Mako Total Knee

Clinical summary

Volume 9

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1. Introduction

Total knee arthroplasty (TKA) is an established and successful procedure for the treatment of end-stage knee arthritis.[1] Survivorship at 10 years is commonly reported in the 90th percentile,[2] while outcomes reported using patient-reported outcome measures (PROMs) demonstrate that TKA also delivers a functional benefit to patients.[3] Despite the demonstrable benefits of TKA, satisfaction rates are known to be lower than for total hip arthroplasty.[4] Reported dissatisfaction rates for TKA are around 20%.[5,6] TKA is also known to be sensitive to surgical factors such as implant positioning and soft tissue balance.[7,8] Inaccuracies in positioning and soft tissue balance have the potential to reduce implant survivorship and impact negatively on patient outcomes.[7-9]

Mako SmartRobotics™ combines 3D CT-based planning and AccuStop™ haptic technology into one platform which, in comparison to manual techniques, has been shown in clinical settings to have increased accuracy and precision of component placement to plan.[10,11] These results were achieved, in part, by preoperative three-dimensional planning, which takes into account each patient's specific anatomy. This plan can be virtually modified intraoperatively to address implant position, soft tissue balancing and flexion contractures. Features include intraoperative visual, auditory and tactile feedback provided to the user. The robotic-arm assisted technology also has an automatic switch-off option that is designed to prevent the sawblade from cutting outside the designated surgical field. This document summarizes the evidence to date supporting the use of robotic-arm assisted technology during TKA.

2. Accuracy and precision in TKA

Mako robotic-arm assisted technology offers the potential to enhance TKA. Several studies have demonstrated the efficiency of 3D planning,[12] the benefits of intraoperative joint balancing[13] and the potential for soft tissue protection.[14,15] Robotic-arm assisted total knee arthroplasty (RA-TKA) has also been found to reduce surgical variability among surgeons early in their surgical experience.[16]

2.1 Accuracy and precision with Mako Total Knee

A patient's unique anatomy and disease state can vary significantly, creating operative case complexity for the surgeon. Robotic-arm assisted technology enables the surgeon to make intraoperative decisions based on preoperative planning based on preoperative computed tomography (CT). An intraoperative feedback loop allows for implant placement adjustments, allowing surgeons to determine joint balance based on soft tissue feedback prior to making any bone cuts. Marchand et al. (2018) considered intraoperative balancing and resection data for 335 patients who underwent RA-TKA.[13] Preoperative plans were adjusted to achieve balance, defined as having a medial and lateral flexion gap difference within 2 mm. Regardless of disease state or types of deformities, all patients achieved a post-bone cut extension gap difference of between -1 mm and 1 mm (mean -0.1 mm) and 99% of patients achieved a post-bone cut flexion gap difference of between -2 mm and 2 mm (mean 0 mm) **(Figure 1)**. Additionally, there were no final minor soft tissue releases because all knees were balanced prior to bone cuts and there were no further changes during trial stage. The capacity to visualize changes in joint balancing and adjust component position prior to bone cuts allowed the surgeon to adopt a balancing resection technique associated with robotic-arm assisted surgery.

Figure1. Knee (A) extension and (B) flexion final implant planning; 100% of patients achieved a post-bone cut extension gap difference between -1 and 1 mm (mean -0.1 mm), and 99% of patients achieved a post-bone cut flexion gap difference of between -2 mm and 2 mm (mean 0 mm).[13]

The ability to preoperatively plan can assist in selecting appropriately sized implants,[17] a factor which is critical to the success of TKA.[18] Robotic-arm assisted technology requires the use of a preoperative CT that is used to perform 3D templating. In a study performed by Bhimani et al. (2017), consecutive patients underwent unilateral RA-TKA.[12] Three-dimensional planning software specific to the Mako System was used to provide an initial preoperative implant plan which was then updated intraoperatively based on risk of anterior femoral notching. This minimized medial and lateral overhang of the tibial and femoral implants and maximized tibial cortical contact. The plan matched the implanted component size correctly in 96% of femoral implants and in 89% of tibial baseplates. In comparison, studies comprising a 2D technique matched the implanted implant size in 43.6% to 68% of cases.[12] For the 3D technique, all disparities between the predicted and actual tibial sizes were due to the presence of osteophytes.[12] One hundred percent of the actual tibial baseplates and femoral implants used were within one size of the preoperatively predicted size. There were no cases of femoral notching or of medial or lateral implant overhang on the femoral or tibial sides.

Additionally, studies have shown that the use of the Mako Total Knee system has impacted surgeons' selection of implant size. Across three recent studies, RA-TKA has demonstrated superior accuracy and consistency in implant sizing and polyethylene liner selection compared to manual techniques.[19-21] Bernstein et al. found that RA-TKA, using CT-based 3D planning, resulted in larger tibial baseplates and smaller femoral components, potentially optimizing bone coverage and biomechanics.[19] Bourgeault-Gagnon et al. showed that RA-TKA significantly reduced the prevalence of liner thickness outliers and deviation from planned thickness, with a short learning curve to achieve reproducibility.[20] Henry et al. demonstrated that CT-based preoperative templating in RA-TKA accurately predicted final implant sizes within one size in over 98% of cases, improving operating room efficiency and reducing waste.[21] Collectively, these findings highlight the potential of RA-TKA to enhance surgical precision, reduce variability, and improve procedural efficiency.

While manual TKA (M-TKA) has demonstrated clinical success,[22] a meta-analysis of component alignment found mechanical axis malalignment of greater than 3° in 9.0% of computer-assisted surgeries and 31.8% M-TKA surgeries.[23] In a cadaveric study, a high-volume surgeon with no prior clinical robotic experience performed a matched pair comparison of M-TKA to RA-TKA on six cadaveric specimens (12 knees).[24] A learning curve was considered and the first three specimens were eliminated from comparison. The last three RA-TKA and M-TKA matched pairs found that RA-TKA demonstrated greater accuracy and precision of bone cuts and component placement to plan compared to M-TKA. On average, RA-TKA (n=6) final bone cuts and final component positions were 5.0 and 3.1 times more precise to plan than the M-TKA control, respectively.

Furthermore, this study demonstrated RA-TKA has the potential to increase both the accuracy and precision of bone cuts and implant positioning to plan for an experienced manual surgeon who is new to RA-TKA. The ability to properly align components to plan during TKA is paramount to implant function and survivorship.[25, 26] Therefore, a nonrandomized, prospective multicenter clinical study was conducted to compare implant placement accuracy to plan between a RA-TKA and M-TKA cohort.[27] All patients received a CT scan at approximately six weeks postoperatively to analyze implant placement to plan. Average component positions for manual and RA-TKAs are provided in **Table 1**. Comparing absolute deviation from plan between groups, RA-TKA demonstrated clear benefits for tibial component alignment to plan (1.5° vs. 0.8°, $p<.001$), tibial slope (2.7° vs. 1.1°, $p<.001$) and femoral component rotation (1.4° vs. 0.9°, $p<0.02$). Femoral component and overall limb alignment accuracy were comparable ($p>0.10$). Compared to M-TKA, RA-TKA cases were typically 47% more accurate to plan for tibial component alignment, 59% more accurate to plan for tibial slope and 36% more accurate to plan for femoral component rotation.

	M-TKA (n=52)	RA-TKA (n=58)	p-value[1]
Overall limb alignment	2.4 / 1.8 (0.8, 2.6)	2.2 / 2,1 (0.9, 2.7)	0.972
Tibial component alignment	2.1 / 1.5 (0.8, 2.5)	1.2 / 0.8 (0.4, 1.6)	<.001
Tibial component posterior slope	3.0 / 2.7 (1.3, 4.5)	1.3 / 1.1 (0.6, 1.7)	<.001
Femoral component alignment	1.3 / 1.0 (0.3, 1.7)	0.9 / 0.8 (0.3, 1.4)	0.198
Femoral component rotation[2]	1.9 / 1.4 (0.9, 2.5)	1.1 / 0.9 (0.7, 1.5)	0.015
Femoral component flexion	n/a[3]	1.8 / 0.8 (0.4, 1.6)	

1. Stratified Wilcoxon (Van Elteren) test controlling for center
2. Includes 30 manual and 30 RA-TKA of one site (CT data of second site was in progress at time of publication)
3. Femoral flexion is not explicitly targeted with manual TKA technique

Table 1. Absolute deviation from surgical plan (degrees, mean/median (25th, 75th percentiles)

In a clinical study, Sire et al.[28] (2020) evaluated accuracy of intraoperative component alignment for 29 cases through postoperative CT analysis of component placement when compared to the intraoperative plan for component placement. Overall, intraoperatively measured component alignment was within 1.03° to 1.90° of plan and overall limb alignment was within 1.29° of plan, which was comparable to findings from previously reported RA-TKA literature. In addition to component alignment, Sire et al.[29] considered accuracy of bone resection to plan of procedures performed using the Mako Total Knee System. Bone resection depths of the distal femoral, anterior femoral and tibial cut planes were measured on a series of 45 consecutive cases. A total of 37 patients had their data captured using the Mako System software. In total, 99 out of 105 (94.29%) of bone resection measurements taken were within 1 mm of the plan **(Figure 2)**.

