Robotic-arm assisted TKA: A growing and promising technology

Total knee arthroplasty (TKA) is a highly effective treatment for end-stage degenerative joint disease and has helped patients regain functional mobility with reduced pain and improved quality of life. Every year, almost 700,000 primary TKA procedures are performed in the US.[1] This number is expected to grow to 3.48 million procedures by 2030—an increase of more than 600%.[2]

Robotic technology, which has been used in orthopedic surgery for more than two decades, is popular because of its potential to simplify procedures, reduce instrumentation, and enhance accuracy and reproducibility of component placement. The goals of this technology include improving patient outcomes and reducing costs over the episode of care (EOC).[3]

Currently available robotic technology used in TKA can be classified according to cutting type (direct versus indirect) and cutting control (boundary control, haptic, or autonomous). Direct cutting robotic systems are designed to cut the bone to the final desired shape. In contrast, indirect robotic systems machine features in the bone to allow placement of cutting jigs or hold cutting jigs in place.[4]

Robotic technology can also be classified in terms of cutting control. In boundary control, the robotic-arm is controlled and propelled by the surgeon. The robotic-arm is free to move within the set boundary, but it is deactivated if it travels beyond the predetermined boundary. In haptic control, human interaction is required to move the robotic-arm, but the robotic-arm's movement is designed to be constrained within a haptic border. Autonomous systems, on the other hand, move without a human hand controlling them.[4]

Robotic technology in the OR

Learning curve

Fleischman et al defined learning curve with robotic-assisted TKA (RATKA) as the number of cases needed to achieve time neutral to the surgical team's operative time when performing manual TKA. To achieve this, they estimated the need to perform 10 to 15 RATKA cases, regardless of experience level of the surgeon. Although longer surgical time has frequently been cited as a disadvantage of robotic technology, data showed that time neutral could be achieved after a few cases.[5]

Kevin Barga, MS, RN, CCRP

Kayani et al assessed surgical team anxiety levels by having a team composed of the surgeon, anesthesiologist, scrub personnel, and circulating RN complete the Spielberger State-Trait Anxiety Inventory (STAI) questionnaire. They reported an increase in stress level during the initial learning phase, but STAI scores improved and went back to baseline levels after seven cases as the team became more proficient with the standard RATKA workflow, which includes setting up trays and instruments, positioning of the robotic-arm in the OR, and preparing the pins, checkpoints, and arrays for bone registration.[6]

Ergonomically challenging tasks—such as patient handling, soft tissue retraction, transferring equipment and instrument sets, and static motion—are common in the OR.[7] Using motion sensors to monitor shoulder and lower back movement and posture in a cadaveric lab setting, Scholl et al found that RATKA reduced the risk of neck injury and increased satisfaction for the surgeon.[8] A surgical assistant was also found to have reduced ergonomic risk because RATKA eliminated the need to participate in instrument placement and reduced participation in soft tissue retraction.[8,20]

In another study, two surgeons wore biometric-enabled shirts that collected data on energy expenditure as they performed 35 manual and 29 RATKA procedures. For both surgeons, RATKA cases

Mako total knee robotic-arm. Photo courtesy of Stryker. Used with permission.

took longer and increased the surgeons' total energy expenditure. Interestingly, the RATKA cases required one less surgical assistant, reducing the total staff required for the procedure.[9]

Surgical outcomes

Accuracy in component positioning and limb alignment can influence outcomes and implant durability. Data from 105 cases performed using haptic-guided RATKA were prospectively collected at the Hospital for Special Surgery in New York. The researchers found high reliability and accuracy of coronal tibial, coronal femoral, and tibial sagittal alignment when comparing the executed intraoperative plan at 1 year postoperatively via biplanar hip-to-ankle radiographs.[10]

CT imaging is used to create a patient-specific 3D model of the patient's unique knee anatomy preoperatively. Marchand et al reported that 97% of femoral implants and 99% of tibial baseplates were correctly predicted within one implant size in 335 cases using CT scans and 3D preplanning software.[11] Researchers concluded that better implant size prediction has the potential to improve OR efficiency.

