stryker

# 2017 vol. 3
# Mako Partial Knee, Total Hip and Total Knee

**Clinical evidence**

# Introduction

This document aims to summarize the clinical evidence currently available on joint replacement surgeries conducted using the Mako System.

The Mako System offers three unique steps: enhanced planning, dynamic joint balancing, and robotic-arm assisted bone preparation. In the Partial Knee and Total Hip applications, this system has been shown to facilitate more accurate positioning to plan[1,2] and has shown enhanced patient reported outcomes.[3-5] The Mako Total Knee application was designed based on the clinically successful Mako Partial Knee and Total Hip applications with the goal of minimizing surgical complications by enabling surgeons to have a more predictable surgical experience. In a laboratory study, Mako Total Knee Technology demonstrated accurate placement of implants to a personalized surgical plan[6] as well as soft tissue protection around the ligaments of the knee.[7] As early clinical outcomes are being generated, patients receiving a TKA with the Mako System, have shown reduced pain and increased satisfaction when compared to a manual cohort at six months.[8]

## What are the potential benefits of Mako?

### Surgical outcomes

Successful clinical outcomes following total joint replacement are dependent on component placement.[9,10] Instability and infection in knee arthroplasty and early mechanical failures and dislocation in hip arthroplasty continue to be primary reasons for revision.[11,12] The Mako System is designed to minimize the margin of error associated with component placement, and to enhance the accuracy and reproducibility of partial knee arthoplasty (PKA)[4,13-15] total knee arthroplasty (TKA)[6] and total hip arthoplasty (THA).[5,16-18] Clinical studies have shown that the Mako Partial Knee and Total Hip applications have the potential to be both accurate and reproducible in component placement to plan.[1,2,19,20] The Mako Total Knee application has demonstrated component placement accuracy to plan[6] and soft tissue protection in a laboratory setting.[7]

In addition, short surgical times have been reported with the Mako Partial Knee application. In two studies, Coon et al. have reported tourniquet times of 30.7 minutes for medial PKA and 35.5 minutes for lateral PKA.[21,22]

#### Accuracy and reproducibility in partial knee arthroplasty

A key clinical paper was recently published by Bell et al., which reports on a randomized controlled trial comparing 120 patients with robotic-arm assisted PKA (Restoris MCK n=62) to manually implanted PKA (Oxford n=58).[1] The study compared the pre-operative plan of femoral and tibial component positioning against the actual alignment achieved in three different planes (axial, coronal, and sagittal).[1] Results showed more accurate component positioning with lower root mean square (RMS) errors and significantly lower median errors in all six component parameters (p<0.01).[1] The proportion of patients with tibial slope within 2° of the target position was significantly greater using the robotic-arm assisted technique when compared to the manual technique (80% compared with 22%, p=0.0001) demonstrating that the Mako System more consistently placed the PKA implant to plan **(Figure 1)**.[1]

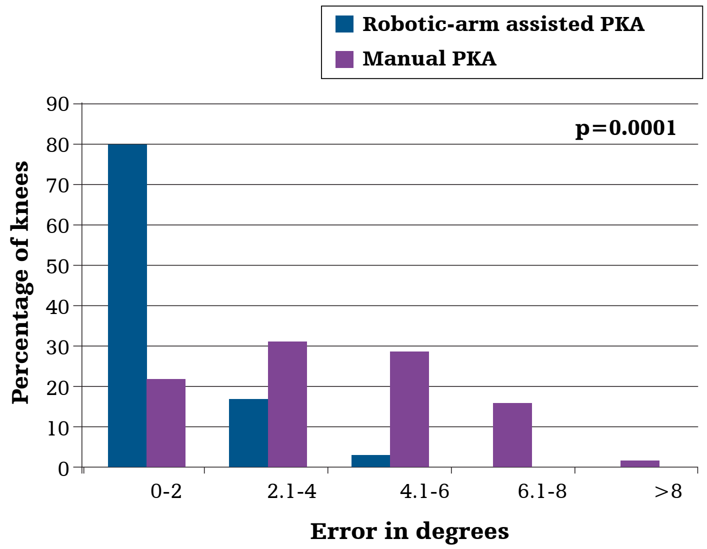



**Figure 1. Bell et al., showed that use of robotic-arm assisted PKA enabled surgeons to place the tibial and femoral components more accurately and consistently to plan.[1]**

In addition, clinical evaluation of the variance in knee alignment published by Lonner et al., demonstrated lower RMS error of the tibial slope (1.9° vs 3.1°) and varus/valgus (1.8° vs 3.4°) orientation when using the Mako System compared to manual instrumentation in PKA procedures.[14] In this study of two consecutive series, 31 patients underwent Mako Partial Knee surgery while 27 patients underwent manual PKA.[14] The variance using manual instrumentation was 2.6 times greater than the robotic-arm assisted bone preparation method.[14]

These studies demonstrate that robotic-arm assisted technology allows the surgeon to accurately and consistently place the femoral and tibial PKA components to plan.[1,13-15]

#### Accuracy and reproducibility in total hip arthroplasty

In a multicenter clinical trial including 110 patients, acetabular cup position was compared between pre-operative plan, intra-operative assessment, and achieved radiographic measure.[2] Results confirmed that intraoperative robotic arm-assistance achieved greater accuracy in preparation and position of the acetabular cup during total hip arthroplasty **(Table 1)**.[2]

**Table 1** - The average inclination and anteversion values of the acetabular components in the study, showing the pre-operative plan, measures recorded interoperatively, and those measured from plan radiographs using the Martell method.[2]

| | Pre-op plan | Intra-op robotic-arm measurements | Martell radiographic measurement |
|---|---|---|---|
| Inclination | 40.0º ± 1.2º | 39.9º ± 2.0º | 40.0º ± 4.1º |
| Version | 18.7º ± 3.1º | 18.6º ± 3.9º | 21.5º ± 6.1º |
| Count (n) | 119 | 119 | 110 |