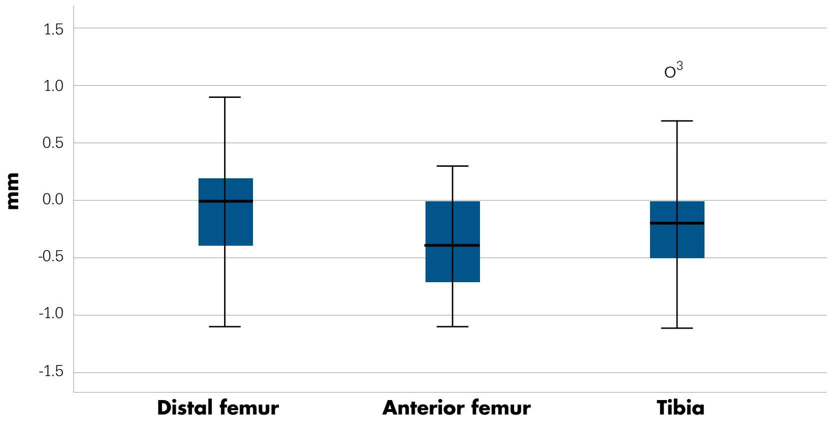


Figure 2. Sire et al.[29] measured bone resection depth for the distal femoral, anterior femoral and tibial cut planes. Box and whisker plots of the bone resections performed highlight the median, interquartile range, maximum and minimum values. Positive values indicate more bone was resected than planned, and negative values indicate less bone was resected than planned.

Byren et al. evaluated the impact of RA-TKA on radiographic outcomes when performed by a low-volume, non-arthroplasty-trained orthopedic surgeon.[30] Comparing 19 RA-TKAs with 41 M-TKAs, the research found that RA-TKA significantly reduced radiographic outliers such as tibial slope deviations and notching, while also trending toward improved tibial tray alignment. The study concludes that RA TKA offers measurable benefits in surgical precision for surgeons who perform TKAs infrequently, though further research is needed to confirm long-term outcomes and broader applicability.

A study by Summers et al compared accuracy of RA-TKA with M-TKA in achieving both coronal and sagittal alignment targets.[31] Conducted by three high-volume surgeons, the study analyzed 201 RA-TKAs and 364 M-TKAs, finding that RA-TKA significantly reduced radiographic outliers across nearly all measured parameters, particularly in sagittal alignment. RA-TKA achieved more accurate femoral and tibial sagittal angles, anterior and posterior condylar offsets, and proximal tibial angles, with a higher proportion of patients having no alignment outliers and fewer with multiple outliers. While both techniques showed similar results for femorotibial angle alignment, RA-TKA consistently outperformed M-TKA in precision and consistency. The study concludes that RA-TKA offers superior alignment accuracy, especially in the sagittal plane, which may contribute to improved implant longevity and functional outcomes, though further research is needed to confirm clinical correlations.

2.2 Restoring kinematic function

Placement of a component according to plan is not the only factor that can influence stability in TKA; to achieve a functionally stable knee, the implant must also be placed with respect to the patient's individual anatomy. In particular, a patient's posterior condylar offset ratio (PCOR) and Insall-Salvati index (ISI) may correlate with the final achievable joint range of motion (ROM). Sultan et al. (2019) conducted a prospective, cohort-matched study to compare 43 consecutive RA-TKA cases with 39 M-TKA cases.[32] Four- to six-week postoperative radiographs were used to assess each patient's PCOR and patella height based on the ISI. The mean postoperative PCOR was larger in M-TKA when compared to the RA-TKA cohort (0.53 vs. 0.49; p=0.024) **(Table 2)**. The absolute mean difference between pre-and postoperative PCOR was larger in manual when compared to robotic-arm assisted TKA (0.03 vs. 0.004; p=0.01). In addition, the number of patients who had postoperative ISI outside of the normal range (0.8 to 0.12) was higher in the manual cohort (12 vs. 4). In conclusion, patients who underwent RA-TKA had smaller mean differences in PCOR, which has been previously shown to correlate with better joint ROM at one year following surgery.[33] In addition, these patients were less likely to have values outside of normal ISI, which meant they were less likely to develop patella baja,[34] a condition in which the patella impinges onto the patellar component, leading to restricted flexion and overall decreased ROM.

Comparison of robotic-arm assisted and manual radiographic measurements

	RA-TKA	M-TKA	p-value
Preoperative Insall-Salvati index	0.91 (0.59-1.23)	0.93 (0.61-1.3)	0.469
Postoperative Insall-Salvati index	1 (0.1-1.5)	1 (0.7-1.5)	0.049
Preoperative PCOR	0.49 (0.4-0.6)	0.50 (0.4-0.6)	0.937
Postoperative PCOR	0.49 (0.41-0.55)	0.53 (0.41-0.6)	0.024
Absolute mean difference in PCOR	0.004	0.03	0.05

Table 2. The posterior condylar offset ratio is defined as the ratio of the posterior condyle offset to the diameter of the femur (a) or PCOR = A/B. The use of the robotic-assisted system allowed the surgeon to more closely reproduce the preoperative PCOR when compared to use of manual instrumentation.[32]

Surgeons use many different philosophies when balancing a TKA. Literature has typically described 2D alignment philosophies such as mechanical alignment and kinematic alignment. More recently, Functional Knee Positioning (FKP) has been described as a 3D balancing strategy that utilizes intraoperative technology based on 3D CT scan to assess individualized plan position and subsequently balance the knee prior to bone cut, helping to minimize the need for soft tissue releases.[35] Literature has begun to report on the use of functional positioning related to patient reported outcomes.[35,36] In the first study of its kind, Clark et al. compared 2-year outcomes of patients who underwent a functionally aligned TKA with an initial mechanical plan with those who underwent functionally aligned TKA with an initial individualized alignment plan using symmetrical resections. In this study, patients with constitutional varus (CPAK Type I) knees reported the greatest improvement in outcomes. This study demonstrated using an implant alignment plan that considers a patient's native joint line led to a final functional implant position with greater joint line obliquity.[37]

In a study by Manara et al, they compared functional alignment (FA) and adjusted mechanical alignment (aMA) techniques in RA-TKA using cruciate-retaining implants.[38] Among 60 randomized patients, FA more consistently reproduced native knee kinematics, particularly the medial pivot pattern, which occurred in 58.6% of FA cases versus only 19.4% in aMA. Lateral pivot patterns, associated with poorer outcomes, were significantly more common in the aMA group (35.5%). Although overall patient-reported outcomes at one year were similar between alignment groups, those with medial pivot kinematics showed superior scores in measures such as the Forgotten Joint Score, EQ-5D VAS, and Kujala score. The study concludes that FA better restored native knee biomechanics and was associated with improved clinical outcomes, suggesting that alignment technique directly influences intraoperative kinematics and postoperative function.

Retaining the posterior cruciate ligament (PCL) during total knee arthroplasty is designed to preserve femoral rollback and improve extensor function.[39, 40] Kinsey et al. (2019) studied how protection of the PCL during TKA correlated to femoral rollback during active flexion as well as total range of motion.[41] A prospective, comparative cohort study was performed which included 33 M-TKAs and 44 RA-TKAs enrolled consecutively. At six weeks postoperative, the RA-TKA group showed a positive linear correlation between knee flexion angle with femoral rollback ($r=0.63$, $p<0.01$), while the M-TKA group showed no association ($r=0.00$, $p=0.998$). Additionally, the RA-TKA group showed 8° greater mean flexion compared to the M-TKA group ($p=0.031$) **(Figure 3)**. The RA-TKA group showed a pattern strongly consistent with physiological rollback, while the M-TKA group showed no association. Increased femoral rollback was directly associated with greater passive knee flexion after implantation and in terms of clinical outcome, the RA-TKA group overall showed greater average knee flexion at short-term follow-up.

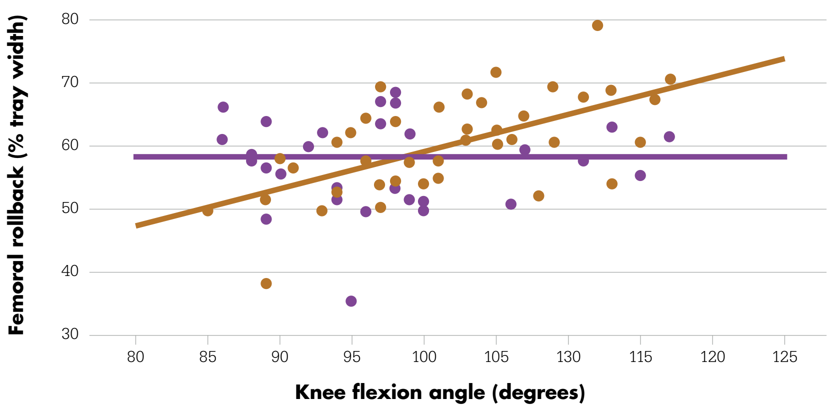


Figure 3. Kinsey et al. evaluated the influence of PCL preservation on femoral rollback. A scatter plot was used to show association of femoral rollback with knee flexion angle measured from postoperative lateral radiographs of the same CR TKA device implanted with RA-TKA (gold) vs. M-TKA (purple). The RA-TKA group showed strong positive linear correlation ($p=0.63$, $p<0.001$) while the M-TKA group showed no association ($r=0.00$, $p=0.998$)[41]

Gregori et al. evaluated the safety and short-term outcomes of functional alignment (FA) when using RA-TKA for patients with valgus deformity. In a cohort of 58 patients with preoperative valgus alignment (HKA ≥ 183°), FA was performed using the RA-TKA without soft tissue releases. At a median follow-up of 18 months, 86.2% of patients achieved coronal alignment within the safe zone (HKA 177–183°), and significant improvements were observed in Knee Society Scores, with excellent Oxford Knee Scores and Forgotten Joint Scores. Only two complications occurred (one aseptic loosening and one infection), and implant survivorship was favorable. The study concludes that FA in RA-TKA is an appropriate technique for valgus knees, achieving satisfactory alignment and clinical outcomes by accommodating individual soft tissue laxities rather than enforcing neutral alignment.[42]

2.3 Soft tissue protection

A cadaveric study was performed to assess soft tissue protection in TKA by examining damage to 14 soft tissue structures, including the deep medial collateral ligament (dMCL), posterior cruciate ligament, popliteus, iliotibial band (ITB) and patellar ligament, following RA-TKA and M-TKA.[15] A total of 24 paired cadaveric knees (12 RA-TKA and 12 M-TKA) were prepared by four surgeons. An additional two surgeons, blinded to the method of preparation, graded structure damage using direct visual grading and arthroscopic imaging. No intentional soft tissue releases were performed in either group to balance the knee. Grading of soft tissue damage postoperatively determined that significantly less damage occurred to the PCL in the haptic-controlled RA-TKA than in M-TKA specimens ($p=0.004$) **(Figure 4)**. RA-TKA specimens also experienced less damage to the dMCL ($p=0.186$), ITB ($p=0.5$), popliteus ($p=0.137$) and patellar ligament ($p=0.5$). It was concluded that these findings can potentially be attributed to RA-TKA using a stereotactic boundary to constrain the sawblade, which can prevent unwanted soft tissue damage.

