Mako® Partial Knee arthroplasty: clinical summary

Mako clinical evidence

Version 8

1. Introduction

Partial knee arthroplasty (PKA), also termed unicompartmental knee arthroplasty (UKA) when associated with a single compartment, has been performed for isolated single compartment knee osteoarthritis (OA) since the 1970s.[1] PKA can be carried out in the medial, lateral and/or patellofemoral (PF) compartments.

When compared to total knee arthroplasty (TKA), studies have shown that medial PKA patients experience greater retention of normal knee kinematics and accelerated recovery, while suffering less blood loss and reduced postoperative morbidity.[2-5] Lateral PKA is less common, comprising around one-eighth of all PKA cases.[6] However, lateral PKA has also been shown to be an effective treatment in the appropriate patient, with survivorship and outcomes comparable to medial PKA.[6-8] Patellofemoral arthroplasty has also demonstrated significant benefits to the patient when compared to TKA. A 2018 double-blinded study showed that patients who underwent PF arthroplasty for isolated PF arthritis had a better overall knee-specific quality of life than patients who underwent TKA throughout the first two years after the operation.[9]

Despite the volume of evidence demonstrating the benefits of PKA, the procedure is known to be sensitive to surgical factors such as implant positioning and soft tissue balance.[10] This was recently highlighted in a study by Kazarian et al.,[11] where data from 253 medial PKA patients was retrospectively analyzed to assess the implant survival and radiographic outcomes after PKA, as well as the impact of component alignment and overhang on implant survival. All procedures in the study were performed by two high-volume surgeons. The results showed that the incidence of PKA revisions and alignment outliers were greater than expected, even among high-volume arthroplasty surgeons performing an average of 14 PKAs per year.[2] Both alignment and overhang outliers were significant risk factors for implant failure.[11] The researchers emphasize that the ability of low-volume PKA surgeons to consistently attain accuracy in implant position is an important factor to investigate to help enhance PKA survivorship.[11] The Mako System was introduced to provide accurate implant alignment and anatomic restoration and soft-tissue balancing, thereby helping the surgeon restore native knee kinematics and enhance patient outcomes.[12-14] This document summarizes the evidence to date that supports the use of Mako Robotic-Arm Assisted Surgery for PKA (Mako Partial Knee) including the most recent national joint registry data.[15,16]

2. What evidence is available on Mako Partial Knee?

Successful clinical outcomes following joint replacement are dependent on component placement and on restoring the natural kinematics of the knee. Component malalignment in PKA has been associated with stress concentrations, bone fracture and poor clinical outcomes.[17-20] The Mako System is designed to minimize the margin of error associated with component placement and to enhance the accuracy and reproducibility of PKA. Additionally, the Mako System helps enable the surgeon to dynamically balance soft tissue tensioning intraoperatively, with the goal of recreating natural knee kinematics. Clinical studies have shown that Mako Partial Knee has the potential to produce accurate and reproducible component placement in accordance with preoperative plans[19] and to reestablish soft tissue balance.[20]

St Mart et al. (2022)[21] conducted a prospective study to assess clinical and radiological outcomes for robotic-assisted unicompartmental knee arthroplasty (UKA or PKA): Early lessons from the first 100 consecutive knees in 85 patients. The study aimed to evaluate clinical and radiological outcomes following robotic-assisted PKA as well as any potential learning curves associated with the introduction of the technology. The primary outcome measures were patient-reported outcome measures (PROMs) including Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Knee Society Score (KSS) and Oxford Knee Score (OKS), complications, implant survivorship, component positioning and learning curve. Eighty-five patients comprising 100 knees were recruited and followed for 21.0 ± 4.3 months. At two years, there were significant and sustained improvements in PROMs. A cumulative learning curve of 20 cases was noted. The study concluded that robotic-assisted PKA achieved excellent implant accuracy to plan and clinical outcomes in the short-term.

2.1 Component placement accuracy

A key clinical paper on Mako accuracy, published by Bell et al.[19], reports on a randomized controlled trial (RCT) involving 120 patients. The study compared patients who received robotic-arm assisted PKA (Restoris MCK n=62) with those who underwent manually implanted PKA (Oxford n=58). Comparisons were made between groups in terms of the preoperative plan of femoral and tibial component positioning against the actual alignment achieved in three different planes (axial, coronal and sagittal). Results showed more accurate component positioning in the robotic-arm assisted group, with lower root mean square (RMS) errors and significantly lower median errors in all six component parameters ($p<0.01$). The proportion of patients with tibial slope within 2° of the target position was significantly greater using the robotic-arm assisted technique than the manual technique (80% compared with 22%, $p=0.0001$). It was concluded that the Mako System more consistently placed the PKA implant in accordance with the preoperative plan **(Figure 1)**.

Percentage of knees with components positioned within 2° of the target value

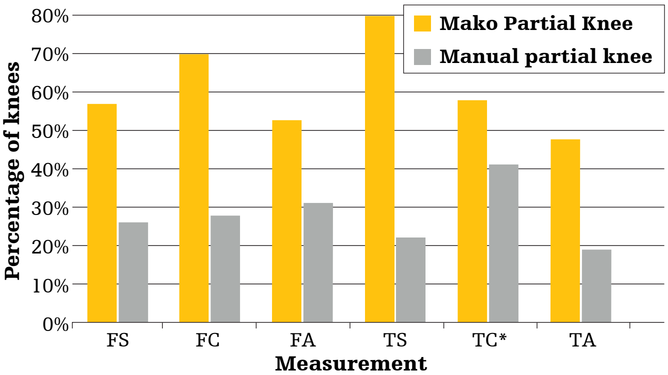

Figure 1. Bell et al. (2016) showed that use of robotic-arm assisted PKA enabled surgeons to place the tibial and femoral components more accurately and consistently to plan. FS= Femoral Sagittal, FC=Femoral Coronal, FA= Femoral Axial, TS= Tibial Sagittal, TC*= Tibial Coronal, TA=Tibial Axial. * = non-significant parameter.[17]

These results were corroborated by a 2018 study performed at University College Hospital in London, England, by Kayani et al.[22] A single surgeon compared implant placement accuracy using radiographs from 60 consecutive conventional PKAs (Oxford) compared to the surgeon's first 60 consecutive Mako Partial Knees (Restoris MCK). The Mako group had significantly ($p<0.001$) more accurate placement to plan for the femoral and tibial implants, as well as more accurate recreation of the knee's mechanical alignment, posterior tibial slope and joint line height.

