Mako® Total Knee arthroplasty:
clinical summary

Mako clinical evidence

Volume 5

1. Introduction

Total knee arthroplasty (TKA) is an established and successful procedure for the treatment of end-stage knee arthritis.[1] Survivorship at ten 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]

The Mako Total Knee application, in comparison to manual techniques, has been shown in a cadaveric and clinical setting 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 intra-operatively to address implant alignment, soft tissue balancing, and flexion contractures. Additional features include intra-operative visual, auditory, and tactile feedback to the user. The robotic-arm assisted technology also has an auto 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.

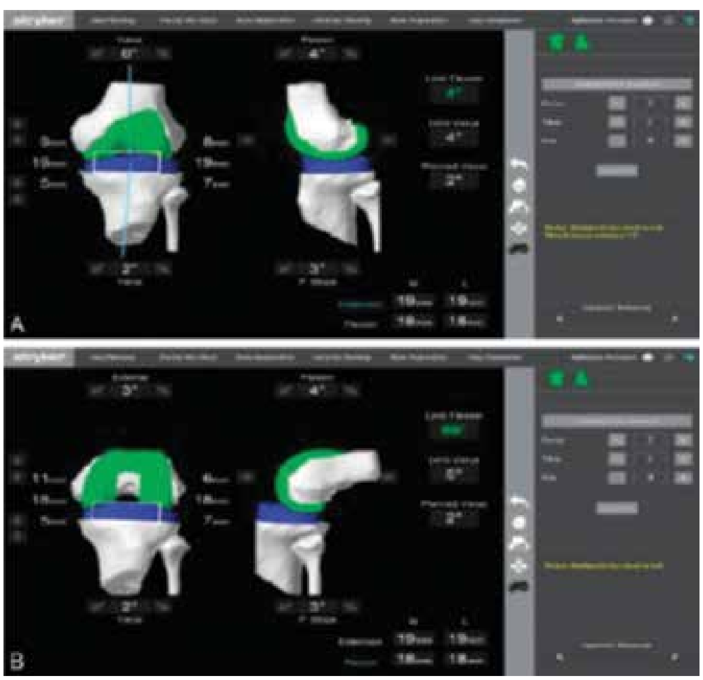


Figure 1. Knee (A) extension and (B) flexion final implant planning; 100% of patients achieved a post-bone cut extension gap difference between -1 and 1mm (mean, -0.1mm) and 99% of patients achieved a post-bone cut flexion gap difference of between -2mm and 2mm (mean, 0mm).[13]

2. What is the evidence to support the science behind Mako Total Knee?

Overall, robotic-arm assisted technology offers the potential to enhance TKA through a combination of pre-operative planning,[12] intra-operative adjustments,[13] and guided bone resections.[11,14] Several studies have demonstrated the efficiency of 3D planning,[12] the benefits of intra-operative 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 intra-operative decisions based on pre-operative planning, which is carried out utilizing computed tomography (CT). An intraoperative feedback loop allows for implant placement adjustments which helps 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] Pre-operative plans were adjusted to achieve balance, defined as having a medial and lateral flexion gap difference within 2mm. Regardless of disease state or types of deformities, all patients achieved a post-bone cut extension gap difference of between -1 and 1mm (mean, -0.1mm) and 99% of patients achieved a post-bone cut flexion gap difference of between -2mm and 2mm (mean, 0mm) (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.

The ability to pre-operatively 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 pre-operative CT that is used to perform 3D templating. In a study performed by Bhimani et al. (2017),[54] consecutive patients underwent unilateral Mako Total Knee.[12] Three-dimensional planning software specific to the Mako System was used to provide an initial pre-operative implant plan which was then updated intra-operatively, 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 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 pre-operatively 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 (CAS) 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 6 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, retrospectively. Furthermore, 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 non-randomized, prospective multi-center clinical study was conducted to compare implant placement accuracy to plan between a RATKA and manual TKA cohort.[24] All patients received a computed tomography (CT) scan at approximately 6 weeks post-operatively 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.