**Table 1**[2]

**Figure 2A**

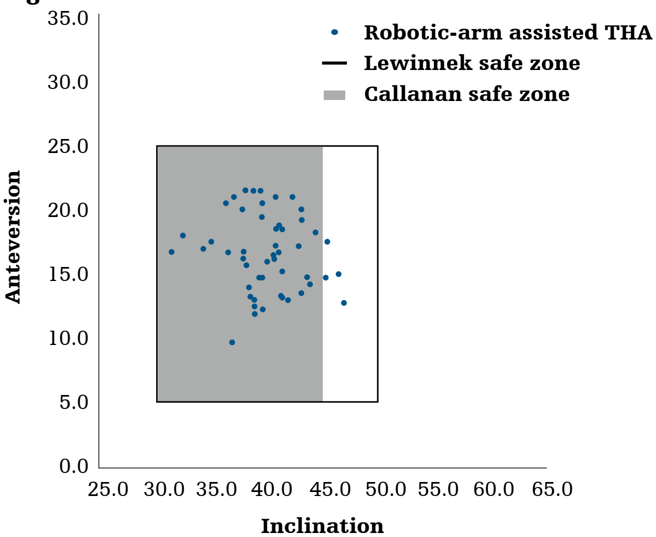



**Figure 2B**

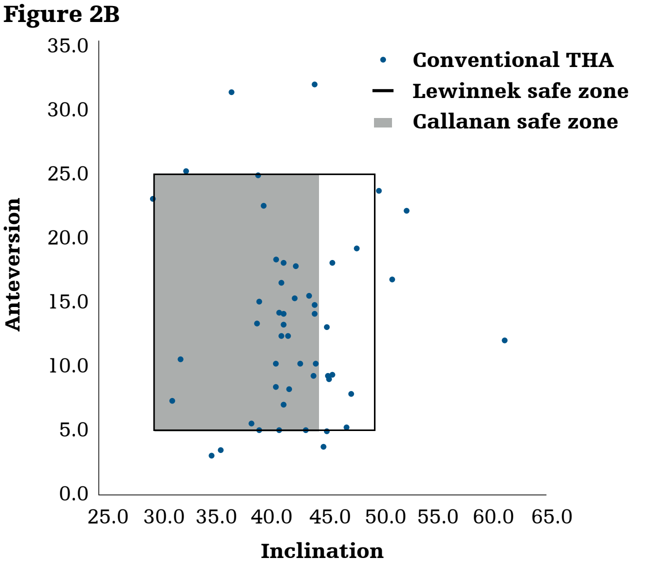



**Fig. 2A-B Scatterplots of the (A) robotic-assisted and (B) conventional cups in the safe zones of Lewinnek et al. and Callanan et al. are shown.**[16]

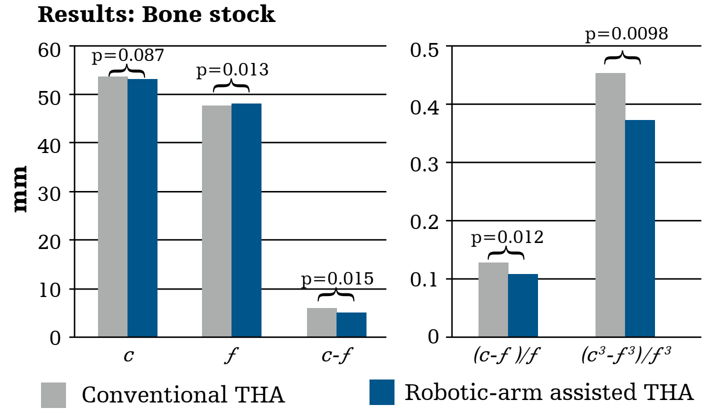
Domb et al. conducted a study involving six surgeons at a single institute, where 1,980 THA surgeries were evaluated.[20] The aim of this study was to understand the influence of surgical guidance and approach.[20] Robotic-arm assisted surgery resulted in a significantly greater percentage of components placed in Callanan's safe zones than all other modalities including navigation and fluoroscopy guided ($p<0.05$).[20] This study highlighted the consistency of the robotic-arm assisted technology based on a large patient series.[20]

In another clinical study, which compared robotic-arm assisted THA against manual THA, 50/50 of robotic-arm assisted THAs were within the safe zone as described by Lewinnek compared with 40/50 of the conventional THAs ($p=0.001$).[16] 92% of robotic-arm assisted THAs were in the modified safe zone as described by Callanan compared with 62% of conventional THAs ($p=0.001$).[16] Use of the Mako System allowed for more consistent placement of the cup in both safe zones **(Figure 2A-B)**.[16]

Clinical evidence continues to build on the potential benefits of robotic-arm assisted THA seen in cadaveric studies. These investigations have demonstrated robotic-arm assisted surgery is accurate within 1.0 ± 0.7mm for leg length/ offset.[23] Compared to manual THA, robotic-arm assisted THA was five times more accurate in cup inclination and 3.4 times more accurate in cup anteversion.[23] A recent publication highlighted influence of head center of rotation (COR) on the risk of hip dislocation.[24] A potential benefit of robotic-arm assisted THA is that it has been shown to be significantly more accurate in reproducing COR when compared to manual implantation which may result in reduced incidence of hip dislocation.[23]

The amount of bone stock reamed during primary THA can also have an important influence on recreating the center of rotation as well as preserving bone in primary THA patients.[25]

**Results: Bone stock**




c-f = bone thickness lost over course of surgery

(c-f)/f = bone thickness lost through surgery per width of the femoral head

$(c^3)-f^3/f^3)$=volume of bone lost through surgery

**Figure 3. Illustrates that Mako system's single reaming technique preserves bone as compared to conventional THA's sequential reaming technique**[25]

Suarez-Ahedo et al., studied bone preservation during primary THA and performed a matched pair control study, where, when compared to conventional THA (n=57), robotic-arm assisted THA (n=57) allowed for more precise reaming which led to the use of smaller acetabular cups in relation to the patient's femoral head size.[25] Using acetabular cup size relative to femoral head size as a surrogate measure of acetabular bone resection, these results suggest greater preservation of bone stock using robotic-arm assisted THA compared to conventional THA.[25] This may reflect increased translational precision during the reaming process **(Figure 3)**.[25]

