

# Mako<sup>®</sup> Partial Knee arthroplasty: clinical summary



## Mako clinical evidence



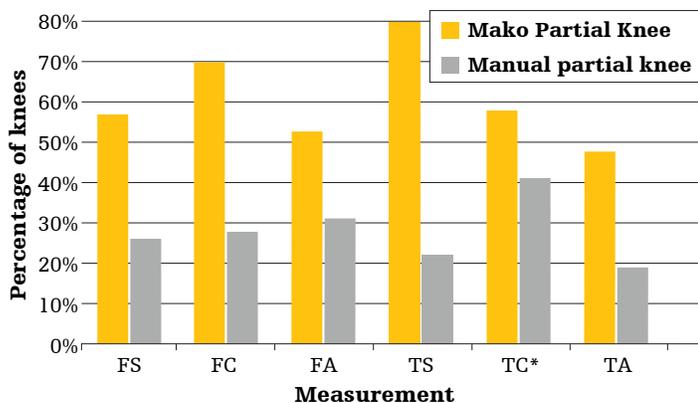
## 1. Introduction

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.<sup>1</sup> 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.<sup>2-5</sup> 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.<sup>6-8</sup> 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.<sup>9</sup>

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.<sup>10</sup> The Mako System was 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.<sup>11-13</sup> This document summarizes the evidence to date that supports the use of Mako Robotic-Arm Assisted Surgery for partial knee arthroplasty.

**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.<sup>16</sup>**

## 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.<sup>14,15</sup> 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,<sup>16</sup> and to reestablish soft tissue balance.<sup>17</sup>

### 2.1 Component placement accuracy

A key clinical paper on Mako accuracy, published by Bell et al. (2016), 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).<sup>16</sup> 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 ( $p < 0.01$ ).<sup>16</sup> 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).<sup>16</sup>

These results were corroborated by a recent study performed at University College Hospital in London, England, by Kayani et al. (2018).<sup>18</sup> 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 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.<sup>18</sup>

### 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.<sup>18</sup> 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.<sup>18</sup>

Jinnah et al. (2010) have previously performed an extensive multi-center study to understand how learning curve may influence surgical time for Mako Partial Knee.<sup>19</sup> 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 ± 20 min. The shortest average surgical time for an individual surgeon was 38 ± 9 min 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).<sup>19</sup>

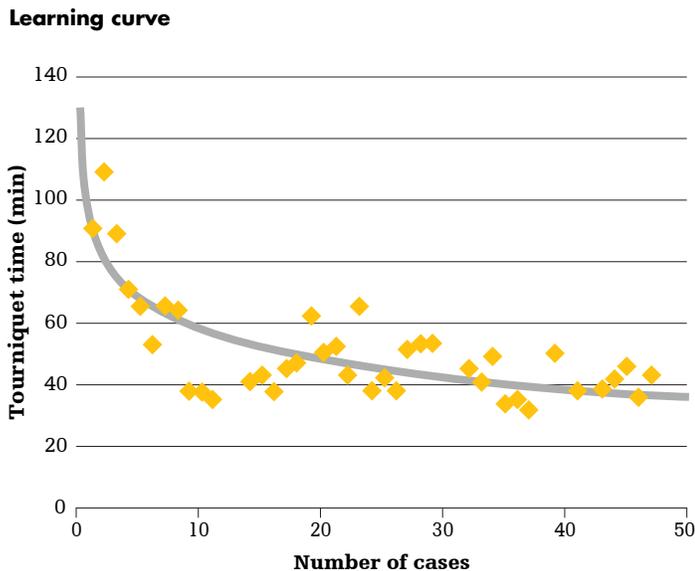


Figure 2. Typical Mako Partial Knee learning curve graph showing one surgeon's first 50 cases from a multi-center study by Jinnah et al. (2010). After approximately 13 cases, surgical time reached a steady state.<sup>19</sup>