A study was performed at Washington University School of Medicine, U.S., by Kazarian et al.[23] where postoperative radiological outcomes from 86 consecutive robotic-assisted UKAs were retrospectively reviewed and compared to 253 manual UKAs drawn from a prior study at the same institute.[2] For the robotic-assisted group, 91.6% of all alignment measurements and 99.2% of all overhang measurements were within the target range. All alignment and overhang targets were simultaneously met in 68.6% of RAUKAs. When comparing radiological outcomes between the RAUKA and MUKA groups, statistically significant differences were identified for rates of outliers in femoral coronal angle (2.3% vs. 12.6%; $p = 0.006$), femoral sagittal angle (17.4% vs. 50.2%; $p < 0.001$), tibial coronal angle (5.8% vs. 41.5%; $p < 0.001$), and tibial sagittal angle (8.1% vs. 18.6%; $p = 0.023$), as well as anterior (0.0% vs. 4.7%; $p = 0.042$), posterior (1.2% vs. 13.4%; $p = 0.001$), and medial (1.2% vs. 14.2%; $p < 0.001$) overhang outliers.

Matassi et al.[24] considered the likelihood of robotic-assisted surgery in reducing the variability of coronal and sagittal component positioning between high- and low-volume surgeons. A prospective cohort of 161 robotic-arm assisted medial UKA patients were divided into two groups: patients operated on by "high-volume" or "low-volume" surgeons. They recorded intraoperative lower-limb alignment, component positioning, and surgical timing. Postoperatively, they assessed coronal and sagittal femoral/tibial component alignment, ROM and patient-reported outcomes out to 1-year follow-up. Of the recruited knees, 149 ("high-volume": 101; "low-volume": 48) met inclusion. No clinical difference in mechanical alignment nor coronal/sagittal component positioning were found ($p > 0.05$) between groups. A significant difference was recorded in surgical timing ("high volume": 57 minutes; "low-volume": 86 minutes; $p < 0.05$). No superficial or deep infections or other major complications were developed during the follow-up. Robotics surgery in MUKA confirmed its value in improving the reproducibility of such a technical procedure, with satisfactory clinical outcomes. Moreover, it almost eliminates any possible differences in component positioning, and lower limb alignment among low-and high- volume knee surgeons.

2.1.1 Correction angle

Alongside placement accuracy, Kumar et al.[26] published a study on the importance of correction of PKA postoperative angle. The goal of the study was to understand the correlation between optimal postoperative varus deformity, correction angle and physiological constitutional varus deformity, and the influence of these parameters on WOMAC scores. Robotic-assisted unicompartmental knee arthroplasty in 143 knees were retrospectively assessed with WOMAC scores preoperatively and after surgery at intervals up to 2 years. The results showed that corrections angles were more consistent in robotic than non-robotic outcomes and that preoperative varus and correction angles were well correlated. Mean preoperative and postoperative varus deformities were 10.2° and 4.8°, respectively, with a mean correction angle of 5.4°. The preoperative varus and correction angles were found well correlated ($r = 0.815$). However, the amount of improvement in the WOMAC total score was was not correlated with postoperative varus angle.

The results suggest that there was a significant improvement in the WOMAC score for patients at 1.5 months, 3 months, 6 months, 1 year and 2 years ($p < 0.001$), however, the amount of improvement in the WOMAC total scores overall appeared not to be influenced by the degree of correction and that the correction angle is mostly related to the preoperative varus deformity. More research was recommended.

2.2 Surgical team learning curve

During this initial set of 60 Mako Partial Knee cases within the Kayani et al. study, the surgeon also noted a learning curve of six cases for operating time and surgical team confidence levels to become consistent with conventional PKA statistics.[22] The learning curve did not influence any of the associated accuracy variables, and accuracy to plan achieved with the Mako System was consistent between the surgeon's first Mako case and last 10 Mako cases. This indicated that Mako Partial Knee surgery did not have a learning curve for accuracy in achieving the planned femoral and tibial implant position. Further, no additional risk was observed for postoperative complications during the surgical team learning curve.[22]

Jinnah et al.[25] have previously performed an extensive multicenter study to understand how learning curve may influence surgical time for Mako Partial Knee.[25] Eight hundred and ninety-two patients had a Mako Partial Knee performed by 13 different surgeons. Surgical time was measured from insertion of the first bone pin to the acceptance of the final trial components. The average surgical time for all surgeons was 56 ± 20 minutes. The shortest average surgical time for an individual surgeon was 38 ± 9 minutes and the longest was 70 ± 29 minutes. An average learning curve of 13 cases was proposed for the surgical time to reach a steady state **(Figure 2)**.

Learning curve

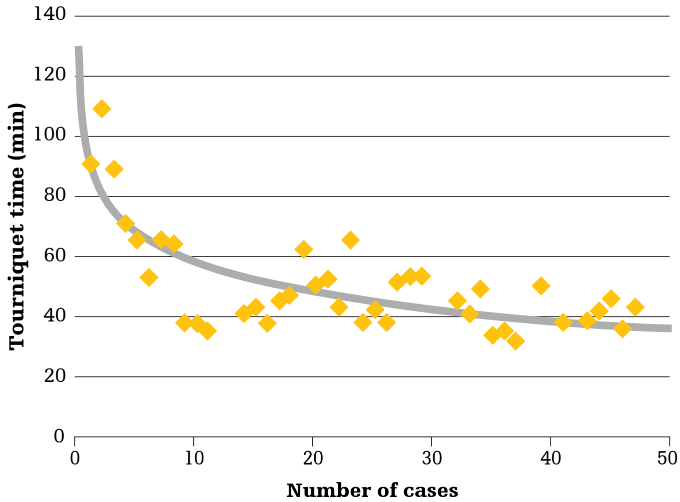

Figure 2. Typical Mako Partial Knee learning curve graph showing one surgeon's first 50 cases from a multicenter study by Jinnah et al. (2010). After approximately 13 cases, surgical time reached a steady state.[20]

Tay et al.[27] concluded that the learning curve for Mako Partial Knee is 11 cases. The study aim was to assess operating times, patient outcomes, limb alignment and component placement for both low and high-volume surgeons. Five surgeons performed 152 consecutive robotic-arm assisted primary medial PKA, and measurements of interest were recorded. Patient outcomes were measured with Oxford Knee Score, EuroQol-5D, and Forgotten Joint Score at six weeks, one year and two years. The surgeons were divided into 'low' and 'high' usage groups based on total PKA (manual and robotic) performed per year.

A learning curve of 11 cases was found, with a statistically significant decrease in operative time between the learning phase and the proficiency phase ($p=0.01$), a significant improvement in femoral rotation between the two phases ($p=0.02$), and more accurate insert sizing between the phases ($p=0.03$), which highlighted areas that require care during the learning phase. Despite decreased 6-week EQ-5D-5L VAS in the proficiency group (77 cf. 85, $p < 0.01$), no difference was found in implant survival (98.2%) between learning and proficiency phases ($p=0.15$), or between 'high' or 'low' usage surgeons ($p=0.23$) at 36 months. This suggests that the learning curve did not lead to early adverse effects in this patient cohort. The conclusion was that PKA robotic-arm assisted surgery showed learning curves for operative time (11 cases), and insert sizing, but not for implant survival at early follow-up. The short learning curve regardless of PKA usage indicated that robotic-arm assisted PKA may be particularly useful for low-usage surgeons.

