Mako Partial Knee arthroplasty: evidence of clinical and commercial efficacy
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. A PKA can be carried out in the medial, lateral, 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 post-operative morbidity. Lateral PKA is less common, comprising around one-eighth of all PKA cases. However, lateral PKA has also been shown to be an effective treatment, in the appropriate patient, with survivorship and outcomes comparable to medial PKA. PF arthroplasty has also demonstrated significant benefits to the patient when compared to TKA. A recent double blinded study showed that patients undergoing PF arthroplasty for isolated PF arthritis had a better overall knee-specific quality of life than patients undergoing TKA throughout the first 2 years after the operation.

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. The Mako System has been introduced with a view to providing accurate implant alignment and anatomic restoration and soft-tissue balancing, thereby restoring native knee kinematics and improving patient outcomes. This document summarizes the evidence to date that supports the use of Mako Robotic Arm-Assisted Surgery for partial knee arthroplasty.

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 UKA has been associated with stress concentrations, bone fracture and poor clinical outcomes. 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 the Mako Partial Knee has the potential to produce accurate and reproducible component placement in accordance with pre-operative plans and to re-establish soft tissue balance.

2.1 Component placement accuracy

A key clinical paper on Mako accuracy, published by Bell et al. (2016), reports on a randomized controlled trial involving 120 patients. The study compared patients receiving 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 pre-operative 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 pre-operative plan (Figure 1).

These results were corroborated by a recent study performed at University College Hospital in London, England, by Kayani et al. (2018). 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 of the femoral and tibial implants, as well as more accurate recreation of the knee’s mechanical alignment, posterior tibial slope, and joint line height.

2.2 Surgical team learning curve

During this initial set of 60 Mako Partial Knee cases within the Kayani et al. (2018) study, the surgeon also noted a learning curve of 6 cases for operating time and surgical team confidence levels to become consistent with...
conventional PKA statistics. The learning curve did not influence any of the associated accuracy variables, and accuracy 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 post-operative complications during the surgical team learning curve.

Jinnah et al. (2010) have previously performed an extensive multi-centre study to understand how learning curve may influence surgical time for Mako Partial Knee. 892 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 ± 20min. The shortest average surgical time for an individual surgeon was 38 ± 9min and the longest was 70 ± 29 min. An average learning curve of 13 cases was proposed for the surgical time to reach a steady state (Figure 2).

2.3 Soft tissue balance

From a soft tissue perspective, Plate et al. (2013) 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 knees receiving Mako Partial Knee. Gap distances at 0°, 30°, 60°, 90°, and 110° flexion were assessed pre-operatively and after final component implantation, to establish whether ligament balancing was restored. Ligament balancing was accurate up to 0.53mm compared to the preoperative plan. These results indicate the Mako System was capable of accurately and precisely reproducing the desired soft tissue balance.

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 in accordance with pre-operative plans and to effectively restore soft tissue balancing. This technology is associated with a short learning curve to achieve time neutral surgery compared to manual surgery, without influencing the ability to achieve high accuracy.

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

Mako Partial Knee has been shown to deliver demonstrable clinical benefits. Studies have been carried out to investigate implant survivorship, patient satisfaction, clinical outcomes, and functional outcomes in medial Mako Partial Knee, with favourable results in comparison to other surgical methods. In lateral and PF Mako Partial Knee, promising clinical and functional outcomes have also been observed. Furthermore, in both medial and lateral PKA, congruence of the non-surgical and surgical compartments has been found to be restored, supporting the hypothesis that the resultant redistribution of contract forces across the patellofemoral joint could secondarily treat PF symptoms.

