Mako® Total Knee arthroplasty: clinical summary

Mako clinical evidence

Volume 6

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 three key components, 3D CT-based planning, AccuStop™ haptic technology and insightful data analytics, into one platform which, in comparison to manual techniques, has been shown in cadaveric and clinical settings to have increased accuracy and precision of component placement to plan.[10,11] These achievements were accomplished, 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 alignment, soft tissue balancing and flexion contractures. Additional 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 prevents 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

Overall, robotic-arm assisted technology offers the potential to enhance TKA through a combination of preoperative planning,[12] intraoperative adjustments[13] and guided bone resections.[11,14] 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 (RATKA) has also been found to reduce surgical variability among surgeons early in their surgical experience.[16]

2.1 Accuracy and precision

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, which is carried out utilizing computed tomography (CT). An intraoperative feedback loop allows for implant placement adjustments, which help surgeons determine joint balancing 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 Mako Total Knee.[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.

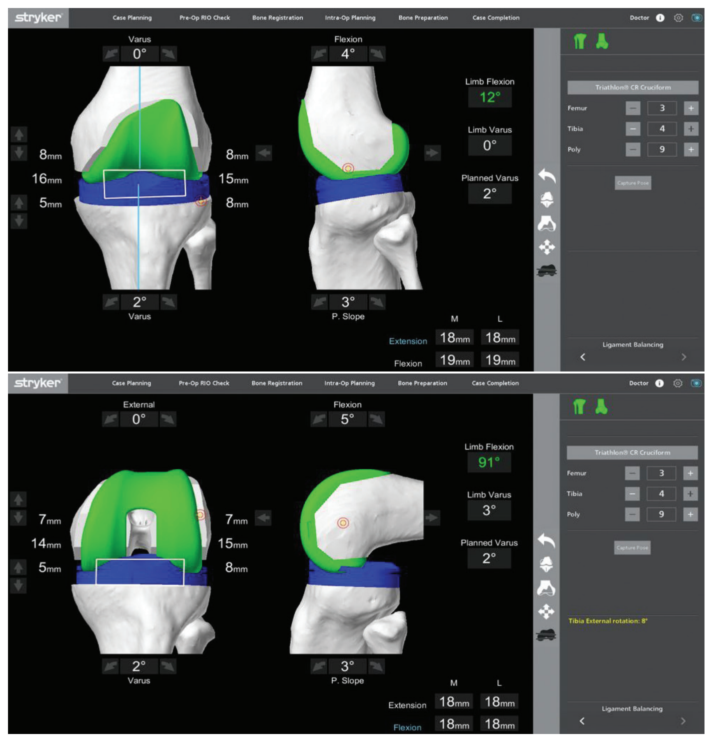


Figure 1. Knee (A) extension and (B) flexion final implant planning; 100% of patients achieved a post-bone cut extension gap difference between -1 and 1 mm (mean -0.1 mm), and 99% of patients achieved a post-bone cut flexion gap difference of between -2 mm and 2 mm (mean 0 mm).[13]

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 Mako Total Knee.[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 software predicted component size exactly in 96% of femoral implants and in 89% of tibial baseplates. In comparison, studies comprising a 2D technique predicted the correct 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.

While manual TKA has demonstrated clinical success,[19] a meta-analysis of component alignment found mechanical axis malalignment of greater than 3° in 9.0% of computer-assisted surgeries and 31.8% of manual TKA (MTKA) surgeries.[20] In a cadaveric study, a high-volume surgeon with no prior clinical robotic experience performed a matched pair comparison of MTKA to RATKA on six specimens (12 knees).[21] A learning curve was considered, and the first three specimens were eliminated from comparison. The last three RATKA and MTKA matched pairs found that RATKA demonstrated greater accuracy and precision of bone cuts and component placement to plan compared to MTKA. On average, RATKA (n=6) final bone cuts and final component positions were 5.0 and 3.1 times more precise to plan than the MTKA control, respectively. Furthermore, this study demonstrated RATKA 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 RATKA.

The ability to properly align components to plan during TKA is paramount to implant function and survivorship.[22,23] Therefore, a nonrandomized, prospective multicenter clinical study was conducted to compare implant placement accuracy to plan between a RATKA and manual TKA cohort.[24] All patients received a CT scan at approximately six weeks postoperatively to analyze implant placement to plan. Average component positions for manual and RATKAs are provided in Table 1. Comparing absolute deviation from plan between groups, RATKA 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 manual TKA, RATKA 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.

Table 1. Absolute deviation from surgical plan (degrees, mean/median (25th, 75th percentiles))[24]

	MTKA (n=52)	RATKA (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 RATKA 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

In a clinical study, Sire et al.[25] (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 Mako Total Knee arthroplasty literature. In addition to component alignment, Sire et al.[26] 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).