2.3 Soft tissue balance and bone preservation

From a soft tissue perspective, Plate et al.[20] considered that the ability to effectively restore a patient's ligament length and tension may help with restoration of normal knee kinematics and muscle lever arms of the knee joint. Their study examined the accuracy of dynamic, real-time ligament balancing for 52 Mako Partial Knees. Gap distances at 0°, 30°, 60°, 90° and 110° flexion were assessed preoperatively and after final component implantation to establish whether ligament balancing was restored. Ligament balancing was accurate up to 0.53 mm compared to the preoperative plan. These results indicated the Mako System was capable of accurately and precisely reproducing the desired soft tissue balance.

In addition to this, a cadaveric investigation was carried out with the aim of quantifying the amount of bone preserved in robotic medial PKA compared to robotic TKA.[28] Eleven knees were selected and analyzed from seven cadavers. Results showed that robotic PKA procedures resected an average of 11.6±1.33 cm^3 (range: 9.85-13.7 cm^3) whereas total knee procedures resected an average of 59.7±9.65 cm^3 (range: 47.4-78.3 cm^3), demonstrating that for this study population, only 17% to 19% of the bone volume was resected in robotic PKA compared to robotic TKA. The study highlighted that in robotic PKA, the femur preparation is contoured to match the implant, which may in turn contribute to enhanced bone preservation and retention of bone stock.

In another cadaveric study by Hampp et al.[29], they compared the extent of soft-tissue trauma sustained through robotic-arm assisted PKA and manual PKA. Five surgeons, confident in robotic-arm assisted PKA and manual partial knee techniques, were asked to prepare a total of 24 cadaveric knees. Afterwards two independent surgeons were asked to estimate trauma to the patellar tendon, quadriceps tendon, anterior cruciate ligament (ACL), medial collateral ligament (MCL), medial capsule, posterior capsule, and posterior cruciate ligament (PCLs) using a five-grade system where Grade 1 represented complete tissue preservation and Grade 5 represented over 76% tissue trauma. When compared to the manual PKA group, robotic-arm assisted PKA had lower total trauma grading ($p<0.01$), lower posterior capsular damage ($p<0.01$), and less severe ACL damage ($p<0.01$). The authors concluded that based on this analysis the use of robotic-arm assisted devices for PKA can result in significantly less soft tissue trauma compared to manual PKA.

2.4 Summary of evidence

These studies demonstrated that robotic-arm assisted technology equipped the surgeon to accurately and consistently place the femoral and tibial PKA components[19] in accordance with preoperative plans, and to effectively restore soft tissue balancing.[20] This technology is associated with a short learning curve to achieve time neutrality compared to manual surgery, without influencing the ability to achieve high accuracy.[26]

3. What are the potential clinical benefits of Mako Partial Knee?

Mako Partial Knee has been shown to deliver demonstrable clinical benefits.[12-14,32,33] Studies have investigated implant survivorship, patient satisfaction, clinical outcomes and functional outcomes in medial Mako Partial Knee, with favorable results in comparison to other surgical methods.[12-14,32,33-42] In lateral and PF Mako Partial Knee, promising clinical and functional outcomes have also been observed.[43,44] Furthermore, in both medial and lateral PKA, congruence of the nonsurgical and surgical compartments has been found to be restored, supporting the hypothesis that the resultant redistribution of contact forces across the patellofemoral joint could help address PF symptoms.[42,43,44]

3.1 Survivorship

Favorable survivorship data was shared by Vakharia et al. at the American Association of Hip and Knee Surgeons 2020 annual meeting.[46] His site performed a retrospective review of prospectively collected data in their institution's registry on patients who underwent robotic-arm assisted medial UKA. The final query consisted of 185 patients. Patients had a mean age of 64.9 years and mean body mass index (BMI) of 31.6kg/m^2 with a mean follow-up of 9.98 years. Ten-year survivorship of the study cohort demonstrated 98% survivorship 9.98 years following the index procedure. Majority of the patients stated they were either "very satisfied" (80.95%) or "satisfied" (16.19%) with the outcomes of their procedure. Furthermore, two patients were revised during the study period. This study was the first to longitudinally follow a large cohort of patients undergoing robotic-arm assisted medial UKA and report on long-term survivorship and patient-satisfaction.

In a U.S. study published by Burger et al.[37] they evaluated midterm implant survivorship for robotic-arm assisted PKA patients. The research involved a retrospective review of patients who underwent robotic-arm assisted PKA between 2007 and 2016. Study participants received a fixed-bearing medial or lateral PKA, patellofemoral arthroplasty (PFA), or bicompartmental knee arthroplasty (involving a PFA plus medial PKA), and the mean follow-up was 4.7 years (2.0 to 10.8).[37] The five-year survivorship rate of medial PKA (n=802), lateral PKA (n=171) and PFA/bicompartmental knee arthroplasty (n=35/10) was 97.8%, 97.7% and 93.3%, respectively.[37]

Comparable data was previously confirmed in a multicenter longitudinal study evaluating short- and midterm survivorship of robotic-arm assisted medial PKA, which demonstrated 98.8% survivorship (in 909 knees) at 2.5-year follow-up and 97% survivorship (in 432 knees) at 5.5-year follow-up.[12,23] This survivorship rate was greater than rates derived from high-volume surgeon data and registry data for conventional PKA **(Figure 3)**.[12,23] The study concluded that the favorable survivorship observed resulted from Mako's ability to help enable surgeons to achieve more accurate component positioning when compared to implant placement using manual techniques.[12,23]

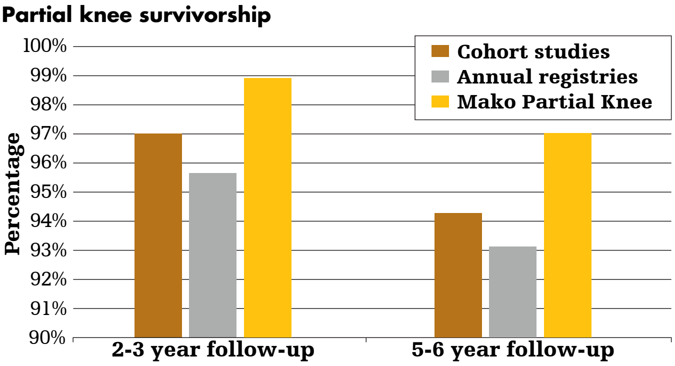

Figure 3. Survivorship data from Pearle et al. (2017)[22] and Kleeblad et al. (2018)[12] on robotic-arm assisted PKA compared to studies in literature and annual registries reporting 2 to 3 years and 5 to 6 years conventional PKA survivorship data.

An RCT by Gilmour et al.[48], comparing patients who underwent medial Mako Partial Knee (Restoris MCK) with those who underwent manual medial PKA (Oxford) demonstrated encouraging results. Specifically, Mako Partial Knee patients had 100% survivorship compared to 96.3% in the manual group at two years post-operation. The 100% survivorship rate was maintained in the robotic group at five years post-operation.