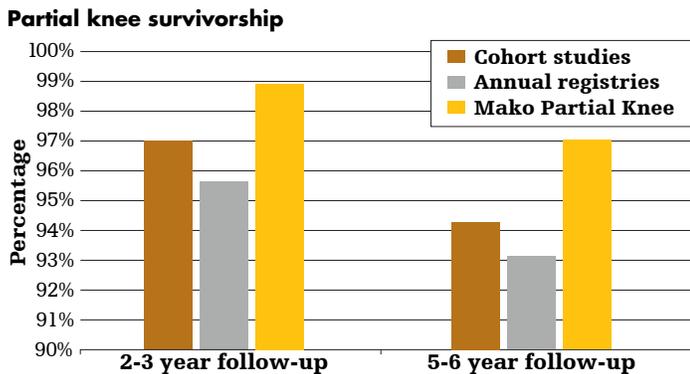


Figure 3. Survivorship data from Pearle et al. (2017)<sup>20</sup> and Kleeblad et al. (2018)<sup>11</sup> on robotic-arm assisted PKA compared to studies in literature and annual registries reporting 2 to 3 years and 5 to 6 years conventional PKA survivorship data.

## 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.<sup>17</sup> Their study examined the accuracy of dynamic, realtime 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 0.53mm compared to the preoperative plan.<sup>17</sup> These results indicated 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,<sup>16</sup> in accordance with preoperative plans and to effectively restore soft tissue balancing.<sup>17</sup> 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.<sup>18</sup>

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

Mako Partial Knee has been shown to deliver demonstrable clinical benefits.<sup>11-13, 20-28</sup> Studies have been carried out to investigate implant survivorship, patient satisfaction, clinical outcomes, and functional outcomes in medial Mako Partial Knee, with favorable results in comparison to other surgical methods.<sup>11-13, 20-28</sup> In lateral and PF Mako Partial Knee, promising clinical and functional outcomes have also been observed.<sup>28-31</sup> 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.<sup>32-34</sup>

### 3.1 Survivorship

A multi-center, longitudinal study evaluating short and midterm 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).<sup>11, 20</sup> This survivorship rate was greater than rates derived from high volume surgeon data and registry data for conventional PKA (Figure 3).<sup>11, 20</sup> 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.<sup>11, 20</sup>

A recent RCT by Gilmour et al. (2018), comparing patients who underwent medial Mako Partial Knee (Restoris MCK) with those who underwent manual, conventional medial PKA (Oxford), demonstrated encouraging early results (Figure 4). Specifically, Mako Partial Knee patients had

Partial knee revision rates at 1 year

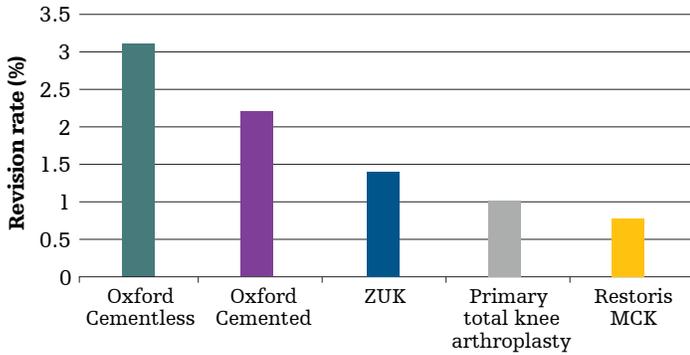


Figure 4. Australian registry revision rates (2017) for the Restoris MCK compared favorably to other implants available in the market.<sup>22</sup>