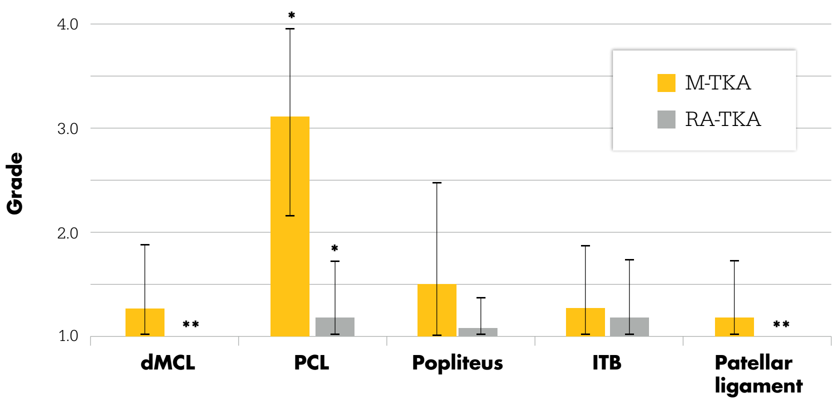


Figure 4. Iatrogenic soft tissue damage was assessed and graded 1-4, where higher numerical values represent higher levels of damage. Average grade values are shown for extent of damage to the dMCL, PCL, popliteus, ITB, and patellar ligament in M-TKA and RA-TKA specimens. Error bars indicate standard deviations.
*PCL showed significant difference ($p<0.05$);
** Grade average ± standard deviation for dMCL and patellar ligament was 1 ± 0.15

Assessment of iatrogenic bone and soft tissue injury was continued by Kayani et al. (2018) in a clinical setting.[14] This study comprised a prospective cohort of 30 consecutive M-TKAs followed by 30 consecutive robotic arm-assisted total knee arthroplasty (RA-TKA) knees. All surgeries were performed by a single surgeon and both groups were prepared for a posterior stabilized prosthesis. Intraoperative photographs of the femur, tibia and periarticular soft tissues were taken before implantation of the prostheses. A macroscopic soft tissue injury (MASTI) classification system was developed to grade iatrogenic bone and soft tissue injuries. Assessment of images indicated that patients undergoing robotic arm-assisted Total Knee had reduced medial soft tissue injury in both passively correctible ($p<0.05$) and non-correctible varus deformities ($p<0.05$), more pristine femoral ($p<0.05$) and tibial ($p<0.05$) bone resection cuts and improved MASTI scores compared to M-TKA ($p<0.05$). Findings from this study were in keeping with the previous cadaveric study.[15] Kayani et al. (2018) reported soft tissue trauma that may be considered subtle subclinical findings but also mentioned previous studies that have shown even limited soft tissue releases may promote changes in local and systemic inflammatory responses, leading to increased pain and delayed postoperative rehabilitation.[14]

To further evaluate this hypothesis on the correlation between soft tissue injury and a systemic inflammatory response, Kayani et al. (2021) performed a prospective randomized controlled trial that included 30 RA-TKAs and 30 M-TKAs to evaluate the patient's serum markers of inflammation.[43] Samples were collected preoperatively as well as postoperatively at six hours, day 1, day 2, day 7 and day 28 following TKA. The RA-TKA group had significantly reduced levels of interleukin-6 (IL-6, $p < 0.001$), tumor necrosis factor-α (TNF-α, $p = 0.021$), ESR ($p = 0.001$), CRP ($p = 0.004$), lactate dehydrogenase ($p = 0.007$) and creatine kinase ($p = 0.004$) at day 7 after surgery compared with M-TKA. RA-TKA was also associated with significantly improved preservation of the periarticular soft tissue envelope ($p < 0.001$) and reduced femoral ($p = 0.012$) and tibial ($p = 0.023$) bone trauma compared with M-TKA.[43] Increased levels of IL-6 and TNF-α in the early postoperative period in the MKA group may be due to a greater overall systemic insult of this procedure compared with RA-TKA.[43] This may be attributable to increased periarticular soft tissue injury and greater femoral and tibial bone surface trauma in M-TKA compared with RA-TKA.[43] The use of a handheld sawblade with manual cutting guides in the M-TKA group may have also created metal debris and promoted additional inflammation in this group. Another possible explanation is the use of intramedullary femoral referencing in the M-TKA group, which has been shown to induce a systemic inflammatory response.[43]

2.4 Influences on surgical intraoperative variables

Hampp et al. (2018) studied two surgeons undergoing orthopaedic fellowship training to better understand how a robotics system can affect surgeon variability and mental exertion when performing TKA.[16] Each surgeon prepared six cadaveric legs for cruciate retaining TKA, with M-TKA on one side (three knees) and RA-TKA on the other (three knees) and under the instruction to execute a full TKA procedure through trialing to achieve a balanced knee. Assessment of the final procedure indicated that robotic technology reduced variability of the TKA procedure. The RA-TKA cases were more likely to use the minimum poly thickness of 9 mm, required less post-resection recuts to achieve a balanced knee and had a greater perceived planarity and the surgeons were more likely to recommend using a cementless implant. Additionally, the operating surgeons reported reduced mental effort when performing bone measurements, tibial bone cutting, knee balancing, trialing and post-resection adjustments with RA-TKA compared to M-TKA. Results indicated that the preplanning and execution of the robotic system were useful in reducing surgical variability and mental exertion for surgeons early in their surgical experience.

3. The adoption of Mako Total Knee in the operating room

Although there are a number of potential benefits to adopting robotic-arm assisted technology,[11-14,44-47] studies have 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.[48] One surgical group has quantified this learning curve to likely take between 10 and 15 cases, regardless of the level of experience of the surgeon.[48] In an intraoperative study, the use of Mako Total Knee was associated with increased energy expenditure from the surgeon, but with one less operating room assistant involved than for a manual procedure.[48] Research in a cadaveric lab setting found that robotic-arm assisted technology resulted in a reduced risk of neck injury and increased satisfaction for the surgeon.[49,50] Furthermore, based on data from another cadaveric lab, a surgical assistant had reduced ergonomic risk as they were no longer required to participate in instrument placement and had reduced participation in soft tissue retraction throughout the procedure.[50]

3.1 Surgical team learning curve

As with most new surgical techniques, there is a learning curve associated with RA-TKA. Sodhi et al. (2017) performed a study to assess this learning curve, in which two surgeons performed a total of 240 robotic-arm assisted cases.[47] 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. **Figure 5** provides surgical times for both surgeons. 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 adequately perform RA-TKA without any added operative time.[47]

Surgical time to perform robotic-arm assisted TKA vs. manual TKA

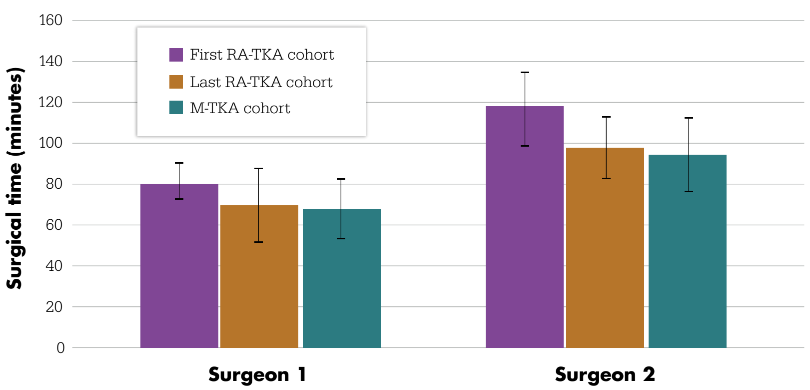


Figure 5. Mean surgical time data for RA-TKA and M-TKA indicate that within a few months, a surgeon should be able to perform RA-TKA without any added operative time. For both surgeons, mean surgical time was greatest for the first cohort of 20 RA-TKA cases when compared to the last cohort of 20 patients. The last cohort of 20 RA-TKA cases were time neutral to the surgeons' 20 M-TKA cases.[47]

Similar results were described by Bhowmik-Stoker and colleagues who evaluated the time-based learning curve of RA-TKA in 146 surgeons at 30 hospitals using a Bayesian model.[51] They found that learning curve, as defined by time neutrality to M-TKA, was observed at the 12th case and the model demonstrated steady state time neutrality between 15 and 20 cases.[51]

In another learning curve study, Fleischman et al. (2018) followed a separate group of two surgeons with differing levels of TKA experience.[48] Each surgeon performed a minimum of 20 RA-TKA cases (n=45) and the times required to perform specific tasks were compared to M-TKA cases (n=48) from the same period. Time points measured included: 1. Tracker placement (pin time), 2. Landmarks and anatomic registration (registration time, 3. Bone preparation and cutting (cutting time) and 4. Ligament balancing and implant trialing (trialing time), where pin time and registration time were specific to the Mako Total Knee application. A mean arthroplasty time of 24.9 minutes was measured for RA-TKA, which was a 22.8 minute reduction in time from the first three RA-TKA cases. There was a 4.2 minute reduction in mean pin time, 5.3 minute reduction in mean registration time, 5.8 minute reduction in cutting time and a 7.3 minute reduction in mean trialing time. It was concluded that surgeons completed their learning curve within their first 10 to 15 cases, regardless of surgical experience.