### Accuracy and precision in total knee arthroplasty

A patient's unique anatomy and disease state can vary significantly creating operative case complexity for the surgeon. The robotic-arm assisted technology provides the surgeon with the ability to make intraoperative decisions based on CT preoperative planning and an intraoperative feedback loop to allow for implant placement adjustments. This technique allows surgeons to determine joint balancing based on soft tissue feedback all prior to making any bone cuts. In a single surgeon study, Marchand et al. considered intraoperative balancing and resection data for over 100 knees.[26] Regardless of disease state of types of deformities, 100% of the preoperative plans were adjusted intraoperatively to achieve balance within 1mm of medial and lateral gaps in flexion (97%) and extension (100%) **(Figure 4)**.[60] Additionally, the majority of knees did not require soft tissue releases to establish a balanced knee.[60] This ability to visualize changes in joint balancing and adjust component position prior to bone cuts allowed the surgeon to adopt a balanced resection technique associated with robotic-arm assisted surgery in a range of case presentations.[6,60]

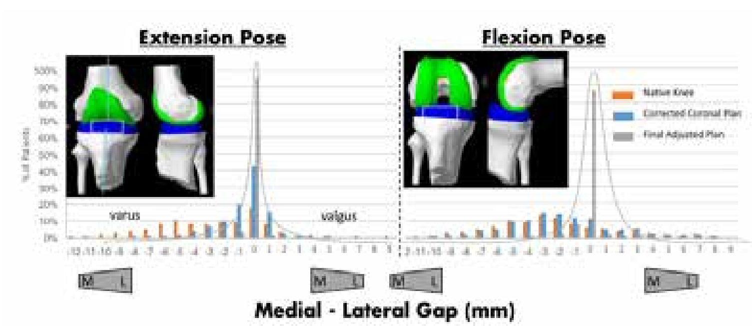



**Figure 4. The RATKA preoperative plans were all adjusted intraoperatively to achieve balance within a 1mm gap size (or difference between medial and lateral gap) in flexion (97%) and extension (100%).[26]**

The use of properly sized implants is critical to the success of TKA[27] and the ability to preoperatively plan can assist in selecting appropriately sized implants.[28] Robotic-arm assisted TKA requires the use of a preoperative CT that is used to perform 3D templating. In a study performed by Bhimani et al., 54 consecutive patients underwent unilateral RATKA.[30] 3D planning software specific to the Mako system was used to provide an initial preoperative implant plan that was intraoperatively updated based on risk of anterior femoral notching, minimizing medial and lateral overhang of the tibial and femoral implants, and maximizing tibial cortical contact.[30] The software was able to predict component size exactly in 96% of femoral implants and 89% of tibial baseplates.[30] While studies considering a 2D technique predicted the correct implant size 43.6% to 68% of cases.[29,31] For the 3D technique, all disparities between the predicted and actual tibial sizes were due to the presence of osteophytes.[30] 100% of actual tibial baseplates and femoral implants used were within 1 size of the preoperatively predicted size.[30] There were no cases of femoral notching as well as medial or lateral implant overhang on the femoral or tibial sides.[30]

While manual total knee arthroplasty has demonstrated clinical success[32], a meta-analysis of component alignment found mechanical axis malalignment of greater than 3° in 9.0% of computer-assisted (CAS) and 31.8% of manual TKA surgeries.[33] In a cadaveric study, a high volume surgeon with no prior clinical robotic experience performed a matched pair comparison of manual TKA (MTKA) to robotic-arm assisted TKA (RATKA) on 6 specimens (12 knees).[6] A learning curve was considered and the first three specimens were eliminated from comparison.[6] The last three RATKA and MTKA matched pairs showed that RATKA demonstrated greater accuracy and precision of bone cuts and component placement to plan compared to MTKA **(Figure 5)**.[6] On average, RATKA (n=6) final bone cuts and final component positions were 5.0 and 3.1 times more precise to plan than the MTKA control respectively.[6] Further, RATKA has the potential to increase both the accuracy and precision of bone cuts and implant positioning to plan for an experienced manual surgeon who is new to RATKA.[6]

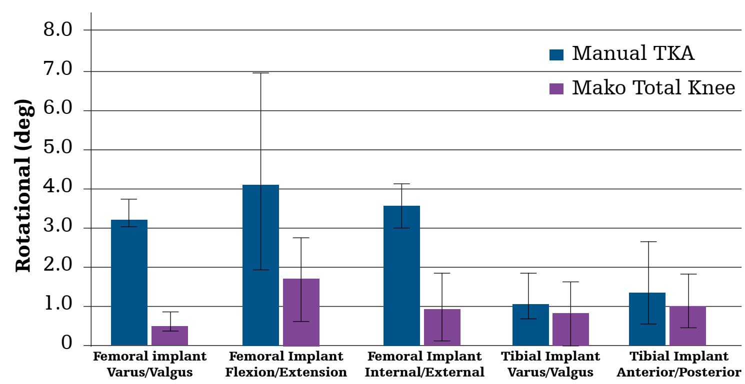



**Figure 5. A learning curve was considered for the cadaveric accuracy study and the first three specimens were eliminated from comparison. The last three RATKA and MTKA matched pairs showed that RATKA demonstrated greater accuracy and precision of bone cuts and component placement to plan compared to MTKA.[6]**

RATKA provides a surgeon the ability to three dimensionally plan a total knee replacement and use intraoperative visual, auditory, and tactile feedback to make desired bone cuts. A cadaveric study was performed to determine the benefits in soft tissue protection by examining the medial collateral

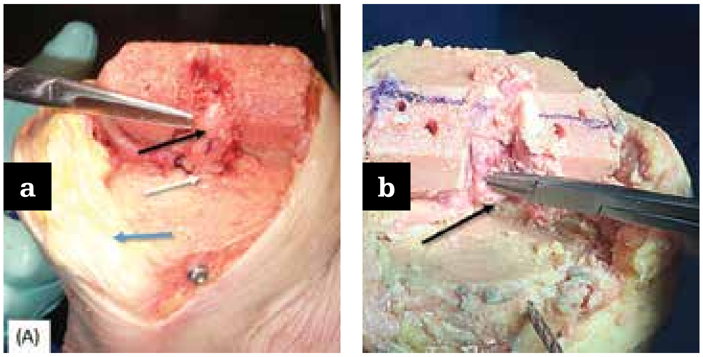



**Figure 6. a) A robotic-arm assisted TKA with bone island preparation in front of PCL. b) Manually performed TKA with arrow pointing to PCL with no bone island preparation. Black arrow points to (a) intact PCL in the RATKA and (b) minor fray of PCL in the MTKA. White arrow outlines bone island. Blue arrow points to intact patellar ligament.[7]**

ligament (MCL), lateral collateral ligament (LCL), posterior cruciate ligament (PCL), and patellar ligament following robotic-arm assisted and manual surgery **(Figure 6)**.[7] For all RATKA cases, there was no visible evidence of disruption of any of the ligaments.[7] All RATKA cases were successfully left with a bone island on the tibial plateau, which protected the PCL **(Figure 6)**.[7] Tibial subluxation and patellar eversion were not required for visualization.[7] In two of the seven MTKA cases, there was slight disruption noted of the PCL, although this did not lead to any apparent change in the functional integrity of the ligament.[7] All MTKA cases required tibial subluxation and patellar eversion to achieve optimal visualization.[7] During bone resections, the tibia in RATKA procedures did not require subluxation.[7]

