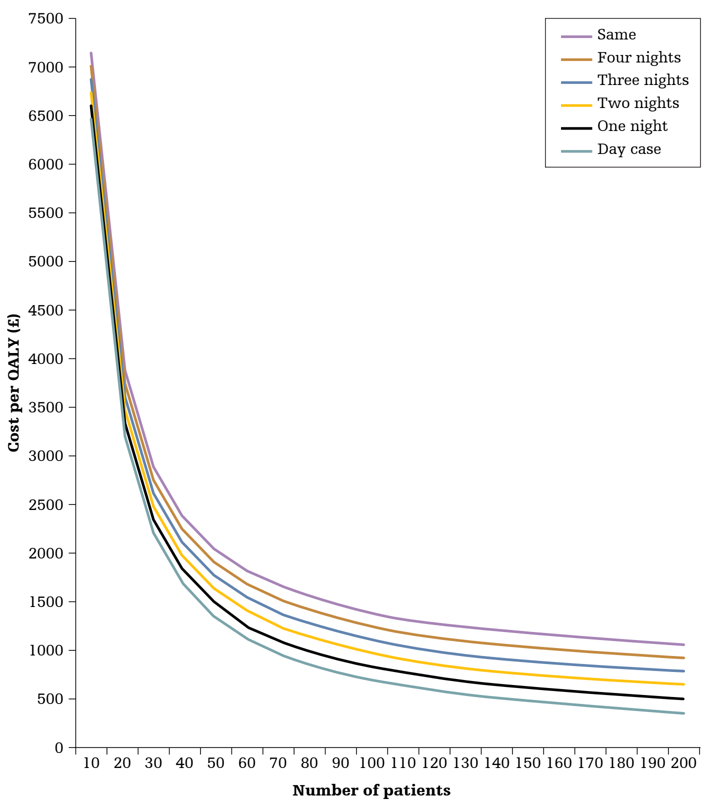


Figure 17. Cost per quality-adjusted-life-year (QALY) of robot-assisted unicompartmental knee arthroplasty according to case volume and length of hospital stay relative to total knee arthroplasty[77]

Robotic-arm assisted PKA procedures may also provide value for hospitals. A hospital in Brisbane, Australia examined the potential cost-savings for the health system and the community through the increased utilization of PKA using robotic-arm assisted PKA vs. conventional TKA. They retrospectively reviewed 240 patients where the first 120 consecutive Mako Partial Knees performed during this period were matched to 120 conventional TKAs. Clinical data from the medical records and costs for procedure for each component were collected. Bivariate analyses were performed on the data to determine if there were statistically significant differences by surgery type in clinical outcomes and financial costs. The hospital found a significantly lower cost incurred for RAPKA vs. TKA with an average saving of AU$7,179 per case. The operating time (86.0 min vs. 75.9 min; $p = 0.004$) was significantly higher for RAPKA compared to TKA but the length of stay was significantly lower (1.8 vs. 4.8 days; $p < 0.001$). This study also found a significant difference in the use of opioids with RAPKA compared to TKA (125.0 morphine equivalent (ME) vs. 522.1 ME, $p < 0.001$).[80]

Studies comparing PKA to TKA have observed that PKA typically requires less rehabilitation,[81] results in fewer postoperative complications,[82] results in patients more likely to forget their artificial joint in daily life[78] and results in improved quality of life.[79] Studies of Mako Partial Knee have not only demonstrated improvements in short-term outcomes[62,65] compared to manual PKA, but have also shown more favorable revision rates[3,20,65,68-72] compared to manual PKA and demonstrated revision rates similar to those seen in TKA. These observed clinical outcomes, coupled with the potential cost-savings demonstrated in assessments of cost-effectiveness, show that Mako Partial Knee has the potential to offer both short- and long-term advantages to patients, providers and payers.

The potential benefits of Mako SmartRobotics™ in total hip arthroplasty

Component positioning (stability and dislocation)

Total hip arthroplasty has been one of the most successful procedures within the field of orthopaedics since the late 1960s.[83] The short and long-term outcomes of THA may be influenced by several factors, including patient demographics, surgical technique and implant features.[84] One of the most important surgeon-controlled factors is component positioning.[84] Component malposition has been linked to higher rates of hip dislocations, poor biomechanics, accelerated wear, leg length discrepancy and revision surgeries.[84] In addition, component malposition is directly associated with dislocations and mechanical loosening, which account for approximately 40% of THA revisions.[85] Successful clinical outcomes following total joint replacement are dependent on component placement and on restoring the natural joint anatomy of the hip.[84] Instability, early mechanical failures and dislocation in hip arthroplasty continue to be primary reasons for revision.[84]