2.2 Restoring kinematic function

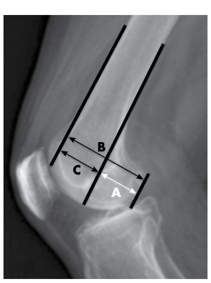
In addition to component placement accuracy to plan, to achieve a functionally stable knee the implant must be placed with respect to the patient's anatomy, specifically their posterior condylar offset ration (PCOR) and Insall-Salvati Index (ISI) may correlate with the final achievable joint ROM. Sultan et al. conducted a prospective, cohort-matched study to compare 43 consecutive RATKA cases with 39 MTKA cases.[25] 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

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

	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 RA TKA of one site (CT data of second site is in process)
3. Femoral flexion is not explicitly targeted with manual TKA technique.

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 pre-operative PCOR when compared to use of manual instrumentation.[25]



	RATKA	MTKA	p-value[1]
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 (PCOR – posterior condylar offset ratio)

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. In addition, these patients were less likely to have values outside of normal ISI, which meant they were less likely to develop patella baja, a condition in which the patella would impinge onto the patellar component, leading to restricted flexion and overall decreased ROM.

Retaining the PCL during total knee arthroplasty is designed to preserve femoral rollback and improve extensor function.[26,27] For this reason, 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. A prospective, comparative cohort study was performed which included 33 manual TKAs and 44 RATKAs enrolled consecutively.[28] At 6-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 degrees greater mean flexion compared the MTKA group ($p=0.031$, Figure 2). 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.

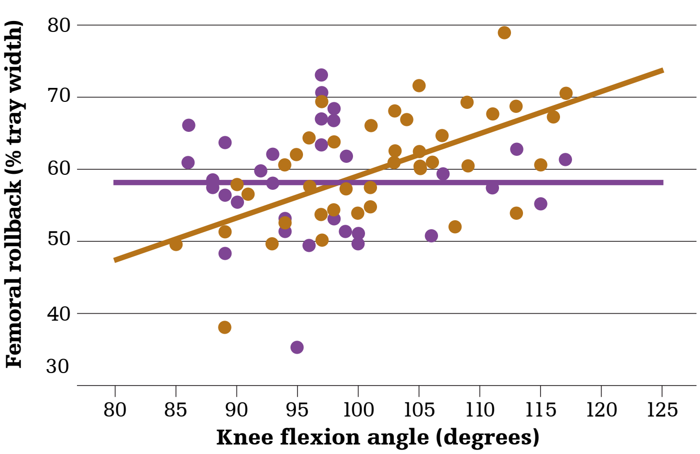


Figure 2. Kinsey et al. evaluated the influence of PCL preservation on femoral rollback. A scatter plot was used to show association of femoral rollback with knee flexion angle measured from post-operative lateral radiographs of the same CR TKA device implanted with RATKA (red) vs. MTKA (blue). The RATKA group showed strong positive linear correlation ($p=0.63$, $p<0.001$) while the MTKA group showed no association ($r=0.00$, $p=0.998$).[28]

2.3 Soft tissue protection

A cadaveric study was performed to determine the benefits of soft tissue protection by examining damage to 14 soft tissue structures, including the deep medial collateral ligament (dMCL), posterior cruciate ligament (PCL), popliteus, iliotibial band (ITB), and patellar ligament, following Mako Total Knee (or robotic-arm assisted TKA, 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 post-operatively determined that significantly less damage occurred to the PCL in the haptic-controlled RATKA than in MTKA specimens ($p=0.004$) (Figure 3). 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.

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. Intra-operative 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

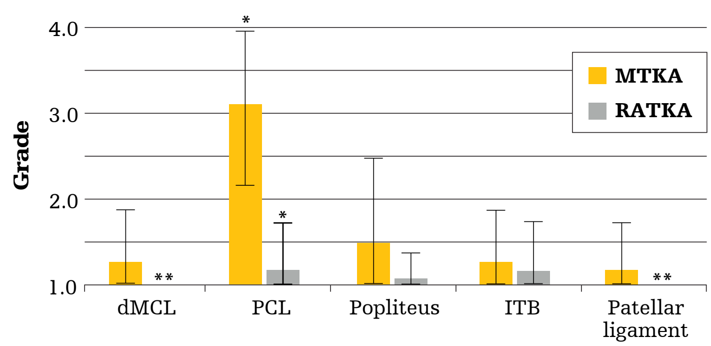


Figure 3. Iatrogenic soft-tissue damage was assessed and graded 1-4, where higher numerical values represent higher levels of damage. Average grade values are shown for extent of damage to the dMCL, PCL, popliteus, ITB, and patellar ligament in MTKA and RATKA specimens. Error bars indicate standard deviations.
*** PCL showed significant difference ($p<0.05$);**
****Grade average ± standard deviation for dMCL and patellar ligament was 1 ± 0.[15]**

