New Technology for Total Knee Arthroplasty Provides Excellent Patient-Reported Outcomes: A Minimum Two-Year Analysis

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ABSTRACT

Introduction: Robotic-assisted total knee arthroplasty has been demonstrated to help increase various patient-reported, clinical, and surgical outcome metrics (PROMs). However, the current literature is limited regarding PROMs data for longer follow-up periods beyond one year. Therefore, the purpose of this study was to 1) report multicenter patient-reported outcomes with multiple metrics, as well as 2) postoperative surgeon-specific outcomes at a minimum two-year follow-up.

Materials and Methods: Five fellowship-trained, high-volume surgeons performed a total of 188 total knee arthroplasty surgeries using the enhanced preoperative planning and real-time intraoperative feedback of a robotic-assisted device. Patients from all surgeons followed similar postoperative rehabilitation beginning on postoperative day one. Patients were evaluated based on the Short Form-12 Questionnaire (SF-12), the Forgotten Joint Score (FJS), and Knee Society total and subscores (KSS). The SF-12 was subdivided into two components: mental composite score (MCS) and physical composite score (PCS). The KSS was subdivided into functional and knee scores. Additionally, surgical outcomes from the latest follow-up visit were evaluated. All patients were evaluated at a minimum of two years follow-up time.

Results: All patients reported excellent postoperative outcomes for all three PROMs. The mean postoperative SF-12 MCS and PCS scores were both 57 points, with 50 as the threshold for norm-based scoring (MCS range: 42 to 69 points; PCS range: 41 to 68 points). The mean FJS was 75 points (range: 14 to 100 points). The mean KSS functional score was 84 points (range: 20 to 100) while the mean Knee Score was 92 points (range: 40 to 100). Similarly, we found that the aseptic revision rates were low (n=2, 1.06%, one for unexplained pain, and another for a post-traumatic tibial fracture) with few other postoperative complications (n=7 patients [3.7%]) in our cohort.

Conclusion: Our analysis found that patients had excellent outcomes across multiple PROM metrics. Future work can build on these results with large patient populations over longer follow-up intervals. Nevertheless, these results provide the foundation and evidence to support the continued use of this innovative technology for total knee arthroplasties.

INTRODUCTION

Over the past decade, substantial technological innovations have made their way into the operating room.1–3 Some of these tools can now actively assist surgeons when performing procedures by using enhanced preoperative planning and real-time intraoperative feedback, especially in the field of orthopaedics.4–6 This feedback can immediately guide the surgeon to better ensure that bone cuts are only made in the desired regions, providing added safety, accuracy, and precision to the respective procedure.7–8 Notably, these advancements have been shown to demonstrate accurate and consistent implant placement in total knee arthroplasty (TKA).9–11 Robotic-assisted TKA (RATKA) has subsequently been shown to prolong implant survival, decrease complication rates, and improve patient outcomes.12,13

However, as many of these new tools have only recently become common practice, it is critical to regularly evaluate outcomes. Previously, the efficacy of robotically-assisted TKA were evaluated at three-month, six-month, and one-year follow-ups.14–16 A multicenter study comparing 252 patients (102

- 2 -
manual and 150 robotic) based on the 2011 Knee Society Scoring System found that RATKA patients had larger improvements in walking and standing (6.0 vs. 4.8 points), standard activities (11.4 vs. 10.1 points), advanced activities (6.2 vs. 4.6 points), functional activities total score (22.8 vs. 21.2 points), pain with walking (4.3 vs. 4.1 points), total symptoms score (10.5 vs. 10.3 points), satisfaction score (17.0 vs. 15.5 points), and expectations score (4.8 vs. 4.0 points) as compared to patients who underwent manual TKA. At six months, it was found that RATKA patients had more improved physical function scores, lower postoperative pain (p<0.05), and higher satisfaction (p<0.05) compared to traditionally-performed TKA. Similarly, significant improvements in both total- (p=0.05) and physical-function scores (p=0.02) were found for robotically-assisted patients compared to the manual cohort at one-year follow up. While these results have been favorable, there is a paucity in the literature in evaluating longer-term follow-up periods. Notably, patient-reported outcomes (PROMs) have not been reported for RATKA patients at two years following the index procedure.