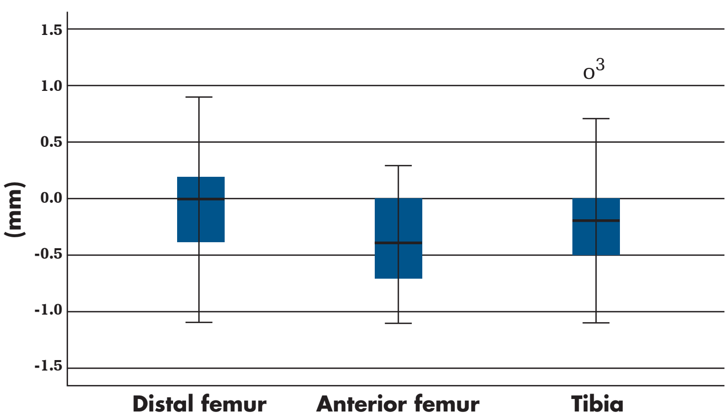
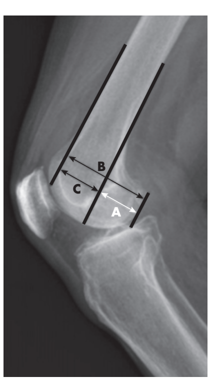


Figure 2. Sire et al.[26] measured bone resection depth for the distal femoral, anterior femoral and tibial cut planes. Box and whisker plots of the bone resections performed highlight the median, interquartile range, maximum and minimum values. Positive values indicate more bone was resected than planned, and negative values indicate less bone was resected than planned.

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 RATKA cases with 39 MTKA cases.[27] 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 MTKA when compared to the RATKA 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 RATKA had smaller mean differences in PCOR, which has been previously shown to correlate with better joint ROM at one year following surgery.[71] In addition, these patients were less likely to have values outside of normal ISI, which meant they were less likely to develop patella baja,[70] a condition in which the patella impinges onto the patellar component, leading to restricted flexion and overall decreased ROM.

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.[27]



	RATKA	MTKA	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

Comparison of robotic-arm assisted and manual radiographic measurements

Retaining the posterior cruciate ligament (PCL) during total knee arthroplasty is designed to preserve femoral rollback and improve extensor function.[28,29] 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.[30] A prospective, comparative cohort study was performed which included 33 manual TKAs and 44 RATKAs enrolled consecutively. At six weeks postoperative, the RATKA group showed a positive linear correlation between knee flexion angle with femoral rollback ($r=0.63$, $p<0.01$), while the MTKA group showed no association ($r=0.00$, $p=0.998$). Additionally, the RATKA group showed 8° greater mean flexion compared the MTKA group ($p=0.031$, Figure 3). The RATKA group showed a pattern strongly consistent with physiologic rollback, while the MTKA group showed no association. Increased femoral rollback was directly associated with greater passive knee flexion after implantation, and in terms of clinical outcome, the RATKA group overall showed greater average knee flexion at short-term follow-up.

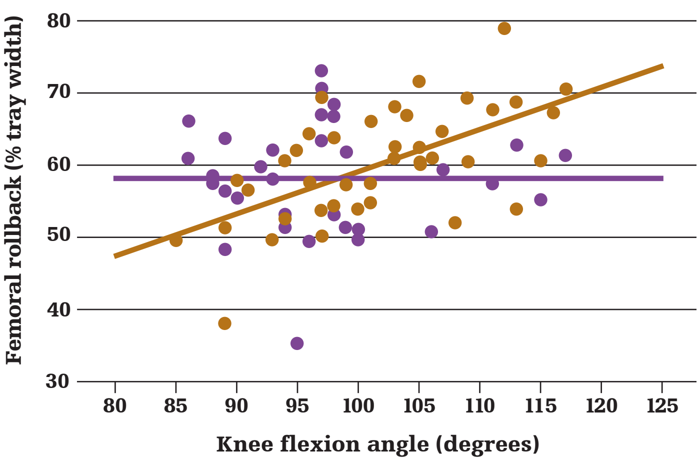


Figure 3. Kinsey et al. evaluated the influence of PCL preservation on femoral rollback. A scatter plot was used to show association of femoral rollback with knee flexion angle measured from postoperative lateral radiographs of the same CR TKA device implanted with RATKA (red) vs. MTKA (blue). The RATKA group showed strong positive linear correlation ($p=0.63$, $p<0.001$) while the MTKA group showed no association ($r=0.00$, $p=0.998$).[30]

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 Mako Total Knee (RATKA) and MTKA.[15] A total of 24 paired cadaveric knees (12 RATKA and 12 MTKA) 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 RATKA than in MTKA specimens ($p=0.004$) (Figure 4). RATKA 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 RATKA using a stereotactic boundary to constrain the sawblade, which can prevent unwanted soft tissue damage.