To understand how patient outcomes are influenced during a surgeon's learning curve, Naziri et al. (2019) reported on a single surgeon experience comparing their first 40 RA-TKA cases to a matched consecutive MATKA cohort.[52] During the first 40 cases, the RA-TKA group had a slightly greater overall surgical time when compared to the MATKA group (82.5 minutes vs. 78.3 minutes, p=0.002), however this difference was no longer statistically significant when only the second set of 20 RA-TKA cases was considered (81.1 minutes vs. 78.3 minutes, p=0.254). During this 40-case cohort, the RAKTA cohort showed a reduced length of stay (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 Knee Society Scores (KSS) or lower extremity activity scale (LEAS) at 30, 60 and 90 day follow-up between groups. It was concluded that the surgeon's learning curve for RA-TKA appeared to progress rapidly, with a comparable OR time to M-TKA by the second 20 cases.

To help sites reach an efficient workflow, Hiraoka et al. (2025) published on how to create an efficient intra-operative workflow. They explored the impact of applying efficiency principles on operational excellence of surgery by collecting data via an AI-enabled camera, to measure operative time, staff activities and instrument usage.[53] patients were divided over 8 surgical days between Oct 2023 and May 2024. They all had Mako RA-TKA performed by the same 5 person OR team including an experienced surgeon, instrumenting nurse, circulating nurse, anesthesiologist and a sales representative. Their findings indicated that better OR preparation, consistent staff allocation and effective staff training can reduce surgical times, minimize waste and improve OR throughput. These learnings are worth understanding as Mako is introduced into a new OR environment, to help create an efficient workflow.[53]

3.2 Surgical team usability

Studies show how robotic arm-assisted TKA impacts the patient.[44,46] Recent work has sought to understand how this technology affects the surgeon. Literature indicates that multiple factors can influence a surgeon's incidence of injury.[54,55] Approximately 44% to 66% of orthopaedic surgeons have had a work-related injury attributed to poor surgeon posture.[56, 57] Additionally, hospital staff routinely takes on ergonomically challenging tasks, which has been shown to decrease longevity of performing in the operating room.[58] Thus, it may be beneficial to institute measures to lessen the likelihood for injury by improving ergonomics in the operating room and decreasing energy expenditure for surgeons and operating room staff.

Ergonomics is the study of people's efficiency in their working environment. When evaluating the ergonomics of orthopaedic surgery, the cervical spine, lumbar spine and shoulders are the areas of greatest concern.[56, 57] Motion sensors placed in these locations can indicate whether performing surgical procedures such as TKA place strain and the amount of such strain by measuring angles, elevation and electromyography. Workload questionnaires can also assess surgeons' mental and physical demands when performing surgical procedures. In a study focused on surgeon ergonomics, it was found that the surgeon had lower overall ergonomic risk when performing RA-TKA compared to M-TKA as well as a reduced occiput angle.[58,59] Improved ergonomics were attributed to the surgeon's arm having a more favorable range of motion and reduced number of repetitive tasks. Additionally, surgeons reported a higher overall satisfaction with performing a RA-TKA compared to M-TKA as well as less mental and physical demand based on the results of a workload questionnaire.[59]

A second study, performed by Gapinski et al. (2025), used a posture-tracking wearable to evaluate time spent slouching of three high volume TKA surgeons who were proficient in both manual and robotic-assisted TKA procedures.[60] They prospectively considered 55 manual TKAs and 48 Robotic-assisted TKAs. The wearable device was positioned on the surgeons' spine at the level of the cervicothoracic junction to collect motion of the spine. Slouching was defined as 30° of flexion from the neutral spinal axis. Results showed surgeons reduced slouching by 30% while performing RA-TKA compared to M-TKA which converted to an average 19.3 minutes of case time ($p < 0.001$). Gapinski et al concluded surgeons performing RA-TKA cases spend significantly less case time and case percentage in a slouched posture compared to primary M-TKA cases.[60]

Blevins et al. (2018) performed an intraoperative study to assess how the use of RA-TKA can influence energy expenditure when compared to M-TKA.[49] This study found that a lower-volume arthroplasty surgeon expended less energy when using the Mako System compared to high-volume arthroplasty surgeons using Mako and when carrying out M-TKA.[49] In addition, this study found that one fewer surgical assistant was needed in the operating room when performing Mako Total Knee procedures.[49]

Finally, a study by Scholl et al. (2018) focused on the ergonomics of a surgical assistant.[58] It was found that the surgical assistant demonstrated less shoulder movement when performing RA-TKA compared to M-TKA as there was no placement of jigs and array placement and bone registration required less shoulder elevation compared to motions performed during M-TKA.[58]

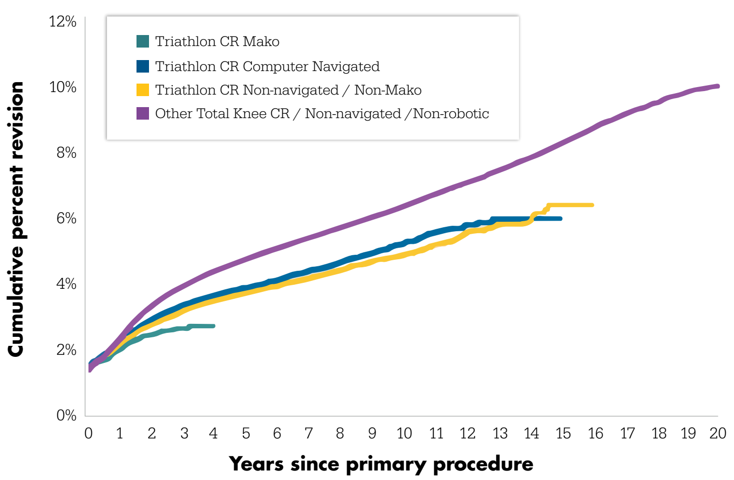
To help reduce the risk of injury to surgeons, it is important to evaluate the ergonomics of surgical procedures and help surgeons to more efficiently perform their cases. In the above studies, evaluation of surgeon energy expenditure, posture and mental demand determined that Mako Total Knee demonstrated improved ergonomics compared to manual TKA.[49, 59, 60] Shoulder motion was also improved for an orthopaedic surgical assistant.[58] Utilizing Mako Total Knee may help improve the posture and ergonomics of orthopaedic surgeons and orthopaedic surgical staff.

4. What are the potential clinical benefits of Mako Total Knee?

The Mako Total Knee application was launched in June 2016. Initial Mako Total Knee patients continue to be followed as they reach postoperative time points and a growing cohort of publications have become available on clinical outcomes.[44,46,61-71] Studies have investigated implant survivorship,[69] clinical outcomes,[44,46,61-68] functional outcomes,[61-63, 70] hospital length of stay[46,71] and early pain management[46,72,73] in Mako Total Knee patients, with favorable results in comparison to other surgical methods.

4.1 Survivorship

In a special report from the Australian Orthopaedic Association, early revision data for TKA procedures performed with the Mako robotic-arm assisted system in the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) were compared against conventional instrumented and computer navigated TKA revision data.[69] The 3-year cumulative percent revision (CPR) for RA-TKA procedures with the Triathlon Cruciate Retaining (CR) prosthesis was 1.3%. The CPR using the same prosthesis with computer navigated and conventional instrumentation was 2.0% and 1.8%, respectively (Table 3). **Figure 6** shows statistically lower rates of revision for RA-TKA over the study period (4.95 years) when compared to Triathlon CR computer navigated (HR = 0.72 (95% CI 0.60 to 0.86, p<0.001).[69]



HR - adjusted for age and gender

Triathlon CR Mako vs. Triathlon CR Computer Navigated

Entire Period: HR=0.69 (0.58, 0.82),p<0.001

Triathlon CR Mako vs. Triathlon CR Non-Navigated Non-Mako

Entire Period: HR=0.72 (0.60, 0.86),p<0.001

Triathlon CR Mako vs. Other Total Knee CR Non-Navigated Non-Robotic

0 - 9Mth: HR=0.64 (0.53, 0.76),p,0.00

9Mth - 1.5Yr: HR=0.49 (0.41, 0.59),p,0.001

1.5Yr+:HR=0.48 (0.41, 0.58),p<0.001

Figure 6. Cumulative percent revision of minimally stabilized primary TKA (all diagnoses) from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR).[69]

A retrospective study performed by Woelfle et al, evaluated the impact of RA-TKA on the success of cementless component fixation using a single implant system.[74] Among 319 cementless components implanted by five surgeons between 2018 and 2022, RA-TKA was used in 123 femoral and 92 tibial cases, while M-TKA was used in 50 femoral and 54 tibial cases. At an average follow-up of 18.7 months, 97.8% of components achieved successful fixation. Notably, no femoral components in either group failed due to aseptic loosening, but four manually implanted tibial components required revision, compared to none in the RA-TKA group, a statistically significant difference (7.4% vs. 0.0%, $p = 0.009$). The findings suggest that while femoral component fixation was consistently successful, RA-TKA significantly improved tibial component survivorship in cementless TKA.