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 post-operative rehabilitation.[14] Further studies are necessary to determine if the observed periarticular injury will have an impact on systemic inflammatory response and post-operative 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 (3 knees) and Mako Total Knee on the other (3 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 9mm, required less post-resection recuts to achieve a balanced knee, 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 clear benefits to adopting robotic-arm assisted technology,[11-14, 29-31] 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.[32] 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.[33] 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.[34] 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.[35] 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.[36]

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.[32] 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 4 provides surgical times for both surgeons. For Surgeon 1, mean operative

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

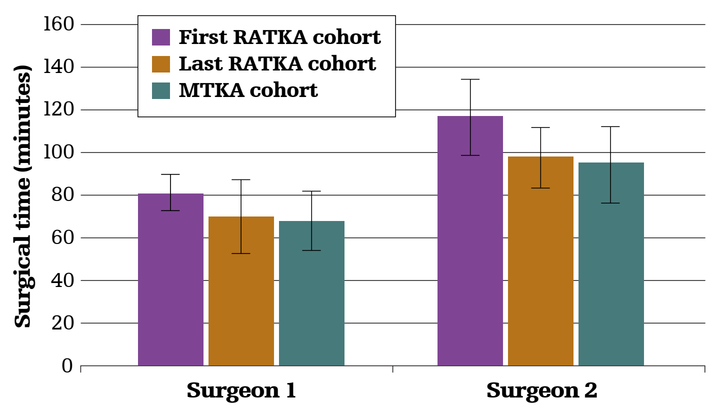


Figure 4. Mean surgical time data for RATKA and MTKA indicate that within a few months, a surgeon should be able to perform RATKA without any added operative time. For both surgeons, mean surgical time was greatest for the first cohort of 20 RATKA cases when compared to the last cohort of 20 patients. The last cohort of 20 RATKA cases were time neutral to the surgeons' 20 MTKA cases.[32]

time between the first and last cohorts 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 should be able to adequately perform RATKA without any added operative time.[32]

In a separate learning curve study, Fleischman et al. (2018) followed a separate group of two surgeons with differing levels of TKA experience.[33] 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 10-15 cases, regardless of surgical experience.

To understand how patient outcomes are influenced during a surgeon's learning curve, Sastry et al. reported on a single surgeon experience comparing their first 40 RATKA cases to a matched consecutive MATKA cohort.[37] During the first 40 cases, the RATKA had a slightly greater overall surgical time when compared to the MATKA group (82.5min vs 78.3min, $p=0.002$) however this difference was no longer statistically significant when only the second set of 20 RATKA cases was considered (81.1min vs 78.3min, $p=0.254$). During this 40-case cohort, the RAKTA cohort showed a reduced LOS (1.27 days vs 1.92 days, $p>0.001$), and an improved ROM at 90 days (+3.8° vs. -8.7°, $p<0.05$). No significant difference was noted in postoperative KSS or 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

Many studies have focused on understanding how robotic-arm assisted TKA impacts the patient[29, 31] while little has been done to understand how this technology affects the surgeon. Approximately 44 to 66% of orthopaedic surgeons have had a work-related injury attributed to poor surgeon posture.[40,41] Literature indicates that multiple factors can influence a surgeon's incidence of injury.[38,39] Additionally, hospital staff routinely take on ergonomically challenging tasks which has been shown to decrease longevity of performing in the operating room.[39] 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.[41,42] Motion sensors placed in these locations can indicate whether performing surgical procedures, such as total knee arthroplasty (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.[35,43] 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 a workload questionnaire.[43]

Blevins et al. performed an intraoperative study to assess how the use of robotic-arm assisted TKA can influence energy expenditure when compared to manual TKA.[34] 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.[34] In addition, this study found that one less surgical assistant was needed in the operating room when performing Mako Total Knee procedures.[34]

Finally, a study by Scholl et al. focused on the ergonomics of a surgical assistant.[36] 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.[36]