Promising data was published in the 2022 Australian Joint Registry,[15] which reported the cumulative percent revision for Restoris MCK medial PKA as 1.5% at one year, 3.2% at three years and 4.1% at five years. These rates were lower when compared to all cases performed without robotic assistance, which were reported to be 2.0%, 4.2% and 5.6% at one, three, and five years, respectively. Furthermore, the cumulative revision rate of the Restoris MCK medial PKA also compared favorably to the revision rate for all Oxford medial PKA replacements, which were 2.2% at one year, 5.7% at three years, and 8.2% at five years.

Similarly, the Restoris MCK partial knee system appears in the NJR[16] report for the first time in 2022. Restoris MCK currently has an ODEP rating of 5A and is the best performing partial knee at five years with a revision rate of 1.70%.[16]

Bayoumi et al.[30] presented 10-year survivorship and satisfaction results at EFORT 2022 based on data from a multicenter study. The multicenter longitudinal study evaluated short, mid and long-term survivorship of robotic-arm assisted medial UKA, which demonstrated 98.8% survivorship at 2.5-year follow-up (n = 909), 97% survivorship at 5.5-year follow-up (n = 432), and 92.2% survivorship at 10.2-year follow-up (n = 528). Unexplained pain and aseptic loosening were the most common modes of failure. Additionally, this survivorship rate was greater than rates derived from high-volume surgeon data and registry data for conventional PKA. When considering patient satisfaction, the majority of Restoris MCK medial PKA patients were "very satisfied" or "satisfied" with their joint replacement; 92% of patients reported satisfaction with their knee 2.5-years postoperatively, 91% reported satisfaction at 5.5-years, and 92% reported satisfaction at 10.2-years.

These findings were also reflected in a study conducted by St Mart et al.,[40] who examined the cumulative revision rate of Restoris MCK components implanted with the Mako System using data from the Australian Joint Registry between 2015 and 2018. The researchers found that the robotic-assisted PKA with Restoris had significantly lower overall revision rate compared to other types of non-robotically-assisted PKA procedures.

The revision rates for Mako Partial Knee with Restoris MCK have been published in cohort studies, economic analyses, level I clinical trials (RCTs) and international registries **(Figure 4)**. The evidence supports excellent survivorship of the Restoris MCK implant.

Midterm survivorship for isolated lateral compartmental arthritis:

Midterm survivorship for robotic-assisted PKA was investigated by Heckmann et al.[41] This retrospective case series assessed results of all lateral PKAs performed by a single surgeon between 2013 and 2019. Patient demographics, surgical variables and Kozinn and Scott criteria were collected, and implant survivorship was estimated using the Kaplan-Meier method with the endpoint being conversion to TKA.

Registry medium term outcomes

The results identified 84 lateral PKAs which met the inclusion criteria with a mean follow-up of 4.0 years (range 2.0-7.0). Five-year survivorship was 92.9% (95% confidence interval [CI] 84.5-96.7) with all cause revision and 100% conversion to TKA as an endpoint. Six-year survivorship was 88.9% with one additional patient being revised to TKA after five years. The average Forgotten Joint Score was 82.7% and patient satisfaction 4.7/5.

The study reported high midterm survivorship and excellent patient-reported outcomes and concluded that robotic-assisted lateral PKA is a viable treatment option for isolated lateral compartment arthritis.

Survivorship

Multiple studies demonstrate a low revision rate for Mako Partial Knee

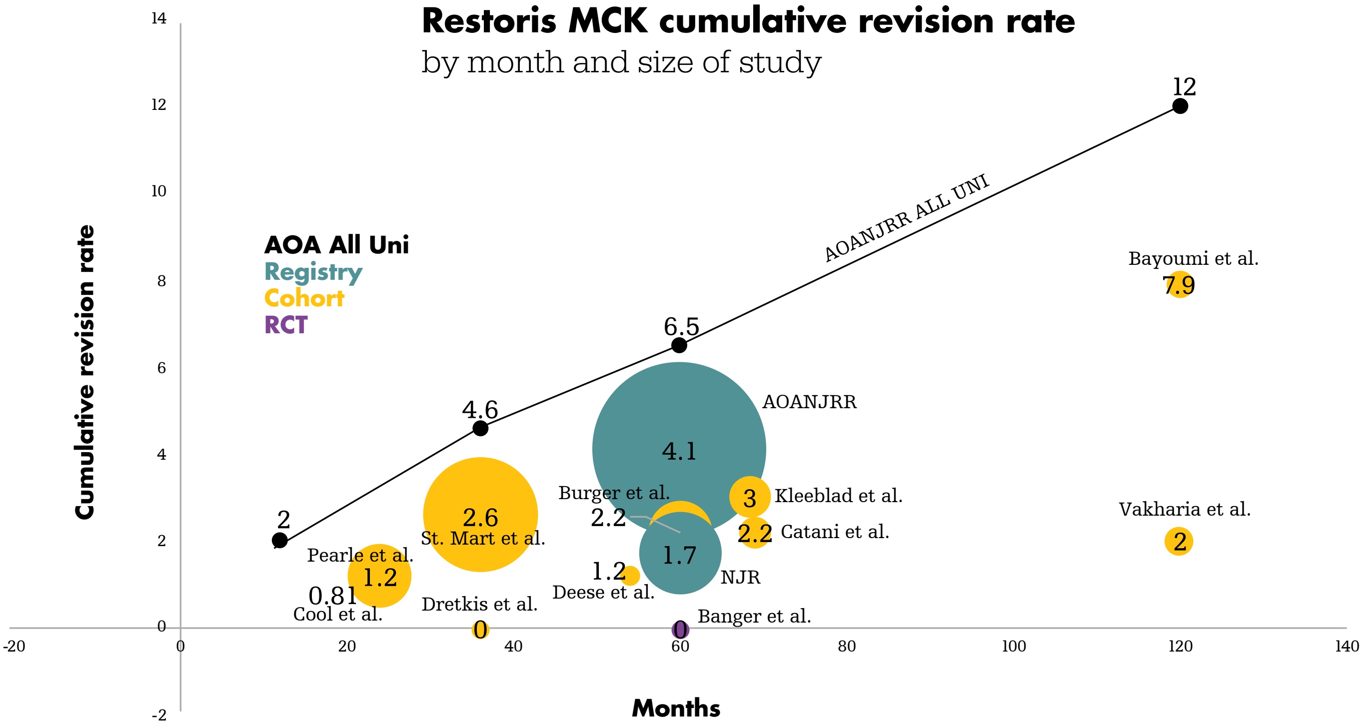

Figure 4. Graph indicating Mako Partial Knee revision rates with data taken from cohort studies, economic analyses, level I clinical trials (RCTs) and international registries.[12, 15, 16, 30, 40, 46, 48, 49, 50, 51, 52, 53, 56]