4.2 Patient reported outcomes

Chen et al. performed a retrospective study to compare the 90-day complication rate between M-TKA and RA-TKA.[75] Cases from large patient cohorts (43,865 M-TKA, 26,706 RA-TKA) across 93 hospitals from January 2017 to December 2020 were evaluated. Complication rates were compared between the cohorts using Fischer's exact test analysis for: deep vein thrombosis, pulmonary embolism, venous thromboembolism (VTE), pain, cellulitis/cutaneous abscesses, superficial and deep surgical site infection (SSI) and transfusion. The analysis discovered, at 90 days post operation, RA-TKA patients had significantly less cellulitis and VTEs. There were higher cellulitis/cutaneous abscesses ($p=0.28$) and VTE ($p=0.008$) in M-TKA compared to the RA-TKA. The cause of the reduced rate of cellulitis/cutaneous abscesses may be attributed to less soft tissue damage in the RA-TKA cases while the lower VTE rate is most likely related to the use of intramedullary rods in M-TKA.[77]

Marchand et al. (2017, 2019, 2021) published a single surgeon study that was performed on consecutive RA-TKA patients matched with consecutive M-TKA patients.[61-63,76] A Western Ontario and McMaster Universities Arthritis Index (WOMAC) survey including pain, stiffness and physical function subcategories was administered to patients at their six-month, one-year and two-year postoperative visits. The RA-TKA cohorts demonstrated significantly improved mean total satisfaction and physical function scores when compared to the M-TKA cohorts at six months, one year and two-years.[61-63,76] Additionally, at six months and two-years the RA-TKA cohort had significantly reduced total pain score when compared to the M-TKA cohort.[61,62] Although it involved a limited cohort, this study showed promising outcomes for up to two years for RA-TKA patients when compared to the M-TKA control group.[61-63,76] The three year post operative clinical outcomes also showed promise.[63,76]

There was 100% survivorship at final follow-up at 3 years. The pain scores in the RA-TKA cohorts were 1 ± 2 (range, 0 to 14) while M-TKA was 2 ± 3 (range, 0 to 17) ($p<0.05$). Physical function scores in the RA-TKA cohort were 3 ± 4 (range, 0 to 18) compared to the M-TKA cohort 5 ± 4 (range, 0 to 32) and mean total WOMAC scores for the RA-TKA cohort were 5 ± 4 (range, 0 to 32) compared to 7 ± 8 (range, 0 to 35) ($p < 0.05$) in the M-TKA cohort.[78] **(Table 3)**. These results indicate the potential of this surgical tool to help improve short-term pain, physical function and total satisfaction scores. [61-63,76]

Final follow-up WOMAC scores	Robotic-assisted TKA	Manual TKA	p-value
Pain	1±2 (range, 0–14)	2±3 (range, 0–17)	<0.05
Physical function	3±4 (range, 0–18)	5±5 (range, 0–19)	<0.05
Total	5±4 (range, 0–32)	7±8 (range, 0–35)	<0.05

Abbreviations: TKA, total knee arthroplasty; WOMAC, Western Ontario and McMaster Universities Index.

Table 3. Absolute deviation from surgical plan (degrees, mean/median (25th, 75th percentiles)

As the body of evidence grows, several studies have reported early follow up. A retrospective review was performed by Wang et al. (2019), where a single high-volume surgeon performed 148 RA-TKA cases and 159 M-TKA cases with matched demographics.[64] The RA-TKA cohort experienced a significantly longer tourniquet time when the learning curve phase was included (96.8 minutes vs. 91.6 minutes, p=0.001), however this difference was not observed when the last 20 RA-TKA cases were compared to the M-TKA cases (93.8 minutes vs. 91.6 minutes, p=0.506). Postoperatively, the RA-TKA 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 improved outcomes followed through to one year, where the RA-TKA group had improved KOOS Jr. (p=0.034) and FJS (p=0.021) **(Table 4)**. These favorable results for the RA-TKA group indicate patient outcomes continued to be improved out to one year postoperative when compared to the conventional M-TKA technique.[64]

	M-TKA (159)	RA-TKA (148)	p-value
	Preop PROMs		
VR-12 MCS	55.32 (52.81–57.82)	55.01 (53.03–57.00)	0.853
VR-12 PCS	32.93 (30.83–35.03)	31.77 (29.99–33.54)	0.408
KOOS, Jr	53.93 (49.72–58.14)	52.90 (49.85–55.95)	0.697
FJS	N/A	N/A	—
UCLA	5.23 (4.38–6.07)	5.34 (4.94–5.74)	0.820
	Postop PROMs		
VR-12 MCS	55.27 (53.61–56.92)	55.84 (54.10–57.57)	0.345
VR-12 PCS	41.15 (39.19–43.10)	43.18 (41.36–44.99)	0.562
KOOS, Jr	72.18 (69.34–75.02)	76.31 (73.89–78.73)	0.041
FJS	52.69 (41.36–64.02)	58.62 (52.22–64.98)	0.024
UCLA	5.65 (5.25–6.04)	8.08 (5.73–6.43)	0.070
	Δ PROMs		
VR-12 MCS	−1.48 (−5.50–2.54)	0.56 (−1.99–3.11)	0.378
VR-12 PCS	9.83 (7.38–12.28)	11.09 (7.13–15.05)	0.928
KOOS, Jr	15.57 (7.58–23.55)	23.58 (18.88–28.27)	0.037
FJS	N/A	N/A	
UCLA	0.47 (−0.28–1.23)	0.76 (0.30–1.22)	0.078

Table 4. Patient reported outcome measures reported by Wang et al. (2019).[64]

In a study led by Malkani et al. (2019), five fellowship trained, high-volume surgeons at different institutions performed a total of 188 total knee arthroplasty surgeries using Mako Total Knee and had a two-year minimum clinical follow-up.[66] All patients reported excellent postoperative outcomes for FJS, SF-12 and KSS. The mean postoperative SF-12 Mental Component Score (MCS) and Physical Component Score (PCS) were both 57 points, with 50 as the threshold for norm-based scoring (MCS range: 42 to 69 points; PCS range: 41 to 68 points). The mean FJS was 75 points (range: 14 to 100 points). The mean KSS functional score was 84 points (range: 20 to 100) while the mean KSS knee score was 92 points (range: 40 to 100). Similarly, the authors found that aseptic revision rates were low (n=2, 1.06%, one for unexplained pain and another for a post-traumatic tibial fracture) with few other postoperative complications (n=7 patients [3.7%]) in this cohort. This analysis found that patients had excellent outcomes across multiple PROMs and clinical metrics at midterm patient follow-up after a RA-TKA.[66]

In a follow-up to the study by Malkani et al. (2019), the same 188 RA-TKA patients were paired to a consecutive equal number of control patients who underwent M-TKA by each of the specific surgeons for comparison.[67] All patients followed similar postoperative rehabilitation starting on postoperative day one. Rates of manipulation under anesthesia (MUAs) were evaluated within and between cohorts. Additionally, the percent difference of rates was calculated to compare cohorts. All patients were evaluated at a minimum of two-years follow-up time from the index procedure. It was found that the overall MUAs for the RA-TKA cohort was 1.06% (2/188 patients), while it was 4.79% in the control cohort (9/188, p=0.032) **(Figure 7)**. Given that MUAs can be a marker of knee stiffness following total knee arthroplasty, the lower rate observed in the RA-TKA cohort indicates that RA-TKA cohort patients had less knee stiffness and, therefore, greater initial postoperative range of motion than the control cohort. Based on this data, assistive technologies may have an advantageous role contributing to enhanced patient outcomes.

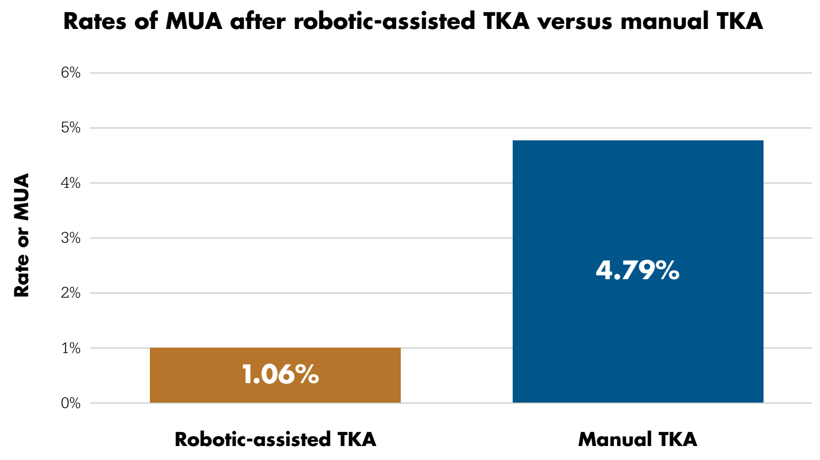


Figure 7. Malkani et al. found a 4.5-fold increase in MUA rates for their manual TKA cohort when compared to the robotic–assisted TKA cohort (4.79% vs. 1.06%, p=0.032).[67]

Gustke et al. (2020) compared an initial and consecutive series of RA-TKA cases to a group of non–robotic-arm assisted total knee arthroplasties (NRA-TKA).[68] At two years, a total of 70 RA-TKA patients (87.5% follow-up rate) and 70 NRA-TKA patients (76.9% follow-up rate) reported KS-KS, KS-FS and FJS. Results indicated both cohorts began to reach maximum KS-KS at two-year follow-up. The RA-TKA group had a 10-point higher median KS-FS at two-year follow-up when compared to the NRA-TKA group (100.0 vs. 90.0, respectively). Although this is not a statistically significant difference (p=0.097), it does represent a minimal clinically important difference.[77] The median FJS at two years was 61.5 for the NRA-TKA group and 75.0 for the RA-TKA group **(Figure 8)**. Again, though not statistically significant (p=0.2046), the 13.5-point difference in FJS in the RA-TKA cohort also represents a minimal clinically important difference.[78]