3.1 Survivorship

A multi-centre, longitudinal study evaluating short- and mid-term survivorship of robotic-arm assisted medial PKA demonstrated 98.8% survivorship (in 909 knees) at 2.5 year follow-up (Pearle et al., 2017) and 97% (in 432 knees) at 5.5 year follow-up (Kleeblad et al., 2018). This survivorship rate was greater than rates derived from high volume surgeon data and registry data for conventional PKA (Figure 3). It was concluded that favourable 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.
A recent RCT by Gilmour et al. (2018), comparing patients who underwent Mako Robotic-Arm Assisted medial PKA (Restoris MCK) with those who underwent manual, conventional medial PKA (Oxford), demonstrated encouraging early results (Figure 4). Specifically, Mako Partial Knee patients had 100% survivorship compared to 96.3% in the manual group, 2 years post-operation.21

Similar promising data was published in the 2017 Australian Joint Registry, which reported the cumulative revision rate for the Restoris MCK medial PKA as 0.8% at one year. This compared favourably to the revision rate for all Oxford medial PKA Replacements (2.2%) and is the lowest rate for any PKA implant reported (Figure 4). Furthermore, it is important to highlight that the revision rate of 0.8% in Restoris MCK is in fact lower than the reported cumulative revision rate for primary total knee replacement, which was 1.0% at 1 year.22

3.2 Patient satisfaction

In a multi-centre, longitudinal clinical trial, patients undergoing medial Mako Partial Knee surgery were “very satisfied” or “satisfied” with their joint replacement.11,20 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.11,20 A total of 92% of patients reported satisfaction with their knee 2.5 years post-operatively and 91% of patients reported satisfaction at 5.5 years (Figure 5).11,20 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 6 year follow-up.23

3.3 Clinical outcomes

One RCT performed found that patients undergoing medial Mako Partial Knee experienced less pain than those undergoing manual surgery during the 90 day post-operative period (Blyth et al., 2017).12 Median pain scores were 55.4% lower in robotic arm-assisted patients than in patients undergoing manual surgery (Figure 6).24

![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.12)

![Forgotten joint score](Figure 7. FJS at 1- and 2-years post-operation showing significantly higher scores in the medial Mako Partial Knee group (p=0.002 and p=0.004, respectively).24)
compared to manual patients from day one to week eight (Figure 6). Furthermore, the robotic arm-assisted patients had a better American Knee Society Score (AKSS) at three months and one year postoperatively, as well as a greater proportion of patients showing improvements in their UCLA Activity Score. Through binary logistic regression, the study was also able to predict the key factors associated with achieving excellent outcomes on the AKSS. These were found to be a pre-operative UCLA Activity Score level >5 and the use of robotic-arm surgery.

In a separate study, 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. Scores were compared between 65 patients who underwent medial Mako Partial Knee and 65 patients who underwent manually instrumented TKA. Results suggest patients who undergo medial robotic-arm assisted PKA are more likely to forget their artificial joint in daily life (Figure 7).

A similar trend was seen in the study carried out by Blyth et al. (2017), where three months post-operatively the proportion of patients achieving a forgotten joint score of >80% was almost double in the robotic-arm assisted cohort compared to the manual PKA cohort.

Using the Mako System, Coon et al. (2017) performed 152 (71.3%) medial PKAs, (15.5%) lateral PKAs, 20 (9.4%) medial bicompartamental PKAs, and 8 (3.8%) patellofemoral PKAs. All surgical procedures had high patient satisfaction with an average of 82.5% reporting being very satisfied or satisfied at six months and increasing to 89.5% at two years. The lateral PKA group reported 100% satisfaction two years post-operation. Overall, results suggested positive clinical and patient-reported outcomes of robotic-arm assisted medial, lateral, PF, and bicompartamental PKA.

3.4 Functional outcomes

Gait analysis was used to compare outcomes of robotic-arm assisted PKA patients to those of manual Oxford PKA patients, in an RCT. Motesharei et al. (2018) compared the gait of 31 robotic PKA patients to 39 Oxford PKA patients, one year post-operatively. 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°) (Figure 8 and Table 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).

