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# SYSTEMATIC REVIEW Robotic arm-assisted versus manual unicompartmental knee arthroplasty

A SYSTEMATIC REVIEW AND META-ANALYSIS OF THE MAKO ROBOTIC SYSTEM

# Aims

This systematic review aims to compare the precision of component positioning, patientreported outcome measures (PROMs), complications, survivorship, cost-effectiveness, and learning curves of MAKO robotic arm-assisted unicompartmental knee arthroplasty (RAU-KA) with manual medial unicompartmental knee arthroplasty (mUKA).

# **Methods**

Searches of PubMed, MEDLINE, and Google Scholar were performed in November 2021 according to the Preferred Reporting Items for Systematic Review and Meta-Analysis statement. Search terms included "robotic", "unicompartmental", "knee", and "arthroplasty". Published clinical research articles reporting the learning curves and cost-effectiveness of MAKO RAUKA, and those comparing the component precision, functional outcomes, survivorship, or complications with mUKA, were included for analysis.

## **Results**

A total of 179 articles were identified from initial screening, of which 14 articles satisfied the inclusion criteria and were included for analysis. The papers analyzed include one on learning curve, five on implant positioning, six on functional outcomes, five on complications, six on survivorship, and three on cost. The learning curve was six cases for operating time and zero for precision. There was consistent evidence of more precise implant positioning with MAKO RAUKA. Meta-analysis demonstrated lower overall complication rates associated with MAKO RAUKA (OR 2.18 (95% confidence interval (Cl) 1.06 to 4.49); p = 0.040) but no difference in reintervention, infection, Knee Society Score (KSS; mean difference 1.64 (95% Cl -3.00 to 6.27); p = 0.490), or Western Ontario and McMaster Universities Arthritis Index (WOMAC) score (mean difference -0.58 (95% Cl -3.55 to 2.38); p = 0.700). MAKO RAUKA was shown to be a cost-effective procedure, but this was directly related to volume.

# Conclusion

MAKO RAUKA was associated with improved precision of component positioning but was not associated with improved PROMs using the KSS and WOMAC scores. Future longerterm studies should report functional outcomes, potentially using scores with minimal ceiling effects and survival to assess whether the improved precision of MAKO RAUKA results in better outcomes.

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## Introduction

Robotic unicompartmental knee arthroplasty (UKA) is associated with improved precision of prosthesis implantation,<sup>1</sup> which is proposed to lead to both improved functional outcomes<sup>2</sup> and implant survival.<sup>3</sup> However, there have been conflicting reports as to the benefit of robotic UKA.<sup>4</sup> These contrasting results may relate

to the robotic system used, as these vary in their navigation and cutting technologies. The MAKO robotic arm-assisted UKA (RAUKA) system (MAKO Robotic Interactive Orthopaedic System; Stryker, USA) is a semi-active system allowing the surgeon to interact with the robot during bone preparation, implant alignment, and knee balancing.<sup>5</sup> These are important

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Author	Year	Learning curve	Alignment	Function	Complications	Survival	Cost
Banger et al	2021						
Bell et al	2016						
Blyth et al	2017						
Clement et al	2019						
Cool et al	2019						
Gilmour et al	2018						
Hansen et al	2014						
Kayani et al	2018						
Kayani et al	2019						
Lonner et al	2010						
Moschetti et al	2016						
Park et al	2019						
St Mart et al	2020						
Wong et al	2019						

Heat map of studies included in the systematic review and metaanalysis.

Complete Preferred Reporting Items for Systematic Review and Meta-Analysis flow diagram showing the identification, screening, eligibility, and inclusion process.

surgeon-controlled variables that affect patient outcomes, implant stability, and long-term survivorship.<sup>6,7</sup>

Current systematic reviews comparing RAUKA with manual UKA (mUKA) have not considered robotic systems in isolation.<sup>8-12</sup> Fully active robotic systems, or boundary systems, have been associated with a greater rate of complications compared to semi-active robotic arm-assisted systems.<sup>13,14</sup> While these reports have critically assessed clinical outcomes, the included studies were heterogeneous, including different robotic and implant systems. Among the four recent meta-analyses performed with pooled functional outcomes, only one of 21 (5%) reported by van der List et al,<sup>9</sup> three of seven (39%) reported by Fu et al,<sup>10</sup> four of the of seven studies (57%) reported by Zhang et al<sup>12</sup> were semi-active MAKO RAUKA. The variety of robotic systems included may have prevented the specific advantages of RAUKA compared to mUKA being clearly demonstrated.