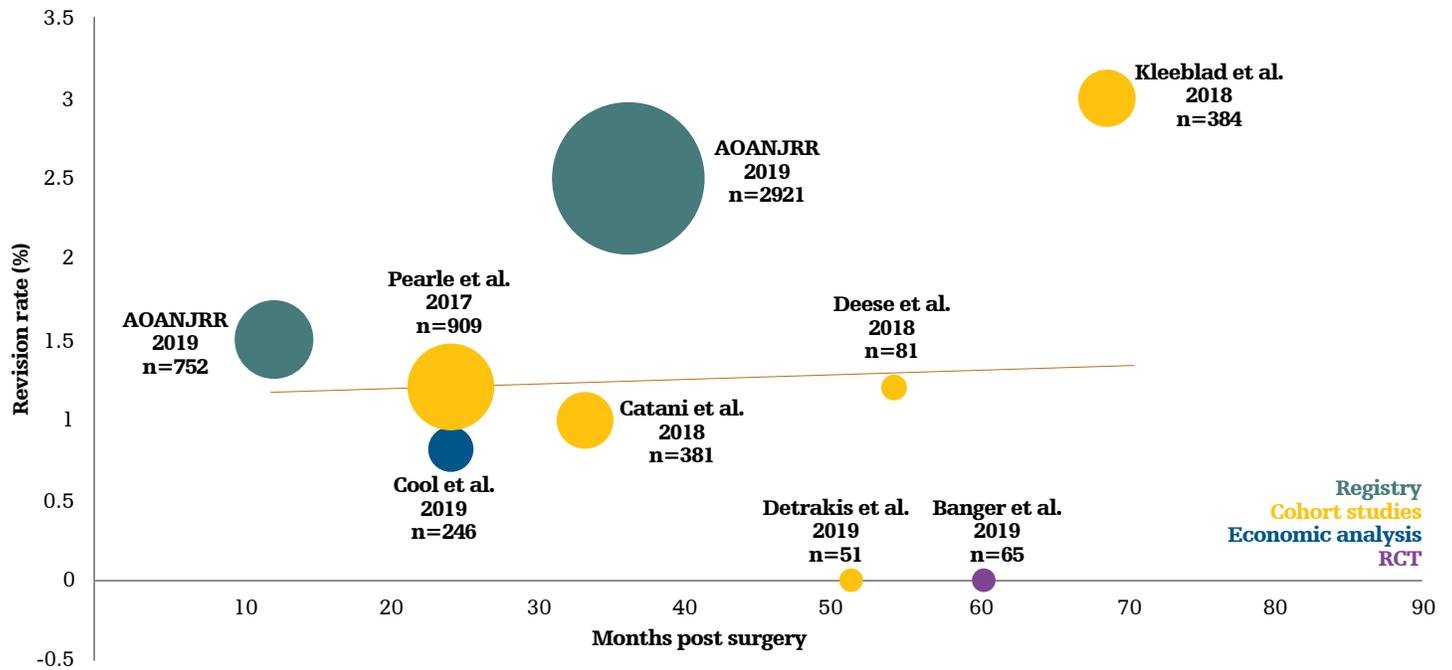


Figure 5. Graph indicating Mako Partial Knee revision rates with data taken from cohort studies, economic analyses, level I clinical trials (RCT) and international registries.<sup>11,20,22,41,43-45,47-49</sup>

100% survivorship compared to 96.3% in the manual group, 2 years postoperation.<sup>21</sup>

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 favorably 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.<sup>22</sup>

The revision rates for Mako Partial Knee have been published in cohort studies, economic analyses, level I clinical trials (RCT) and international registries (Figure 5). The evidence supports excellent survivorship of the Restoris MCK implant.

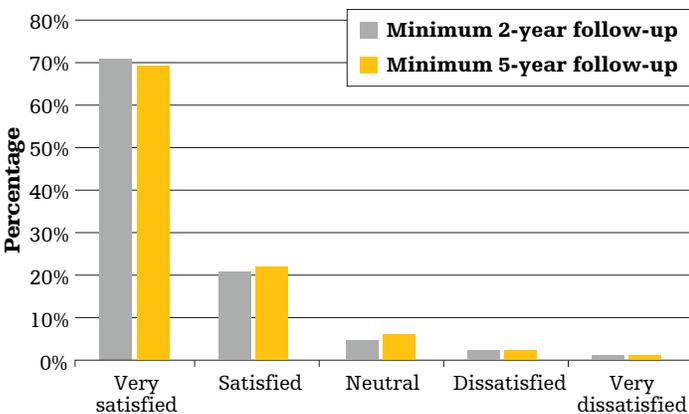
### 3.2 Patient satisfaction

In a multi-center, longitudinal clinical trial, patients were “very satisfied” or “satisfied” with their joint replacement.<sup>11,20</sup> 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.<sup>11,20</sup> A total of 92% of patients reported satisfaction with their knee 2.5 years postoperatively and 91% of patients reported satisfaction at 5.5 years (Figure 6).<sup>11,20</sup> 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.<sup>23</sup>