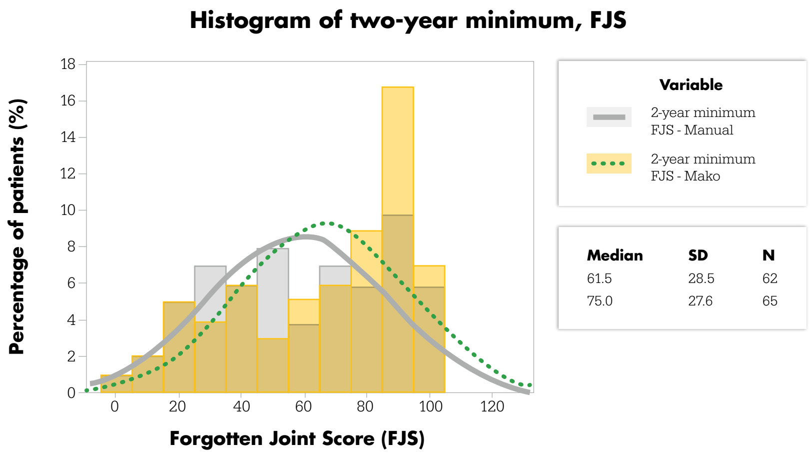


Figure 8. Histogram of the Forgotten Joint Scores (FJS) provided for the NRA-TKA and RA-TKA groups at two-year minimum follow-up.[68]

Promising outcomes for Forgotten Joint Score and UCLA activity scores were seen at five-year follow up in a study performed by Fontalis et al.[79] Comparing 60 consecutive M-TKA and 60 consecutive RA-TKA cases, the study demonstrated superior FJS and UCLA activity scores in the RA-TKA cohort. Mean FJS for the RA-TKA cohort was 74.3 (SD 15.9) compared to 67.5 (SD, 14, p=0.020) in the M-TKA cohort. Regarding other PROMs, the average UCLA activity score was 6.5 (SD, 1.7) and KSS knee score of 88 in comparison to the 5.8 (SD, 1.8, p=0.002) UCLA activity score and 85.8 (SD, 8.9, p=0.951) KSS knee score recorded in the manual cohorts.[79]

Encouraging functional outcomes were found in a prospective multicenter study published by Zhang et al. (2021) that investigated parameters affecting functional recovery and intendent living.[70] A total of 143 patients received RA-TKA between July 2016 and October 2018. Of these, 50 were employed before surgery and their work was categorized based on the physical demands (light, moderate and heavy). Their return-to-work along with LOS, hospital discharge disposition, employment status and return-to-driving, were analyzed. Direct to home discharge occurred in 96% of the patients at a mean LOS of 1.2±0.57 days. All but two (96%) returned to driving at a mean of 45 days (range, 4 to 127 days) with no difference right vs. left knee. Eighteen patients (37%) drove within three weeks, again with no side differences. Forty-five patients (90%) returned to work at a mean of 57 days (range, 1 to 127 days). Eight patients (16%) returned to work within three weeks. This study showed that within three months, >90% of RA-TKA patients were able to return to driving and working.[70]

Two independent sites out of India investigated sleep quality following TKA, comparing RA-TKA and M-TKA using the Pittsburgh Sleep Quality Index (PSQI). Masilamani et al. followed 200 patients over six months and found that while both groups experienced peak sleep disturbances one week postoperatively with gradual improvement, there was no statistically significant difference in sleep quality between RA-TKA and M-TKA, despite RA-TKA patients reporting significantly lower pain scores.[80] Londhe et al. conducted a randomized controlled trial of 68 patients assessed at eight weeks post-TKA, found that RA-TKA patients had significantly better sleep quality than M-TKA patients (mean PSQI 5.69 vs. 6.25, $p = 0.0057$), suggesting that robotic techniques may enhance recovery through reduced pain and optimized implant positioning.[81]

4.3 Length of stay and early postoperative pain

Hospital length of stay (LOS) after TKA has been decreasing in part due to efforts to reduce the costs and overall health care burdens associated with these procedures.[71] Archer et al. (2021) used a large-scale database that included both RA-TKA and M-TKA cases.[71] All cases were performed between January 1, 2018 to March 31, 2019 and came from hospitals that performed both RA-TKA and M-TKA. A total of 10,296 patients were included: 5,993 in the M-TKA group and 4,303 in the RA-TKA group. The mean LOS was significantly lower in RA-TKA (1.68 ± 0.86 days) compared with M-TKA (1.86 ± 0.94 days) procedures ($p < 0.00001$). In the RA-TKA group, 2,049 (47.6%) were discharged in 1 day or less compared with 2,325 (38.8%) in the M-TKA group ($p < 0.0001$). The proportion discharged home was significantly higher for patients who underwent RA-TKA (91.3%) compared with M-TKA (87.4%) TKAs ($p < 0.00001$). These results suggest the health care burden resulting from an upsurge of TKA procedures in our aging population might be addressed in part by increased utilization of robotic assistance.[71]

The opioid crisis in the U.S. has heightened awareness regarding the need for effective pain management, including prescribing opioids only when indicated, at the lowest effective dose and for the shortest duration necessary. In a review of recent publications where data was collected on pain and opioid use, three individual prospective studies compared early postoperative pain and inpatient total morphine equivalent consumption for RA-TKA compared to manual or computer-navigated TKA.[72] These three trials represented a global analysis with studies performed in the United States,[73] United Kingdom[46] and Australia.[82] In addition to the focus on pain management, these publications reported on early patient outcomes including knee ROM prior to discharge, hospital length of stay and discharge status. These three trials, described in more detail below, attributed the observed improvement in early postoperative pain and morphine equivalent consumption associated with RA-TKA to enhanced component placement accuracy and reduction in iatrogenic injury to soft tissue.

In the U.S. based trial, Bhimani et al. (2020) compared 140 consecutive patients who underwent RA-TKA and 127 consecutive patients who underwent M-TKA with minimum six-week follow-up.[73] It was found that patients who underwent RA-TKA had lower average visual analog scale (VAS) pain scores at rest and during activity at two weeks and six weeks (Figure 9) following the index surgery. At six weeks, the RA-TKA group also required 3.2 mg less morphine equivalents per day and had a significantly greater percentage of patients that were free of opioid use compared to the M-TKA group (70.7% vs. 57.0%, respectively). Patients in the RA-TKA group had a shorter LOS (1.9 days vs. 2.3 days) and had a greater percentage of patients discharged on postoperative day one (41.3% vs. 20.5%) when compared to the M-TKA group.

In a retrospective study published by Pearson et al., 200 patient cases were reviewed to evaluate in-patient post-operative outcomes and post-discharge outcomes of RA-TKA versus M-TKA focusing primarily on opioid consumptions post-operatively.[83] The study showed patients in the RA-TKA cohort had a decrease in LOS (1.58 vs. 2.18 days, $p < 0.001$) as well as morphine equivalents (73.52 vs. 102.50, $p = 0.017$). Additionally, fewer patients who received RA-TKA reported requiring opioids at 6-weeks post-op compared to patients who received M-TKA (37 vs. 61, $p = 0.001$).[83]

The Australian-based trial performed by Nevelos et al. (2019)[82] set out to address challenges associated with patient dissatisfaction, including component malalignment,[84] joint overstuffing,[85] poor joint balancing,[86] or inability to restore the native joint line.[87] To do this, the site performed a clinical trial to understand if the choice of computer-navigated versus robotic-arm assisted surgical system correlated to differences in patient-reported metrics and clinical outcomes.[82] A prospective, parallel control study was performed on 75 RA-TKA and 75 Computer-Navigated TKA (CN-TKA) patients in which patients were followed to collect hospital metrics and patient-reported outcomes up to 90 days postoperative. The RA-TKA group had a significant reduction in LOS (3.1 vs. 4.1, $p<0.001$), improved ROM at one day postoperative ($p<0.001$), as well as significantly less pain the day of and day after surgery ($p=0.03$ and 0.006, respectively). The RA-TKA group required significantly less inpatient total morphine equivalent consumption ($p=0.001$) compared to the CN-TKA group.

The United Kingdom-based trial was a prospective, consecutive series, single-surgeon study where Kayani et al. (2018) 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.[46] The RA-TKA 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 LOS) and improved maximum flexion at discharge.[46] In summary, this study was associated with decreased pain, improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based TKA.[46]

In a Hong Kong (HK) based study, a retrospective review was performed on the HK public health system's electronic medical database that captures 80% of patient care locally. Patients were identified if they underwent primary TKA in a HK hospital between Jan 2021 and Dec 2023. They were also able to extract data on surgical technique, dividing patients into M-TKA, RA-TKA, and Computer Navigated TKA (CN-TKA) cohorts. The robotic cohort was further broken down into type of robotic system, creating a Mako TKA cohort. Only Mako (9.7%) demonstrated reduced 90-day emergency department attendance compared to M- TKA (13.1%; $p = 0.009$). No differences in 90-day reoperation rate and mortality were observed between all groups. This team concluded that robotic TKA served as a promising technology. Mako was distinguished from the other robotic cohorts, referencing to Mako's haptic guidance that protects soft tissues leading to reduced early pain.[88]

4.4 Impact of implant design

A retrospective study, performed by Koutserimpas et al, considered the impact of polyethylene insert design—cruciate-substituting (CS) versus posterior-stabilized (PS)—on outcomes in RA-TKA performed under functional alignment (FA) principles.[89] Among 329 patients with a minimum two-year follow-up, both CS and PS groups demonstrated comparable results in terms of Knee Society Scores, Forgotten Joint Scores, range of motion, and implant survivorship. While PS implants had a slightly higher rate of intraoperative lateral condyle fractures and CS implants showed femoral component revisions due to instability, overall complication rates were similar. The study concludes that both insert types were effective when selected based on patient-specific anatomy and ligament integrity, supporting individualized implant selection in FA-guided RA-TKA.