This systematic review and meta-analysis was conducted to compare the precision of component positioning, patient-reported outcome measures (PROMs), complications, and survivorship of MAKO RAUKA with mUKA, and to report the cost-effectiveness and learning curve associated with MAKO RAUKA.

# Methods

Cochrane, MEDLINE, PubMed, and Google Scholar were searched by two independent researchers (JZ, NN) in November 2021 according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement (Figure 1),<sup>15</sup> to identify relevant articles published in the English language. Prior to the search, the study was registered on the PROSPERO International prospective register of systematic reviews (ID no. CRD42021233413). All identified article titles and abstracts were screened independently by the same two authors, with those meeting the inclusion criteria screened further by full-text review. Full-text reviews were also carried out when it was not clear from the abstract if studies were of relevance. Discussion and unanimous consensus were met regarding the inclusion of all proposed studies for full-text review among the authors. Full-text studies were further evaluated against the inclusion and exclusion criteria. Manual searching of references from identified articles were carried out to look for any additional studies that should have been included.

Search terms and criteria for inclusion. Search terms included: arthroplasty, knee [MeSH] with all entry terms, robotic surgical procedure [MeSH] with all entry terms, and robotic-assisted. A single search of Cochrane, PubMed, and MEDLINE databases yielded 179 abstracts. Two searches of Google Scholar using the search terms "all-in-title: robot unicompartmental knee" and "all-in-title: robotic unicompartmental knee" yielded 24 articles in total. Clinical trials were included if they involved patients undergoing UKA; compared RAUKA and mUKA (randomized and non-randomized); included outcome variables related to the proposed research questions; and had been published between January 2000 and November 2021. Studies were excluded if they

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Forest plots of pooled precision in implant alignment, comparisons in a) femoral component coronal alignment error, b) femoral component sagittal alignment error, c) tibial component coronal alignment error, and d) tibial component sagittal alignment error. CI, confidence interval; IV, inverse variance; mUKA, manual medial unicompartmental knee arthroplasty; RAUKA, robotic arm-assisted unicompartmental knee arthroplasty; RMSE, root mean square error; SD, standard deviation.

were conference abstracts; animal studies; in vitro studies or articles published in a form other than clinical trials; or studies without quantitative data. For the purposes of this review, there was a focus on MAKO robotic systems. Therefore, other semi-active (e.g. NAVIO Surgical System; Smith & Nephew, USA) and fully active robotic systems were excluded from analysis. If multiple studies reported results from the same patient cohort, only the study with the higher quality score was included.

**Data extraction**. The information recorded from eligible studies included the name of the first author, the year of publication, sample size, study design, robot type, demographic characteristics, mean follow-up period, and outcome variables including implant position, learning curve, PROMs, pain scores, length of hospital stay, complications, and survival.

**Outcome measures.** The primary objectives were to report the learning curves, precision of component positioning, functional outcomes, and complications within the included studies. Secondary objectives included presenting the demographic data and implants used across the included articles, as well as any cost-effectiveness evaluations done for the use of the robotic technique.

**Quality assessment.** The quality of all included studies was assessed by two authors (JZ, NN) using the National Institutes of Health Quality Assessment Tool for Controlled Intervention Studies or Observational Cohort and Cross-Sectional Studies.<sup>16</sup> The assessment tool uses 14 questions to enable allocation of a score to each article (poor, fair, or good). If there are disagreements regarding the scoring of a study, consensus was met after discussion between both assessors.

