



A clinical review of robotic navigation in total knee arthroplasty: historical systems to modern design

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- Robotic-assisted total knee arthroplasty (RA-TKA) has shown improved reproducibility and precision in mechanical alignment restoration, with improvement in early functional outcomes and 90-day episode of care cost savings compared to conventional TKA in some studies. However, its value is still to be determined.
- Current studies of RA-TKA systems are limited by short-term follow-up and significant heterogeneity of the available systems.
- In today's paradigm shift towards an increased emphasis on quality of care while curtailing costs, providing value-based care is the primary goal for healthcare systems and clinicians. As robotic technology continues to develop, longer-term studies evaluating implant survivorship and complications will determine whether the initial capital is offset by improved outcomes.
- Future studies will have to determine the value of RA-TKA based on longer-term survivorships, patient-reported outcome measures, functional outcomes, and patient satisfaction measures.

Keywords: RA-TKA; robotic-assisted total knee arthroplasty; total knee arthroplasty

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Introduction

As value in healthcare has shifted to a measurement of quality relative to the cost, there is a greater emphasis on improving clinical and functional outcomes and patient satisfaction.¹ This is especially relevant in elective primary total knee arthroplasty (TKA), which is one of the most commonly performed surgical procedures in the United States and has projected exponential growth in

the upcoming decade.^{2–5} Increased long-term survival, functional outcomes and satisfaction following TKA are therefore becoming more important to both the patient and the healthcare system as a whole. Despite marked advances in implant designs, surgical techniques, and postoperative rehabilitation programmes, multiple studies demonstrate that nearly 20% of patients remain dissatisfied with their overall outcomes after primary TKA.^{6–15}

Dissatisfaction is believed to be multifactorial and secondary to component malposition, patient selection and establishing expectation management preoperatively.¹⁶ Since component positioning, alignment and equal soft tissue balance are critical for a successful TKA,¹⁷ malalignment in the coronal, sagittal and rotational planes continues to increase implant failure rates and cause poor clinical outcomes.^{16–19} Bone cutting inaccuracies up to 4° in the coronal plane and 11° in the sagittal plane have been reported to occur during conventional primary TKA, with guide movement contributing to 10–40% of the total cutting error.^{17,20–22} Therefore, TKA technological development, including computer-assisted navigation (CAN), has focused on surgical technique improvement to reliably identify overall limb alignment and to assist in guide placement for bony cuts. However, medium-term and long-term CAN-TKA clinical function outcomes and survivorship have been shown to be similar to conventional TKA despite improved radiographic alignment and fewer outliers achieved with navigation assistance.^{23–26}

The global medical robotic market that was valued at \$7.24 billion in 2015 is projected to grow to \$20 billion by 2023.²⁷ The most important factor fuelling the market growth is the overall superior economic and social advantage of medical robots over traditional human operators with added procedural value.²⁷ Robotic-assisted TKA (RA-TKA) has gained momentum within the past 10 years to better control surgical variables by mitigating technical

errors caused by insecure cutting guides and imprecise bone cuts.²⁸ Studies have also shown superior results with RA-TKA versus CAN-TKA, with shorter operative duration, less coronal/sagittal deviation and increased accuracy of mechanical axis alignment restoration.^{16,29,30} Newer robotic platforms have further evolved to allow clinicians to track patient experience and outcomes throughout the perioperative period with the collection of validated patient-reported outcome measures (PROMs).^{31–33} This comprehensive review investigates the advent of robotic navigation, historical and commercially available systems, learning curve, clinical outcomes, cost-analysis and limitations to better understand the value of RA-TKA.

Robotic total knee arthroplasty systems

History

Since the first CAN arthroplasty procedure in 1997, the use of technology in TKA has grown tremendously in an attempt to improve surgical technique for more reliable component placement and alignment.³⁴ CAN technology utilizes either infrared (IR) or electromagnetic (EM) registration signalling that facilitated real-time feedback for instrumentation positioning and bony resection.^{35–37} However, both modalities had limitations with line of sight and metal interference.^{16,35–37} Despite these innovations, long-term study of the first 26 CAN-TKA demonstrated only 85% patient satisfaction without significant improvement in implant survivorship compared to conventional TKA at 10-year mean follow-up.³⁸