The Mako System is designed to help the surgeon minimize the margin of error associated with component placement and to enhance the accuracy and reproducibility of THA. In a U.S. multicenter clinical trial including 110 patients, acetabular cup position was compared between preoperative plan, intraoperative assessment and achieved radiographic measure. Results confirmed that surgeons using intraoperative robotic-arm assistance achieved greater accuracy to plan in preparation and position of the acetabular cup during THA.[86] Consecutive primary robotic-arm assisted THAs (RATHAs) performed by one surgeon at three intervals were analyzed in a retrospective cohort study: the initial 100 consecutive manual THAs (MTHAs) in clinical practice (2000), the last consecutive 100 MTHAs before RATHA technology introduction (2011), and the first consecutive 100 RATHA cases (2012). The rate of acetabular component placement within the Lewinnek safe zone was the highest in the RATHA cohort (77%), followed by late MTHA (45%) and early MTHA (30%). RATHA resulted in an additional 71% improvement in accuracy to plan in the first year of use.[1]

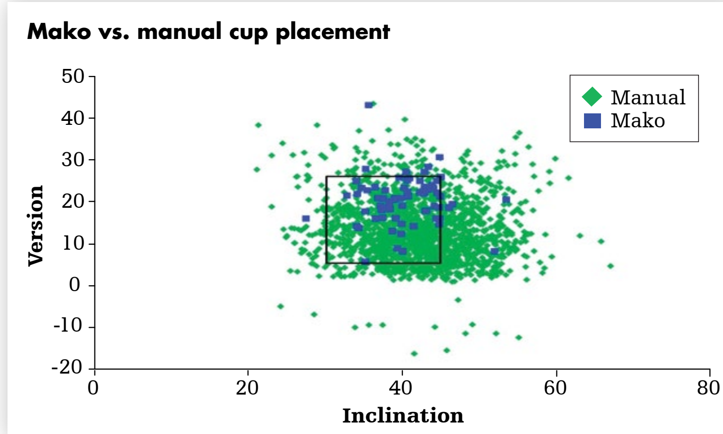


Figure 18. Mako vs. manual cup placement in total hip arthroplasty[86]

In another study involving six surgeons at a single U.S. institute, 1,980 THA surgeries were evaluated. The aim of this study was to understand the influence of surgical approaches and modes of guidance. Robotic-arm assisted THA resulted in a significantly greater percentage of components placed in Callanan safe zones than all other modalities, including navigation- and fluoroscopy-guided approaches.[87]

In a study conducted between 2008 and 2012 comparing THA using manual alignment techniques with THA using Mako robotic-arm assisted alignment, Mako Total Hips were matched to historical manual THAs.[88] As shown in Figure 19a, 100% of the robotic-arm assisted THAs were placed within the Lewinnek safe zone for anteversion and inclination vs. 80% (40/50) of the manually aligned and implanted THAs in Figure 19b. Similarly, 92% of the RATHAs were within the Callanan safe zone vs. only 62% of MTHAs.[88]