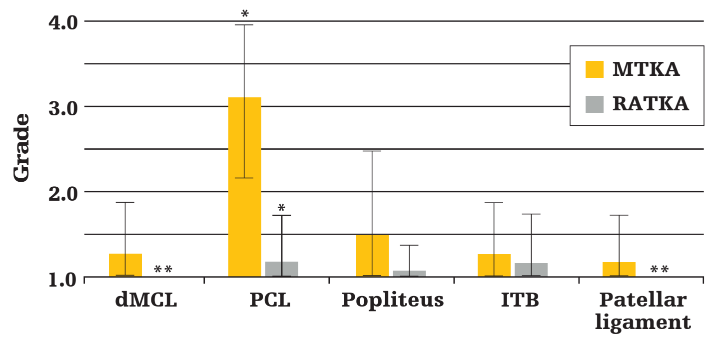


Figure 4. Iatrogenic soft tissue damage was assessed and graded 1-4, where higher numerical values represent higher levels of damage. Average grade values are shown for extent of damage to the dMCL, PCL, popliteus, ITB, and patellar ligament in MTKA and RATKA specimens. Error bars indicate standard deviations.
***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 MTKAs followed by 30 consecutive Mako Total 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 Mako 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 conventional 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] The authors indicated that further studies are necessary to determine if the observed periarticular injury will have an impact on systemic inflammatory response and postoperative patient pain.

2.4 Reduced surgical variability

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 MTKA on one side (three knees) and Mako Total Knee 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 Mako Total Knee 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 Mako Total Knee compared to MTKA. 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,[11-14,31-33] 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.[34] 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.[35] 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.[36] 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.[37] 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.[38]

3.1 Surgical team learning curve

As with most new surgical techniques, there is a learning curve associated with RATKA. 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.[34] 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 RATKA without any added operative time.[34]

Surgical time to perform robotic-arm assisted TKA versus manual TKA

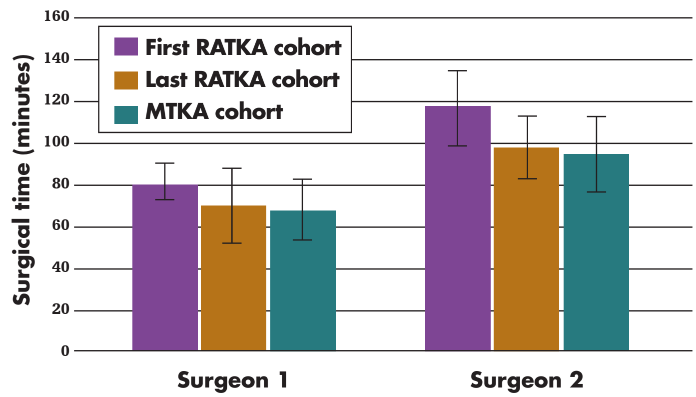


Figure 5. Mean surgical time data for RATKA and MTKA indicate that within a few months, a surgeon should be able to perform RATKA without any added operative time. For both surgeons, mean surgical time was greatest for the first cohort of 20 RATKA cases when compared to the last cohort of 20 patients. The last cohort of 20 RATKA cases were time neutral to the surgeons' 20 MTKA cases.[34]

In another learning curve study, Fleischman et al. (2018) followed a separate group of two surgeons with differing levels of TKA experience.[35] Each surgeon performed a minimum of 20 Mako Total Knee cases (n=45) and the times required to perform specific tasks were compared to conventional 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 RATKA, which was a 22.8-minute reduction in time from the first three Mako Total Knee 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, Sastry et al. (2019) reported on a single surgeon experience comparing their first 40 RATKA cases to a matched consecutive MATKA cohort.[39] During the first 40 cases, the RATKA 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 RATKA 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 RATKA appeared to progress rapidly, with a comparable OR time to MTKA by the second 20 cases.

3.2 Surgical team usability

Studies show how robotic-arm assisted TKA impacts the patient,[31,33] but little has been done to understand how this technology affects the surgeon. Literature indicates that multiple factors can influence a surgeon's incidence of injury.[40,41] Approximately 44% to 66% of orthopaedic surgeons have had a work-related injury attributed to poor surgeon posture.[42,43] Additionally, hospital staff routinely takes on ergonomically challenging tasks, which has been shown to decrease longevity of performing in the operating room.[41] 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.[43,44] 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 Mako Total Knee surgery compared to conventional TKA as well as a reduced occiput angle.[37,45] 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 Mako Total Knee compared to manual TKA as well as less mental and physical demand based on the results of a workload questionnaire.[45]

Blevins et al. (2018) performed an intraoperative study to assess how the use of robotic-arm assisted TKA can influence energy expenditure when compared to manual TKA.[36] This study found that a lower-volume arthroplasty surgeon had less energy expenditure when using the Mako System compared to high-volume arthroplasty surgeons and to conventional TKA.[36] In addition, this study found that one fewer surgical assistant was needed in the operating room when performing Mako Total Knee procedures.[36]

Finally, a study by Scholl et al. (2018) focused on the ergonomics of a surgical assistant.[38] It was found that the surgical assistant demonstrated less shoulder movement when performing Mako Total Knee compared to conventional TKA as there was no placement of jigs, and array placement and bone registration required less shoulder elevation compared to motions performed during conventional TKA.[38]

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 conventional TKA. Shoulder motion was also improved for an orthopaedic surgical assistant. Utilizing Mako Total Knee may help improve the posture and ergonomics of orthopaedic surgeons and orthopaedic surgical staff.