This study has now been repeated at 5 years post-operation by Millar et al. (2018), and the differences seen at 1 year were maintained, albeit on a lower number of patients (25 Mako vs. 21 Oxford). Results showed that the Mako group achieved significantly greater knee flexion in weight acceptance (WA) than the conventional group (Table 2). These findings suggested that the improved alignment offered by the Mako System may result in improved 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 Oxford implant.

| Table 1. Comparison of knee excursion values during loading phase of gait at 1-year post-operation. Standard deviation in brackets. |
|------------------|------------------|------------------|
| **Knee excursion from foot-strike to mid-stance (degrees)** | **Control** | **Mako** | **Oxford** |
|                  | 19.5 (4.0) | 18.0 (4.9) | 15.7 (4.1)* |
| *Significantly different than the control group |

| Table 2. Mean (SD) excursion during weight acceptance for each patient group at 5 years post-operation. |
|------------------|------------------|------------------|
| **Patient Group** | **Mean (SD) excursion during WA (°)** | **P** |
| Mako             | 14.3 (6.4) |  |
| Oxford           | 9.9 (4.2)   | 0.008 |

A clinical study by Borus et al. (2018) assessed functional performance in patients who received robotic-arm assisted PKA, compared to those who received manual TKA. Tests included a 6-minute walk, timed up and go, and stair ascend/descend, which were measured pre-operatively and 6 weeks and 3 months post-operatively. Although a statistically significant difference in functional performance change between groups was not reached, the authors highlighted that at 6 weeks, the robotic PKA group
were 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.28 Very 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 TKA28

Research by Coon et al. (2017) on medial Mako Partial Knees, lateral PKAs, medial bicompartamental PKAs, and patellofemoral PKAs showed that 87.9% of patients were as active or the same as they expected they would be before surgery, 2 years post-operatively.28 In addition, the average distance walked at discharge was 79.8 meters, and 90.9% of patients were walking without support 3 weeks post-operatively.28 Lastly, 65 patients were employed at time of surgery, and 86% of those patients returned to work 6 weeks after their operation.26

3.5 Clinical outcomes of lateral PKA

Lateral PKA is a less frequently performed procedure within the general population, accounting for just one-eighth of PKA cases6 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 benefits through its proven accuracy and reproducible implant positioning, minimizing the margin of error associated with component placement.11 In addition, the platform enables intra-operative dynamic soft tissue balancing to help recreate the patient’s natural knee kinematics.

Promising results have been reported by several studies examining lateral Mako Partial Knee.29–30 For example, a retrospective study conducted by van der List et al. (2016) compared 2-year post-operative functional outcomes using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC score) and forgotten joint awareness (FJS), between 143 medial and 36 lateral Mako Partial Knee procedures (Figure 9).29 Equivalent functional outcomes were noted for both medial and lateral PKA procedures.29

Similar promising survivorship data was published by Augart et al. (2015).30 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 a 100% survivorship at final follow-up without revision to TKA.30

The promising data observed thus far from medial and lateral Mako Partial Knees suggests that the benefits offered by the Mako robotic platform, with regard to surgical planning, precision, reproducibility and intra-operative soft tissue adjustments, have the potential to prevent the occurrence of surgical inaccuracies 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. In all three studies, congruence of the surgical compartment was restored through the Mako procedure and implant. 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 (Figure 10, Figure 11, Figure 12).

3.7 Clinical outcomes of patellofemoral arthroplasty

The purpose of patellofemoral arthroplasty (PFA) 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. Odgaard et al. (2017) used a multi-centre, 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 3 months of knee function post-operatively during the first two years, relative to the PFA patient. It was concluded that PFA was a superior option to TKA in the case of patients with patellofemoral OA.

Encouraging functional data was observed in another study by Noyes et al. (2018), 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 (4 bilateral), with a mean age 40 (range, 22-68) of the patients were less than 50 years old. 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% pre-operatively, rising to 87% post-operatively. A total of 85% of patients in the employed subgroup returned to work post-operatively, and in 6 of the 7 patients who received surgery due to articular cartilage restoration failure, improvement was seen post-operatively and they returned to light sports/work. 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.