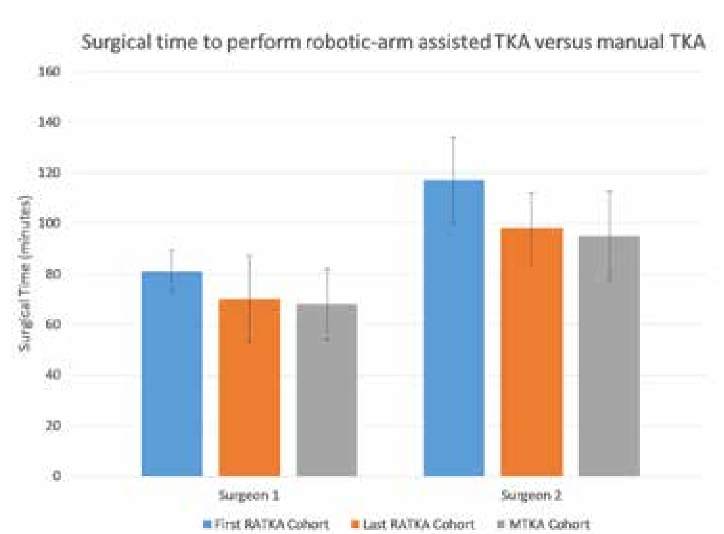



**Figure 7. Mean surgical time data for robotic-arm assisted TKA (RATKA) and manual TKA (MTKA) indicate that within a few months, a surgeon should be able to perform RATKA without adding any operative time. For both surgeons, mean surgical time was greatest for the first cohort of 20 robotic-arm assisted TKA cases when compared to the last cohort of 20 patients. The last cohort of 20 robotic-arm assisted TKA cases were time neutral to the surgeons' 20 manual cases.[33]**

As with most new surgical techniques, there is an associated learning curve with robotic-arm assisted TKA before surgeons can expect ease of use to be similar to that of manual cases. Sodhi et al performed a study to assess this learning curve where two surgeons performed a total of 240 robotic-arm assisted cases.[34] These cases were sequentially grouped into 20 cases and a learning curve was created based on mean operative times.[34] These times were compared to mean operative times for 20 randomly selected manual cases performed by the same surgeon.[34] **Figure 7** provides surgical times for both surgeons.[34] For surgeon 1, mean operative time between the first and last cohorts were reduced from 81 mins to 70 mins ($p<0.05$), respectively.[34] For surgeon 2, mean operative time between the first and last cohorts was reduced from 117 mins to 98 mins ($p<0.05$), respectively.[34] For both surgeons, the final 20 case set was time neutral to their manual cohort.[34] This data implies that within a few months, a surgeon should be able to adequately perform robotic-arm assisted TKA without adding any operative times.[34]

Robotic-arm assisted TKA offers the potential to improve TKA through a combination of preoperative planning, intraoperative adjustments, and guided bone resections. These studies have demonstrated the efficiency of 3D planning, benefits of intraoperative joint balancing, accuracy and precision of component placement to plan, the potential for soft tissue protection and the associated learning curve.[6-8,30,34]

## Clinical outcomes

Early clinical outcomes following joint replacement are critical in assessing the success of the Mako surgery. The following are a group of studies that have quantified outcomes in the short and midterm post-operative period.

### Patient outcomes in partial knee arthroplasty

In a multicenter, longitudinal, clinical trial, patients undergoing Mako Partial Knee surgery were "very satisfied" or "satisfied" with their joint replacement.[3,35] This study

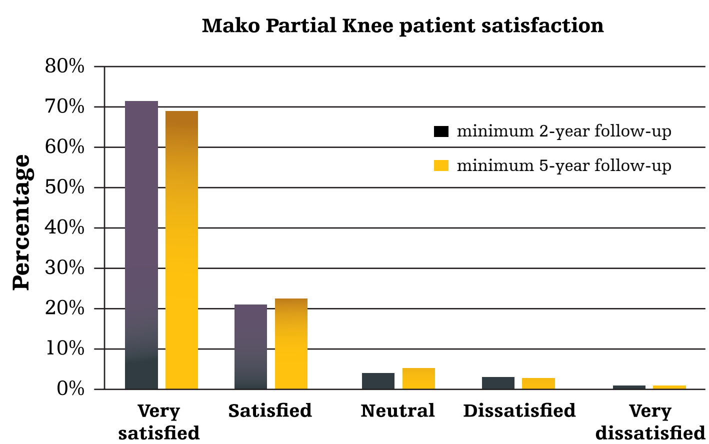



**Figure 8. Kleeblad et al. 2017. Mid-term patient satisfaction with Mako Medial Partial Knee Arthoplasty procedure.[3]**

performed follow-up at 2.5 years (909 knees) and 5.5 years (432 knees) on patients who underwent medial Mako Partial Knee procedures.[3,35] 92% of patients reported satisfaction with their knee at 2.5 years post-operative and 91% of patients reported satisfaction at 5.5 years **(Figure 8)**.[3,35] In a similar study based on the Swedish Knee Arthroplasty Registry, 7,860 patients who underwent manual PKA responded to a satisfaction questionnaire indicating 83% of patients satisfied with their knee at an average 6 year follow-up.[36]