4. What are the clinical outcomes of Mako Total Knee?

The Mako Total Knee application was launched in June 2016. As the initial Mako Total Knee patients begin to reach postoperative time points, publications have become available on early clinical outcomes. Marchand et al. (2017, 2019) published a single-surgeon study that was performed on consecutive cemented RATKA patients matched with consecutive cemented MTKA patients.[31,46] 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 postoperative visit and their one-year postoperative visit.[31,46] The RATKA cohorts demonstrated significantly improved mean total satisfaction and physical function scores when compared to the manual cohorts at six months and one year.[31,46] Additionally, at six months the RATKA cohort had significantly reduced total pain score when compared to the MTKA cohort.[31] These results indicate the potential of this surgical tool to improve short-term pain, physical function and total satisfaction scores.[31,46] Although it involved a limited cohort, this study showed promising outcomes for up to one year for RATKA patients when compared to the MTKA control group.[31,46]

The Mako Total Knee cases from Marchand et al. (2019) continue to be followed as patients reach two years postoperative. Marchand et al. retrospectively followed 196 patients in a longitudinal trial.[47] At two years postoperative, WOMAC, Forgotten Joint Score (FJS) and Patient Joint Perception (PJP) scores were collected. 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 6). Patients reported a median FJS of 65.8 ± 31.1 at two-year follow-up with 36% of patients having 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.[69] 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.

FJS at 2-year follow-up for RATKA patients

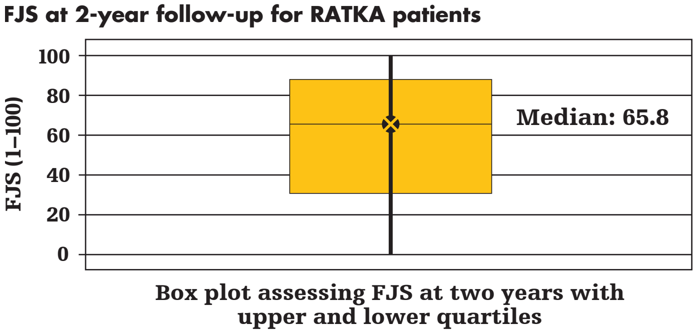


Figure 6. Marchand et al. followed their RATKA patients out to two years and reported a median Forgotten Joint Score of 65.8 ±31.1.[31]

As more robotic-arm assisted TKA patients reach one-year follow-up, studies are beginning to report on these milestone outcomes. A retrospective review was performed by Illgen et al. (2019), where a single high-volume surgeon performed 148 RATKA cases and 159 MTKA cases with matched demographics.[48] The RATKA 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 RATKA cases were compared to the MTKA cases (93.8 minutes vs. 91.6 minutes, $p=0.506$). 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 improved outcomes followed through to one year, where the RATKA group had improved KOOS Jr. ($p=0.034$) and FJS ($p=0.021$, Table 3). These favorable results for the RATKA group indicate patient outcomes continued to be improved out to one year postoperative when compared to the conventional MTKA technique.

Smith et al. (2019) compared 120 consecutive patients undergoing RATKA to a prospective cohort of 103 consecutive patients undergoing TKA with manual jig-based instruments during the same time period.[49] There were no differences in age, gender, baseline Knee Society-Knee Scores (KS-KS) and Knee Society-Function Scores (KS-FS), follow-up and ASA scores between the two groups. TKAs were performed using the same technique, implant design, anesthesia and postoperative treatment protocols. The Likert scoring system demonstrated 94% of the patients in the RATKA group were either very satisfied or satisfied at one-year follow-up versus 82% in the MTKA group ($p = 0.005$). RATKA had a better average overall satisfaction score at one year of 7.1 versus 6.6 in the MTKA group ($p = 0.03$). KS-FS scores in the RATKA cohort were significantly better at six weeks than the MATKA group and one year postoperatively ($p = 0.02$, 0.005), and KS-KS scores in the RATKA cohort were significantly better at one year postoperatively ($p = 0.046$). The authors suggested that RATKA may provide several advantages in TKA, including real-time information to help obtain balanced gaps, as well as the potential for accurate bone cuts, reduced soft tissue injury and achievement of target alignment, which may lead to improved patient satisfaction.

In a study lead by Malkani et al. (2019), five fellowship-trained, high-volume surgeons at different institutions performed a total of 188 total knee arthroplasty surgeries using the Mako Robotic-Arm Assisted Total Knee System and had a two-year minimum clinical follow-up.[50] 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 Mako Total Knee.

In a follow-up to the study by Malkani et al. (2019), the same 188 RAKTA patients were paired to a consecutive equal number of control patients who underwent manual TKA by each of the specific surgeons for comparison. 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 RATKA 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 RATKA cohort indicates that RATKA 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.