4. Is Mako cost-effective?

Although clinical and economic trade-offs between early benefits and later revisions of PKA versus TKA are poorly understood, PKA typically requires less rehabilitation, results in fewer post-operative complications, results in patients more likely to forget their artificial joint in daily life, and improved quality of life. With a rising demand for PKA expected among younger patients who seek restored function and a quicker return to work, a study performed by Ghomrawi et al. (2015) in the U.S., to evaluate the cost-effectiveness of PKA versus TKA in younger and older patients using a validated Markov model. This model utilized cost, revision rate, and quality of life data from National Joint Registries, published literature, the Healthcare Cost and Utilisation Project (HCU) government database, and the internal Health, Safety and Security (HSS) registry. Despite assuming equal post-operative quality of life values for PKA and TKA, the model showed that in patients over 65 years old, PKA was more cost-effective. This result was primarily due to higher rehabilitation costs and higher post-operative complication rates with TKA, despite higher revision rates with PKA. PKA would become cost-effective over TKA for patients under 65 years with a small decrease in the revision rate and a small increase in quality of life.

As cost-effectiveness models are highly dependent on the hospital system, an additional cost-effectiveness model for PKA was created for a hospital system in Philadelphia. Mean contribution profit for PKA (diagnosis-related group [DRG] 470, 81.54) was highly dependent on many factors, including patient age, payer mix, hospital cost-efficiencies, and ratio of reimbursement capture relative to charges. For this analysis, the per-case conservative contribution profit assumption was $3500. A pre-operative computed tomography (CT) scan was part of the robotic PKA protocol (CPT 73700), and generated $125 for this hospital.

At the request of Stryker, Baker Tilly, a third-party consulting company, performed a retrospective review of a US-based payer commercial database for PKA surgeries performed between 2013 and 2015, and reimbursed by a US national commercial health plan. The plan had approximately 25 million members. When comparing medical claims in the database between manual and robotic-arm assisted knee procedures, the latter was associated with lower all-cause readmission rates and lower average cost per readmission. Specifically, robotic-arm assisted surgery was associated with 40% and 66% lower all-cause readmission costs at 30 and 90 days of follow-up, respectively. Robotic-arm assisted surgery was associated with an 88% reduction in revisions (0.4%) in comparison to manual PKA (3.5%, p=0.004) and an
average 33% shorter length of stay (2.2 days) when compared to manual PKA (3.3 days).\textsuperscript{41}

In a cost-effectiveness study carried out in Scotland, patients receiving robotic-arm assisted PKA were compared to those receiving conventional PKA.\textsuperscript{42} Patients treated with robotic-arm assisted PKA required fewer bed days (2.6 days vs 3.0 days) and, based on EuroQoL-5 (EQ-5D) scores 3 months post-surgery, were quicker to achieve greater improvement in their overall health state, compared to those treated using conventional surgery.\textsuperscript{42} However, this difference in overall health was not seen 1 year post-operatively and the Quality Adjusted Life Year (QALY) at 1 year was equivalent between the two procedures.\textsuperscript{42} Longer term follow-up is being performed to establish whether robotic-arm assisted PKA results in improved clinical outcomes or reduced revision rates, based on improved placement accuracy with the robotic-arm assisted technology.\textsuperscript{42}

5. Conclusion

Mako Partial Knee offers the potential for surgeons to achieve component placement accuracy\textsuperscript{16} and soft tissue balancing,\textsuperscript{17} as well as to enhance clinical outcomes.\textsuperscript{11-13,20-28} Patients have reported tangible benefits of robotic-arm assisted procedures, including treatment satisfaction\textsuperscript{11,20} return to activities of daily living,\textsuperscript{28} and a “forgotten” joint.\textsuperscript{12,24} Surgeons are empowered to achieve their target pre-operative plans with precision,\textsuperscript{16} helping distinguish them within their medical communities. The continuum of patient care available with Mako Partial Knee was also shown to likely be more cost-effective than TKA in patients over the age of 65.\textsuperscript{40} Ultimately, the benefits of Mako Partial Knee surgery are reported to be experienced by all key players – patients, surgeons, and health systems.
References


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