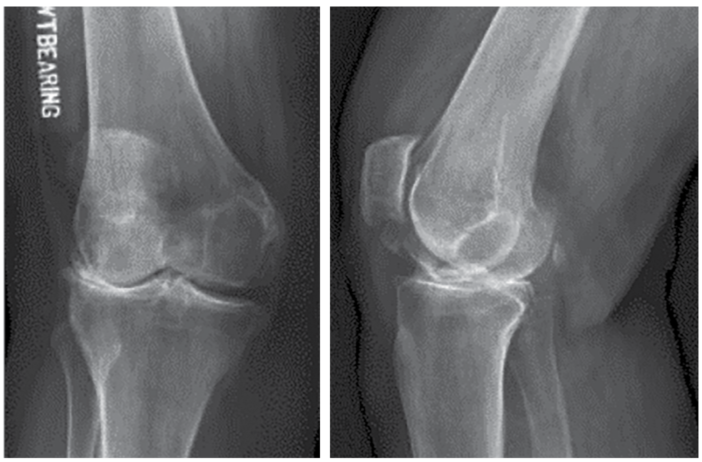
In a second retrospective study by Koutserimpas et al, they evaluated 393 patients undergoing RA-TKA guided by functional knee positioning (FKPs) principles, comparing outcomes between cemented and cementless fixation methods.[90] Both approaches yielded comparable functional results, implant survivorship, and complication rates, with no significant differences in revision rates. However, hematomas were significantly more frequent in the cementless group (12.32% vs. 8.24%, $p = 0.02$), potentially due to the absence of cement's tamponade effect. Subgroup analyses of femoral and tibial components confirmed similar outcomes across fixation types. The study concludes that both cemented and cementless fixation were effective in FKPs-guided RA-TKA, with fixation choice potentially influenced by patient-specific factors and bleeding risk.

Stoltz et al. conducted a retrospective cohort study, comparing outcomes of 393 RA-TKA and 312 M TKAs, all using the same cementless implant design, with a minimum two-year follow-up.[91] RA-TKA patients demonstrated significantly higher postoperative scores in Knee Society Function and Knee scores, WOMAC, and KOOS-JR, as well as greater overall satisfaction (95% vs. 87.4%, p = .001). Although both groups showed significant improvements, RA-TKA yielded superior functional outcomes and satisfaction without increased complication or revision rates. The study attributes these benefits to RA-TKA's ability to provide 3D preoperative planning, precise intraoperative adjustments, and well-balanced soft-tissue gaps, suggesting that robotic technology enhances patient-reported outcomes in cementless TKA.

4.5 Use with complex cases

The Mako Total Knee Technology allows a surgeon to preoperatively plan a case based on a patient CT as well as to intraoperatively adjust that plan based on soft tissue laxity, all prior to making a single bone cut. These features can be beneficial when a patient presents with severe varus/valgus deformities or flexion contractures. In addition to early patient outcomes, Marchand et al. (2018) have also published a case series demonstrating how the Mako System can help surgeons correct severe deformities.[92] Three case studies were presented in which the use of the robotic-arm assisted system allowed the surgeon to achieve desired alignment restoration for patients with severe deformities **(Figure 9)**.

Preoperative radiograph



Postoperative radiograph

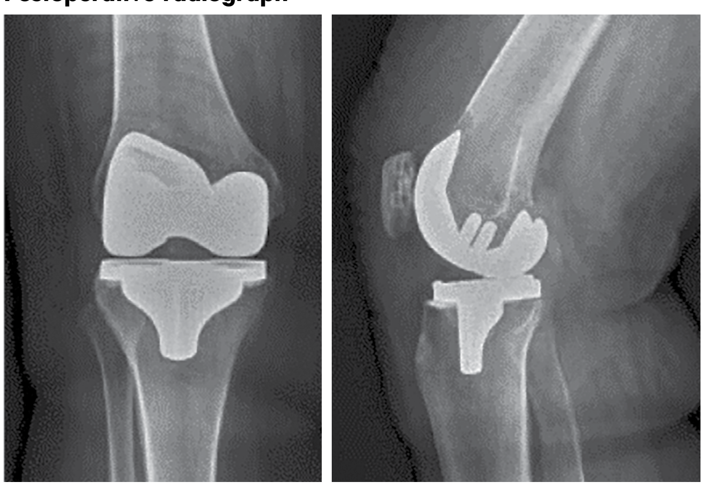


Figure 9. Preoperatively, there was a 9° valgus deformity in extension. Intraoperative balancing and realignment were performed, and the final coronal alignment was 1° valgus. For this case, no soft tissue releases were needed.[92]

There are few large patient cohort studies that investigate patient outcomes as related to internal or external rotation of the femoral component. In an observational, single surgeon study headed by Marchand et al., 876 robotic-arm assisted TKA cases were reviewed for final femoral internal and external rotation relative to the transepicondylar axis. Patients were categorized into <0° to 6° internal and 0° to 6° external femoral rotation. The internal group had an average femoral angle of 2.8° ± 1.5° while the external group had an average of 1.9° ± 1.8°. The study indicated variability in femoral component rotation may help achieve a more functional component position though no effect on patient outcome was reported as both cohorts showed comparably good WOMAC scores at Six-month follow-up.[93]

Valgus knees, representing 10% of TKA patients, offer unique challenges based on unique bone anatomy and soft tissue imbalance.[94,95] Gregori et al. (2025), published on a retrospective review of 58 patient with pre-operative valgus alignment (hip-knee-angle (HKA) ≥ 183°). These patients were followed up at a minimum of 1-year, collecting PROMs, complications, revisions and radiographic measures. 86.2% of patients fell within the goal boundaries (HKA = 177° to 183°), where the femur was adjusted more than the tibia, and no soft-tissue releases were performed. At 1-year post-operative, KSS knee and KSS function both significantly improved (p<0.0001), Oxford Knee Score was an average 45, and Forgotten Joint Score was an average 93, both excellent results. This publication described one possible technique to align and balance valgus knees with modest corrections and no soft tissue releases.[96]

A study by Pierre-Henri et al. (2025) identified 34 valgus preoperatively deformed cases with one-year KOOS and survivorship data. 85% of patients had a residual valgus between 0° to -3° on long leg standing x-rays, 1 patient (4%) had a varus of 1°, and 4 patients (12%) had valgus of more than -3°. Intra-operatively, cases were planned with an average femoral rotation of 2.65° ± 1.87° (range, 0° to 6.8°) of external rotation related to the PCA. At one-year follow-up, there were no reported revisions and the average KOOS value was 80.79 with 76% of patients reporting good or excellent KOOS score.[97]

A prospective study by Kalyan et al., evaluated the effectiveness of RA-TKA in correcting moderate to severe valgus knee deformities using minimally constrained implants.[98] Among 873 RA-TKA procedures performed between August 2020 and May 2022, 21 patients (24 knees) with grade 2–3 valgus deformities and intact medial collateral ligaments were followed for two years. Using functional alignment principles and the Mako Total Knee system, the study achieved significant deformity correction (from 22.43° to 5.26°), improved gap balancing without soft tissue releases, and substantial functional gains, with WOMAC scores improving from 67.58 to 1.38 and KSS scores from 26.67 to 181.96. The technique minimized bone cuts and avoided constrained implants, resulting in no major complications and demonstrating that RA-TKA offered a precise approach for managing complex valgus deformities in TKA.

4.6 Impact of patient obesity

Koutserimpas et al. examined the impact of high body mass index (BMI) on outcomes following RA-TKA using functional knee positioning (FKP) principles.[99] Among 372 patients, those with BMI ≥ 30 kg/m^2 achieved comparable functional outcomes, including range of motion, Knee Society Scores, and Forgotten Joint Scores, to patients with lower BMI. However, the obese group experienced a significantly higher rate of mechanical implant failures (2.99% vs. 0.42%), despite similar alignment and implant positioning. The findings suggest that while RA-TKA with FKP effectively personalizes alignment and restores function across BMI categories, obesity remains a key risk factor for implant-related complications. Further research is needed to optimize surgical strategies and improve long-term implant durability in obese patients.

In retrospective study by Richardson et al., they compared radiographic and intraoperative outcomes of obese patients (BMI ≥ 35 kg/m^2) undergoing TKA using either RA-TKA or M-TKA.[100] Among 119 patients, those treated with RA-TKA had significantly better postoperative alignment, with fewer coronal plane outliers (15% vs. 30.5%) and closer hip-knee-ankle angles to neutral (2.0° vs. 3.1°, $p = .040$). However, robotic-assisted procedures required longer operative and tourniquet times. Estimated blood loss was similar between groups. The findings suggest that RA-TKA may improve alignment accuracy in obese patients, who are more prone to complications from malalignment, though further long-term studies are needed to assess implant durability and functional outcomes.

5. How has Mako Total Knee affected episode-of care costs?

Mako Total Knee provides surgeons with preoperative planning and real-time intraoperative data, allowing for continuous assessment of ligamentous tension and range of motion. Using this technology, soft tissue protection,[14,15] reduced early postoperative pain,[43] improved patient satisfaction,[65] reduced complications such as MUAs,[67] and reduced LOS[36] have been shown. As Mako SmartRobotics™ continues to be adopted, it is also important to understand whether Mako Total Knee is associated with reduced EOC costs. This document contains reference to cost-savings based on U.S. data and is intended as an example only. Cost-savings may differ across regions due to different health systems, treatment plans and associated costs.