### 3.3 Clinical outcomes

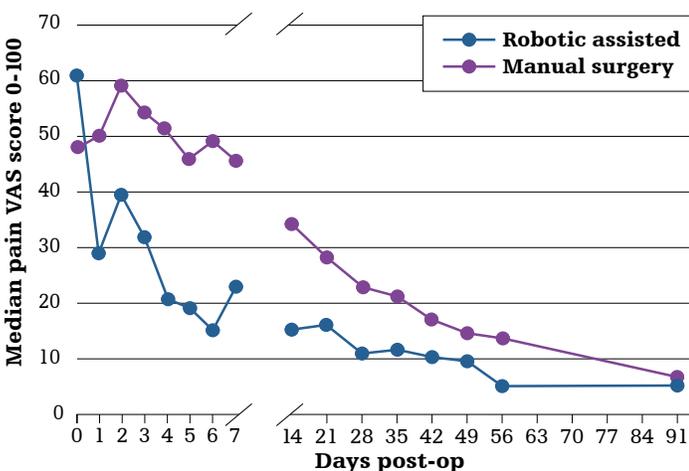
One RCT performed found that patients who underwent medial Mako Partial Knee experienced less pain than those who underwent manual surgery during the 90 day postoperative period (Blyth et al., 2017).<sup>12</sup> Median pain scores were 55.4% lower in robotic-arm assisted patients

**Mako Partial Knee patient satisfaction**



**Figure 6. Mid-term patient satisfaction with medial Mako Partial Knee procedures (Kleeblad et al., 2018 and Pearle et al., 2017).<sup>11,20</sup>**

**Partial knee pain scores**



**Figure 7. Visual analog pain score collected up to 90 days postoperatively in a RCT of manual vs. robotic arm-assisted medial PKA procedures.<sup>12</sup>**

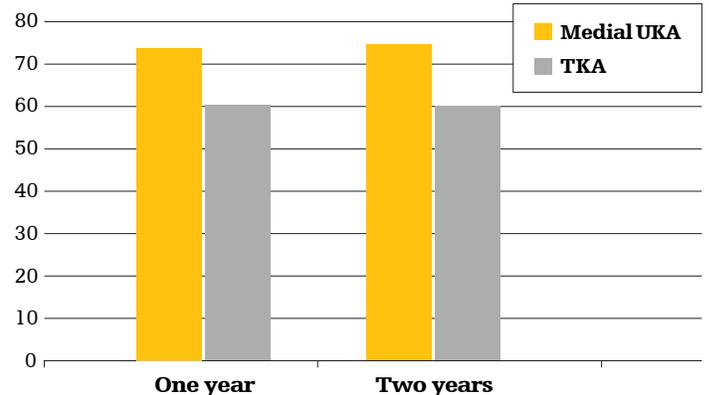
compared to manual patients from day one to day 56 (Figure 7).<sup>12</sup> Furthermore, the robotic-arm assisted patients had a better American Knee Society Score (AKSS) at three months and one year postoperatively, and a greater proportion of robotic-arm assisted patients showed improvements in their UCLA Activity Score.<sup>12</sup> 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 found to be a preoperative UCLA Activity Score level >5 and the use of robotic-arm surgery, although these do not withstand adjustment for multiple comparisons.<sup>12</sup>

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.<sup>24</sup> Zuiderbaan et al. (2015) administered The Forgotten Joint Score (FJS) questionnaire one and two years postoperatively.<sup>24</sup> Scores were compared between 65 patients who underwent medial Mako Partial Knee and 65 patients who underwent manually instrumented TKA.<sup>24</sup> Results demonstrated patients who underwent medial robotic-arm assisted PKA were more likely to forget their artificial joint in daily life (Figure 8).<sup>24</sup>

A similar trend was seen in the study carried out by Blyth et al. (2017), where, although there was no overall statistical difference, the proportion of patients achieving a FJS of >80% at three months postoperatively was almost double in the robotic-arm assisted cohort compared to the manual PKA cohort.<sup>12</sup>