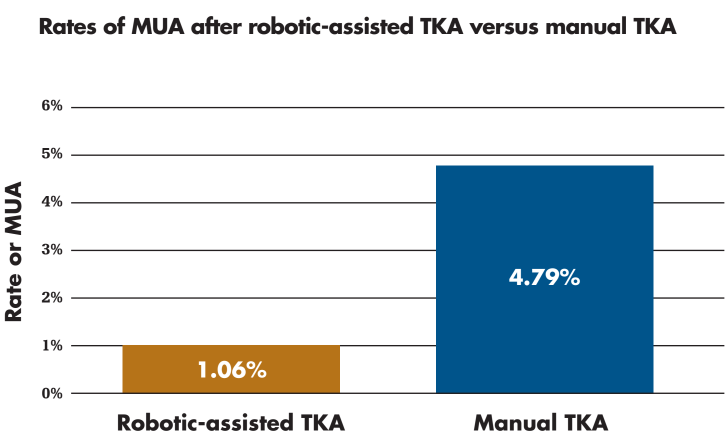


Figure 7. Malkani et al. found a 4.5-fold increase in MUA rates for their manual TKA cohort when compared to the robotic–assisted TKA cohort (4.79% vs 1.06%, p=0.032).[51]

Gustke et al. (2020) compared an initial and consecutive series of RATKA cases to a group of non–robotic-arm assisted total knee arthroplasties (NRA-TKA).[52] At two years, a total of 70 RATKA 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 RATKA 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.[53] The median FJS at two years was 61.5 for the NRA-TKA group and 75.0 for the RATKA group (Figure 8). Although not statistically significant (p=0.2046), the 13.5-point difference in FJS in the robotic TKA cohort also represents a minimal clinically important difference.[54]

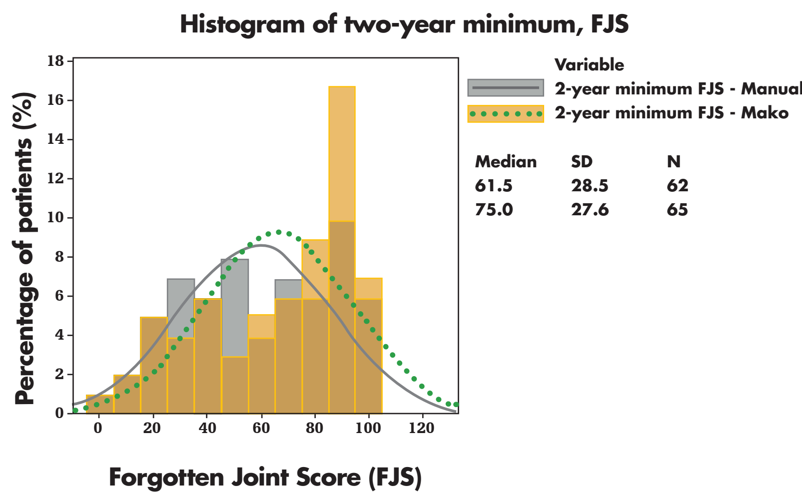
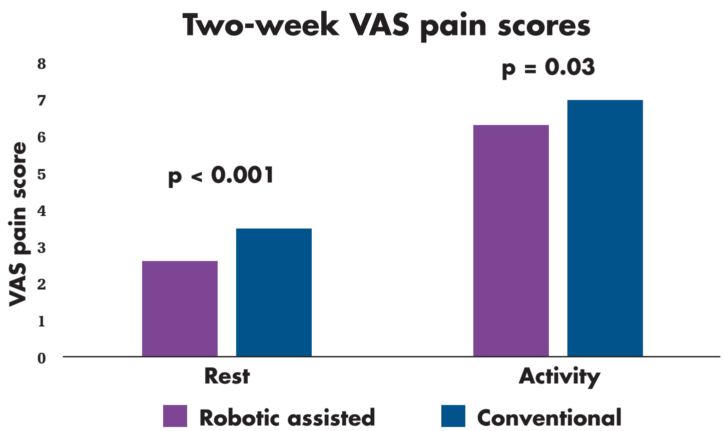


Figure 8. Histogram of the Forgotten Joint Scores (FJS) provided for the NRA-TKA and RA-TKA groups at two-year minimum follow-up.[54]

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 focused 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 robotic-assisted TKA compared to conventional or computer-navigated TKA.[55] These three trials represented a global analysis with studies performed in the United States,[56] United Kingdom[33] and Australia.[57] 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 robotic-assisted 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 RATKA and 127 consecutive patients who underwent conventional TKA with minimum six-week follow-up. It was found that patients who underwent RATKA 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 RATKA 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 conventional TKA group (70.7% vs. 57.0%, respectively). Patients in the RATKA 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 conventional group.