A retrospective review of a U.S.-based payer commercial database for TKA surgeries was performed by Cool et al. (2018) between January 2016 and March 2017.[101] After propensity score matching (PSM), 519 RA- TKA and 2595 M-TKA 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 RA-TKA patients ($p < 0.0001$). Index facility cost and

LOS were less for RA-TKA patients by \$640 ($p = 0.0001$) and 0.7 days ($p < 0.0001$), respectively.101 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 (SNFs) less frequently (12.52% vs. 21.70%, $p < 0.0001$) and they had a 90-day readmission rate reduction of 33% ($p = 0.04$).102 This evidence demonstrated a 90-day EOC cost-savings to Medicare when comparing RA-TKA to M-TKA, driven by reduced facility costs, LOS and readmissions and an economically beneficial discharge destination. [101,102]

A healthcare utilization analysis was performed by Mont et al. (2019) between RA-TKA and M-TKA techniques.[102] They specifically compared: Index costs and discharge dispositions, as well as, 30-day, 60-day and 90-day (a) episode-of-care, (b) postoperative healthcare utilization and (c) readmissions. The same propensity-matched group from Cool et al. (2018) was used in this study to assess trends in total episode payments, healthcare utilization and readmissions at 30, 60 and 90-day time points.[102] The RA-TKA patients had consistently lower average total episode payment than the M-TKA patients when compared at 30, 60 and 90 days **(Figure 10)**. At 30 days, 47% fewer RA-TKA patients utilized SNF services (13.5% vs. 25.4%, $p < 0.0001$) and had lower SNF costs at 30, 60 and 90 days. RA-TKA patients also utilized fewer home health visits and costs at each time point ($p < 0.05$). Additionally, 31.3% fewer RA-TKA patients utilized emergency room services at 30-days postoperatively and had fewer 90-day readmissions (5.2% vs. 7.75%, $p = 0.0423$). It was concluded that RA-TKA was associated with lower 30, 60 and 90-day postoperative costs and healthcare utilization. These results provide promising initial economic insights into RA-TKA and are of increased importance given the emphasis to contain and reduce healthcare costs.

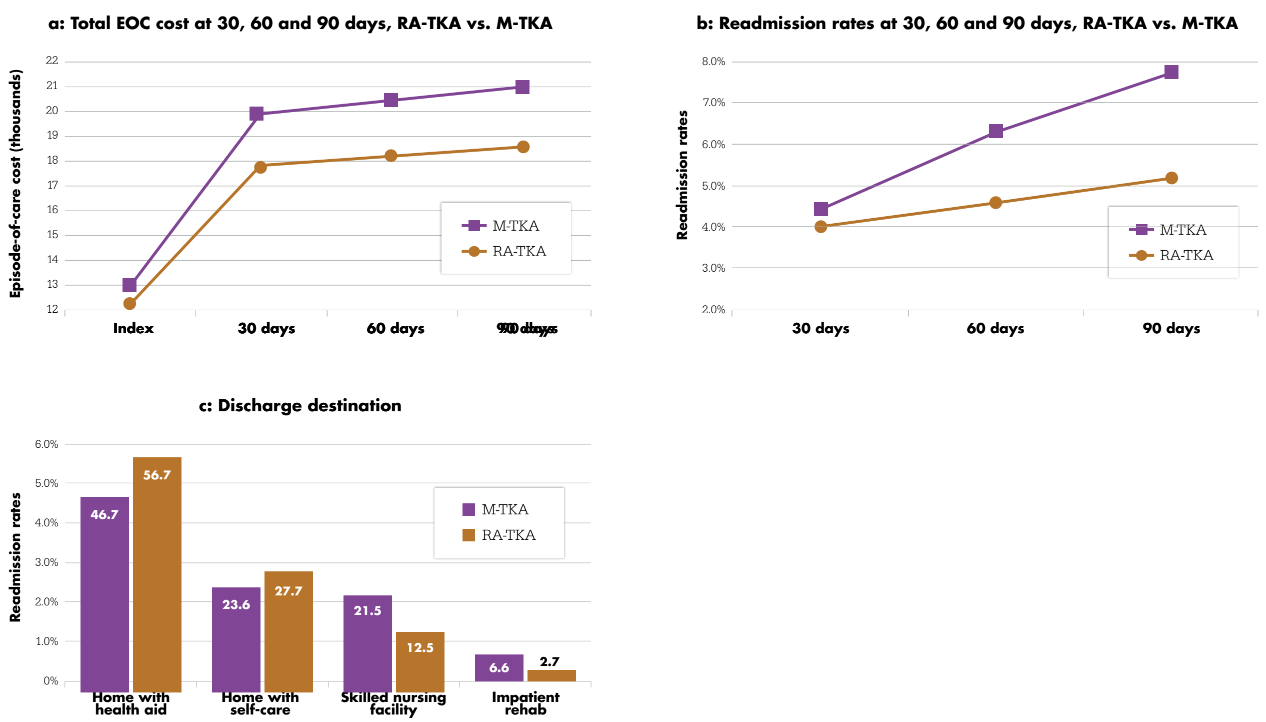


Figure 10. Medicare 100% Standard Analytical Files were queried for RA-TKA and M-TKA cases. Based on propensity-matched cohorts, RA-TKA had (a) reduced episode-of-care cost at 30-, 60- and 90-days postoperative as well as (b) reduced rate of admission at those time points. It was also noticed that (c) RA-TKA cases were more likely to be sent home postoperatively with a health aide or self-care as opposed to a skilled nursing facility or inpatient rehab.[102]

While total joint arthroplasties account for more Medicare expense than any other inpatient procedure,[103] studies have reported the growth of TKA procedures in commercially insured patients under 65. Pierce and colleagues[104] 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 RA-TKA cohort or the M-TKA cohort. Following 1:5 propensity score matching, 357 RA-TKAs and 1,785 M-TKAs 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 RA-TKA cohort (1.80 vs. 2.72 days; $p < 0.0001$). Within the 90 days following the index stay, patients who underwent RA- 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 M-TKA cohort. Patients who utilized home health in the RA-TKA arm used significantly fewer days of home health than M-TKA patients (5.33 vs. 6.36 days; $p = 0.0037$). Cost associated with the utilization of services was substantially lower in the RA-TKA arm; the overall post-index cost was $1,332 less per case in the RA-TKA arm ($6,857 vs. $8,189; $p = 0.0018$). Cost was also significantly less in the RA-TKA 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 RA-TKA arm ($28,204 vs. $32,253; $p < 0.0001$).[104]

Gregory et al. evaluated the 90-day episode of care for 4,135 RA-TKAs matched to 4,135 M-TKA from a U.S. commercial payer database. They found that index costs to the payer for RA-TKA patients were less than those for M-TKA 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 RA-TKA patients were found to be $1,834 less than that for M-TKA patients. RA-TKA patients also had lower average LOS for the index procedures and had a higher percentage of one day stays (47 vs 36%, $p<0.001$) compared to M-TKA.[105]

Ong et al. compared not only the 90-day episode of care, but also the 12-month episode of care for 742 RA-TKA matched to 4452 M-TKAs from the MarketScan database. Their study found that RA-TKA patients had shorter LOS (mean 1.56 versus 1.91 days; $p<0.001$), lower index costs by $1,762 ($32,747 versus $34,509; $p=0.003$), and higher discharges to home rates (51.8 versus 47.8%; $p=0.049$) than M-TKA patients. RA-TKA 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 RA-TKA 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.[106]

In a U.S. study, Cotter and colleagues evaluated costs to their hospital comparing 147 Mako RA-TKA and 139 M-TKA 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 RA-TKA with M-TKA.[107] 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 post-acute care facilities was 52% lower with RA-TKA compared with M-TKA (4.1% RA-TKA vs. 8.6% M-TKA, $p = 0.118$), although not statistically significant due to the small number of occurrences. Patients who underwent M-TKA called the physician's clinic office approximately twice as frequently compared with RA-TKA 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 RA-TKA compared with M-TKA ($15,629.94 vs. 17,720.64, respectively; $p < 0.001$).[107]

Alton et al. performed a retrospective review of a large real-world data hospital billing database within the US healthcare system, including 16,714 RA-TKA patients matched to 51,199 M-TKA patients. In the primary analysis, overall hospital costs of care from index to 90 days post-index were cost-neutral for RA-TKA and M-TKA patients (17,999 vs 17,867, $p \geq 0.05$). Sensitivity analysis found RA-TKA 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 M-TKA (17,512 vs. 17,632, $p \geq 0.05$). RA-TKA 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, RA-TKA patients had fewer emergency room visits ($p < 0.05$) with fewer post-operative inpatient readmissions ($p < 0.05$) compared to M-TKA.[108]

6. Conclusion

In conclusion, the Mako Total Knee application has been shown in a single-center, multi-surgeon study to help surgeons to place implants accurately to plan.[12] In separate cadaveric and clinical studies, soft tissue damage was shown to be reduced when compared to manual TKA surgery.[14,15] Transitioning to new technology is potentially demanding for any operating room. However, surgeons with different levels of TKA experience were able to have Mako procedure times reach a steady state in 10 to 15 cases.[48] In cadaveric and clinical study models, surgeon ergonomics were enhanced by use of robotic-arm assisted technology.[50, 60] In a prospective, consecutive series single-surgeon study, early postoperative pain and blood loss were shown to be reduced with Mako Total Knee when compared to manual surgery.[46] While longer term follow-up is ongoing, multiple studies have shown positive early and mid-term outcomes, as measured using PROMs.[11, 44, 46, 61-71] Additionally, studies have shown that the enhanced clinical outcomes observed to date with Mako SmartRobotics™ have the potential to provide value to patients, providers and payers alike.[101, 104, 107]

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