Knowing the implant sizes that will be used intraoperatively can help hos-

Continued on page 26

Continued from page 25

pital systems with quality control, inventory management, and ensuring that the correct implants are on hand—all of which can help contain costs and enhance patient outcomes.[11] In this study, the number of surgical trays was reduced from 11 to 3, which markedly reduced OR setup time, resources required, and overall operating costs.[11]

Inadvertent bone and soft tissue injury can occur during TKA procedures.[12] Kayani et al compared intraoperative bone and soft tissue injury in manual versus RATKA using the Macroscopic Soft Tissue Injury (MASTI) classification and found reduced bone and peri-articular soft tissue injury in patients undergoing haptic-guided RATKA. Haptic-guided RATKA prevented the sawblade from cutting outside the designated surgical field and thus limited iatrogenic soft tissue injury. Previous studies have shown that minor trauma to soft tissues may lead to inflammatory responses and contribute to pain and delayed postoperative rehabilitation.[12]

One surgeon's experience

Jeffrey Hodrick, MD, a fellowship trained orthopedic surgeon with the Southern Joint Replacement Institute in Nashville, Tennessee, who has been in practice for more than 17 years, shares his thoughts on adopting robotic-assisted technology for knee procedures. Dr Jeffrey Hodrick is a paid consultant of Stryker. The opinions expressed by Dr Hodrick are those of Dr Hodrick and not necessarily those of Stryker. Individual experiences may vary.

Q: What robotic technology do you use, and for how long have you used it?

A: I currently use the Mako Total Knee and Partial Knee applications for every single knee I perform. I have been using the applications for close to 2 years in my practice. I honestly believe the application makes me better, and I am seeing this in my early results. [In Dr Hodrick's experience. Another hospital/site or surgeon's experience may vary.]

Q: How has robotic technology impacted you and your patients?

A: Robotic technology has had a profound impact on the way I approach knee replacement. Although I was trained and used a measured resection approach, I have always thought that the proper technique exists on a spectrum between that and gap balancing techniques. The Mako total knee application allows me to marry the two techniques by using the CT scan-generated data and incorporating the soft tissue tension from the dynamic balancing portion of the case.

Q: How will robotic technology change orthopedics?

A: I am not completely sure, but the early results of robotics for joint replacement are encouraging. My hope is that as we continue to learn and understand more about robotics, we will see a decrease in the percentage of people who are not totally satisfied with their knee replacement after 1 year.

Early clinical outcomes of haptic-guided RATKA

TKA is a highly successful procedure, yet 10% to 20% of patients are dissatisfied with their outcomes.[13] Since 2016, when the haptic-guided total knee application was launched, data have begun to show favorable early clinical outcomes.

Early postop results

A prospective, single-surgeon study by Kayani et al of 40 RATKA patients and 40 patients who had manual or conventional jig-based TKA found that the RATKA group was associated with less postoperative pain ($P<0.001$), less need for analgesics ($P<0.001$), less postoperative blood loss ($P<0.001$), less time to achieve straight leg raise ($P<0.001$), less time to hospital discharge (RATKA resulted in a 26% length of stay [LOS] reduction), and improved maximum flexion at discharge.[14]

A statistically significant shorter LOS was also reported by Naziri et al in a comparison of 40 conventional or manual TKA cases to 40 RATKA cases (1.92 days vs 1.27 days; $P<0.0001$).

No difference was noted in postoperative Knee Society Score (KSS) and complication rates, but better range of motion was seen with RATKA cases at 90 days.[15]

Clark and colleagues demonstrated a statistically significant shorter LOS ($P<0.001$), better postoperative range of motion, and improvement in postoperative pain with statistically significant reduced total morphine consumption ($P=0.001$) in a comparison of 75 RATKA patients and 75 patients with computer-navigated TKAs.[16]

1-year postoperative results

Patient satisfaction at 1 year after surgery was assessed in 150 patients who underwent manual TKA versus RATKA in a study by Denehy et al. Patients were asked to complete the satisfaction portion of the 2011 KSS, developed and validated to better characterize the expectations, satisfaction, and physical activities of patients undergoing TKA.