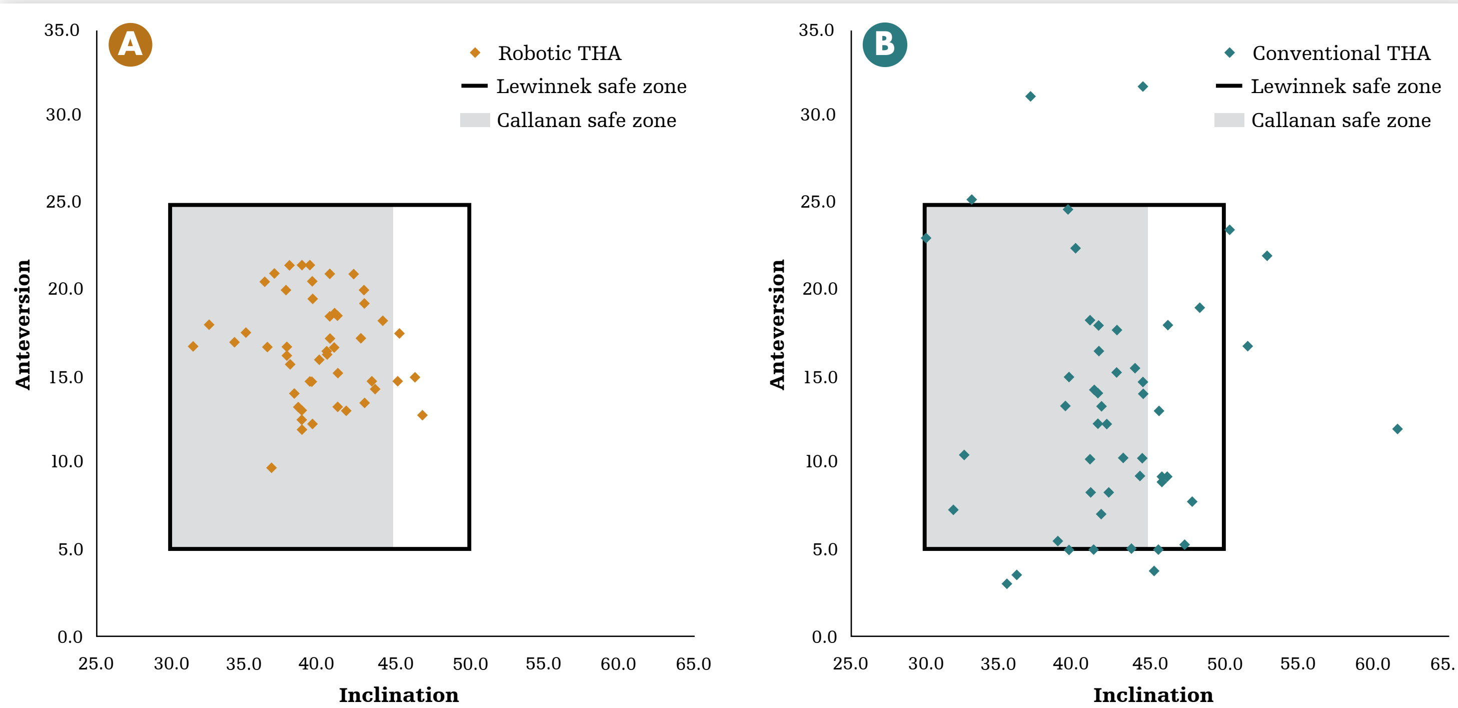


Figure 19a and 19b. Acetabular cup placement within the Lewinnek and Callanan safe zones for Mako Robotic-Arm Assisted Total Hip Arthroplasty (A) and conventional total hip arthroplasty (B)[88]

Mako Total Hip clinical success

Mako Total Hip has demonstrated:

- Enhanced acetabular component placement **accuracy** and **reduced dislocation rates** and **blood loss** when compared with MTHA[1]
- Favorable short-term patient-reported outcomes[89-91]
- The **highest Forgotten Joint Score** reported in literature for THA[90]
- Decreased length of stay compared to MTHA[94]

Potential to restore leg length and hip biomechanics (offset)

Manual total hip procedures may be associated with discrepancies in leg length following surgery.[95] A study examined two methods of intraoperative leg length assessment and found that a discrepancy in leg length of fewer than five millimeters was achieved in only 73% and 67% of patients for the two methods respectively. The same study observed that approximately 25% of patients had a leg length discrepancy of more than five millimeters regardless of which manual surgical method was used.[95]

Another study by Manzotti et al. found that at six months postoperative, the mean postoperative leg length discrepancy was reduced to 5.06 mm (range: 0–12) in a computer-assisted group, compared to 7.64 mm (range: 0–20) in the freehand group.[96] Harris Hip Scores (HHS) post-THA have been reported to be significantly higher in patient groups in which femoral offset was normal or increased relative to the contralateral side.[97]

The use of Mako Total Hip has demonstrated accuracy in achieving desired leg length. In a prospective study, 20 patients received Mako Total Hip and had postoperative CTs performed to measure accuracy to plan of acetabular and femoral implant placement. Postoperative measurements reported accurate recreation of the overall hip length and offset (1.6 mm, standard deviation (sd) 2.9 mm and 0.5 mm, sd 3.0 mm, respectively). Mean stem version as well as mean shell anteversion and inclination angles were similar between intraoperative and postoperative measurements.[95] In a two-year follow-up study of 162 Mako Total Hip patients performed by a single surgeon, no leg length discrepancies were observed.[90]

Allowance for preservation of acetabular bone stock

Preservation of acetabular bone during primary THA is important since proper implant stability and longevity depend largely on the amount of bone stock left after acetabular reaming.[7] Eccentric or excessive acetabular reaming may lead to soft tissue impingement, loosening, altered center of rotation, bone-to-bone impingement, intraoperative periprosthetic fracture, early implant failure due to lack of bone ingrowth and other complications, potentially leading to subsequent revision of THA.[7] In a matched-pair controlled study, the size of the acetabular cup relative to that of the femoral head was used as a surrogate measure of acetabular bone resection. In this study, Mako Total Hip allowed for the use of smaller acetabular cups in relation to the patient's femoral head size compared to conventional THA, indicating greater preservation of bone stock.[7]

Outcomes for total hip arthroplasty

Based on data prospectively collected on primary THAs conducted since August 2000 from a single institution, Mako Total Hip was associated with enhanced accuracy and reproducibility of component placement and reduced early dislocation rates compared to conventional THA as discussed above.[1,87] In this analysis, data was reviewed for all THAs (n = 300 patients) conducted by one fellowship-trained surgeon at a single institution over three time periods in order to compare surgical outcomes[89]:

- Group one (2000 to 2001): First 100 consecutive MTHA cases conducted
- Group two (2011): Last 100 consecutive MTHA cases conducted
- Group three (2011 to 2012): First 100 consecutive Mako THA cases conducted