Technological advancements continue to shape the field of orthopaedics by providing methods of enhancing accuracy while maintaining safety. Therefore, the purpose of this study was to 1) report multicenter patient-reported outcomes with multiple metrics, as well as 2) postoperative surgeon-specific outcomes at a minimum two-year follow up.

### Materials and Methods

#### Patient selection

Five fellowship-trained, high-volume surgeons at academic institutions performed a total of 188 consecutive total knee arthroplasties using enhanced preoperative planning and real-time intraoperative feedback. Patients from all surgeons followed similar postoperative rehabilitation beginning on postoperative day one. This included physical therapy and stretching exercises that were first performed in-hospital, and subsequently, continued later at home or as outpatient therapy. Institutional review board approval was obtained from all these institutions to contribute to this study.

#### Mako Robotic Arm System and Implant

The Mako Robotic-Arm Assisted device (Stryker Orthopaedics, Mahwah, New Jersey) was utilized for all procedures (Fig. 1). This device generates a preoperative surgical plan utilizing CT-scan data to subsequently generate a digital, 3D rendering of the joint. Intraoperatively, the device created haptic boundaries that prevents the saw from leaving the predetermined operative plan. The device also provides real-time patient-specific information regarding alignment and ligament balancing. All patients had a Triathlon® (Stryker Orthopaedics, Mahwah, New Jersey) tricompartmental knee arthroplasty (Fig. 2).

#### Outcome measures

Patients were evaluated based on the Short Form-12 Questionnaire (SF-12), the Forgotten Joint Score (FJS), and Knee Society total and subscores (KSS). The SF-12 was subdivided into two components: mental composite score (MCS) and physical composite score (PCS). The KSS was subdivided into functional and knee scores. All four of these indices have been well-validated PROM measurement tools. Additionally, surgical outcomes from the latest follow-up visit were evaluated. All patients were evaluated at a minimum of two years follow-up time. Further evaluation of complications and surgeon-specific outcomes were performed by each site up to the minimum two-year follow up.

![Figure 1. Mako Robotic-Arm Assisted Partial Knee Arthroplasty System.](image1)

![Figure 2. Triathlon® Total Knee System.](image2)
New Technology for Total Knee Arthroplasty Provides Excellent Patient-Reported Outcomes: A Minimum Two-Year Analysis

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Two-year robotic-assisted TKA patient-reported outcomes

<table>
<thead>
<tr>
<th>PROM</th>
<th>Mean Score</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-12</td>
<td>MCS</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>PCS</td>
<td>57</td>
</tr>
<tr>
<td>FJS</td>
<td></td>
<td>75</td>
</tr>
<tr>
<td>KSS</td>
<td>Function</td>
<td>84</td>
</tr>
<tr>
<td></td>
<td>Knee</td>
<td>92</td>
</tr>
</tbody>
</table>

Abbreviations: TKA=total knee arthroplasty, PROM=patient-reported outcome measure, SF-12=Short Form-12 Questionnaire, FJS=Forgotten Joint Score, KSS=Knee Society Score

OUTCOMES

All patients reported excellent postoperative outcomes for all three PROMs (Table I). The mean postoperative SF-12 MCS and PCS scores were both 57 points, with 50 as the threshold for norm-based scoring (MCS range: 42 to 69 points; PCS range: 41 to 68 points). The mean FJS was 75 points (range: 14 to 100 points). The mean KSS functional score was 84 points (range: 20 to 100), while the mean knee score was 92 points (range: 40 to 100).

Complications

No patients had aseptic loosening of any components. Overall, a 1.06% aseptic revision rate was noted (Table II). Two patients experienced infections, with one patient undergoing a two-stage revision at 15 months (now doing well with KSS score 90 points one year later), while the other underwent an irrigation and debridement with polyethylene liner exchange at 25 months, with retention so far at six months. Two other patients had revision procedures; one patient due to unexplained continued pain at six months, and the other patient fell resulting in a proximal tibial fracture. At latest follow up, both patients recovered successfully and have continued without any further complications. Another patient had a pulmonary embolism that was medically managed and two other patients underwent manipulations under anesthesia due to range-of-motion greater than 110 degrees at final follow up.