For a surgeon to reduce risk of injury, it is important to perform surgical procedures that are ergonomic that will allow surgeons to 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) published on a single surgeon study that was performed on consecutive cemented RATKA patients matched with consecutive cemented MTKA patients.[29,44] A WOMAC survey, including pain, stiffness, and physical function subcategories, was administered to patients at their 6-month and 1-year postoperative visit.[29,44] The RATKA cohorts demonstrated significantly improved mean total satisfaction and physical function scores, when compared to the manual cohorts, at 6 months and 1 year.[29,44] Additionally, at 6 months the RATKA cohort had significantly reduced total pain score when compared to the MTKA cohort.[29] These results indicate the potential of this surgical tool to improve short-term pain, physical function, and total satisfaction scores.[29,44] Although it involved a limited cohort, this study showed promising outcomes for up to 1 year for RATKA patients when compared to the MTKA control group.[29,44]

The Mako Total Knee cases from Marchand et al. continue to be followed as patients reach two-year postoperative. Marchand et al. (2019) retrospectively followed 196 patients in a longitudinal trial.[45] At two-years post-operative 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 pre-operative to two-year follow-up ($p<0.05$, Figure 5). 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 US general population with a similar age rage.[46] 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

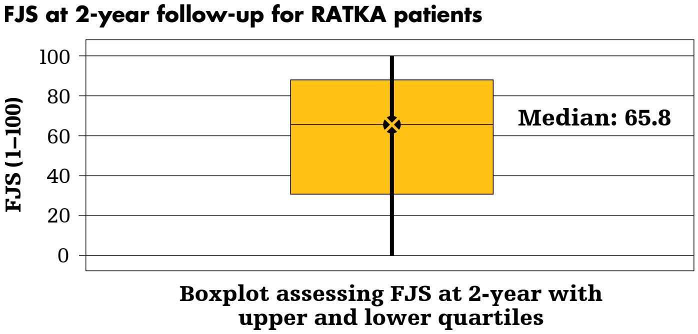


Figure 5. Marchand et al. (2019) followed their RATKA patients out to two-years and reported a median Forgotten Joint Score of 65.8 ±31.1.[45]

Surgical reasons for patient dissatisfaction following TKA include component malalignment,[47] joint over stuffing,[48] poor joint balancing,[49] or inability to restore the native joint line.[50] To address these challenges, computer navigated (CN) and robotic systems have been introduced. Robotic-arm assisted TKA (RATKA) has been shown to improve soft tissue preservation,[14,15] Clark et al. performed a clinical trial to understand if the choice of surgical system correlated to differences in patient reported metrics and clinical outcomes.[51] A prospective, parallel control study was performed on 75 RATKA and 75 computer navigated TKA (CNTKA) patients in which those 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 1 day postop ($p<0.001$), as well as significantly less pain 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.

In a prospective, consecutive series, single-surgeon study, 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.[31] The Mako Total Knee group had less post-operative pain ($p<0.001$), less need for analgesics ($p<0.001$), less post-operative blood loss ($p<0.001$), less time to achieve straight leg raise ($p<0.001$), less time to hospital discharge (Mako Total Knee resulted in 26% reduction in length of stay), and improved maximum flexion at discharge.[31] 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.[31] It is important to also note that this study did not undertake a financial analysis. As a result, financial implications cannot be assumed at this time.

As more robotic-arm assisted TKA patients reach 1-year follow-up, studies are beginning to report on these milestone outcomes. A retrospective review was performed by Illgen et al.,[52] where a single high-volume surgeon performed 148 RATKA cases and 159 MTKA cases with matched demographics. The RATKA cohort experienced a significantly longer tourniquet time when the learning curve phase was included (96.8min vs. 91.6 min, $p=0.001$) however this difference was not observed when the last 20 RATKA cases were compared to the MTKA cases (93.8 min vs 91.6 min, $p=0.506$). Postoperatively the RATKA cohort was more often discharged to home care (95.95% vs 83.65%, $p<0.001$) compared to acute rehabilitation, had a reduced number of physical therapy appointments (11.0 vs 13.3, $p=0.004$), and a lower number of 30-day readmissions (1 vs. 5, $p=0.014$). This trend in improved outcomes followed through to 1-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 indicate patient outcomes continued to be improved out to 1 year postoperative when compared to the conventional MTKA technique.