As shown in Figure 20, Mako Total Hip demonstrated greater accuracy for both acetabular abduction (AAB) and acetabular anteversion (AAV) and demonstrated lower dislocation rates at one year compared with manual THA.[1,89] The average estimated blood loss was also reduced in the patient group that received robotic THA compared to manual.[1,89]

	First 100 manual THA cases	Last 100 manual THA cases	First 100 total hip cases
Early dislocation rate (within first 12 months postoperative)	5%	3%	0%
Limb length discrepancy >1.5 cm	10%	1%	1%
Estimated blood loss	534 mL	438 mL	358 mL
AAB in target zone	66%	91%	100%
AAV in target zone	39%	48%	77%
AAB and AAV in target zone	30%	45%	77%

Figure 20. Postoperative outcomes for patients receiving MTHA vs. RATHA[1,89]

In this same study, while excellent clinical outcomes were noted for both Mako Total Hip and MTHA at a one-year clinical follow-up, patients who had received Mako Total Hip demonstrated significantly higher modified Harris Hip Scores and UCLA activity level compared with MTHA.[1,89]

In a study of early post-operative clinical recovery of 30 rTHA compared to 30 navigated THAs, it was found that surgical time, number of days to independent walking and postoperative pain using a numeric rating scale on postoperative days 7, 10, and 14 were significantly reduced in the rTHA group compared to the nTHA group. The rTHA group also showed a significantly higher post-operative HHS compared to the nTHA group (85.3 ± .3.2 vs. 81.0 ± 8.5, p = 0.014). The authors concluded that compared to the nTHA group, the rTHA group showed improved early clinical recovery.[98]

In a U.S. single-surgeon prospective study of 162 robotic-arm assisted THA patients with minimum follow-up of two years, the mean Forgotten Joint Score-12 (FJS-12), a patient-reported outcome instrument developed to assess the patient's ability to forget the artificial joint in everyday life, was 83.1. This was the highest FJS-12 score ever reported in publicly available literature.[90]

More recently, Domb and colleagues published five-year outcomes of 66 RATHAs propensity matched with 66 MTHAs. They found that the RATHA 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, respectively). The acetabular implant placement by surgeons performing RATHA had a 9- and 4.7-fold reduced risk of placement outside the Lewinnek and Callanan safe

		rTHA (n=30)	nTHA (n=30)	p-value
Surgical time (min)		135.1±13.9	146.2±12.8	0.002*
Intraoperative blood loss (mL)		548.5±203.9	568.7±178.6	0.69
Days to independent walking (days)		7.2±2.0	11.5±3.0	<0.001*
Pain (NRS)	POD 1	2.7±1.2	3.0±1.2	0.28
	POD 3	2.2±1.1	2.6±1.3	0.3
	POD 7	1.4±0.9	2.2±1.2	0.005*
	POD 10	1.0±0.8	1.8±1.1	0.002*
	POD 14	0.3±0.5	1.1±0.9	<0.001*
HHS (points)	preoperative	44.1±6.4	44.2±5.2	0.81
	postoperative	85.3±3.2	81.0±8.5	0.01*

Values are represented as average ± standard deviation. NRS, numeric rating scale; POD, postoperative days; HS, Harris Hip Score.
* Statistically significant difference

Figure 21. Clinical outcomes[98]

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±6.93	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

Figure 22. Minimum five-year outcomes of robotic-assisted primary total hip arthroplasty compared to manual primary total hip arthroplasty[91]

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, RATHA recipients had lesser absolute values of leg length discrepancy and global offset (P = 0.091, P = 0.001). This study demonstrated favorable outcomes for RATHA compared to MTHA at five years postoperative.[91]

Mako has shown reduced dislocation rates compared to manual THA. In a study by Bendich et al. they compared 1770 RATHAs to 3155 CNTHAs and 8877 MTHAs and evaluated reoperations within 1 year of surgery. They found that RATHA was associated with lower risk of revision for dislocation (OR 0.3, p = 0.046) within 1 year of surgery compared to MTHA.[92]

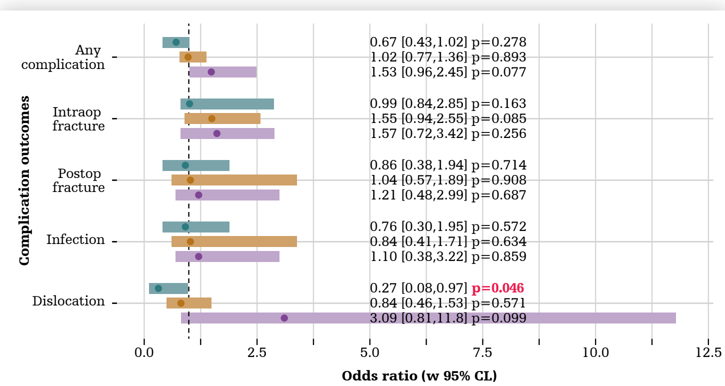


Figure 23. Odds ratios of complications, fractures, infections and dislocations for RATHA, CNTHA and MTHA.[92]