The first surgical robot system was introduced in 1985 based on computed tomography (CT) imaging for neurosurgical biopsies.³⁹ This robot's initial success sparked interest in other surgical fields with robotic transurethral prostate resections in 1989.³⁹ The hypothesized advantages included an increase in three-dimensional (3D) accuracy, increased reproducibility of commonly performed procedures, and increased precision of movements mimicking the motion of the operating surgeon.⁴⁰ By the late 1980s, surgeons began to appreciate the potential advantages of surgical robots compared with computer navigation alone, with the most potential in neurosurgery and orthopaedic surgery. The first orthopaedic robotic-assisted system, the ROBODOC system (THINK Surgical Inc., Fremont, CA, USA), was developed in 1986 and was used for cementless total hip arthroplasty (THA) in 1992.⁴¹ During the past two decades, enthusiasm for robotic-assisted total joint arthroplasty (TJA) has grown tremendously.¹⁶

Passive, active and semi-active

CAN-TKA systems delineate patient anatomical data and provide objective real-time feedback on guide placement

for optimal bone resection and implant placement. However, CAN does not actively control or restrain the surgeon in performing any aspect of the procedure. RA-TKA systems utilize computer software while incorporating advanced imaging to provide a virtual patient-specific 3D reconstruction of the knee. The surgeon calculates the optimal bony resection and final component placement and alignment on the robotic computer software. An intraoperative robotic device physically assists the surgeon in executing the preoperative plan with a high level of precision and accuracy.^{42–48} Every robotic design has a different level of constraint and haptic feedback, and designs are classified as either passive, active or semi-active systems.

Passive modalities are under direct and continuous surgeon control. Contrarily, active robotic platforms perform a designated task completely independent of the surgeon. Semi-active systems provide the surgeon with tactile feedback with procedural safe-guards to ensure accuracy and safety against iatrogenic soft tissue or neurovascular injury.^{16,49} Semi-active modalities utilize haptic feedback through auditory, tactile or visual cues that alert the surgeon about deviations from the preoperatively defined parameters.^{16,49} This helps mitigate excessive or uneven bony resection and component malpositioning. Semi-active robots also self-regulate instrumentation to either slow down or completely stop when deviation outside the computer-generated volume or depth of a defined bone resection occurs. The main robotic-assisted systems historically used are summarized in Table 1.

Image-based versus imageless

Each robotic system requires preoperative plain radiographs or advanced imaging such as CT scan or magnetic resonance imaging (MRI) scans to use in a mapping process to virtually recreate the knee for preoperative and intraoperative planning. The desired resection angle, resection depth, overall limb alignment and implant positioning can be predetermined and set preoperatively onto the robot's computer software. The robot implements the predetermined surgical plan to either position cutting guides or to assist in bony cuts. Preoperative imaging allows consideration of the patient's distinct anatomy which serves as a checkrein for accurate implant placement and allows template adjustment as needed. However, additional increased cost, burden of obtaining additional imaging and increased radiation exposure are potential drawbacks. Furthermore, preoperative CT exposure can have a radiation effective doses greater than 100 mSv, which is significantly greater than the Food and Drug Administration (FDA)'s warning of increased malignancy with effective radiation doses

Table 1. Historical robotic-assisted TKA systems.

Name	Manufacturer	Introduction year	Manufacturer acquisition	Platform	Indication	Type	Technique	Image	Results
CASPAR	Orto-Maquet URS, Schwerin, Germany	1997	Smith & Nephew (Memphis, TN) acquired in 2001	Open	THA TKA	Active	<ul style="list-style-type: none"> Milling CASPAR's active system utilized preoperative CT scans which occurred after an index procedure to place self-tapping bicortical screws as fiducial markers.⁵⁷ The robotic arm performed bony preparation with bone milling based on the preoperative template, fiducial markers and intraoperative anatomic registration. 	CT	<ul style="list-style-type: none"> Seibert et al⁵⁷ were the first to report this technology and compared 70 CASPAR TKA patients with a historical control group of 50 conventional TKA patients and found the postoperative tibiofemoral alignment was within 0.8° (0–4.1°) of the preoperative template compared to 2.6° (0–7°) in the conventional historical control cohort.⁵⁷ After initial success, CASPAR's TKA platform had poor early clinical outcomes with a high incidence of complications and is no longer commercially available.^{57,58}
Acrobot	Imperial College of London	1988	Stanmore Sculptor System (London, England) acquired in 2010 MAKO Surgical acquired the technology in 2013	Closed	UKA TKA	Semi-active	<ul style="list-style-type: none"> Saw Acrobot's robotic arm attached to the operative bed and used haptic feedback to allow the surgeon to make precise bone cuts. This was the first system to introduce haptic response, which paved the way for more contemporary robotic systems. 	CT	<ul style="list-style-type: none"> In a randomized control trial, Cobb et al⁶³ compared 13 UKA performed with Acrobot versus 14 UKA patients performed conventionally. All of the Acrobot UKA patients had coronal tibiofemoral alignment within 2 degrees of the planned position while only 40% of the conventional cohort achieved similar accuracy. The authors also found a trend towards but not achieving statistically significant functional outcome improvement with better Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Knee Society Scores (KSS) at six weeks and three months (p > 0.05).⁶³ Although preliminary TKA found similar accurate results, Stanmore Sculptor System withdrew from robotic platforms when MAKO Surgical acquired the technology in 2013.⁵⁸
PiGalileo	Plus Orthopedics AG, Rotkreuz, Switzerland	–	Smith & Nephew acquired technology in 2007	Closed	TKA	Passive	<ul style="list-style-type: none"> Cutting guide The passive robotic system was computer-controlled and motor operated two-axis positioning device was mounted onto the medial and lateral distal femoral shaft to aide in jig placement.^{58,60,61} 	CT	<ul style="list-style-type: none"> Matziolis et al⁶² examined the spatial implant positioning of 28 TKAs performed traditionally versus 32 TKAs using an imageless computer-assisted system with a mini robot (PiGalileo System, Plus Orthopedics AG, Smith & Nephew, Rotkreuz, Switzerland).