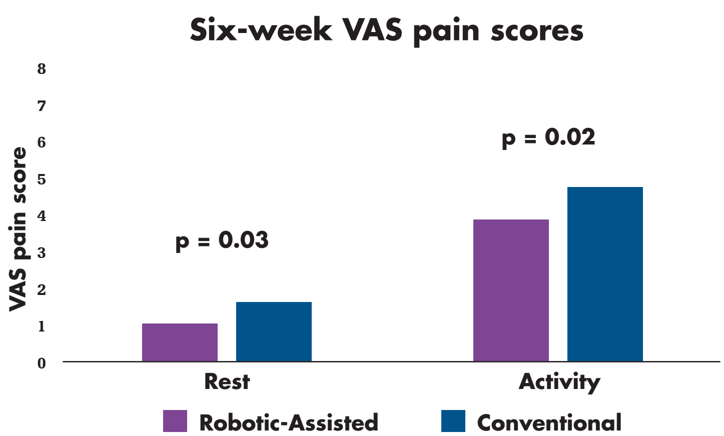


Figure 9. Robotic–assisted TKA demonstrates decreased VAS pain scores at two-weeks and six-weeks postoperatively compared to conventional TKA.[58]

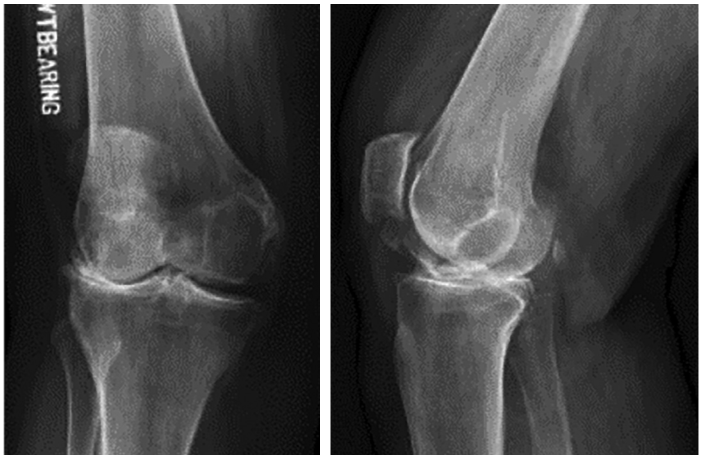
The Australian-based trial performed by Clark et al. (2019)[57] set out to address challenges associated with patient dissatisfaction, including component malalignment,[59] joint overstuffing,[60] poor joint balancing,[61] or inability to restore the native joint line.[62] To do this, the site performed 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.[57] A prospective, parallel control study was performed on 75 RATKA and 75 computer-navigated TKA (CNTKA) patients in which patients were followed to collect hospital metrics and patient-reported outcomes up to 90 days postoperative. The RATKA 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 RATKA group required significantly less inpatient total morphine equivalent consumption ($p=0.001$) compared to the CNTKA 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.[33] 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 LOS) and improved maximum flexion at discharge.[33] 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.[33]

4.1 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. (2017) have also published a case series demonstrating how the Mako System can help surgeons correct severe deformities.[63] 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 10).

Preoperative radiograph



Postoperative radiograph

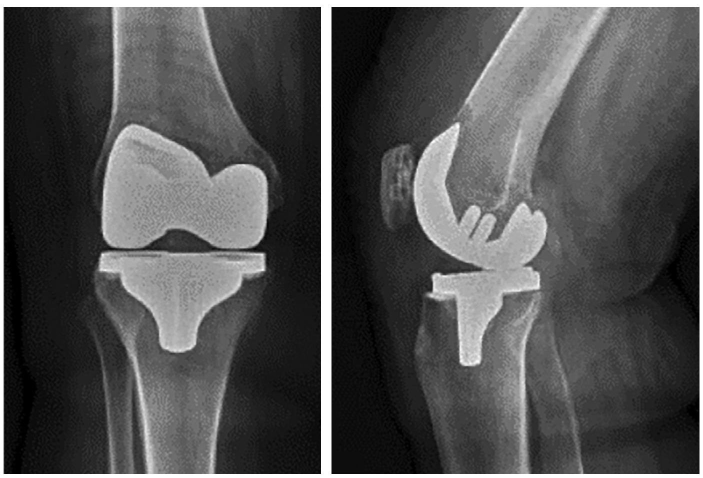


Figure 10. Preoperatively, there was a 9° valgus deformity in extension. Intraoperative balancing and realignment were performed and the final coronal alignment was 1° valgus. For this case, no soft tissue releases were needed.[63]

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,[33] improved patient satisfaction,[47] reduced complications such as MUAs,[51] and reduced LOS[33,56,57] have been shown. These advances have the potential to enhance surgical outcomes and may also reduce episode-of-care (EOC) 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. 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.[64] After propensity score matching (PSM), 519 robotic-arm assisted TKA and 2595 manual TKA cases were assessed to compare EOC cost, index cost, LOS, discharge disposition and readmission rates. Results found overall 90-day EOC costs were $2,391 less for RATKA patients ($p < 0.0001$).[64] Index facility cost and LOS were less for RATKA patients by $640 ($p = 0.0001$) and 0.7 days ($p < 0.0001$), respectively.[64] 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 had a 90-day readmission rate reduction of 33% ($p = 0.04$).[65] This evidence demonstrated a 90-day EOC cost-savings to Medicare when comparing RATKA to MTKA, driven by reduced facility costs, LOS and readmissions, and an economically beneficial discharge destination.[64]