Although no difference was seen in postoperative range of motion between the two groups, 95% of RATKA patients reported statistically significant greater overall satisfaction compared to 75% of those in the conventional TKA group ($P=0.005$). This improved patient satisfaction with RATKA was attributed to real-time intraoperative alignment information and gap balance measurement, which allowed the surgeon to achieve accurate bone cuts, implant placement, and gap balancing.[17]

To assess 1-year postoperative patient satisfaction outcomes in RATKA versus manual TKA, Marchand et al. analyzed 53 consecutive RATKA and 53 consecutive manual TKAs performed by a single orthopedic surgeon at a high-volume institution. Patients completed the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) survey, a validated questionnaire focused on physical function and pain scores.

Researchers found significantly lower total WOMAC scores—indicating overall improved outcomes—in the RATKA cohort ($P<0.05$) compared with the manual cohort. More patients in the RATKA cohort reported lower, and therefore improved, physical function scores ($P<0.05$) than in the manual cohort. Mean postoperative pain scores were 2±3 points (range, 0-14 points) in the RATKA cohort ($P=0.06$) vs 3±4 points (range, 0-11 points) in the manual cohort.[18]

Episode of care cost in manual versus RATKA

	RATKA	Manual TKA	Difference	P-value
Index facility cost	$12,384	$13,024	($640)	0.0001*
Post 90-day costs by setting				
Inpatient	$12,075	$13,267	($1,192)	0.4904
Outpatient	$699	$839	($141)	0.0019*
Emergency room	$614	$736	($122)	0.1600
Skilled nursing facility	$7,201	$7,947	($746)	0.0230*
Home health	$3,045	$3,536	($491)	<0.0001*
Total post 90 days	$5,234	$6,978	($1,744)	<0.0001*
Total episode of care cost (index + 90-day post index)	$18,568	$20,960	($2,391)	<0.0001*

Adapted from Cool C L, Jacofsky D J, Seeger K A, et al. A 90-day episode-of-care cost analysis of robotic-arm assisted total knee arthroplasty. J Comp Eff Res. 2019;8(5):327-336. Used with permission.
*Indicates a statistically significant *P*-value.

Studies have linked RATKA with reduced ergonomic risks.

Outlook for the future

Since its introduction in the market, robotic-assisted technology has generated data showing potential clinical[10-18] and health economic advantages[19] over conventional or manual techniques. Features that may be contributing to improved outcomes in TKA patients include:

- individualized 3D preoperative planning
- intraoperative visual, auditory, and tactile feedback to the user
- an auto switch-off feature that is designed to prevent the sawblade from cutting outside the designated field established during preoperative planning and bone registration
- the ability for intraoperative adjustments
- haptic guided bone resections.

In a longitudinal, retrospective analysis of Medicare claims data evaluating the 90-day EOC costs for manual total knee vs robotic-assisted total knee surgeries, index cost (cost for surgery), LOS, discharge disposition, and readmission rates were assessed. TKA procedures were identified using the 100% Medicare Standard Analytic File. Accounting for baseline differences, propensity score matching was performed 1:5.

The study included 519 RATKA and 2,595 manual TKA procedures. The study showed a reduction in LOS by 0.7 days, significantly fewer patients discharged to SNF (12.52% RATKA vs 21.70 mTKA, $P<0.0001$) as well as a 33% reduction in 90-day readmissions. The overall 90-day average EOC costs to Medicare were $2,391 less for RATKA ($P<0.0001$). These cost reductions are likely attributable to the significantly lower index costs, increased likelihood of being discharged to home shorter LOS, and decreased readmission rates, when compared with mTKA costs.[19] (See Episode of Care Cost table above.)

Haptic-guided RATKA has demonstrated favorable intraoperative, early postoperative, and health economic advantages compared to conventional/manual TKA in various case control studies. Available short-term data show promising results, but further research is needed to measure the long-term impact of this technology with regard to clinical and functional outcomes.

Robotic-arm assisted TKA has the potential to improve patient outcomes and help contain healthcare costs to

Continued on page 29

Technology

Continued from page 27

payers, which is critical for its continued adoption and widespread use. ✣

Kevin Barga, MS, RN, CCRP, is a senior project manager, implant and robotic research, R&D, at Stryker Orthopaedics in Mahwah, New Jersey.