(continued)

Table 1 (continued)

Name	Manufacturer	Introduction year	Manufacturer acquisition	Platform	Indication	Type	Technique	Image	Results
							<ul style="list-style-type: none"> The mini robotic unit did not itself actively perform any cutting operations, but positioned the saw guide for a conventional oscillating saw.⁶¹ The platform was also accompanied with a motorized ligament balancer to aid in soft tissue balancing for surgeons who performed TKA using a gap-balancing technique. 		<ul style="list-style-type: none"> The overall mechanical axis was between 4.8° of valgus and 6.6° of varus alignment in the coronal plane for conventional TKA compared with a smaller range (2.9° of valgus and 3.1° of varus alignment) for the computer navigation with a robot cohort (p = 0.004). The authors further concluded that CAN with a mini robot improved coronal and sagittal femoral component alignment but showed no difference in tibial implant positioning. Other studies using the PiGalileo system using both measured resection and gap-balancing showed no difference in implant survivorship or functional outcomes with equivocal KSS, Functional KSS (FKSS) and Oxford Knee Scores (OKS) at mid-term follow-up (p > 0.05).^{105,106} Plus Orthopedics was acquired by Smith & Nephew in 2007 and the PiGalileo system was subsequently discontinued.

Note. CASPAR, computer-assisted surgical planning and robotics; Acrobot, The Active Constraint robot; UKA, unicompartmental knee arthroplasty; TKA, total knee arthroplasty; THA, total hip arthroplasty; CT, computed tomography; CAN, computer-assisted navigation; KSS, Knee Society Score.

greater than 10 mSv.^{16,50} CT-based robotic platforms often require lengthy preoperative planning, potential inconvenience to both patients and providers along with the reliance on an external engineer for preoperative planning and formatting. However, the advancements of imageless systems as well as the adoption of low-dose CT protocols may help mitigate these risks and further streamline the process.

Though imageless modalities reduce overall operative time and radiation exposure, as well as being more convenient for patients compared to image-based systems, imageless systems are only as accurate as the operator’s bony landmark registration and may introduce an error margin. Patients with significant deformity or bone loss may have altered anatomic landmarks which can pose a challenge during registration for the robotic software. However, studies comparing imageless versus CT-based imaging robotic platforms demonstrate no difference in reliability with landmarking and implant positioning.^{51–53} There are only two systems in the US that utilize an

imageless robotic platform: Navio Surgical System (Smith & Nephew, Memphis, TN, USA)⁵⁴ and OMNIBotics for gap balancing (Corin, Raynham, MA, USA).⁵⁵

Open versus closed platforms

The majority of available robotic systems in the US are regarded as closed platforms. Closed platform systems are only compatible with specific vendor implants.⁴⁷ This may hinder some surgeons in adopting robotic technology if they have a preference towards an implant that does not have a robotic platform. Open platform systems are more appealing due to accommodation of a wide variety of prosthesis designs from multiple different manufacturers. Although open platforms provide a convenience for incorporated 3D implant data for numerous implant systems, they may lack the depth of biomechanical kinematic data present in closed platforms that use proprietary implants.⁵⁶ Currently, TSolution-One (THINK Surgical Inc, Fremont, CA, USA) is the only RA-TKA system on the market with an open platform.⁵⁶