Table 1. Survivorship

Study	Months	n	CRR
Cool et al.[52]	24	246	0.81
Pearle et al.[48]	24	900	1.2
St Mart et al.[40]	36	2851	2.6
Dretakis et al.[50]	36	51	0
Deese et al.[49]	54	81	1.2
Banger et al.[51]	60	65	0
Burger et al.[56]	60	802	2.2
NJR England and Wales[16]	60	1410	1.7
AOANJRR[15]	60	6349	4.1
Kleebad et al.[12]	68.4	384	3
Zambiachi et al.[53]	69	216	2.2
Vacharia et al.[46]	120	185	2
Bayoumi et al.[30]	120	160	7.9
AOANJRR All Uni (2022)[15] (for reference)	12	50	2
	36	50	4.6
	50	50	6.5
	50	50	12

3.2 Patient satisfaction

In a multicenter longitudinal clinical trial, most Mako Partial Knee patients were "very satisfied" or "satisfied" with their joint replacement.[12] This study performed follow-up at 2.5 years (909 knees) and 5.5 years (432 knees) with patients who underwent medial Mako Partial Knee procedures. 92% of patients reported satisfaction with their knee 2.5 years postoperatively and 91% of patients reported satisfaction at 5.5 years **(Figure 5)**. In a similar study based on the Swedish Knee Arthroplasty Registry, 83% of 7,860 patients who underwent manual medial PKA were satisfied with their knee at an average six-year follow-up.[32]

Using the Mako System, Coon et al.[35] performed 152 (71.3%) medial PKAs,[33] (15.5%) lateral PKAs, 20 (9.4%) medial bicompartmental PKAs and 8 (3.8%) patellofemoral PKAs. All surgical procedures had high patient satisfaction with an average of 82.5% of patients reporting being very satisfied or satisfied at six months, which increased to 89.5% at two years. The lateral PKA group reported 100% satisfaction two years post-operation.

Comparable midterm patient satisfaction data was recently published in a large single-surgeon study of 1018 knees,[37] where a large proportion of patients who underwent robotic-assisted PKA reported high satisfaction levels. The mean follow-up was 4.7 years (2.0 to 8.0), and the results showed that 90.7% of medial PKA patients, 92.6% of lateral PKA patients and 78.9% of PFA or bicompartmental knee arthroplasty patients were either very satisfied or satisfied with their knee function.

3.2 Recovery

Barrack et al. report on a single-institution, prospective cohort study showing Mako UKA patients in comparison to manual TKA patients had shorter operating time, less blood loss, better functional outcomes at six weeks post-operative, and less pain at six weeks postoperative.[31] This difference dissipated by two years postoperatively.

3.3 Clinical outcomes

An RCT performed by Blyth et al. found that patients who underwent medial Mako Partial Knee experienced less pain than those who underwent manual surgery during the 90-day postoperative period.[13] Median pain scores were 55.4% lower in robotic-arm assisted patients compared to manual patients from day one to day 56 **(Figure 6)**.[13] Furthermore, the robotic-arm assisted patients had a better American Knee Society Score (AKSS) at three months postoperatively and at one year postoperatively, and a greater proportion of robotic-arm assisted patients showed improvements in their UCLA Activity Score.[13] Through binary logistic regression, the study was also able to predict the key factors associated with achieving excellent outcomes on the AKSS. These factors were a preoperative UCLA Activity Score level >5 and the use of robotic-arm assisted surgery, although these do not withstand adjustment for multiple comparisons.[13]

Mako Partial Knee patient satisfaction

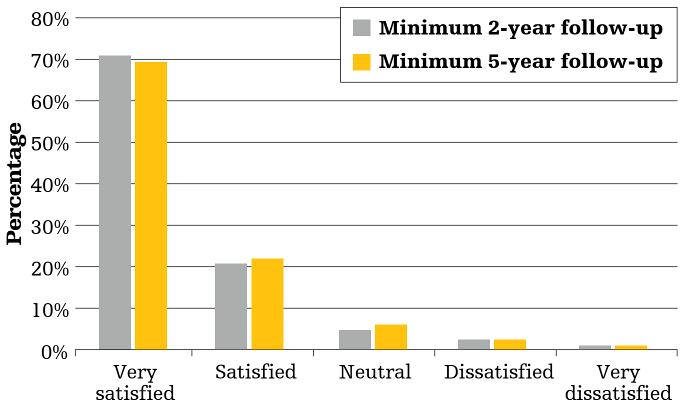

Figure 5. Midterm patient satisfaction with medial Mako Partial Knee procedures (Kleeblad et al., 2018[12] and Pearle et al., 2017[22]).

Partial knee pain scores

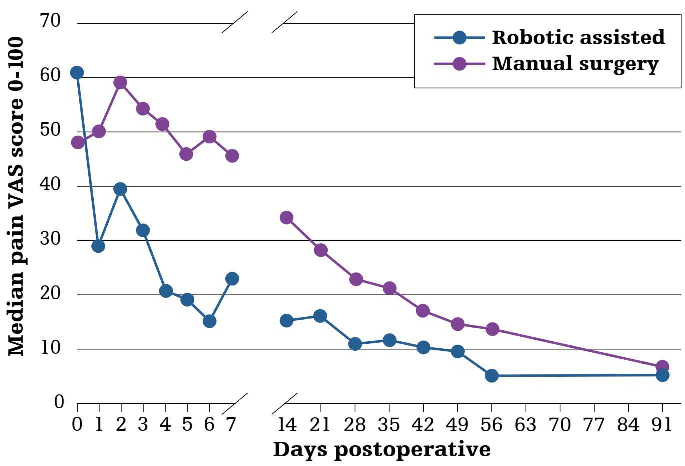

Figure 6. Visual analog pain score collected up to 90 days postoperatively in a RCT of manual vs. robotic arm-assisted medial PKA procedures.[13]

In two separate studies, evidence showed that medial Mako Partial Knee patients were more likely to "forget" their artificial joint during daily life compared to those who underwent manual TKA.[33,34] Zuiderbaan et al. administered The Forgotten Joint Score (FJS) questionnaire one and two years postoperatively.[33] Scores were compared between 65 patients who underwent medial Mako Partial Knee and 65 patients who underwent manually instrumented TKA.[33] Results demonstrated patients who underwent medial robotic-arm assisted PKA were more likely to forget their artificial joint in daily life. Similarly, in a separate powered cohort study from the U.K., conducted by Clement et al.[34,30] patients who underwent Mako Partial Knee were propensity score matched to 90 patients who underwent manual TKA for isolated medial compartment arthritis. The findings from this study showed that the six-month FJS was significantly greater for the robotic PKA group compared to the manual TKA group (difference 24.2, p < 0.001) **(Figure 7)**.