A healthcare utilization analysis was performed by Mont et al. (2019) between RATKA and MTKA techniques.[66] They specifically compared (1) index costs and (2) discharge dispositions as well as (3) 30-day, (4) 60-day, (5) 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.[64] The RATKA patients had consistently lower average total episode payment than the MTKA patients when compared at 30, 60, and 90 days (Figure 11). At 30 days, 47% fewer RATKA patients utilized SNF services (13.5% vs. 25.4%, $p < 0.0001$, Figure 11) and had lower SNF costs at 30, 60, and 90 days. RATKA patients also utilized fewer home health visits and costs at each time point ($p < 0.05$). Additionally, 31.3% fewer RATKA patients utilized emergency room services at 30-days postoperatively and had fewer 90-day readmissions (5.2% vs. 7.75%, $p = 0.0423$, Figure 11). It was concluded that RATKA was associated with lower 30-, 60-, and 90-day postoperative costs and healthcare utilization. These results provide promising initial economic insights into rTKA, and are of increased importance given the emphasis to contain and reduce healthcare costs.

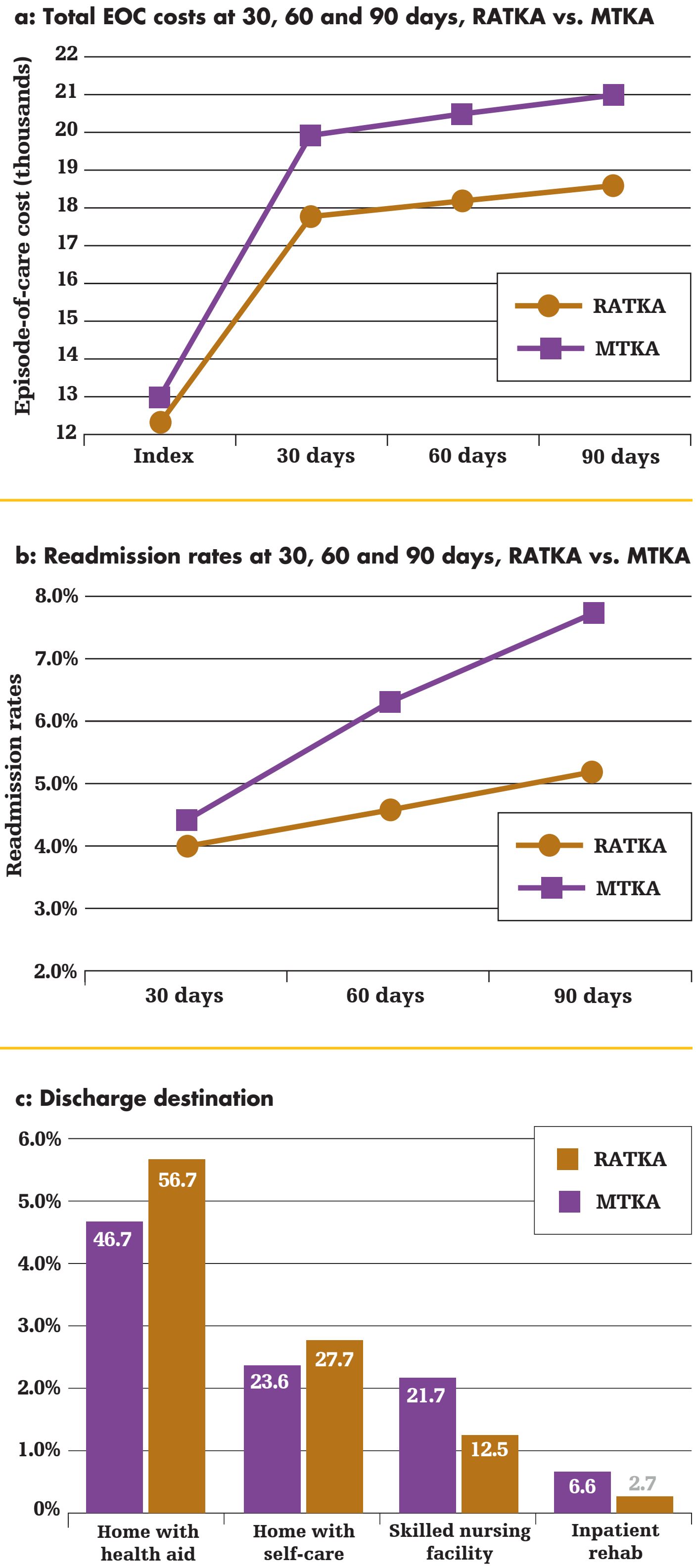


Figure 11. Medicare 100% Standard Analytical Files were queried for RATKA and MTKA cases. Based on propensity-matched cohorts, RATKA had (a) reduced episode-of-care cost at 30-, 60-, and 90-days postoperative as well as (b) reduced rate of admission at those time points. It was also noticed that (c) RATKA 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.[66]