Shaw and colleagues evaluated 523 RATHAs compared to 1724 MTHAs with average 4-year follow-up using data from the Michigan Arthroplasty Registry Collaborative Quality Initiative. They found significantly lower rates of dislocation for RATHA (0.6%) vs MTHA (2.5%). They also found that all cases of unstable RATHA were successfully treated conservatively, whereas 46% of unstable THAs were revised for recurrent instability.[93]

Mako Total Hip health economics

In a retrospective review of the Stryker Health Cloud, a multi-hospital database, RATHA was 1:1 propensity matched to manual THA resulting in 8,536 patients per cohort. The RATHA cohort had a significantly shorter mean length of stay (1.39±0.85 days vs. 1.48±0.91 days, p <0.001), significantly more cases discharged on or before postoperative day one (68.2 vs. 61.7%, p < .001), significantly more patients discharged home and discharged home without home health services, (93.2% vs. 91.8%, p < 0.001 and 47.9% vs. 45.5% p = 0.001), and significantly fewer patients discharged to a skilled nursing facility (SNF) compared to MTHA (5.6% vs. 6.9%, p=0.001). 90-day readmission rates were similar between RATHA and MTHA (3.0% vs. 3.4%, p=0.26). This study demonstrated shorter LOS and reduced resource utilization at discharge for RATHA compared to MTHA.[99]

In a Medicare analysis of the 90-day episode-of-care cost of 938 RATHAs propensity matched to 4,670 MTHAs, RATHA patients were less likely to have post-index IPR or SNF admissions (0.64% vs. 2.68%; p<0.0001 and 20.79% vs. 24.99%; p=0.0041, respectively). 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 HHA visits (14.06 vs. 15.00; p=0.0006) compared to MTHA. RATHA had lower 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. Overall, RATHA patients had 12% ($948) lower average post-index costs compared to MTHA patients (p=0.0004). Total 90-day EOC costs for RATHA patients were found to be $785 less than that of MTHA patients ($19,734 vs. $20,519, p=0.0095).[100]

More recently, a 90-day episode-of-care clinical utility and cost analysis using Blue Health Intelligence (BHI) nationwide commercial insurance database (Health Intelligence Company, LLC, IL, USA) analyzed 1,732 RATHAs 1:5 propensity matched to 8,660 MTHAs. RATHA patients experienced shorter length-of-stay compared to MTHA (1.51 vs 1.71 days; p < 0.0001). In terms of 90-day post-index resource utilization, fewer RATHA patients needed inpatient care (2.31% vs. 3.38%, p = 0.0203), leading to 35.93% less inpatient readmissions (p = 0.0204). Furthermore, less RATHA patients needed hospital outpatient services (44.98% vs. 48.81%, p = 0.0038), leading to 22.25% fewer hospital outpatient encounters (p = 0.0002). RATHA had $1,573 lower overall 90-day episode-of-care costs ($35,436 vs $37,009; p < 0.0001), driven by lower index facility costs ($27,103 vs $28,839, p < 0.0001), post-index inpatient costs ($377 vs. $506, p = 0.0160), and post-index hospital outpatient costs ($801 vs. $999, p = 0.0010).[101]

Maldonado and colleagues evaluated the long-term cost effectiveness of robotic vs. manual THA through a Markov model. 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 1 year over a time horizon of 5 years. They found that RAA THA cohort was cost effective relative to mTHA cohort for cumulative Medicare and cumulative private payer insurance costs over the 5-year period. RAA THA cost saving had an average differential of $945 for Medicare and $1,810 for private insurance relative to mTHA while generating slightly more utility (0.04 quality-adjusted life year). The preferred treatment was sensitive to the utilities generated by successful RAA THA and mTHA. Microsimulations indicated that RAA THA was cost effective in 99.4% of cases. In the U.S. Medicare and private payer scenarios, RAATHA is more cost effective than conventional mTHA when considering direct medical costs from a payer's perspective.[102]

Clement and colleagues evaluated the cost effectiveness of Mako THA compared to manual Total Hip according to the NIH guidelines. They found that Mako Total Hip produced higher QALYs compared to manual and despite the increased cost associated with rTHA, it was a cost-effective intervention relative to mTHA at both 10-year follow-up and for a lifetime horizon and was under the threshold of £20,000 per QALY gained.[103]

Implant waste contributes a significant economic burden to the healthcare system, estimated to cost U.S. hospitals over 36 million dollars annually, and expected to increase with rising demand.[104] In a recent study, a high volume teaching institution measured the proportion of implant waste in over eighteen thousand primary total hip arthroplasty cases, comparing Mako THA, imageless navigation, and manual Total Hip cohorts. The study found that Mako Total Hip wasted a significantly smaller proportion of implants compared to navigation and manual cohorts. When evaluating the surgeon experience, they also found that Mako showed lower implant waste rates for surgeons with less than 20 years of experience compared to navigation or manual, suggesting robotic-arm assisted surgery may aid less experienced surgeons to more consistently prepare and implant an acetabular component, in turn, decreasing acetabular component waste. This is particularly important as reducing waste rates may help reduce operating room expenditure and eliminate unnecessary costs to the healthcare system.[105]

