ROSA® Knee System
2022 Clinical Evidence Summary

Introduction

A report from the Agency for Healthcare Research and Quality has demonstrated that knee arthroplasty is one of the most frequent procedures in the operating room[1]. The success of total knee arthroplasty (TKA) is well established, and the most recent registry reports demonstrate 10- and 15-year cumulative percent revision (CPR) rates of 4.01% - 4.7% and 5.66% – 6.4%, respectively, for primary total knee arthroplasty associated with osteoarthritis[2, 3].

Despite its success, TKA continues to experience revisions related to aseptic failures, with loosening and instability the predominant reasons[4, 5]. Technological advances continue to attempt to address this, but the value of these technologies remains controversial. The reasons for controversy are due primarily to the lack of long-term outcomes and survivorship data[6, 7]. Kort et al. noted that benefits of robotic TKA include improved component positioning, but demonstrating improvements in outcomes, satisfaction, and survivorship is lacking. Still, early outcomes are promising and Mullaji and Khalifa recently reported superior early functional outcomes when reviewing contemporary literature on robotic-assisted TKA[8].

A valuable source of real-world data in orthopaedics has been the use of well-established registries[9, 10]. Graves noted the value of registries is their unique ability to provide comparative data[9]. Additionally, data from registries have been shown to stipulate change in some orthopaedic practices. When looking at the 2022 annual report of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), the data suggests that robotic knee arthroplasty is reducing the CPR rates of primary TKA at two to four years post-operatively[2]. The registry reports CPR rates of robotically assisted TKA at 1.5% (95% CI, 1.4%, 17%) compared to 1.7% (95% CI, 1.7%,1.8%) for non-robotic TKA at two-years follow-up[2]. At four years, the difference in CPR rates between robotic and non-robotic was 2.1% (95% CI, 1.7%, 2.5%) vs. 2.6% (95% CI, 2.6%, 2.7%), respectively (see AOANJRR 2022 Annual Report Table KT60). Interestingly, the reductions in revisions appear to be associated with aseptic failures with the data showing reduced rates for revision due to loosening or instability (see AOANJRR 2022 Annual Report Figure KT69)2.

The ROSA® Knee System is a semi-autonomous robotic arm that assists in the placement of the cutting jig along with providing ligament laxity assessments throughout the primary TKA workflow. It can be used with image-based or imageless modes[11]. The primary purpose of this review is to identify and summarize the literature associated with the ROSA Knee System in relation to accuracy, efficiencies, and outcomes.

Accuracy

There has been a plethora of publications on the ROSA Knee System supporting improved accuracy and precision compared to conventional instrumentation (Tables 1-2)[12-16]. Recent in vivo studies[17, 18] have supported the initial cadaveric studies[14, 19]. In addition to the comparative studies, several other publications support the system being accurate and precise (Tables 1-2)[17, 18, 20, 21] with no discernable learning curve regarding accuracy reported by Bolam et al[22]. The most recent article by Shin et al.[20] reported exceptional accuracy in the coronal plane, but only moderate in the sagittal plane. Though only moderate accuracy was noted by the authors for the sagittal measure, these values are similar to those reported by other systems[23-26]. Further, Shin et al. measured the sagittal axes using what appears to be more anatomical axes than the mechanical axes used by the robotic system, which could explain some of the error[20, 27]. Yoo et al. suggested that measurements of tibial slope can vary by up to 6° dependent on the axis used[27]. In relation to the moderate differences in the femoral flexion angles, differences in accuracies of 1° to 3° are unlikely to affect outcomes[28, 29]. Two studies have investigated the association between femoral flexion and patient reported outcome measures (PROMs)[28, 29]. At one-year follow-up, Govardhan reported no difference in Knee Society Scores (KSS) between patients with less than 5° and patients with more than 5° of femoral component flexion with a maximal flexion of 8° in the sample[28]. Similarly, Nishitani et al. reported no difference in KSS subcomponent scores for symptoms, satisfaction, expectations, and functions between minimal flexion (> 2.5°), mild flexion (2.5° to 5.5°), and moderate flexion (5.5° to 8.5°), but significantly worse scores for patients with excessive flexion (>8.5°)[29].