In a prospective, multi-surgeon study, Carroll et al. (2018) assessed patient satisfaction and outcomes for 105 robotic-arm assisted Total Knee patients at 1 year follow-up.[11] Patients were asked to complete Levels of Emotional Awareness Score (LEAS), Numeric Pain Rating Scale (NPRS), and Knee Injury and Osteoarthritis Score Junior (KOOS Jr).[11] All scores statistically significantly ($p<0.05$) improved from preoperative to one year assessment: LEAS improved from 8 to 10; NPRS improved from 8 to 1; KOOS Jr improved from 78 to 84.6. Patients reported high subjective clinical outcome score improvement at one year.[11]

Denehy et al. (2019) performed a single-surgeon, prospective study to compare 75 consecutive RATKA patients to 75 consecutive MTKA patients.[53] Patients' surgical time and length of stay (LOS) were collected post-operatively. The patients were then followed at one-year to collect patient satisfaction and Knee Society Scores. At one-year, the RATKA cohort reported 95% of patients either very satisfied or satisfied compared to 75% for the MTKA cohort. The RATKA group reported significantly better KSS scores pertaining to recreational activity satisfaction (p=0.02). The RATKA group reported better average overall satisfaction (p=0.03) and KSS function score (p=0.02). Average operative time for RATKA (101 minutes) was significantly higher than the TKA group (87 minutes) ($p<0.01$). However, there was no difference in total operative time in the last 25 robotic cases. The RATKA cohort had a significantly reduced hospital length of stay post-surgery (2.29 vs. 2.61, p=0.05). There were no significant differences in postoperative ROM or complications.

The opioid crisis in the US 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.[54] These three trials represented a global analysis with studies performed in the United States,[55] United Kingdom[31] and Australia.[51] All three trials were consistent in reporting significantly improved patient pain score and reduced use of opioid consumption up to 6 weeks postoperative when compared to either a MTKA or computer assisted TKA group. Study conclusions attributed these improved outcomes to accuracy in component placement and prevention of iatrogenic injury to soft tissues.

The Mako Total Knee technology allows a surgeon to pre-operatively plan a case based on a patient CT as well as intra-operatively 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

Table 3. Patient reported outcome measures at 1-year follow-up

	MTKA	RATKA	p-value
Preop PROM			
VR-12 MCS	55.62 (52.81-58.82)	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 PROM			
VR-12 MCS	55.27 (53.61-56.92)	55.91 (54.31-57.51)	0.291
VR-12 PCS	41.15 (39.19-43.1)	42.89 (41.18-44.61)	0.087
KOOS Jr	72.18 (69.34-75.02)	75.67 (73.26-78.07)	0.034
FJS	52.69 (41.36-64.02)	59.39 (53.14-65.64)	0.021
UCLA	5.65 (5.25-6.04)	6.12 (5.80-6.45)	0.067
Δ PROM			
VR-12 MCS	-1.48 (-5.5-2.54)	0.86 (-1.69-3.41)	0.146
VR-12 PCS	9.83 (7.38-12.28)	11.37 (7.41-15.33)	0.614
KOOS Jr	15.57 (7.58-23.55)	23.41 (18.71-28.10)	0.034
FJS	N/A	N/A	
UCLA	0.47 (-0.28-1.23)	0.73 (0.27-1.19)	0.071

Veterans RAND 12 physical component (VR-12 PCS) and mental component scores (VR-12 MCS), the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS Jr), the Forgotten Joint Score (FJS), and the UCLA Activity Score. Δ PROM – magnitude of change from pre-operative to post-operative scores within each PROM.

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 correct severe deformities.[56] 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 6).

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

Mako Total Knee provides surgeons with pre-operative planning and real-time data, allowing for continuous assessment of ligamentous tension and range-of-motion. Using this technology, soft tissue protection,[14,15] reduced early post-operative pain,[31] and improved patient satisfaction[56] 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 Technology continues to be adopted, it will also be important to understand if Mako Total Knee can reduce episode-of-care (EOC) costs.