References

1. Williams S N, Wolford M L, Bercovitz A. Hospitalization for total knee replacement among inpatients aged 45 and over: United States, 2000–2010. NCHS Data Brief. 2015; 210:1-8.
2. Kurtz S, Ong K, Lau E, et al. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. 2007;89(4):780-785.
3. Lonner J H, Fillingham Y A. Pros and cons: A balanced view of robotics in knee arthroplasty. J Arthroplasty. 2018;33(7):2007-2013.
4. Chen A, Kazarian G S, Jessop G W, et al. Robotic technology in orthopaedic surgery. J Bone Joint Surg. 2018;100(22):1984-1992.
5. Fleischman A N, Lutz R W, Vahedi Kafshgari H, et al. Time-related learning curve of robotic-arm assisted total knee arthroplasty. Poster 5373. 2018 American Academy of Orthopaedic Surgeons.
6. Kayani B, Konan S, Huq S S, et al. Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning. Knee Surg Sports Traumatol Arthrosc. 2019;27(4):1132-1141.
7. Beck D M. Ease that aching back: Ergonomic issues in the OR. OR Nurse. 2008;2(5)47-49.
8. Scholl L Y et al. Surgeon Posture and Workload Demands during Total Knee Arthroplasty. Presented at ORS 2018 Annual Meeting.
9. Blevins K M, Danoff J R, Goel R, et al. Energy expenditure during conventional and robotic-arm-assisted total knee arthroplasty. Orthopaedic Proceedings. Published online April 8, 2019. https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.2019.4.069.
10. Carroll K, et al. Aim Small, Miss Small: Radiographic and Functional Outcomes of Robotic-Assisted Total Knee Arthroplasty at One Year. Presented at ISTA 2018.
11. Marchand R C, Sodhi N, Bhowmik-Stoker M, et al. Does the robotic-arm and preoperative CT planning help with 3D intraoperative total knee arthroplasty planning? J Knee Surg. 2019;32(8):742-749.
12. Kayani B, Konan S, Pietrzak J, et al. Iatrogenic bone and soft tissue trauma in robotic-arm assisted total knee arthroplasty compared with conventional jig-based total knee arthroplasty: A prospective cohort study and validation of a new classification system. J Arthroplasty. 2018;33(8):2496-2501.
13. Bourne R, Chesworth B M, Davis A M, et al. Patient satisfaction after total knee arthroplasty: Who is satisfied and who is not? Clin Orthop Relat Res. 2010;468(1):57-63.
14. Kayani B, Konan S, Tahmassebi J, et al. Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty: A prospective cohort study. Bone Joint J. 2018;100-B(7):930-937.
15. Naziri Q, Cusson B C, Chaudhri M, et al. Making the transition from traditional to robotic-arm assisted TKA: What to expect? A single-surgeon comparative-analysis of the first-40 consecutive cases. J Orthop. 2019;16(4):364-368.
16. Nevelos J, Bhowmik-Stoker M, Faizan A, et al. Do Total Knee Arthroplasty Surgical Instruments Influence Clinical Outcomes? A Prospective Parallel Study of 150 Patients. Presented at 2019 EKS.
17. Denehy K, et al. Patient Satisfaction Following Total Knee Arthroplasty Using Technologic Innovation to Achieve Balanced Gaps: A Prospective Cohort Study. Presented at EKS. 2-3 May 2019. Valencia, Spain.
18. Marchand R C, et al. One-year patient outcomes for robotic-arm-assisted versus manual total knee arthroplasty. J Knee Surg. April 8, 2019; doi: 10.1055/s-0039-1683977. [Epub ahead of print]
19. Cool C L, Jacofsky D J, Seeger K A, et al. A 90-day episode of care cost analysis of robotic assisted total knee arthroplasty. J Comp Eff Res. 2019;8(5):327-336.
20. Scholl L Y, Barga K, Hampp E L, et al. Can surgical technology reduce surgical staff postural demands during total knee arthroplasty? Poster. 2018 OR Manager Annual Conference.

Disclaimer

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker's product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your sales representative if you have questions about the availability of products in your area.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: [Mako, Stryker]. All other trademarks are trademarks of their respective owners or holders.