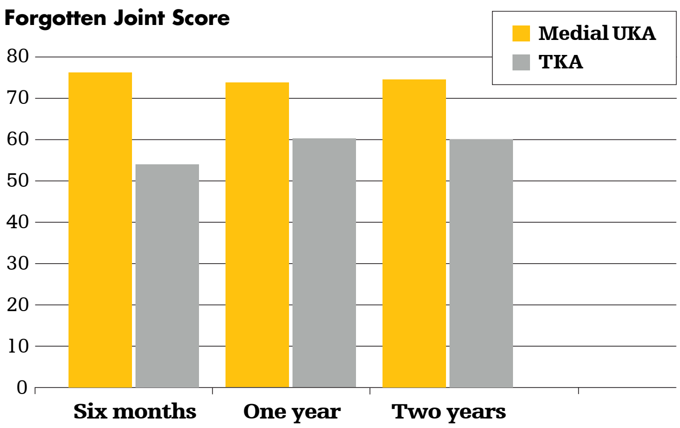

Figure 7. FJS at six months, one and two years post-operation showing significantly higher scores in the medial Mako Partial Knee group (p<0.001, p=0.002 and p=0.004, respectively)[26,27]

Furthermore, the same powered (1:3 ratio) cohort study by Clement et al.[34] published encouraging early postoperative outcomes data, where statistically and clinically significant greater knee-specific functional outcomes were observed in robotic PKA patients compared to those who underwent manual TKA.[34] Findings showed that the robotic PKA group had a significantly greater six-month Oxford Knee Score by nearly eight points, and there was a five-point (95% confidence interval 1.9 to 8.1; p < 0.001) greater improvement in the robotic PKA group compared to the manual TKA group, which was greater than the minimal clinically important difference. This positive early outcome data was further fortified within the study as the researchers also found that the robotic PKA group had significantly better postoperative pain visual analogue scale (VAS) scores compared with the manual TKA group **(Table 2)**.[34]

Table 2. Six-month postoperative outcome measures and differences between robotic PKA vs. manual TKA.[34]

Mean PROM (SD)	rUKA	mTKA	Difference (95% CI)	p-value*
Postoperative OKS	44.2 (4.4)	36.5 (9.4)	7.7 (4.2 to 11.3)	<0.001
Postoperative FJS	77.1 (25.9)	52.9 (32.6)	24.2 (11.2 to 37.2)	<0.001
Postoperative EQ-5D	0.913 (0.126)	0.764 (0.248)	0.148 (0.054 to 0.241)	0.002
Postoperative pain VAS	93.6 (12.3)	76.4 (24.8)	20.5 (9.9 to 31.0)	<0.001

*Unpaired t-test.
CI, confidence interval; EQ-5D, EuroQol five-dimension questionnaire; FJS, Forgotten Joint Score; mTKA, manual total knee arthroplasty; OKS, Oxford Knee Score; PROM, patient-reported outcome measure; rUKA, robotic unicompartmental knee arthroplasty; VAS, visual analog scale.

Overall, results of these studies suggested positive clinical and patient-reported outcomes of robotic-arm assisted medial, lateral PF and bicompartmental PKA[10,12-14,26,34-37,48]

3.4 Functional outcomes

Gait analysis has been used to compare outcomes of robotic-arm assisted PKA patients to those of manual Oxford PKA patients. In an RCT, Motesharei et al.[38] compared the gait of 31 robotic PKA patients to 39 Oxford PKA patients one year postoperatively. Both groups were compared to a control group of 50 healthy subjects obtained from the University of Strathclyde's archive. Results from this study showed statistically significant differences in knee joint kinematics during level walking between the robotic-arm assisted and manual PKA groups. The robotic-arm assisted group achieved a higher knee excursion (18.0°, SD 4.9°) compared to the manual group (15.7°, SD 4.1°) There was no significant difference between the healthy group and the robotic-arm assisted group, but there was a significant difference between the healthy group and the manual group (p<0.001).

Partial knee gait

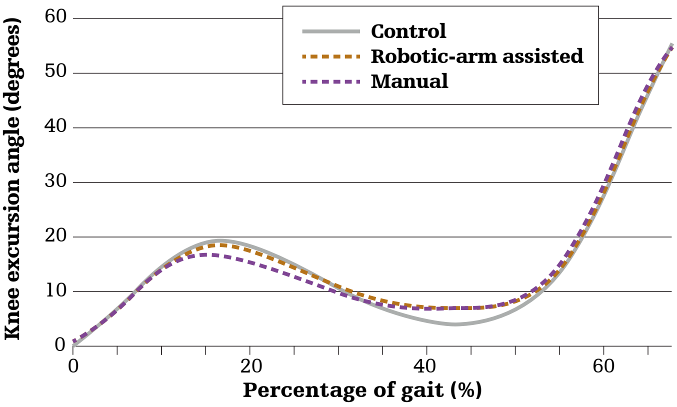

Figure 8. Mean knee excursion angles of the control group, the robotic-arm assisted and manual PKA groups during the stance phase of gait at one year post-operation.[38]

This study was repeated at five-years postoperatively by Millar et al.,[14] though on fewer patients (25 Mako vs. 21 Oxford), and the differences seen at one year were maintained. Results showed that the Mako group achieved significantly greater knee flexion in weight acceptance than the conventional group **(Table 4)**. These findings suggested that the improved alignment offered by the Mako System may result in enhanced function of the knee during gait, and that the use of the Mako System resulted in a gait pattern that facilitated the normal function of the knee more closely than the conventional technique.[14,38]

A clinical study by Borus et al.[39] assessed functional performance in patients who received robotic-arm-assisted PKA compared to those who received manual TKA. Tests included a six-minute walk, timed up and go, and stair ascend/descend, which were measured preoperatively and at six weeks and at three months postoperatively. Although a statistically significant difference in functional performance change between groups was not reached, the authors highlighted that at six weeks, the robotic PKA group was able to walk an additional 21.00 meters (68.90 feet) compared to just 5.95 meters (19.52 feet) for the manual TKA group. Remarkably similar functional differences were observed with the timed up and go and stair ascend/descend tests, suggesting that robotic PKA provided functional benefits that were at least equivalent to manual TKA.

Research by Coon et al.[36] on medial Mako Partial Knees, lateral PKAs, medial bicompartmental PKAs and patellofemoral PKAs showed that at two years postoperatively, 87.9% of patients were as active or the same as they expected they would be before surgery. In addition, the average distance walked at discharge was 79.8 meters, and 90.9% of patients were walking without support three weeks postoperatively. Lastly, 65 patients were employed at time of surgery, and 86% of those patients returned to work six weeks after their operation.

3.5 Clinical outcomes lateral PKA

Lateral PKA is less frequently performed within the general population, accounting for just one-eighth of PKA cases.[6] However, this procedure has been shown to be effective for the appropriate patient, achieving reliable improvements in pain, function and implant survivorship.[6-8] The Mako robotic platform offers potential benefits through its demonstrated accuracy and reproducible implant positioning, helping to minimize the margin of error associated with component placement.[12] In addition, the platform enables intraoperative dynamic soft tissue balancing to help the surgeon recreate the patient's natural knee kinematics.