Table 1. The ROSA Knee System is more accurate and precise in achieving the planned coronal plane alignment (Hip-Knee-Ankle Angle) than conventional TKA.

	Outliers>3° of plan (%)			Deviation from target, mean ± SD		
	Robotic	Conventional	P value	Robotic	Conventional	P value
Schrednitzki[16]	0/71 (0%)	75/308 (24.3%)	<0.001	1.01° ± 0.08°	2.05° ± 0.11°	<0.001
Hasegawa[18]	0/36 (0%)	NA	NA	0.6°	NA	NA
Shin[20]	4/37 (11%)	NA	NA	NA	NA	NA
Parratte[13]	4 (10%)*	8 (20%)*	>0.05	NA	NA	NA
Vanlommel[15]	3/58 (5.2%)	19/79 (24.1%)	0.003	NA	NA	NA
Rossi[17]	NA	NA	NA	1.2° ± 1.1°	NA	NA
Batailler[12]	2/40 (5%)*	12/40 (30%)*	0.003	NA	NA	NA
Seidenstein[14]	0/14 (0%)	5/20 (25%)	NA	0.8° ± 0.6°	2.0° ± 1.6°	0.004
Parratte[19]	0/30 (0%)	NA	NA	-0.03° ± 0.87°	NA	NA

*Outliers considered as <175°

An important aspect of all robotic systems is the ability to accurately register the landmarks and conduct a dynamic assessment. Charette et al. recently reported that the ROSA Knee System has excellent inter- and intra-rater reliability for both of these activities, and the reliability was consistent whether or not image-based planning was used[30]. In this cadaveric study, they also reported no difference in the ability of a resident, an arthroplasty fellow, and a fellowship trained arthroplasty surgeon to accurately perform the registration of landmarks and evaluate the soft tissue laxity.

Table 2. The ROSA Knee System is accurate and precise in achieving the planned tibial and femoral angles. Absolute Mean Errors from planned angles ± Standard Deviations (% > ± 3°), unless otherwise indicated.

	Outliers>3° of plan (%)			Deviation from target, mean ± SD		
	Robotic	Conventional	P value	Robotic	Conventional	P value
Schrednitzki[16]	0/71 (0%)	75/308 (24.3%)	<0.001	1.01° ± 0.08°	2.05° ± 0.11°	<0.001
Hasegawa[18]	0/36 (0%)	NA	NA	0.6°	NA	NA
Shin[20]	4/37 (11%)	NA	NA	NA	NA	NA
Parratte[13]	4 (10%)*	8 (20%)*	>0.05	NA	NA	NA
Vanlommel[15]	3/58 (5.2%)	19/79 (24.1%)	0.003	NA	NA	NA
Rossi[17]	NA	NA	NA	1.2° ± 1.1°	NA	NA
Batailler[12]	2/40 (5%)*	12/40 (30%)*	0.003	NA	NA	NA
Seidenstein[14]	0/14 (0%)	5/20 (25%)	NA	0.8° ± 0.6°	2.0° ± 1.6°	0.004
Parratte[19]	0/30 (0%)	NA	NA	-0.03° ± 0.87°	NA	NA

*Percentages updated per author's response to *Letter to the Editor*. Ŧ reported as actual mean ± Standard deviation

Efficiency

The adoption of robotics in arthroplasty is unique to each surgeon and practice. Some have reported that the decision to incorporate this system in review came down to their "desire to improve health care quality and outcomes and provide value in our practice"[31]. They report reviewing their data with hopes to support or refute this claim. In describing his personal journey through robotics, Lonner reported his decision to adopt the ROSA Knee System was the potential of this system to optimize surgical efficiencies, precision, and improve ergonomics[32].

The surgical workflow has been described in several papers[11, 19, 21, 33]. Alessi et al. noted the diverse abilities of the system when performing primary TKA and reported that it can be used for either gap balancing or measured resection techniques[21]. The robotic system is intended to work alongside the surgeon without excessively sacrificing autonomy[11, 33]. Batailler et al. also noted that, along with measured resection or gap balancing, surgical philosophy for alignment is left to surgeon preference[11, 34].