In addition to patient satisfaction, a randomized control study was performed by Blyth et al. that demonstrated patients undergoing Mako Partial Knee experienced less pain during the 90 day post-operative period.[4] Results from this study indicated that robotic arm-assisted patients reported significantly lower post-operative pain levels, and median pain scores were 55.4% lower in the robotic cohort compared to manual patients from day one to week eight **(Figure 9)**.[4]
Furthermore, the robotic arm-assisted patients had a better American Knee Society Score at three months, and at one year post operatively, a greater proportion of patients receiving robotic-arm assisted surgery improved their UCLA Activity Score.[4] Through binary logistic regression the study was also able to predict the key factors associated with achieving excellent outcomes on the AKSS, they were found to be a preoperative UCLA Activity Score level> 5 and the use of robotic-arm surgery.[4]

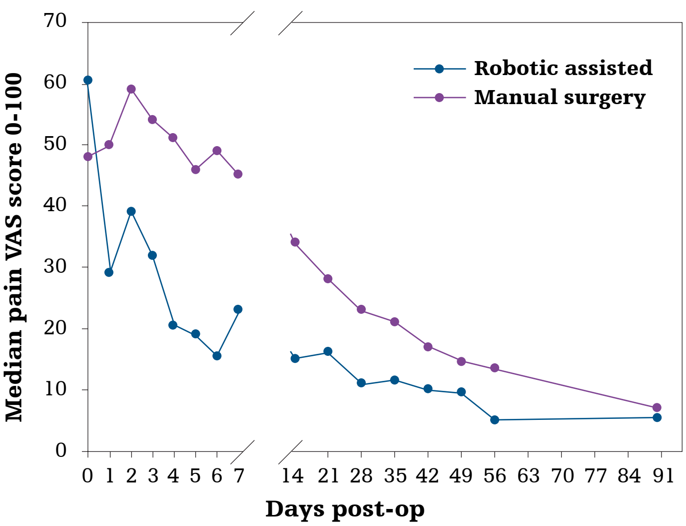



**Figure 9. Visual Analog Pain Score collected to 90 days post-operative in a RCT of manual vs robot arm-assisted PKA procedures.[4]**

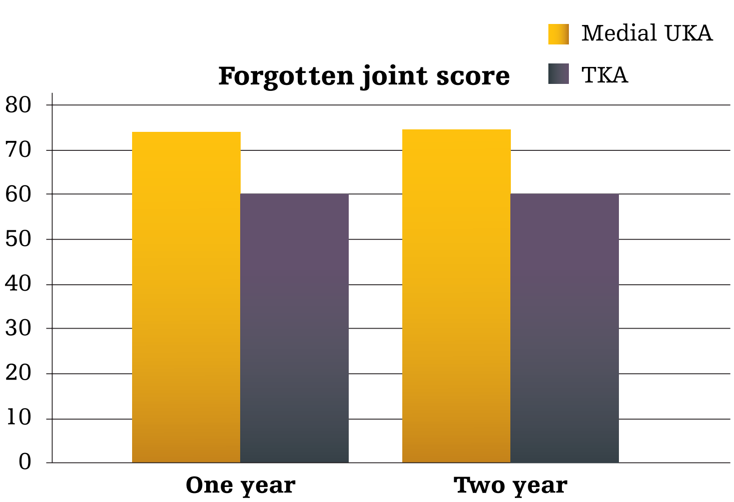



**Figure 10. FJS at one and two years showing significantly higher scores in Medial PKA group (p=0.002 and p=0.004 respectively).[37]**

Additionally, Mako Partial Knee patients are more likely to "forget" their artificial joint during daily life compared to those who undergo manual TKA.[37] In a study by Zuiderbaan et al., The Forgotten Joint Score (FJS) was administered at one and two years post-operative.[37] Scores were compared between 65 patients who underwent medial Mako Partial Knee and 65 patients who underwent manually instrumented TKA.[37] Results suggest patients who undergo robotic-arm assisted PKA are more likely to forget their artificial joint in daily life **(Figure 10)**.[37]

A similar trend was seen in the Blyth et al. study, where at 3 months post-operatively, the proportion of patients achieving a FJS score of >80% was almost double in the robotic-arm assisted cohort compared to the manual cohort.[4]

Using the Mako System, Coon et al. 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 very satisfied or satisfied at 6 months and increasing to 89.5% at two years.[21] The lateral PKA group reported 100% satisfied at 2 years post-operative.[38] Additionally, 87.9% of patients were as active or the same as they expected they would be before surgery at 2 years post-operative.[38] In addition, this work reported the average distance walked at discharge was 79.8 meters and 90.9% of patients walking without support at 3 weeks post-op.[38] Lastly 65 patients were employed at time of surgery, and 86% of patients returned to work at 6 week follow up.[38] Overall, results suggest positive clinical and patient reported outcomes of robotic-assisted medial, lateral, PF, and bicompartmental PKA.[21,22,38]

In a clinical study by Borus et al., 26 patients (27 knees) who underwent robotic-arm assisted PKA required less physical therapy (PT) to reach the same functional goals when compared to patients who had manual TKA at six weeks post-operative.[39] Significant differences were seen in knee extension (p=0.04), knee flexion (p<0.01), and quadriceps strength (p=0.03).[39] As PT accounts for a significant portion of the episode of care for knee arthroplasty, this may result in a decreased economic burden.[40]

## Patient outcomes in total hip arthroplasty

**Table 2[5]. Patient-reported outcomes (PROMs) comparing rTHA and mTHA patient groups**

| | Group (rTHA n=100, mTHA n=100) | Preoperative | Postoperative | PROMs (postoperative-preoperative) | p-value |
|---|---|---|---|---|---|
| mHHS (mean and standard deviation) | rTHA | 49.6 (16.3) | 92.1 (10.5) | 43.0 (18.8) | < 0.001 |
| | mTHA | 49.2 (14.8) | 86.1 (16.2) | 37.4 (18.3) | < 0.001 |
| | p-value | 0.865 | 0.002 | 0.035 | |
| SF12-MCS (mean and standard deviation) | rTHA | 54.1 (10.4) | 54.6 (9.1) | 0.4 (9.7) | 0.629 |
| | mTHA | 53.1 (9.6) | 53.0 (10.2) | 0.5 (11.5) | 0.970 |
| | p-value | 0.459 | 0.245 | 0.962 | |
| SF12-PCS (mean and standarddeviation) | rTHA | 33.5 (9.6) | 46.0 (10.5) | 12.5 (11.8) | < 0.001 |
| | mTHA | 30.3 (8.0) | 44.4 (11.0) | 14.0 (11.9) | < 0.001 |
| | p-value | 0.010 | 0.282 | 0.404 | |
| WOMAC (mean and standard deviation) | rTHA | 45.6 (18.9) | 16.0 (14.9) | -29.6 (21.4) | < 0.001 |
| | mTHA | 47.1 (14.7) | 17.3 (15.5) | -28.5 (18.3) | < 0.001 |
| | p-value | 0.536 | 0.538 | 0.618 | |
| UCLA (mean and standard deviation) | rTHA | 5.1 (1.9) | 6.3 (1.8) | 1.2 (1.7) | < 0.001 |
| | mTHA | 4.8 (1.8) | 5.8 (1.7) | 1.0 (1.9) | < 0.001 |
| | p-value | 0.227 | 0.033 | 0.429 | |