A retrospective review of a US-based payer commercial database for TKA surgeries was performed by Cool et al. (2019) between January 2016 and March 2017.[57] After propensity score matching, 519 robotic assisted TKA and 2,595 manual TKA cases were assessed to compare EOC cost, index cost, LOS, discharge disposition and readmission rates. Results found overall 90-day EOC costs to payer were $2,391 less for robotic assisted TKA patients ($p<0.0001$).[57] Index facility cost and LOS were also less for robotic assisted TKA patients by $640 ($p=0.0001$) and 0.7 days ($p<0.0001$), respectively.[57] Additionally, robotic assisted patients were discharged to self-care more frequently (56.65% vs. 46.67%, $p<0.0001$) and SNF less frequently (12.52% vs. 21.70%, $p<0.0001$) and had a 90-day readmission reduction of 33% ($p=0.04$).[57] This evidence indicated a potential cost savings to payers associated with robotic assisted TKA versus manual TKA. This 90-day EOC savings for the robotic assisted TKA group was driven by reduced facility costs, LOS and readmissions, and an economically beneficial discharge destination.[57] The cost related data in this study relates to analyses performed in the United States and, although this data is compelling, it must be understood that cost-effectiveness data may differentiate across regions due to different healthcare and hospital systems, treatment plans and associated costs.

A US-based health care utilization analysis between robotic-arm assisted TKA and manual TKA techniques was performed by Mont et al. (2019).[58] They specifically compared (1) index costs and (2) discharge dispositions, as well as (3) 30-day (4) 60-day (5) 90-day (a) episode-of-care, (b) postoperative healthcare utilization, and (c) readmissions. The same propensity matched group from Cool et al. was used in this study to assess total episode payments, healthcare utilization, and readmissions, at 30-, 60-, and 90-day time points. The RATKA cohort demonstrated consistently lower average total episode

Preoperative radiograph

Postoperative radiograph

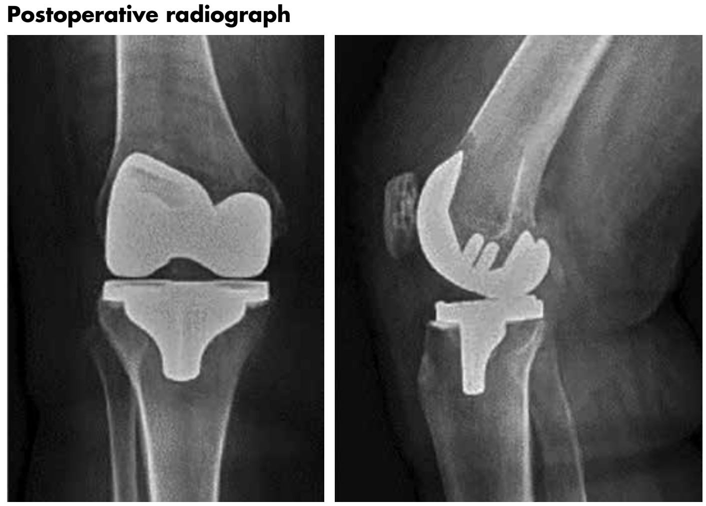


Figure 6. Pre-operatively, there was a 9-degree valgus deformity in extension. Intra-operative balancing and realignment were performed and the final coronal alignment was 1-degree valgus. For this case, no soft tissue releases were needed.[56]

payment than the MTKA cohort when compared at 30-, 60-, and 90-days (Figure 7a). At 30-days, 47% fewer RATKA patients utilized skilled nursing facility (SNF) services (13.5 vs. 25.4%, p<0.0001, Figure 7c) and RATKA patients 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 RATKA patients had fewer 90-day readmissions (5.2 vs. 7.75%, p=0.0423, Figure 7b). It was concluded that RATKA was associated with lower 30-, 60-, and 90-day postoperative costs to payers and healthcare utilization. These results are of marked importance given the emphasis to contain and reduce health care costs and provide initial economic insights into RATKA with promising results. Similar to Cool et al., the data in the analysis performed by Mont et al. related to analyses performed in the United States and indicative only of this region since cost savings may differentiate across regions due to differences in healthcare systems, treatment plans and associated costs.