In summary, use of the Mako System in total hip arthroplasty has demonstrated more accurate component positioning,[1,88,89] bone preservation,[7] improved clinical outcomes and the potential for cost-savings.[100,101,102]

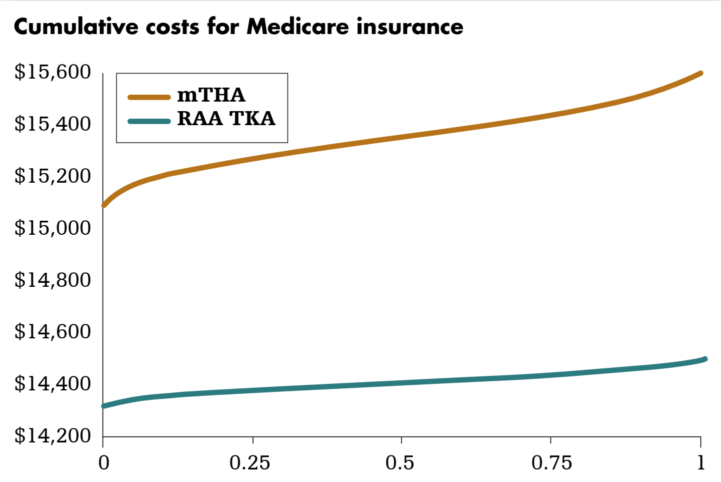


Figure 24. Graph showing the cumulative costs for Medicare. The values are derived from 100,000 simulations using a probabilistic sensitivity analysis. $ = 2019 U.S. dollars, mTHA = manual total hip arthroplasty, RAA = robotic-arm assisted, THA = total hip arthroplasty[102]

How Mako SmartRobotics™ differs from other robotic platforms

Mako SmartRobotics™ possesses several key features that differentiate it from other robotic surgery platforms. After a thorough surgical plan is created and approved by the surgeon, the Mako System assists surgeons with executing that plan using AccuStop™ haptic technology. The implant position, tracking and soft tissue balancing are assessed in a virtual 3D model by combining a preoperative CT and intraoperative bone registration. A CT scan uses a combination of 2D and digital geometry processing to generate a 3D image of the body. While plain film radiographs (X-rays) provide a 2D image of the scanned area, anatomic structures may overlap, creating an image which is less detailed than a CT scan. In a CT image, overlapping structures are eliminated, making the internal anatomy easier to visualize. In knee and hip arthroplasty procedures, the femoral version and tibial torsion[78] can provide critical guidance when planning a case. Bony anatomic landmarks of the femur and tibia can be clearly identified using 3D imaging technologies. After a surgeon assesses implant size and position in the preoperative plan, the robotic-arm is introduced to the surgical site. The robotic-arm uses AccuStop™ haptic technology to help ensure only the desired bone is resected. The robotic-arm will give resistance, an audible warning and ultimately turn off if the surgeon attempts to move the cutting tool on the robotic-arm outside the boundaries created in the preoperative plan.

While various other robotic systems include a robotic arm, robotic-guided cutting jigs or different navigation strategies,[98] the Mako System has the capability to virtually create and modify the 3D preoperative plan before an incision is made, and the surgeon is able to analyze and modify the preoperative plan before bone resection even begins.

Some joint arthroplasty techniques do not require a CT scan at all prior to surgery. For example, some orthopaedic navigation systems are "model-based", where information from a CT scan is not utilized. Instead, navigation software calculates an individual model of the patient's anatomy based on defined landmarks on the bone, which are acquired using a navigated instrument (registration).[106] After optional planning on the model (e.g., virtual orientation and placement of the joint implant), the actual procedure follows, where the surgeon is supported by relevant information added through the navigation system (navigation).[107]

Surgeons may not adopt robotic technology and may instead elect to continue to perform their cases manually. For manual total knee arthroplasty, a surgeon uses X-rays of the joint to visually identify the desired implants and positioning/alignment of the implants. During the surgery, mechanical instruments such as rods placed inside or outside of the bones and blocks are used to measure and assess the angle and resection depth of the bone cuts. The bone cuts are performed with a hand-held powered saw, which is typically guided by a cutting block which has been pinned to the bone. This technique requires the surgeon to be able to visualize the edges of the bone while making the cuts in order to avoid cutting into the soft tissues inadvertently. The surgeon then uses trial implants to assess the cuts and make any alterations necessary before the final implants are placed and the wound is closed.