Upon adoption of the system, Haffar et al. evaluated the ergonomic effects of the system compared to conventional instrumentation[35]. Specifically, they evaluated cardiorespiratory and ergonomic data of the operating surgeon in 20 consecutive robotic cases compared to 20 consecutive conventional cases. Ultimately, they reported less surgeon physiological stress, energy expenditure, and postural strain with the robotic system compared to conventional instrumentation.

The ROSA Knee System has also been reported to have a relatively rapid learning curve for operative times with similar complication rates as conventional instrumentation[15, 22]. Polikandriotis and Cafferky described early cases following adoption taking as long as 30 minutes more than conventional[31]. However, they noted that after 10 robotic-assisted cases surgical times were consistent with conventional cases, requiring approximately 45 – 60 minutes. They also suggested that proficiency is likely affected by the surgeon's willingness to adopt and the volume at which the system is implemented. When evaluating the learning curves specifically, Bolam et al. and Vanlommel et al. reported learning curves ranging from 5 – 15 cases[15, 22]. Of interest to the orthopaedic surgeon and administrators at the hospital is the ability to achieve time neutrality with conventional instrumentation when adopting new technologies. Bolem et al. reported no differences in operative times between robotic and conventional TKA[22]. In contrast, other studies have reported increased operative times with robotic-assisted TKA[12, 15, 34]. Further studies are needed to determine if this is associated with speed of adoption or related to individual surgeon and center workflows. Additionally, the evaluation of total operating room time between robotic and non-robotic cases is needed.

The ability to use plain radiographs for pre-operative planning, or no imaging at all, removes the patient and administrative burden of ordering more advanced imaging. Image-based cases are accomplished with the use of the X-Atlas® 2D to 3D Technology (Zimmer Biomet, Montreal, Quebec, CA). Massé and Ghate described this process and evaluated the accuracy of this system, concluding that the imaging technology can accurately reconstruct a three-dimensional bone model from two-dimensional, pre-operative, orthogonal, long-leg radiographs[36]. Using this imaging technology, Klag et al. reported improved accuracy of implant size prediction compared to pre-operative templating on two-dimensional films alone[37]. Additionally, the use of plain film radiographs results in less radiation exposure to the patient compared to CT imaging[38]. This amount is not negligible as CT scans of the knee for pre-operative planning have been shown to provide similar radiation doses as approximately 48 chest X-rays[32].

Outcomes

Outcome data surrounding this relatively new system is limited, but positive. Kenanidis et al. reported no difference between robotic-assisted TKA and conventional instrumentation in patient reported outcome measures (PROMs) and overall satisfaction of the knee at the three-month follow-up[39]. However, at six months, the robotic-assisted TKA group had higher Forgotten Joint and Oxford Knee scores, less pain, and more patients indicated they would undergo the procedure again (Table 3). Similarly, Parratte et al. demonstrated improvements in the Knee Society Knee and Function scores at six months in the robotic group (Table 3)[12], and Batailler et al. reported improved six-month Knee Society function[11] compared to conventional TKA. At 12-month follow-up, Mancino et al. reported higher post-operative Knee Society Knee and Function Scores in robotic assisted TKA compared to navigation-assisted TKA without differences in other PROMs evaluated[33].

Mancino et al. noted both higher maximum range of motion (ROM) post-operatively and greater changes in ROM in the robotic-assisted group[34]. The ROM at one-year was reported as least square (LS) means and was 119.4° (95% Confidence interval [CI], 116.54° – 122.35°) for robotic TKA compared to 107.1° (95% CI, 103.47° – 110.64°) in the control. This represents a LS mean difference of 12.39° (7.77-17.01°, $p < .0001$). This difference is associated with a minimal clinically important outcome of substantial change as reported by Wilson et al[40]. They also reported a greater improvement in the arc of motion by 11.67° (95% CI 7.36° – 15.7°, $p<0.001$). Fary et al. have also reported on improved early ROM in robotic vs conventional with an increase of 7° more at one month in the robotic group[41].

Kenanidis et al. reported no complications in either group (Table 4); however, the sample size was likely too small to detect a real difference if any were actually present[39]. Both Mancino et al. and Parratte et al. reported minimal complications between robotic-assisted and their controls (Table 4)[13, 34]. In their learning curve analysis, Vanlommel et al. also noted minimal complications between robotic-assisted and conventional (Table 4)[15].