**Categorical analysis of modified Harris Hip Score**

| | rTHA | mTHA | |
|---|---|---|---|
| 90-100 | 75.0% (75) | 61.0% (61) | 0.034 |
| 80-89 | 13.0% (13) | 15.0% (15) | 0.684 |
| 70-79 | 6.0% (6) | 5.0% (5) | 0.756 |
| < 70 | 6.0% (6) | 19.0% (19) | 0.005 |

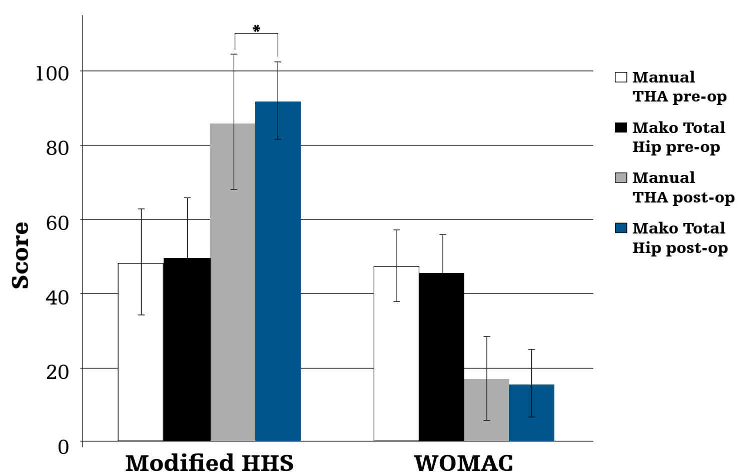



**Figure 11. Statistically higher modified HHS were shown for Mako Total Hip patients[17]**

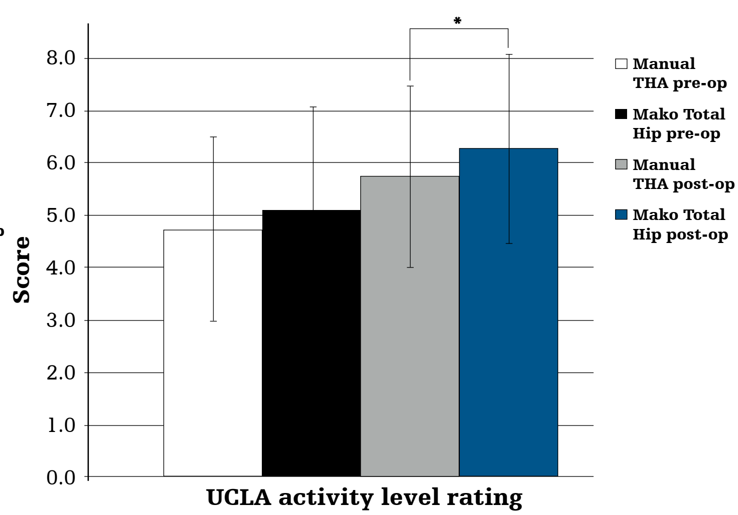



**Figure 12. Statistically higher UCLA scores were shown for Mako Total Hip patients[17]**

| Table 3 . Six-month manual versus robotic TKA WOMAC scores | | | |
|---|---|---|---|
| **Surgical technique** | **Manual TKA** | **Robotic arm-assited TKA** | ***p*=Value** |
| **Mean 6-mo postoperative WOMAC–pain** | 5 + 3 (range: 0-10) | 3 + 3 (range: 0-8) | <0.05 |
| **Mean 6-mo postoperative WOMAC–physical function** | 9 + 5 (range: 0-17) | 4 + 5 (range: 0-14) | 0.055 |
| **Mean 6-mo postoperative WOMAC–total score** | 14 (range: 0-27, SD:+8) | 7 (0-22); SD:+8) | <0.05 |

**Abbreviations: SD, standard deviation; TKA, total knee arthroplasty; WOMAC, Western Ontario and McMaster Universitues Arthritis Index.[8]**

In a prospective review of 100 consecutive THAs, Illgen and colleagues studied the effects of learning curve on the outcome for three groups of patients; Illgen's first 100 manual THA cases (2000-2001), last 100 manual THA cases (2010-2011) and first 100 Mako Total Hip cases (2011-2012).[5,17]

Dislocation was more frequent in group one (5/100, 5%) and group two (3/100, 3%) compared with group three (0/100, 0%) ($p<0.05$) at the one year follow up interval.[5,17] In addition, Mako Total Hip demonstrated significantly higher modified Harris Hip scores (92.1 ± 10.5 vs. 86.1 ± 16.2, $p = 0.002$) and UCLA activity-level (6.3 ± 1.8 vs. 5.8 ± 1.7, $p = 0.033$) compared with manual total hips at minimum one-year follow-up **(Figure 11 & 12, Table 2)**.[5,17]

Perets et al. have reported on minimum two year outcomes and complications for patients who received Mako Total Hip arthroplasty.[41] For the 162 cases considered, the average time of surgery was 76.7 minutes which is comparable to times reported in literature for manual surgeries.[42] Patients reported high satisfaction of 93% and an average Harris Hip Score of 91.1.[41] In addition, Hamilton et al. provided their patients with the Forgotten Joint Score (FJS-12) questionnaire as it has been shown to have low ceiling effects and appropriate for use for longer term outcomes in well-performing groups after THA.[43] Literature has reported a FJS-12 ranging from 50.9 ± 25.3 to 80 ± 24 for patients who received manual THA.[44,45] Perets et al. reported a FJS-12 of 83.1 which, to date, is the highest found in literature in THA.[41]