6. Conclusion

In conclusion, the Mako Total Knee application has been shown in a single-center, multi-surgeon study, to be able to place implants accurately to plan.[11] In a separate cadaveric and clinical study, 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.[33] In a cadaveric study model, surgeon and surgical assistant ergonomics were improved by use of robotic-arm assisted techology.[35,36]

In a prospective, consecutive series, single-surgeon study, early post-operative pain and blood loss were shown to be reduced in Mako Total Knee when compared to manual surgery.[31] Multiple studies have shown early outcomes measured using PROMs to be positive,[11,29-31] although longer term follow-up is on-going. Additionally, studies have shown potential cost savings to the payer at 90 days post-operative when performing a Mako Total Knee compared to a manual TKA where this savings was driven by reduced facility cost, LOS and readmissions, and an economically beneficial discharge destination.[57]

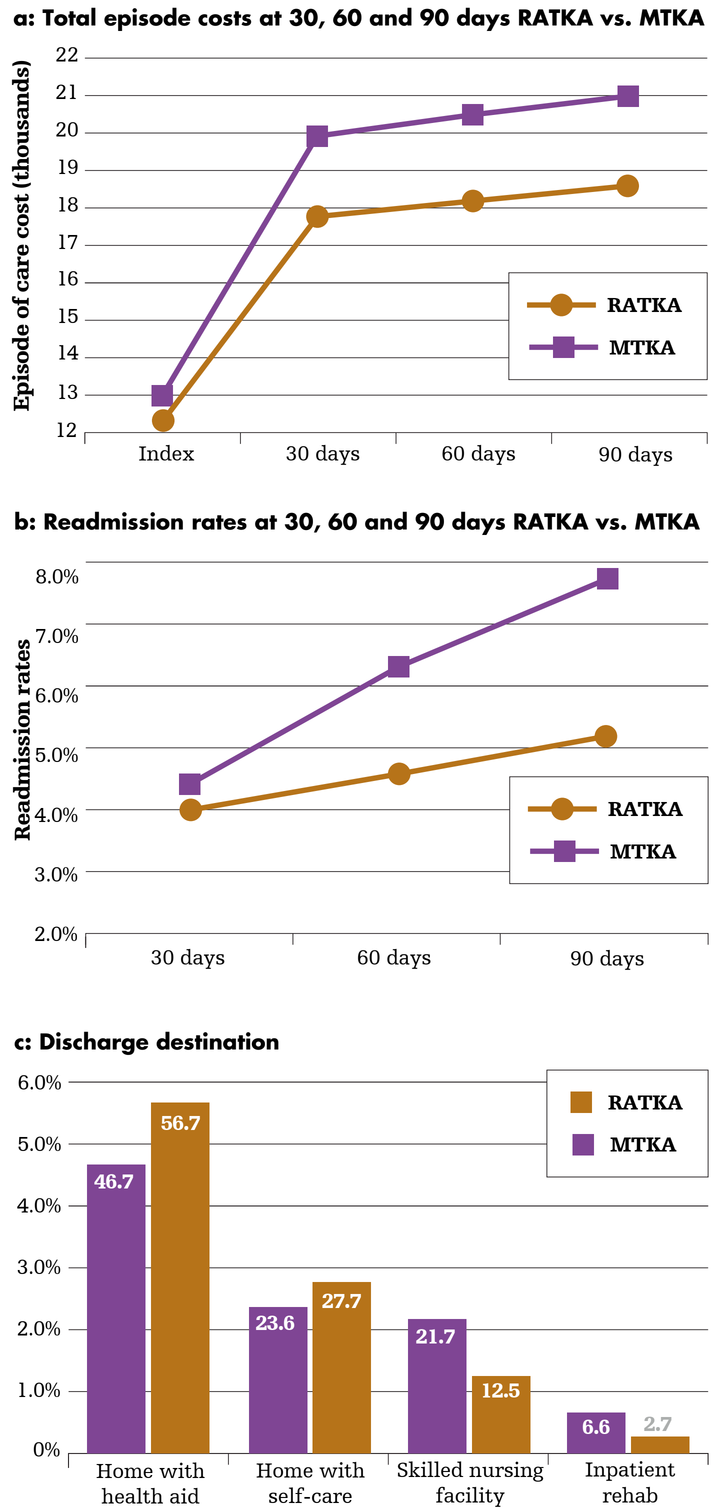


Figure 7. Medicare 100% Standard Analytical Files were queried for RATKA and MTKA cases. Based on propensity matched cohorts, RATKA had (a) reduced episode of care cost at 30-, 60-, and 90-days postoperative as well as (b) reduced rate of admission at those time points. It was also noticed that (c) RATKA cases were more likely to be sent home postoperatively with health aid or self-care as opposed to a skilled nursing facility or inpatient rehab.[58]

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