Using the Mako System, Coon et al. (2017) performed 152 (71.3%) medial PKAs,<sup>33</sup> (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.<sup>25</sup> The lateral PKA group reported 100% satisfaction two years postoperation.<sup>26</sup> Overall, results suggested positive clinical and patient-

**Forgotten joint score**



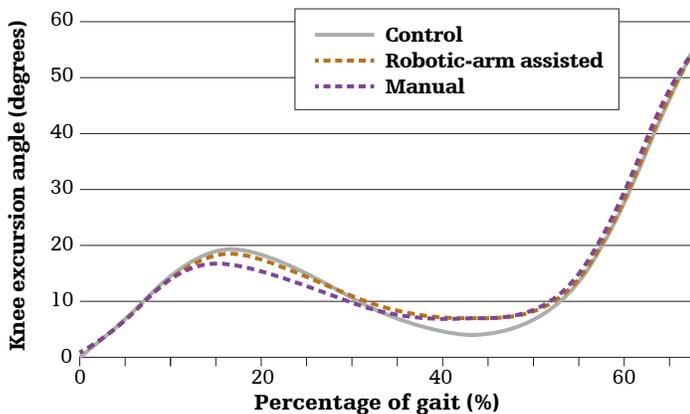
**Figure 8. FJS at 1- and 2-years post-operation showing significantly higher scores in the medial Mako Partial Knee group (p=0.002 and p=0.004, respectively).<sup>24</sup>**

reported outcomes of robotic-arm assisted medial, lateral, PF, and bicompartamental PKA.<sup>25-26</sup>

### 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 postoperatively.<sup>27</sup> Both groups were compared to a control group of 50 healthy subjects obtained from the University of Strathclyde's archive.<sup>27</sup> 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 9 and Table 1).<sup>27</sup> 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).<sup>27</sup>

**Partial knee gait**



**Figure 9. Mean knee excursion angles of the control group, the robotic-arm assisted and manual PKA groups during the stance phase of gait at 1-year post-operation.<sup>27</sup>**

**Table 1. Comparison of knee excursion values during loading phase of gait at 1-year post-operation. Standard deviation in brackets.<sup>27</sup>**

	Control	Mako	Oxford
<b>Knee excursion from foot-strike to mid-stance (degrees)</b>	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.<sup>13</sup>**

Patient Group	Mean (SD) excursion during WA (°)
<b>Mako</b>	14.3 (6.4)
<b>Oxford</b>	9.9 (4.2)
<b>P</b>	0.008

This study has now been repeated at 5 years postoperation 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).<sup>13</sup> Results showed that the Mako group achieved significantly greater knee flexion in weight acceptance (WA) than the conventional group (Table 2).<sup>13</sup> 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.<sup>13,27</sup>

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.<sup>28</sup> Tests included a 6-minute walk, timed up and go, and stair ascend/descend, which were measured preoperatively and 6 weeks and 3 months postoperatively. 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.<sup>28</sup> 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 TKA.<sup>28</sup>

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 postoperatively.<sup>26</sup> In addition, the average distance walked at discharge was 79.8 meters, and 90.9% of patients were walking without support 3 weeks postoperatively.<sup>26</sup> Lastly, 65 patients were employed at time of surgery, and 86% of those patients returned to work 6 weeks after their operation.<sup>26</sup>

### 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 cases.<sup>6</sup> However, this procedure has been shown to be effective for the appropriate patient, achieving reliable improvements in pain, function, and implant survivorship.<sup>68</sup> The Mako robotic platform offers benefits through its demonstrated accuracy and reproducible implant positioning, helping to minimize the margin of error associated with component placement.<sup>11</sup> In addition, the platform enables intraoperative 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.<sup>29,30</sup> For example, a retrospective study conducted by van der List et al. (2016) compared 2-year postoperative 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 10, Table 3).<sup>29</sup> Equivalent functional outcomes were noted for both medial and lateral PKA procedures.<sup>29</sup>

Similar promising survivorship data was published by Augart et al. (2015).<sup>30</sup> 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  $\pm$  10.7 months, who had a 100% survivorship at final follow-up without revision to TKA.<sup>30</sup> 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 intraoperative soft tissue adjustments, have the potential to help enhance surgical accuracy during these technically demanding procedures.