The Mako robotic system has demonstrated, through published clinical studies, higher accuracy and precision to plan for implant placement and sizing for total knee, total hip and partial knee arthroplasty compared to manual techniques.[4,107,108] Mako is also currently the only robotic-arm bone preparation system in the marketplace that uses AccuStop™ haptic technology and that has the ability to cut with a saw, burr with a burr and ream with a reamer.

Learning curve of Mako SmartRobotics™

The learning curves of robotic-arm assisted TKA, PKA and THA have been explored in the literature. Kayani and colleagues evaluated 60 Mako Partial Knees and compared them to 60 manual partial knees. They found their learning curve for surgical time and surgical team confidence levels to be six cases. They also found that improved accuracy to plan was experienced from the first case, indicating that Mako Partial Knee surgery did not have a learning curve for accuracy in achieving the planned femoral and tibial implant position. Further, no additional risk for postoperative complications was observed during the surgical team learning curve.[61]

A study by Jinnah et al. quantified the learning curve of robotic-arm assisted PKA. A total of 892 patients received a PKA performed by 11 different surgeons using the Mako System. Each surgeon had performed at least 30 surgeries with this technology, and the surgical time of the final 20 surgeries of each surgeon was averaged to define a steady state surgical time. The study measured the number of surgeries required to obtain two consecutive and three total surgeries completed within the 95% confidence interval of the steady state surgical time of that particular surgeon. Results showed that the number of surgeries required to have three surgeries completed within the 95% CI of the steady state surgical time was 13 (range: five to 29), and the number required to have two consecutive surgeries within this same time frame was 16 (range: four to 42).[112]

Mako Total Knee studies have also shown a learning curve associated with Mako Total Knee before a surgical team can become time neutral to their operative time when performing manual TKA. Sodhi et al. performed a study to assess this learning curve in which two surgeons performed a total of 240 robotic-arm assisted cases.[113] Each case was allocated to a group of 20 sequential cases and a learning curve was created based on mean operative times. These times were compared to mean operative times for 20 randomly selected manual cases performed by the same surgeon. For Surgeon 1, mean operative time between the first and last cohort was reduced from 81 minutes to 70 minutes ($p < 0.05$). For Surgeon 2, mean operative time between the first and last cohort was reduced from 117 minutes to 98 minutes ($p < 0.05$). For both surgeons, the final 20-case set was time neutral to their manual cohort. This data implies that within a few months, a surgeon may be able to perform robotic-arm assisted TKA without any added operative time compared to manual TKA.[113]

System*	Application†	Cutting type	Cutting control
TSolution One	TKA	Direct	Autonomous
Mako	UKA	Direct	Haptic
Mako	TKA	Direct	Haptic
Mako	THA	Direct	Haptic
NAVIO	UKA	Direct	Boundary control
NAVIO	TKA	Indirect	Boundary control
ROSA	TKA	Indirect	Cutting guide
OMNIBotics	TKA	Indirect	Cutting guide
SpineAssist	Pedicle screw	Indirect	Cutting guide
Globus	Pedicle screw		Cutting guide

Figure 25. Cutting robotic systems used in orthopaedics[110,111]

***TSolution One is manufactured by Think Surgical; Mako, by Stryker; NAVIO, by Smith & Nephew; ROSA, by Zimmer Biomet; OMNIBotics, by OMNI; SpineAssist, by MAZOR Robotics; and Globus, by Excelsius Medical.**
†THA = total hip arthroplasty, TKA = total knee arthroplasty, and UKA = unicondylar knee arthroplasty[110,111]

To understand how patient outcomes are influenced during a surgeon's learning curve, Naziri et al. reported on a single-surgeon experience comparing that surgeon's first 40 RATKA cases to a matched consecutive MTKA cohort.[114] During the first 40 cases, the RATKA cohort had a slightly greater overall surgical time when compared to the MTKA group (82.5 min vs. 78.3 min, p=0.002), however this difference was no longer statistically significant when only the second set of 20 RATKA cases was considered (81.1 min vs. 78.3 min, p = 0.254). During this 40-case cohort, the RAKTA cohort showed a reduced LOS (1.27 days vs. 1.92 days, p > 0.001) and an improved ROM at 90 days (+3.8° vs. -8.7°, p < 0.05). No significant difference was noted in postoperative KSS or lower extremity activity scale at 30-, 60-, and 90-day follow-up between groups. The authors concluded that the surgeon's learning curve for RATKA appeared to progress rapidly, with a comparable OR time to MTKA by the second 20 cases.