**Statistical analysis.** Simple descriptive analyses were performed for learning curves of RAUKA and for studies comparing the precision of component positioning, PROMs, complications, and cost-effectiveness between RAUKA and mUKA. Data were extracted from studies comparing the precision of component positioning, PROMs (Knee Society Score (KSS)<sup>17</sup> and Western Ontario and McMaster University Osteoarthritis Index (WOMAC)),<sup>18</sup> complications, and revision rates between RAUKA and mUKA to enable meta-analysis to be undertaken



Forest plot of pooled Knee Society Scores. Cl, confidence interval; IV, inverse variance; mUKA, manual medial unicompartmental knee arthroplasty; RAUKA, robotic arm-assisted unicompartmental knee arthroplasty; SD, standard deviation.

for these outcomes. Complications and revision rates were statistically assessed using the Peto method and the odds ratios (ORs) were presented as the effect measure. The precision of component positioning, KSS, and the WOMAC scores were assessed using inverse variance and the mean difference was presented as the effect measure. For each outcome variable, 95% confidence intervals (CIs) were presented. Heterogeneity among the studies was assessed using the chi-squared test and I<sup>2</sup>. A fixed effect model was applied when I<sup>2</sup> < 30%, and a random effects model when I<sup>2</sup> > 30%. A p-value < 0.05 was considered statistically significant in cases in which trials have no event in one arm or another.

# **Results**

There were 179 articles identified in the initial search of databases and reference lists. After initial screening of titles and abstracts, 34 articles met the inclusion criteria for review. On full-text screening, a further 20 studies were excluded from analysis (Figure 1). Overall, 14 studies met the inclusion criteria (Supplementary Table i);<sup>1,4,19–30</sup> 11 studies were identified from Cochrane, MEDLINE, and PubMed, one additional study from Google Scholar, and two from manual searching of references. Figure 2 shows the heat map of studies included. The year of publication ranged from 2010 to 2021. Of the 14 studies identified, four were randomized controlled trials (RCTs),<sup>20,22,28,29</sup> two were Markov decision cost economic analyses,<sup>19,21</sup> three were prospective,<sup>24,27,30</sup> and the remaining five were retrospective.<sup>1,4,23,25,26</sup>

**Learning curve.** One study reported the learning curves for RAUKA: Kayani et al<sup>24</sup> found RAUKA was associated with a learning curve of six cases for operating time (p < 0.001) and surgical team confidence levels (p < 0.001). There was no learning curve in RAUKA for precision of implant positioning, joint line restoration, postoperative limb alignment, clinical outcome, or complications.

Implant alignment. Five studies compared implant alignment and component positioning between RAUKA and mUKA.1,4,23,24,28 Four of the five studies reported that RAUKA resulted in more precise implant positioning.<sup>1,23,24,28</sup> Both Park et al1 and Bell et al28 concluded that RAUKA resulted in fewer outliers for both femoral and tibial implant positioning. The reporting of alignment was found to be heterogeneous across the studies, with some studies reporting on root mean square error (RMSE), some comparing the mean angle postoperatively, and some not reporting the standard deviation (SD). The authors of two studies (Kayani et al24 and Bell et al28) were contacted for the SDs of the RMSEs reported, and the forest plot is shown in Figure 3. The meta-analysis showed that the implant position was significantly more accurate, and there were fewer outliers among the RAUKA group compared to the mUKA group. There was variability in the alignment targets for the RAUKA technique, as the method individualizes the bone cuts to native joint anatomy. While all the mUKAs were performed using standard jig references, specific targets of under-correction and posterior slopes were not specifically declared in three out of five of the studies included.

**Functional outcomes**. Six clinical studies reported the functional outcomes following RAUKA compared to mUKA.<sup>1,20,22,25,27,29</sup> Different outcome scores were used across the included studies, with the KSS being the most reported, followed by WOMAC. KSS for RAUKA and mUKA are shown in the forest plot in Figure 4. Likewise, the WOMAC scores are shown in the forest plot in Figure 5. Neither meta-analysis demonstrated a difference in the KSS (mean difference 1.64 (95% CI -3.00 to 6.27); p = 0.490, z-test) or WOMAC score (mean difference -0.58 (95% CI -3.55 to 2.38); p = 0.700, z-test) between RAUKA and mUKA in short- to mid-term follow-up.