Additionally, at two years, there were no leg length discrepancies or dislocations reported.[41] Post-operatively six patients reported fractures (greater trochanteric n=3 and calcar n=3) and six had complications such as deep vein thrombosis and infection.[41]

## Preoperative Radiograph


## Postoperative Radiograph

**Figure 11. Preoperatively there was a 9-degree valgus deformity in extension. Intraoperative balancing and realignment were performed and the final coronal alignment was 1-degrees valgus. For this case, no soft tissue releases were needed.[49]**

**Patient outcomes in total knee arthoplasty**

As the initial RATKA patients begin to reach postoperative time points, publications have become available on early clinical outcomes. Marchand et al published on a single surgeon study that was performed on twenty consecutive cemented RATKA patients matched with twenty consecutive cemented MTKA patients.[8] A WOMAC survey, including pain, stiffness, and physical function subcategories, was administered to patients at their 6 month postoperative visit.[8] The RATKA cohort demonstrated significantly lower mean pain scores, better overall physical function scores, and greater patient satisfaction and clinical outcomes.[8] These results indicate the potential of this surgical tool to improve short-term pain, physical function, and total satisfaction scores.[8] Although a limited cohort, this study showed promising short-term outcomes for RATKA patients when compared to the MTKA control group.[8] **(Table 3)**

In another early outcome study, Dr. Gavin Clark presented on results from fifty MTKA cases compared to ninety RATKA cases, all performed by the presenting surgeon.[46] At three months postoperative, a Forgotten Joint Score Survey was provided to study participants.[46] Results indicated a significantly lower Forgotten Joint Score for the RATKA (36.24 ± 6.51) cohort compared to the MTKA cohort (45.70 ± 8.15).[46] This indicates that, at early follow-up, the RATKA patients were less aware of their previously problematic knee during activities of daily living.[46]

In a large, single surgeon study, Marchand et al. considered patient focused hospital metrics for 473 RATKA patients.[26] This study set included an evenly created demographic group with an approximate 2:3 ratio for males to females with an average BMI of 31.7 and average age of 66.5 years.[26] Patient average length of stay postoperatively was 2.1 days, compared to an average 2.2 days reported the previous year, prior to RATKA integration.[26,47] After discharge, 86% of patients returned home as compared to the US national average of 20% returning home and an additional 35% returning home with the aid of home health services.[48] At 30 days postoperative, 2.1% of patients had a readmission, compared to a national average of 5.4%.[26,48] Also of note, none of the readmissions were Mako System related.[26] For this patient group, there were no reported surgical site infections, pin site fractures, adverse events due to soft tissue damage, and no conversion from a RATKA case to a MTKA case intraoperatively.[26]

The Mako TKA technology allows a surgeon to preplan a case based on a patient CT as well as intraoperatively adjust that plan based on soft tissue laxity, all prior to making a single bone cut. These features can be beneficial when presented with a patient with severe varus/valgus deformities or flexion contractures. In addition to early patient outcomes, Marchand et al. also published a case series demonstrating how the Mako System enables surgeons to correct severe deformities.[49] Three case studies were presented where the use of the robotic-arm assisted system allowed the surgeon to achieve desired alignment restoration for patients with severe deformities **(Figure 11)**.[49] The results from this case report highlight the potential of the robotic-arm assisted technology to help surgeons achieve desired alignment restoration, even in patients with severe deformities.[49]

## Survivorship

Early and mid-term results have demonstrated favorable survivorship in patients undergoing Mako Robotic-Arm Assisted Surgery.[3,35] A multicenter, longitudinal study conducted by Pearle et al. and Keeblad et al. evaluated short and mid-term survivorship of robotic-arm assisted PKA and demonstrated a 98.8% survivorship (in 909 knees) at 2.5 year follow-up and 97% (in 432 knees) at 5.5 year follow-up.[3,35] This survivorship rate was greater than high volume surgeon data and registry data as summarized by Kleeblad and Pearle **(Figure 12)**.[3,35] It was concluded that the low annual revision rate observed in this study demonstrated Mako's ability to enable surgeons to achieve more accurate component positioning to plan when compared to implant placement using manual techniques.[3,35]

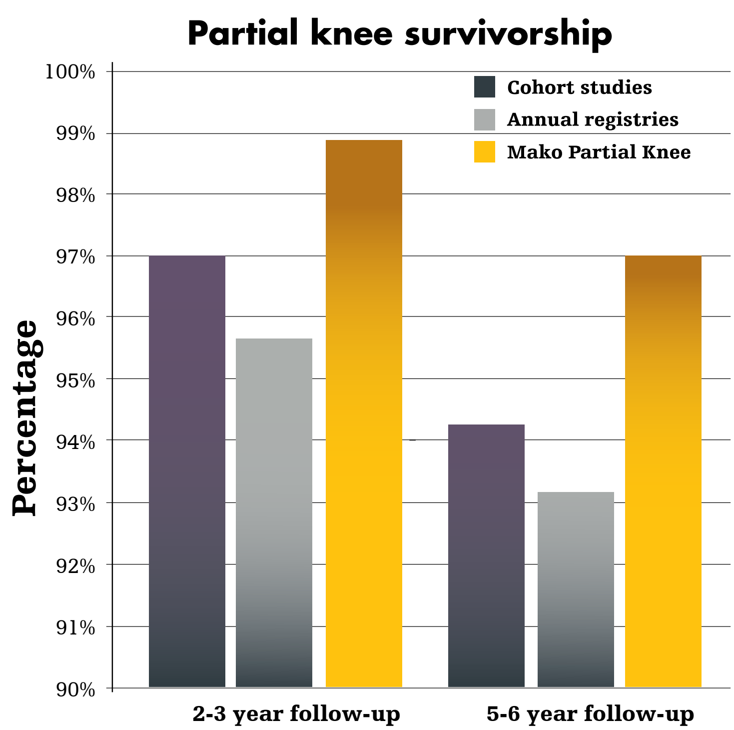



**Figure 12. Survivorship data from Pearle et al. and Kleeblad et al. studies on the robotic-arm assisted PKA compared to studies in literature and annual registries reporting 2 to 3 year and 5 to 6 year UKA survivorship data.[3,35]**