Recently, Bhowmik-Stoker and colleagues evaluated the time-based learning curve of RA-TKA in 149 surgeons at 30 hospitals using a Bayesian model. They found that learning curve, as defined by time neutrality to manual TKA, was observed at the 12th case and the model demonstrated steady state time neutrality between 15 and 20 cases.[115]

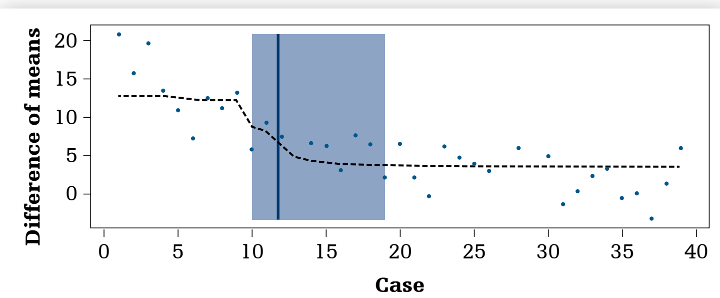


Figure 26. The model shows that the shift to time neutrality occurs between 15 and 20 cases with an inflection point at 12[115]

Redmond et al. researched the learning curve during the adoption of RATHA as measured by component position, operative time and complications.[116] 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 36–70; and 3) Group C consisted of patients 71–105.[116] The authors reported a decreased risk of acetabular component malposition with Mako experience (P < 0.05).[116] Operative time appeared to decrease with increasing surgical experience with the Mako System (P < 0.05). A learning curve of 35 cases was observed with a decreased incidence of acetabular component outliers.

Heng and colleagues conducted a retrospective review of a single surgeon's last 45 conventional THAs performed prior to the surgeon's first 45 robotic-arm assisted THA. Surgical time, LOS in hospital, LOS in rehabilitation, transfusion rates and any complications were compared. The authors found that the average surgical time was 96.7 minutes for the robotic group and 84.9 minutes for the conventional group, however each robotic operation was approximately one minute shorter than the previous robotic operation and the average time for the last 10 robotic cases decreased to 82.9 mins.[94] Compared to conventional THA, there was no increased risk of complications or transfusions, and the authors noted there may be less chance of intraoperative acetabular fractures due to the single-ream, minimal bone resection technique utilized in the robotic procedure. LOS in the robotic group that did not go to rehabilitation was shorter by approximately one day and although a statistical analysis for LOS in rehabilitation was not performed due to small numbers, there was a tendency for shorter LOS in the robotic group as well.[94]

Kayani and colleagues evaluated 50 patients receiving conventional manual THA and 50 patients undergoing robotic-arm assisted acetabular cup positioning during THA. Independent observers recorded surrogate markers of the learning curve including operative times, confidence levels amongst the surgical team using the state-trait anxiety inventory (STAI) questionnaire, accuracy in restoring native hip biomechanics, acetabular cup positioning, leg-length discrepancy, and complications within 90 days of surgery. They found that integration of robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for operative times and surgical team confidence levels but there was no learning curve effect for accuracy in restoring native hip biomechanics or achieving planned acetabular cup positioning and orientation.[117]

Overall, the data showed that baseline operative times can be achieved, while increasing accuracy to plan.

The adoption of Mako SmartRobotics™

By the end of March 2024, Mako systems were installed in 43 countries and every state in the U.S. Since launch, over 500,000 1.5 million joint replacements have been performed with Mako worldwide.[118] Additionally, over 900 surgeons were trained on Mako Technology in the U.S. in 2021 alone.[119] The increasing adoption of Mako SmartRobotics™ Technology is supported by clinical success reported in published literature.

Mako has demonstrated the potential to deliver value through enhanced outcomes such as:

- Reduced pain and use of pain medications in TKA[2,41,44]
- Reduced complications such as dislocation in THA, MUA in TKA and revision in UKA[3,48,89,92,93]
- Increased patient satisfaction in TKA, THA and UKA[44,91]
- In TKA and THA, reduced utilization of health services such as skilled nursing, home health aide, readmissions and emergency room[50,51,53,54,55,100]
- Reduced payer cost in TKA, UKA and THA[50,51,53,54,55,69]

Additionally, patients have reported benefits of Mako robotic-arm assisted procedures such as:

- Treatment satisfaction and return to activities of daily living[89,91] for Mako Total Hip
- Treatment satisfaction[3,65], return to activities of daily living[79] and a "forgotten" joint[60,67] for Mako Partial Knee
- Positive early outcomes measured using PROMs[2,38,42,43] for Mako Total Knee; longer-term follow-up is ongoing

In summary, Mako SmartRobotics™ enables surgeons to achieve their target preoperative plans with precision, which may help distinguish them within their medical communities. The enhanced clinical outcomes observed to date with Mako SmartRobotics™ have the potential to provide value to patients, providers and payers alike.

Worldwide, through Q1 2024:

1.5 million+ Mako procedures performed globally to date*

18 years of robotic-arm assisted surgery experience

Mako Systems installed in **44 countries** and every U.S. state*

1,500+ patents and patent applications established globally

Over 425 published, peer reviewed **studies**

*Stryker's 2024 sales data

Cost-savings observed in the studies described in this document may differ across regions or countries due to differences in healthcare systems, treatment plans and associated costs.

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