**Complications and survivorship.** Five studies reported on the complications between RAUKA and mUKA groups.<sup>4,20,24,27,29</sup> Overall complication rates were low, and the most common



Forest plot of pooled Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores. Cl, confidence interval; IV, inverse variance; mUKA, manual medial unicompartmental knee arthroplasty; RAUKA, robotic arm-assisted unicompartmental knee arthroplasty; RMSE, root mean square error; SD, standard deviation.

complications were superficial or deep infections. No study reported any pin-site fractures. Six studies compared revision rates between RAUKA and mUKA.<sup>4,22,25,26,29,30</sup>

A forest plot of pooled reported complication data demonstrated no significant differences in superficial and deep infection rates (OR 2.8 (95% CI 0.93 to 8.38); p = 0.070, z-test) or in early re-intervention rates (OR 2.20 (95% CI 0.79 to 6.09); p = 0.130, z-test) in the mUKA group compared to RAUKA group in short-term follow-up (Figure 6). However, the overall complication rate was higher in mUKA compared to RAUKA (OR 2.18 (95% CI 1.06 to 4.49); p = 0.040, z-test). Registry data are typically not included in systematic reviews, as they do not appear on the search engines commonly used. However, this review included a study from the Australian registry,<sup>30</sup> as it is the only published paper evaluating the early survivorship of RAUKA prostheses compared with mUKA systems using registry data. Our pooled data, with a mean follow-up of 1.71 years (SD 0.93), demonstrated a 1.72% revision rate for RAUKA, whereas the mUKA revision rate was 3.32%, which is consistent with mUKA data from UK and New Zealand national joint registries with reported three-year revision rates of 3.71% and 3.7%,<sup>31,32</sup> respectively.

**Cost**. Three studies reported on cost in relation to RAUKA.<sup>19,21,26</sup> Two studies used Markov decision analysis to report the cost-effectiveness, with both reporting RAUKA to be a cost-effective procedure.<sup>19,21</sup> In the UK, Clement et al<sup>19</sup> used a model with annual case volume of 100 cases and found the excess cost per quality-adjusted life year (QALY) of RAUKA to be £1,170 relative to mUKA. For a high-volume centre performing 200 RAUKAs per year with a length of stay of one day less than

manual UKA, the cost per QALY may be as low as £574. In the USA, Moschetti et al<sup>21</sup> concluded that although RAUKA was more costly than mUKA, it offered a slightly better outcome, with an additional 0.06 QALYs at an incremental cost of \$47,180 per QALYs, given a case volume of 100 cases annually. They found RAUKA was cost-effective when case volume exceeded 94 cases per year, two-year failure rates were below 1.2%, and total system costs were < \$1.426 million. Cool et al<sup>26</sup> was the only study comparing mean costs between RAUKA and mUKA. It reported that RAUKA incurred lower mean costs for the index stay plus revisions (\$26,001 vs \$27,915; p > 0.05) than mUKA over a 24-month period; however, this was not statistically significant.

# Discussion

There are several key findings from this review. There was no learning curve for implant precision using RAUKA, whereas for surgical proficiency, stress, and confidence levels the learning curve was small. Component positioning for RAUKA was more precise when compared with mUKA. The early to mid-term PROMs were similar between RAUKA and mUKA. RAUKA had a lower overall complication rate compared to mUKA in the early to mid-term. RAUKA was a cost-effective procedure when compared to mUKA, but this depended on surgical volume.

The learning curve barrier for initial adoption was small for RAUKA. Decreasing operating times were noted after the first six RAUKA cases.<sup>24</sup> This is coupled with the fact that there was no learning curve for precision of implant positioning. A major



Forest plot of pooled reintervention and infection rates. CI, confidence interval; M-H, Mantel-Haenszel analysis; mUKA, manual medial unicompartmental knee arthroplasty; RAUKA, robotic arm-assisted unicompartmental knee arthroplasty; SD, standard deviation.

benefit of RAUKA over mUKA is the zero-patient learning curve for precision, whereas mUKA has a 25-patient learning curve, which is associated with excess patient morbidity and higher revision rates.<sup>33</sup> The suggested minimum case volume for mUKA was 25 cases per year to reduce revision risk,<sup>34</sup> or at least 20% of a surgeon's knee arthroplasty practice.<sup>35</sup> With the high precision and small learning curve, these figures may not apply to RAUKA.