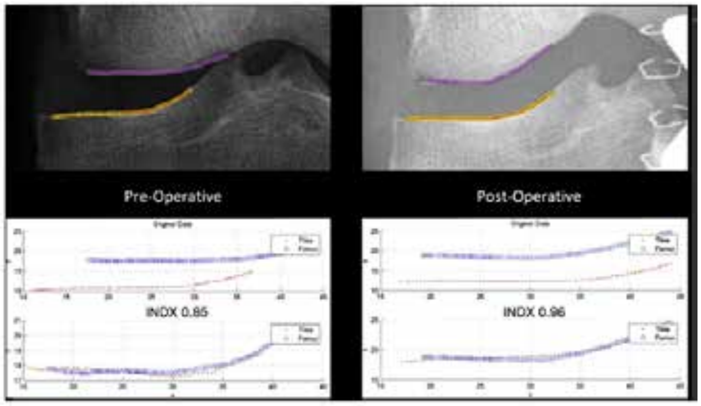



**Figure 13. Khamaisy et al. 2016. The performed iterative closest point algorithm calculates the congruence index (noted as INDX in the figure) of the lateral compartment pre- and postoperatively following manual digitization of the femoral and tibial surfaces in patients who received a Mako medial UKA.[51]**

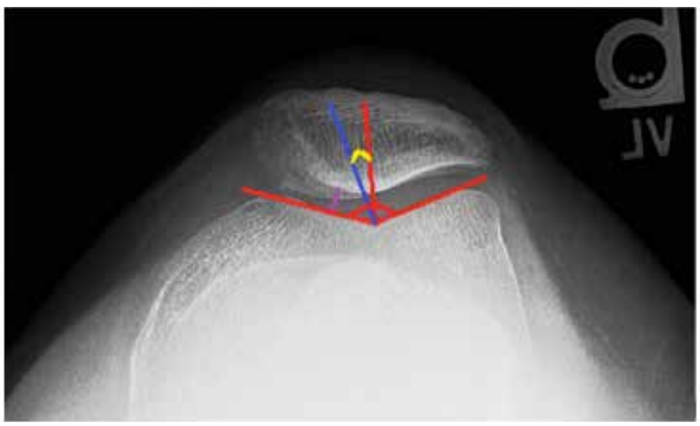


**Figure 14. Pre-operative Merchant view of a left knee. The trochlear angle (red angle) is 140°. The congruence angle (yellow angle) is 14°. The medial patella–femoral joint space is represented by the purple line.[51]**

**Figure 15. Post-operative Merchant view of a left knee. The trochlear angle (Red angle) is 140°. The post-operative congruence angle (yellow angle: 6°) is decreased compared to the preoperative one (Fig 15). Moreover, the medial patella–femoral joint space (purple line) is increased by 1.5 mm following UKA.[51]**

## 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, medial and lateral compartment congruency have been conducted at Hospital for Special Surgery in New York, NY.[50-52] In all three studies, congruence of the surgical compartment was restored through the Mako procedure and implant.[50-52] Congruence and joint line of the non-operative compartment was also restored ($p=0.001$).[51] The authors hypothesized that the improved patellofemoral congruence after Mako Partial Knee may lead to redistribution of contract forces across the patellofemoral joint and secondarily treat patellofemoral symptoms **(Figure 13, Figure 14, Figure 15)**.[51]

The purpose of patellofemoral arthoplasty (PFA) is to address the pain caused at the patellofemoral joint without treating with a more substantial total knee surgery that would sacrifice additional bone. However, past literature has reported on conflicting success rates of PFA as a surgical treatment for patellofemoral osteoarthritis (OA).[53,54] Odgaard et al. used a multi-center, double-blinded RCT to compare clinical outcomes associated with PFA and TKA to establish whether there is an advantage to either option.[55] They found that PFA patients recovered quicker than TKA patients, and the functional outcomes were better for PFA patients.[55] The average TKA patient lost almost three months of knee function during the first two years relative to the PFA patient.[55] It was concluded that PFA is a superior option to TKA in the case of patients with patellofemoral OA.[55]

## Business outcomes

Clinical and economic tradeoffs between early benefits and later revisions of PKA versus TKA are poorly understood. PKA typically requires less rehabilitation, results in fewer post-operative complications, and may offer patients improved knee function and 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 was performed by Ghomrawi et al. to evaluate the cost effectiveness of PKA vs TKA in younger and older patients using a validated Markov model.[56] This model utilized cost, revision rate, and quality of life data from National Joint Registries, published literature, the HCUP government database, and the internal HSS registry.[56] Despite assuming equal post-operative quality of life values for PKA and TKA, the model showed that in patients over 65, PKA was more cost-effective.[56] This result was primarily due to higher rehabilitation costs and higher post-operative complication rates with TKA, despite higher revision rates with PKA.[56] PKA would become cost effective over TKA for patients under 65 with a small decrease in the 20 year revision rate and a small increase in quality of life.[56]

As cost effectiveness models are highly dependent on hospital system, an additional cost effectiveness model for UKA was created for a hospital system in Philadelphia.[56] Mean contribution profit for PKA (diagnosis-related group [DRG] 470, 81.54) is highly dependent on many factors, including patient age/ payer mix, hospital cost-efficiencies, and ratio of reimbursement capture relative to charges.[55] For this analysis, the per-case conservative contribution profit assumption was $3500.[56] A preoperative computed tomography (CT) scan is part of the robotic PKA protocol (CPT 73700) and generated $125 for this hospital.[56]

Baker Tilly, a third party consulting company, performed a retrospective review at the request of Stryker, of commercial data from PKA surgeries performed between 2013-2015 and reimbursed by a national commercial health plan consisting of approximately 25 million members.[58] When comparing medical claims between manual and robotic-arm assisted knee procedures, results showed robotic-arm assisted surgery was associated with lower all-cause readmission rates and lower average cost per readmission.[58] 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.[58] 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).[58]

## Conclusions

Mako offers the potential for surgeons to achieve component placement accuracy and to enhance clinical outcomes.[56,57,59] Patients report tangible benefits of the robotic-arm-assisted procedures, including satisfaction[3], return to activities of daily living,[39] and a "forgotten" joint.[37] Surgeons have the ability to achieve their target plan and the continuum of care for their patients available with Mako may help distinguish them in their community.

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