Table 3. Improved PROMS in ROSA Knee System vs. controls, summarized using mean ± standard deviation unless otherwise indicated.

	Robotic	Conventional	P value
Kenanidis[39]			
Forgotten Joint Score (6 months)	71.6 ± 8.3	61.9 ± 8.1	<0.001
Oxford Knee Score (6 months)	37.8 ± 3.8	34.8 ± 4.0	0.006
Post-operative VAS* (6 months)	1 (2)	2 (2)	0.025
Would undergo operation again?	30/30	26/30	0.038
Mancino[34]			
Knee Society Knee Score (12 months)	84.5 ± 10.7	70.4 ± 14	<0.001
Knee Society Functional Score (12 months)	86.4 ± 12.9	70.5 ± 16.9	<0.001
Parratte[13]			
Knee Society functional score (6 months)	83.7 ± 15	73.3 ± 15	0.008
Improvement in Knee Society knee score (6 months)	59.3 ± 11.9	49.3 ± 9.7	0.003
Improvement in Knee Society functional score (12 months)	48 ± 26	29.5 ± 20	0.004
Batailler[12]			
Knee Society functional score (6 months)	93.3 ± 7.6	80.7 ± 8.7	<0.001

*values given as median and (interquartile range)
Ŧ values presented as fractions with "yes" as numerator and total sample size for the cohort as the denominator.

Table 4. Complications present post-operatively.

	Robotic, n (%)	Control, n (%)	P value
Kenanidis[39]	0 (0%)	0 (0%)	NA
Mancino[34]			
Revision TKA	0 (0%)	2 (4.26%)	0.232
Infection	1 (2%)	2 (4.26%)	>0.99
Aseptic Loosening	0 (0%)	1 (2.13%)	0.485
Reoperations	1 (2%)	3 (6.38%)	0.191
DAIR*	1 (2%)	1 (2.13%)	>0.99
Wound Complication	2 (4%)	4 (8.7%)	0.426
Parratte[13]			
DAIR*	1 (2.5%)	0 (0%)	NA
Traumatic Distal Femoral Fracture	0 (0%)	1 (2.5%)	NA
Vanlommel[15]			
Arthrofibrosis	2 (2.2%)	1(1.1%)	NA
Surgical site infection	1 (1.1%)	3 (3.3%)	NA
Deep vein thrombosis	1 (1.1%)	0 (0%)	NA
Periprosthetic joint infection	0 (0%)	1 (1.1%)	NA

*DAIR: debridement antibiotics and implant retention

Conclusion

Multiple studies support the ability of the ROSA Knee System to accurately and reliably assist the surgeon in placing the cutting guide and achieving the planned cut angles and resections[12-14, 16-20]. The system has been shown to be easily incorporated into the surgical workflow with a rapid initial learning curve[15, 21, 22, 31]. The flexibility of the system allows for a variety of surgical techniques[21, 31, 33] and has been shown to reduce surgeon stress compared to conventional instrumentation[35]. Additionally, patient and administrative burdens of obtaining advanced imaging are unneccesary and radiation exposure is minimized[32, 38]. Early studies have demonstrated improved outcomes, including PROMs, ROM, pain and satisfaction, with minimal complications during the immediate (4-12 weeks) and early (6 - 12 months) post-operative period[12, 13, 15, 34, 39]. In addition to the current potential values seen in these studies, there is also added value in the data provided by this robotic system. Lonner et al. recently demonstrated the ability to connect the intra-operative data provided by the ROSA Knee System with post-operative step counts and PROMs data in a commercial system[42]. They reported associations with the degree of intra-operative laxity decisions and patient recovery outcomes. This information may be used to guide future care; however, the authors recommend more robust investigations be performed prior to making surgical decisions based on the current data.

This review summarizes the value of the ROSA Knee System and its ability to:

- Improve component positioning
- Improve early patient outcomes
- Decrease radiation exposure
- Potentially change practice as more data is evaluated and used to better understand the intricacies of intra-operative decisions

The long-term outcomes and survivorship of TKA using the ROSA Knee System are yet to be determined, but the addition of this technology to assist in TKA procedures has been shown to have both patient and surgeon benefits.

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