Promising results have been reported by several studies examining lateral Mako Partial Knee.[54,55] For example, a retrospective study conducted by van der List et al.[54] compared two-year postoperative functional outcomes using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC score) and FJS, between 143 medial and 36 lateral Mako Partial Knee procedures. Equivalent functional outcomes were noted for both medial and lateral PKA procedures.[54]

Similar promising survivorship data was published by Augart et al.[55] The authors performed a search of their institution's joint registry and found 88 lateral robotic-arm assisted PKA patients, with a mean follow-up of 24.4 months ±10.7 months, who had 100% survivorship at final follow-up without revision to TKA.[55] The promising data observed thus far from medial and lateral Mako Partial Knees suggests that the potential benefits offered by the Mako robotic platform, with regards to surgical planning, precision, reproducibility and intraoperative soft tissue adjustments, have the potential to help enhance surgical accuracy during these technically demanding procedures.

3.6 Continuum of care

As mean patient age decreases, partial knee arthroplasty is often indicated as a conservative treatment to delay need for a total knee replacement. Studies of joint line restoration, patella tracking, and medial and lateral compartment congruency have been conducted at Hospital for Special Surgery in New York.[42-44] In all three studies, congruence of the surgical compartment was restored through the Mako procedure and implant. Congruence and joint line of the nonoperative compartment were also restored (p=0.001).[42] The authors hypothesized that the improved patellofemoral congruence after Mako Partial Knee may lead to redistribution of contact forces across the patellofemoral joint and secondarily treat PF symptoms.[42,55]

Similarly, in a 2020 study by Burger et al.,[56] researchers aimed to explore the effect of patellofemoral joint pathology on lateral PKA. In particular, the effect of preoperative radiological degenerative changes and alignment on patient-reported outcome measures (PROMs) after lateral PKA was evaluated, as well as the influence of lateral PKA on the alignment of the patellofemoral joint.[56] A consecutive series of 140 knees in 130 patients who underwent Mako robotic-arm assisted fixed-bearing lateral PKA were retrospectively reviewed. Radiological evaluation was conducted to obtain a Kellgren Lawrence (KL) grade, an Altman score and alignment measurements for each knee. Postoperative PROMs were assessed using the Kujala (Anterior Knee Pain Scale) score, Knee Injury and Osteoarthritis Outcome Score Joint Replacement (KOOS JR) and satisfaction levels. The results showed that at mean 4.1 years (2.0 to 8.5) follow-up, good to excellent Kujala scores were reported, and the presence of mild to moderate preoperative patellofemoral joint osteoarthritis had no impact on these scores (KL grade 0 vs. 1 to 3, $p = 0.203$; grade 0 to 1 vs. 2 to 3, $p = 0.674$). Comparable scores were reported by patients with osteoarthritis evident on either the medial or lateral patellofemoral joint facet, and patients with abnormal patellar congruence and tilt angles ($\geq 17°$ and $\geq 14°$, respectively) reported good to excellent Kujala scores. Furthermore, it was evident that lateral PKA resulted in improvements to patellofemoral alignment.[56] The findings from this study are encouraging as this is the first study demonstrating that mild to moderate preoperative radiological degenerative changes and malalignment of the patellofemoral joint are not associated with poor patient-reported outcomes at midterm follow-up after lateral fixed-bearing PKA. The researchers went on to suggest that this may be explained by realignment of the patella and the resulting redistribution of loads across the patellofemoral joint.[56]

3.7 Outcomes of patellofemoral arthroplasty

The purpose of patellofemoral arthroplasty is to address the pain caused at the patellofemoral joint without performing a more substantial total knee surgery that would sacrifice additional bone. However, past literature has reported conflicting success rates of PFA as a surgical treatment for patellofemoral OA.[57,58] Odgaard et al.[59] used a multicenter, double-blinded RCT to compare clinical outcomes associated with PFA and TKA to establish whether there was an advantage to either option. They found that PFA patients recovered quicker than TKA patients, and the functional outcomes were also better for PFA patients. The average TKA patient lost almost three months of knee function postoperatively during the first two years, relative to the PFA patient. It was concluded that PFA was a superior option to TKA in patients with patellofemoral OA.[59]

Encouraging functional data was observed in another study by Noyes et al.,[45] which examined the early results of 33 prospective, consecutive third generation Mako PFA procedures. The authors analyzed both sports and work activity levels in younger active patients. The study included 33 consecutive PFAs in 29 patients (four bilateral), with a mean age 40 (range, 22-68). All patients received a comprehensive clinical evaluation, Cincinnati Knee Rating and International Knee Documentation Committee (IKDC) objective rating. They also received radiographic evaluation. Results showed high levels of participation in light sports: 22% preoperatively, rising to 87% postoperatively. A total of 85% of patients in the employed subgroup returned to work postoperatively, and in six out of seven patients who received surgery due to articular cartilage restoration failure, improvement was seen postoperatively, and they returned to light sports/work.[46] This research demonstrated that robotic-arm assisted PFA was a successful treatment option in younger active patients with isolated PF arthritis, enabling the majority of those patients to return to low-impact recreational activities and occupations.[45]

3.8 Outcomes of bicompartmental knee arthroplasty

Bicompartmental knee arthroplasty (BiKA) may be an alternative for TKA candidates with localized arthritis. The advantages of BiKA in comparison to TKA is that it is more minimally invasive.[60] It requires less bone removal and preserves the anterior and posterior ligaments which may lead to better stability and proprioception for the patient.[60-64] Studies have reported BiKA resulting in less scaring, need for less blood transfusions, reduced surgical morbidity, and faster rehabilitation when compared to TKA.[60] However, there are also concerns around the complication rates for BiKA with component positioning listed as possible culprit.[17,19]

Gaudiani et al.[64] published on their prospectively maintained cohort of 50 patients (53 knees) who underwent BiKA (patellofemoral and medial compartment) at five- and seven-year follow-up. The group reported high survivorship rates, with 96% at five years and 93% at seven years.[57] At a mean follow-up of 7.1 years (range 7.0 – 7.3), 89% of patients reported being either satisfied of neutral with their BiKA where 11% reported being not satisfied. A mean Knee Society – Function Score of 80.5 ± 15.8 with 82% of patients reporting walking more than 10 blocks, 89% walking without support, and 100% able to go up and down stairs with 61% requiring use of a handrail.[64]

3.9: Complication and revision

In 2022 Sun et al.[65] conducted a systematic review and meta-analysis to compare complication and revision rates of robotic-assisted vs. manual PKAs. They considered eligible case-control studies comparing robotic-assisted and conventional PKA with data from all eligible articles independently extracted by two authors. Differences in outcomes between robotic-assisted and conventional PKA were analyzed by calculating the corresponding 95% CIs and pooled relative risks (RRs).[65]