**Figure 10. Preoperative and post-operative radiographs of: medial Mako Partial Knee (left), and lateral Mako Partial Knee (right).<sup>29</sup>**

**Table 3. Mean ( $\pm$ SD) scores of WOMAC and FJS of all patients undergoing medial and lateral UKA and stratified by postoperative alignment as neutral or undercorrected.<sup>29</sup>**

Postoperative alignment	Score	N	Medial UKA	Lateral UKA	Medial vs. lateral	
All patients <sup>a</sup>	WOMAC	143	89.8 $\pm$ 11.7	36	90.2 $\pm$ 12.4	0.855
	FJS	95	71.2 $\pm$ 24.5	25	70.9 $\pm$ 28.2	0.956
Neutral aligned patients ( $-1^\circ$ to $3^\circ$ )	WOMAC	85	90.9 $\pm$ 11.4	19	87.2 $\pm$ 12.5	0.200
	FJS	57	72.6 $\pm$ 22.6	12	55.3 $\pm$ 28.5	0.024*
Undercorrected patients ( $3^\circ$ to $7^\circ$ )	WOMAC	51	88.5 $\pm$ 11.6	15	96.0 $\pm$ 5.4	0.001*
	FJS	38	68.2 $\pm$ 26.8	13	85.3 $\pm$ 19.5	0.020*
Neutral vs. undercorrected	WOMAC	143	0.214		0.005*	
	FJS	143	0.199		0.010*	

UKA indicates unicompartmental knee arthroplasty; FU, follow-up; WOMAC, Western Ontario and McMaster Universities Arthritis Index; FJS, Forgotten Joint Score. Neutral alignment for medial UKA indicates one degree of valgus to three degrees of varus and for lateral UKA indicates one degree of varus to three degrees of valgus.

Undercorrected alignment for medial UKA indicates three degrees to seven degrees of varus and for lateral UKA indicates three degrees to seven degrees of valgus.

\* Indicates a significant difference with  $p < 0.05$ .

<sup>a</sup> 12 patients with medial UKA and 2 patients with lateral UKA had no postoperative hip-knee-ankle radiograph and could not be included for subgroup analysis.

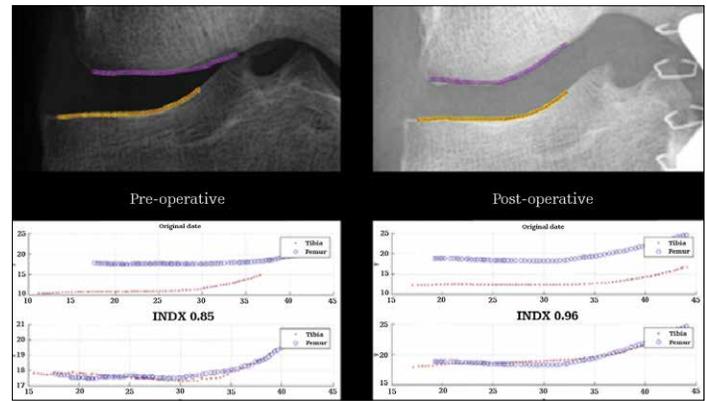
### 3.6 Continuum of care

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.<sup>32-34</sup> In all three studies, congruence of the surgical compartment was restored through the Mako procedure and implant.<sup>32-34</sup> Congruence and joint line of the nonoperative compartment was also restored ( $p=0.001$ ).<sup>32</sup> 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 11,<sup>34</sup> Figure 12,<sup>33</sup> Figure 13<sup>33</sup>).