While total joint arthroplasties account for more Medicare expense than any other inpatient procedure,[67] studies have reported the growth of TKA procedures in patients under 65. Pierce and colleagues[68] evaluated 90-day episode-of-care costs associated with TKA in a commercially insured population. TKA procedures were identified using the Optum Insights Inc. database. The procedures were stratified in one of two groups, RATKA or MTKA cohorts. Following 1:5 PSM, 357 RATKAs and 1,785 MTKAs were included in the analysis. Utilization and associated costs were analyzed for 90 days following the index procedure. 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 skilled nursing visits (1.68 vs. 6.05%; $p < 0.0001$), compared to mTKA patients. Patients who utilized home health in the RATKA arm utilized significantly fewer days of home health than MTKA patients (5.33 vs. 6.36 days; $p=0.0037$). The overall post-index cost was $1,332 less per case in the RATKA arm than the mTKA arm ($6,857 vs. $8,189; $p = 0.0018$). Cost was also significantly less 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; $p < 0.0001$). Additionally, the overall length of stay was significantly lower for those in the RATKA arm (1.80 vs. 2.72 days; $p < 0.0001$).

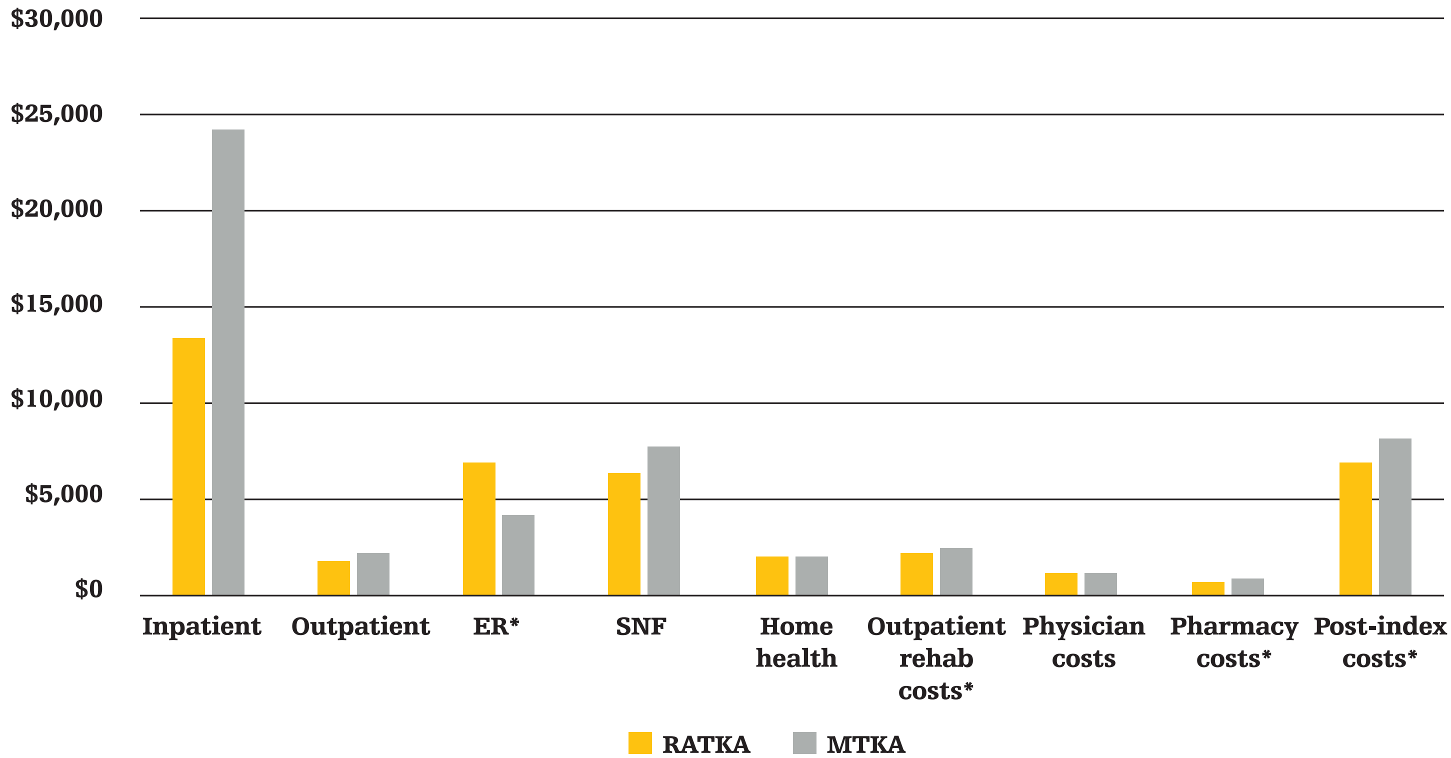


Figure 12. Average post-index 90-day pay amounts for patients who underwent RATKA vs. MTKA.[68]
*** Indicates statistically significant p values**

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.[11] 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, two surgeons with different levels of TKA experience were able to have Mako procedure times reach a steady state in 10 to 15 cases.[35] In a cadaveric study model, surgeon and surgical assistant ergonomics were enhanced by use of robotic-arm assisted techology.[37,38]

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.[33] While longer term follow-up is on-going, multiple studies have shown positive early outcomes, as measured using PROMs.[11, 31-33] 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.[31-33,50-51,64,66,68]

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