RAUKA was shown to result in fewer alignment outliers when compared to mUKA. The ability to consistently deliver greater precision allows for consistent joint reconstruction, and may result in consistent collateral ligament tensioning compared to manual techniques. Good ligament tensioning has been considered a prerequisite for good function and longevity in UKA, and could influence long-term outcomes.<sup>36</sup> The precision delivered by RAUKA, added to intraoperative feedback during tensioning, could minimize instability and component malpositioning that may result in edge-loading and early revision. There was a lack of standardization in the reporting of the methods used for "individualizing" the robotic UKA, resulting in significant variability in the compromises made by each surgeon to achieve a balanced knee. This makes comparisons and meta-analyses more difficult to interpret. Although RAUKA has been shown to be more precise for component position, to deliver true accuracy the surgical target must be known. Future longer-term studies reporting the clinical outcomes of RAUKAs should therefore describe the techniques used with clear alignment strategies presented to enhance comparisons of outcomes.

The current meta-analysis demonstrates no difference in the short-term PROMs for RAUKA, compared to mUKA, for pooled KSS and WOMAC scores. There may be a ceiling effect observed for these PROMs, which is an intrinsic limitation of the PROMs used. The Forgotten Joint Score has a limited ceiling effect,<sup>37</sup> and may be a better tool to demonstrate measurable clinically significant differences between RAUKA and mUKA in future studies.<sup>5,33</sup>

Overall, the number of complications was low, but a trend towards higher revision and re-intervention rates associated with mUKAs was noted. Currently, Banger et al<sup>22</sup> is the RCT with the longest follow-up period of five years, which reported a much lower re-intervention rate in the RAUKA group compared to the mUKA group (0% vs 9%, respectively). Our pooled data of more than 13,000 cases showed a cumulative 2.94% revision rate for RAUKA (n = 397), lower than mUKAs across all national registries, suggesting a lowered hazard ratio with the use of the MAKO robotic arm-assisted system. This may result from a reduction of the potential to over-correct limb alignment using mUKA, which in turn increases potential progression of arthritis in the lateral compartment and survival.38 This was not associated with higher complications such as infections, arthrofibrosis requiring manipulation under anaesthesia, wound dehiscence, deep vein thrombosis, or pin-site fractures. Only 71% of the weighted studies  $(n = 5/7)^{4,22,25,26,29}$  included in the complication and revision analysis had a minimum follow-up of two years, with only one having a follow-up of five years for the RAUKA group.<sup>22</sup> This indicates a need for improved evidence

with longer follow-up to accurately assess longer-term complication and revision rates.

There are key limitations of the dataset that should be acknowledged. First, the inclusion criteria, such as English language, may have excluded relevant studies. Second, the methodology has known limitations regarding the type of studies included. Four of the 14 studies included data from one RCT, with the meta-analysis including both randomized and non-randomized studies. Third, there was an important variability between the studies with respect to the type of outcome measurements used, the follow-up period, and cohorts evaluated. There was a limited number of studies included and most presented short-term follow-up data. Future studies with longer-term follow-up will be needed to provide more conclusive findings in assessing the outcomes and benefits.

MAKO RAUKA was associated with improved precision of component positioning but was not associated with improved patient-reported outcomes using the KSS and WOMAC scores. Future longer-term studies should report functional outcomes potentially using scores with minimal ceiling effects and survival to assess whether the improved precision of MAKO RAUKA results in better outcomes.

Take home message



with improved precision in component positioning with a small learning curve.

- It was related to lower revision rates, although functional outcomes are similar to manual techniques.

- MAKO unicompartmental knee arthroplasty was associated

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# **Supplementary material**

Table showing studies included in the systematic review.

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