The results included in the final meta-analysis were taken from a total of 16 studies involving 50,024 patients. It was found that robotic-assisted PKA had fewer complications (RR: 0.52, 95% CI: 0.28 to 0.96, p=0.036) and lower revision rates (RR: 0.42, 95% CI: 0.20 to 0.86, p=0.017) than conventional PKA. No significant differences in non-implant-specific complications between the two surgical techniques (RR: 0.80, 95% CI: 0.61 to 1.04, p=0.96) were observed. No publication bias was found in this meta-analysis.[65]

4. Is Mako cost-effective?

Compared to TKA, studies have shown that UKA patients have fewer postoperative complications,[66] improved FJS,[34,35] and higher quality-adjusted life-years (QALYs) in older patients.[52,67,68]

With rising demand for PKA in patients who seek restored function and a quicker recovery time, a U.S. study performed by Kazarian et al.[67] evaluated the cost-effectiveness of PKA compared to TKA as well as nonsurgical treatment (NST). Using a Markov decision analytic model, the authors assessed lifetime costs and QALYs as function of age at time of initial treatment (ATIT) of patients with end-stage unicompartmental knee osteoarthritis. The analysis included direct medical and indirect costs. Models were run for ATITs at five-year intervals from 40 thro was more cost-effective compared to NST for patients aged 40 to 86. Furthermore, when surgical treatments were compared, PKA dominated TKA by generating more QALYs than TKA for all ATITs. The authors further concluded that if PKAs were performed as 12% to 20% of the total volume of knee arthroplasties versus the less than 8% observed, it would lead to a lifetime cost-savings of 987 million to 1.5 billion U.S. dollars and increased lifetime QALY accumulation of 124,403 to 217,705 across the U.S. population.[67]

In a separate U.K.-based study, a Markov decision analysis by Clement et al.[68] was performed to assess the cost-effectiveness of robotic PKA (rPKA) relative to manual TKA (mTKA) and manual PKA (mPKA) for patients with isolated medial compartment OA of the knee with a mean age of 65 years.[68] The study objective was to identify the cost per quality adjusted life-year of rPKA relative to mTKA and mPKA. Model inputs included hospital costs, implant survival and mortality rate. Using a model with an annual case volume of 100 patients, the cost per QALY of rPKA was £1,395 and £1,170 relative to mTKA and mPKA, respectively. The cost per QALY was influenced by case volume: a low-volume center performing 10 cases per year would achieve a cost per QALY of £7,170 and £8,604 relative to TKA and PKA, respectively. For a high-volume center performing 200 rPKAs per year with a mean two-day length of stay, the cost per QALY would be £648; if performed as day cases, the cost would be reduced to £364 relative to TKA. For a high-volume center performing 200 rPKAs per year with a shorter length of stay of one day relative to PKA, the cost per QALY would be £574 **(Figure 14**[69]**)**. Furthermore, the cost per QALY of rPKA decreased with reducing length of hospital stay and with increasing case volume, compared with mTKA and mPKA.[68] The model showed that rPKA was a cost-effective alternative to mTKA and mPKA for patients with isolated medial compartment OA of the knee.

In summary, these models demonstrated that in patients with isolated medial compartment arthritis, PKA was observed to be a more cost-effective procedure compared to nonsurgical treatment and TKA for the specified age groups modelled, thus concluding rPKA was cost effective compared to TKA.

A hospital in Brisbane, Australia St Mart et al.[41] examined the potential cost-savings for the health system and the community in a broadly accessible model through the increased utilization of PKA using robotic-arm assisted PKA vs. conventional TKA. They retrospectively reviewed 240 patients where the first 120 consecutive Mako Partial Knees performed during this period were matched to 120 conventional TKAs. Clinical data from the medical records and costs for procedure for each component were collected. Bivariate analyses were performed on the data to determine if there were statistically significant differences by surgery type in clinical outcomes and financial costs. The study found a significantly lower cost incurred for robotic-arm assisted PKA vs. TKA with an average savings of AU$7,179 per case. The operating time (86.0 min vs. 75.9 min; $p=0.004$) was significantly higher for PKA but the length of stay was significantly lower (1.8 vs. 4.8 days; $p<0.001$). This study also found a significant difference in the use of opioids in PKA compared to TKA (125.0 morphine equivalent (ME) vs. 522.1 ME, $p<0.001$).[41]

In the U.S., in a study by Cool et al.,[52] reasons for revisions and associated costs were analyzed for unicompartmental arthroplasty cases. UKA procedures were identified using a commercial administrative claims database to evaluate hospital admissions for revision surgeries. Robotic UKA (rUKA, Mako Partial Knee) and manual UKA (mUKA, manual partial knee) procedures performed between March 1, 2013 and July 31, 2015 were used to calculate the rate of revisions within 24 months of the index procedure. Cases were propensity matched 2:1 based on age, sex, race, geographic division, high-cost comorbidities and concentration of healthcare specialists per 100,000 population to control for outside confounding factors at case index. A total of 738 commercial health plan patients (246 rUKA, 492 mUKA) were selected for inclusion in the analysis. Results indicated fewer revision procedures in rUKA (0.81% (2/246) vs. 5.28% (26/492); $p=0.0017$) and rUKA patients incurred lower mean costs for the index stay plus revision(s) ($26,001 vs. $27,977; $p>0.05$). Lower length of stay at index was also noted in the rUKA group (1.77 vs. 2.02 days; $p=0.0047$). The study concluded that patients who underwent rUKA had fewer revision procedures, shorter LOS and incurred lower mean costs at 24 months.[52]

Findings from a 2020 U.K. cohort study involving 30 Mako Partial Knees compared to 90 propensity-matched manual TKAs showed that the length of stay was significantly ($p < 0.001$) shorter in the robotic-arm assisted PKA group (median two days, interquartile range (IQR) one to three) compared to the manual TKA group (median four days, IQR three to five). The shorter length of stay observed in this study was considered a cost saving for the center relative to mTKA.[34]

The cost-effectiveness studies described above all differed in inputs specific to their country, local region, hospital system or payer. These studies demonstrated that robotic-arm assisted partial knee arthroplasty, in comparison to manual TKA or manual partial knees, was associated with lower costs and/or improvements in QALY.[67-69]

5. Conclusion

Mako Partial Knee offers the potential for surgeons to achieve component placement accuracy[19] and soft tissue balancing,[20] as well as to enhance clinical outcomes.[12-14,32-39,47,48] Patients have reported tangible benefits of robotic-arm assisted procedures, including treatment satisfaction,[12,33,35,37,48] return to activities of daily living[35] and a "forgotten" joint.[13,33,34] Surgeons are empowered to achieve their target preoperative plans with precision,[19] helping distinguish them within their medical communities. The cost-effectiveness studies described here demonstrated favorable economic returns, lower costs and better improvements in QALY for patients who received robotic-arm assisted partial knees in contrast to those received TKA or manual partial knees.[67-69] Ultimately, the benefits of Mako Partial Knee surgery are reported to be experienced by all key players – patients, surgeons and health systems.

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