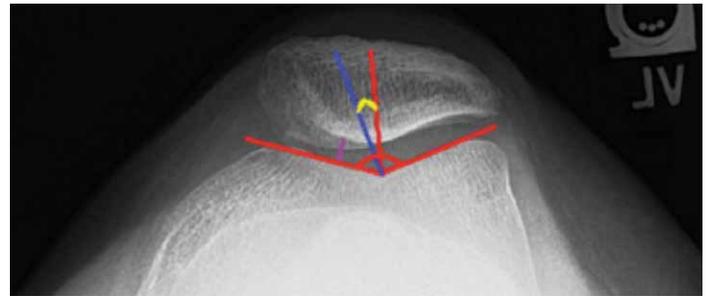
### 3.7 Clinical outcomes of patellofemoral arthroplasty

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.<sup>35-36</sup> Odgaard et al. (2017) used a multi-center, double-blinded RCT to compare clinical outcomes associated with PFA and TKA to establish whether there was an advantage to either option.<sup>37</sup> They found that PFA patients recovered quicker than TKA patients, and the functional outcomes were also better for PFA patients.<sup>37</sup> The average TKA patient lost almost 3 months of knee function post-operatively during the first two years, relative to the PFA patient.<sup>37</sup> It was concluded that PFA was a superior option to TKA in the case of patients with patellofemoral OA.<sup>37</sup>

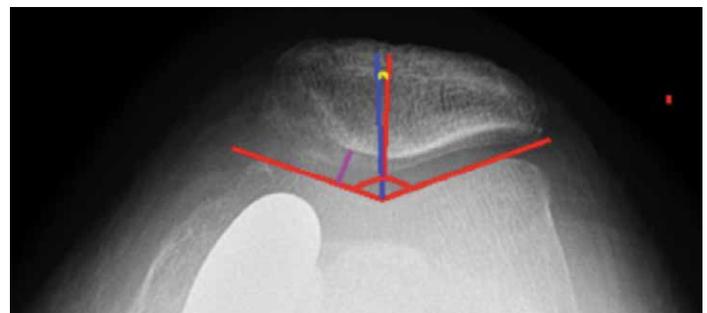
Encouraging functional data was observed in another study by Noyes et al. (2018), which examined the early results of 33 prospective, consecutive third-generation Mako PFA procedures.<sup>31</sup> The authors analyzed both sports and work activity levels in younger active patients. The study included 33 consecutive PFAs in 29 patients (4 bilateral), with a mean age 40 (range, 22-68).<sup>26</sup> 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 6 of the 7 patients who received surgery due to articular cartilage restoration failure, improvement was seen postoperatively and they returned to light sports/work.<sup>31</sup> 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.<sup>31</sup>



**Figure 11. Khamaisy et al. (2016). Iterative closest point algorithm was performed to calculate the congruence index (noted as INDX in the figure) of the lateral compartment pre- and post-operatively following manual digitization of the femoral and tibial surfaces in patients who received a medial Mako Partial Knee.<sup>34</sup>**



**Figure 12. Preoperative Merchant view of a left knee. The trochlear angle (red angle) is 140°. The congruence angle (yellow angle) is 14°. The medial patellofemoral joint space is represented by the purple line.<sup>33</sup>**



**Figure 13. Post-operative Merchant view of a left knee. The trochlear angle (red angle) is 140°. The post-operative congruence angle (yellow angle: 6°) was decreased compared to the preoperative one (Figure 12). Moreover, the medial patellofemoral joint space (purple line) was increased by 1.5mm following PKA.<sup>33</sup>**

#### 4. Is Mako cost-effective?

Compared to TKA, studies have shown that UKA patients have fewer post-operative complications,<sup>38</sup> improved FJS,<sup>24</sup> and higher quality-adjusted life-years (QALYs) in older patients.<sup>39-40</sup>

With rising demand for PKA in patients seeking a shorter recovery time than that associated with TKA, a study performed by Kazarian et al. in the U.S., evaluated cost effectiveness in patients who received either a PKA or non-surgical treatment.<sup>51</sup> 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 unicompartamental knee osteoarthritis undergoing TKA, UKA, and non-surgical treatment (NST) (Figure 14). The analysis included direct medical and indirect costs. Models were run for ATITs at 5-year intervals from 40 through 90 years of age. Results indicated surgery was more cost-effective than NST for all ages. The model also showed that UKA dominated TKA for ages 40-69, indicating UKA provided better clinical outcomes at lower costs.