DISCUSSION

Robotic-arm assisted TKA has been shown to have a number of clinical, surgical, and patient-specific outcome advantages. These advantages have been noted through clinical and cadaver studies that have shown potentially superior alignment and component placement, which can result in improved patient satisfaction compared to manual techniques. However, the current literature is limited regarding PROM data for longer follow-up periods, utilizing multiple PROMs, and with pooled data from multiple institutions. Our analysis examined PROMs in 188 RATKA patients at a minimum two-year follow up and found excellent postoperative patient satisfaction scores as measured by the SF-12, KSS, and FJS metrics. Similarly, we found that the aseptic revision and infections rates were low, with postoperative complications only occurring in less than 4% in our cohort.

Our study has some limitations. We did not account for various patient factors that may have influenced outcome measures such as age, comorbidity burden, or baseline severity of osteoarthritis or pain. However, given that we examined a large cohort from multiple large academic centers, it is likely that our findings represent a diverse patient population and therefore, are generalizable. Additionally, given that our analysis was aimed at solely reporting PROM values at this unprecedented follow-up period, this limitation allows for future evaluations to compare these variables across longer study periods. Despite these limitations, our analysis found that patients undergoing RATKA reported excellent outcomes and experienced low rates of complications.

Multiple studies have previously reported on improved patient outcomes following robotic TKA, though some of these devices are older and different than the one evaluated in this study. Liow et al. reported significant improvements in KSS function (p<0.001) and knee scores (p<0.001) for 31 robotically-assisted TKA patients at two-year follow up. The authors similarly reported significant improvements on various Short Form (SF-36) functional assessment components (p<0.05). At a mean follow up of five years (range, 3 to 7 years), Kim et al. found significant improvements in KSS function, KSS knee, SF-36 physical components, and SF-36 mental component scores (all p-values ≤0.001) in 32 robotically-assisted TKAs. Similarly, Cho et al. reported on 155 robotically-assisted TKAs with a mean follow up of 11 years. The authors found significant improvements in all clinical outcome measures including the SF-12 mental and physical components as well as KSS pain and function scores (all p-values < 0.001).

There has been mixed data regarding whether robotic surgery improves outcomes compared to manually-performed TKAs. In their randomized-controlled trial that was comprised of 60 knees, Liow et al. found significant improvements for SF-36 vitality (p=0.03) and emotional (p=0.02) quality of life components at two-year follow up for the...
robotic cohort (n=31) compared to manual TKA patients (n=29). These authors further found that a larger percentage of patients reached a minimum clinically important difference for the SF-36 vitality score in the robotic-assisted cohort (48% vs. 14%, p=0.009).

Similarly, Kayani et al. reported that there was significantly reduced postoperative pain (p<0.001), a decreased number of physiotherapy sessions (p<0.001), and improved maximum knee flexion at discharge (p<0.001) for robotically-assisted TKA patients compared to those undergoing manual TKA.

Conversely, Song et al. conducted a randomized-controlled trial of 100 patients and found no significant differences in postoperative Western Ontario and McMaster Universities Arthritis Index (WOMAC) and Hospital for Special Surgery (HSS) scores between the robotically-assisted (n=50) and manually-performed (n=50) TKAs. Similarly, in their systematic review and meta-analysis of articles reporting on the effectiveness of robotically-assisted hip and knee arthroplasty, Karunaratne et al. found that functional outcomes were comparable between patients undergoing robotic- and manually-performed procedures. However, the authors did find that most studies had risk of bias with an overall low-quality strength of evidence. Additionally, these studies also evaluated older technology-based devices, unlike that which was evaluated in this study.

**CONCLUSION**

Assistive-operative technologies have been shown to provide intraoperative advantages for surgeons, as well as post-operative advantages for patients. Because many of these technologies have only recently been introduced into the operating room, to date, two-year PROMs have not been reported by any previous study. Our analysis found that patients had excellent outcomes across multiple PROM metrics. Future work can build on these results with large patient populations over longer follow-up intervals. Nevertheless, these results provide the foundation and evidence to support the continued use of these technological innovations for total knee arthroplasty.

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