In a similar analysis from a British hospital, a Markov decision analysis was performed to assess the cost-effectiveness of rUKA (Mako Partial Knee) relative to manual TKA and manual UKA for patients with isolated medial compartment OA of the knee with a mean age of 65 years.<sup>52</sup> The study objective was to identify the cost per quality adjusted life-year (QALY) of rUKA relative to manual TKA and manual UKA. 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 rUKA was £1395 and £1170 relative

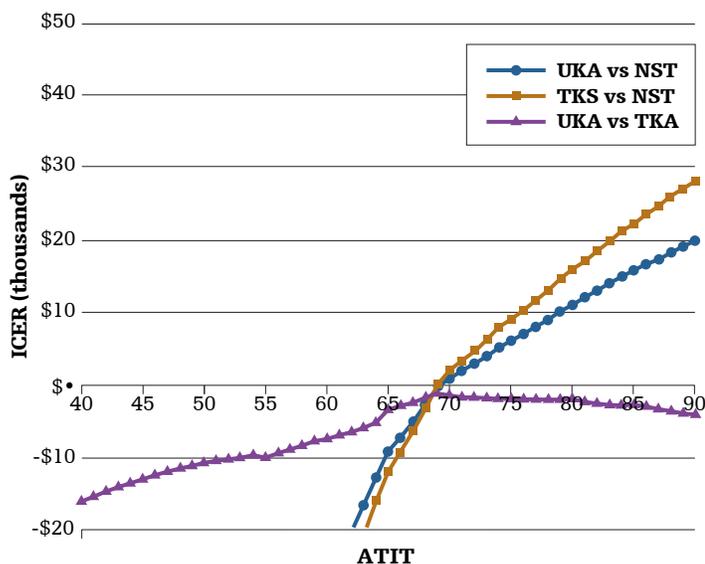


Figure 14. ICER values comparing UKA with NST, TKA with NST, and UKA with TKA by age.<sup>51</sup>

to TKA and UKA, respectively. The cost per QALY was influenced by case volume: a low-volume center performing ten cases per year would achieve a cost per QALY of £7170 and £8604 relative to TKA and UKA. For a high-volume center performing 200 rUKAs 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 rUKAs per year with a shorter length of stay of one day relative to manual UKA, the cost per QALY would be £574. The cost per QALY of rUKA decreased with reducing length of hospital stay and with increasing case volume, compared with TKA and UKA.

In summary, these models demonstrated that UKA was more cost effective than non-surgical treatment for all age groups modeled, and more cost effective than TKA for patients ages 40–69.

A hospital in Brisbane, Australia examined the potential cost savings for the health system and the community in a broadly accessible model through the increased utilization of UKA using robotic-arm assisted UKA vs. conventional TKA.<sup>42</sup> 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 UKA vs. TKA with an average savings of AU\$7179 per case. The operating time (86.0 min vs. 75.9 min;  $p=0.004$ ) was significantly higher for UKA 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 between UKA compared to TKA (125.0 morphine equivalent (ME) vs. 522.1 ME,  $p<0.001$ ).<sup>42</sup>

In the US, in a study by Cool et al., reasons for revisions and associated costs were analyzed for unicompartamental arthroplasty cases.<sup>45</sup> 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.

The cost-effectiveness studies described above all differed in inputs specific to their country, local region, hospital system or payer. These studies demonstrated patients who received robotic-arm assisted partial knees, in comparison to TKA or manual partial knees, had favorable economic returns, lower costs and better improvements in QALY.<sup>45,52</sup>

## 5. Conclusion

Mako Partial Knee offers the potential for surgeons to achieve component placement accuracy<sup>16</sup> and soft tissue balancing,<sup>17</sup> as well as to enhance clinical outcomes.<sup>11-13,20-28</sup> Patients have reported tangible benefits of robotic-arm assisted procedures, including treatment satisfaction,<sup>11,20</sup> return to activities of daily living,<sup>28</sup> and a “forgotten” joint.<sup>12,24</sup> Surgeons are empowered to achieve their target preoperative plans with precision,<sup>16</sup> 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.<sup>45,52</sup> 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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