Historical TKA robotic systems

Early generation RA-TKA systems were introduced in Europe in the late 1980s as active systems. After surgical exposure was performed, the active robots completed the predefined plans without operator intervention. However, the older generation robots added tremendous surgical time and were associated with higher blood loss.^{57,58} These early systems had poor early clinical outcomes with high rates of failure and subsequently fell out of favour.^{57,58} Tactile systems with haptic feedback and overall technological improvements addressed some of the mechanisms of failure of older active platforms, such as soft tissue protection.⁵⁹ Early generation tactile systems demonstrated increased implant alignment and placement accuracy with more consistent ligament soft tissue balance.^{60–62} Radiological and clinical outcome improvement increased the popularity and paved the way for newer generation modern RA-TKA platforms.^{58,63} Historical robotic-assisted systems are summarized in Table 1.

Contemporary TKA robotic systems

Active systems

TSolution-One® (active system – milling/requires CT imaging)

ROBODOC® (Curexo Technology, Fremont, CA, USA), the earliest active robot system used in arthroplasty, was the first FDA-approved robotic technology in orthopaedic surgery.¹⁶ In 2014, THINK Surgical Inc. acquired Curexo Technology and introduced the next generation open robotic system, TSolution-One Surgical System, which successfully obtained FDA clearance for TKA in 2019. TSolution-One is an active-autonomous, CT-based system that helps recreate overall desired limb alignment through an image-based preoperative planning system (Fig. 1). The open platform system helps the surgeon design a preoperative template based on the surgeon's desired prosthesis.⁵⁶

ROBODOC's robot-assisted arm and 3D planning workstation were rebranded as TCAT® and TPLAN® respectively.⁵⁶ The system retains the active bone milling functionality of the ROBODOC and a rigid mating framework has been incorporated to minimize outside reference range errors due to patient positioning (Fig. 2).⁵⁶ Compared with its predecessor, TSolution-One is fiducial free and uses a digitizer to locate the exact position of the patient's anatomy to mill joint surfaces for component placement.¹⁶ The TCAT® robotic-assisted tool proceeds to complete all femoral and tibia bone cuts with a robotic milling device.⁵⁶ Although the surgeon maintains control over the milling tool with a manual override button and is



Fig. 1 TSolution-One® System, THINK Surgical Inc, Fremont, California.

Source: Adapted from Liow MHL, Chin PL, Pang HN, Tay DK, Yeo SJ. THINK surgical TSolution-One (Robodoc) total knee arthroplasty. *SICOT J* 2017;3:63.

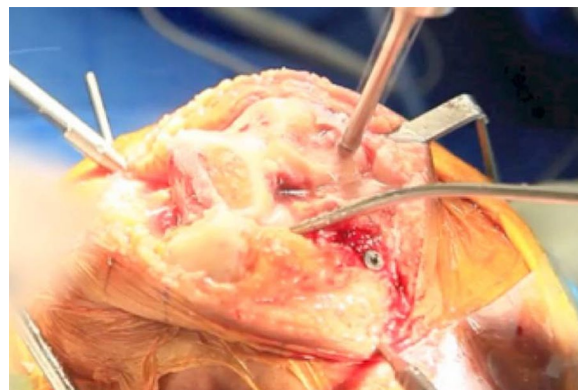


Fig. 2 TCAT® bone milling tool preparing the femur.

Source: Adapted from Liow MHL, Chin PL, Pang HN, Tay DK, Yeo SJ. THINK surgical TSolution-One (Robodoc) total knee arthroplasty. *SICOT J* 2017;3:63.

responsible for soft tissue protection, the robot completes the bony preparation steps independently with consistent water cooling irrigation and removal of milling debris without the ability for intraoperative adjustments while the preoperative plan is executed.^{16,56}

Earlier studies demonstrate increased risk of complications during the learning phase of active robotic systems. Although ROBODOC had greater mechanical axis alignment restoration accuracy compared to conventional TKA, Park and Lee⁴² reported six of their initial 32 active robotic TKA procedures had short-term complications including superficial infection, patellar tendon ligament

rupture, patella dislocation, supracondylar fracture and patellar fracture and common peroneal injury. Compared with ROBODOC, TSolution-One has shown improved preliminary clinical outcomes with excellent radiological results.⁵⁶ Multiple studies comparing TSolution-One TKA and conventional TKA demonstrate 0% mechanical axis deviators in the robotic cohort.^{47,56} However, there are no published long-term clinical outcomes of TSolution-One TKA, with short and medium-term studies demonstrating no significant difference in functional outcomes when compared to conventional TKA.^{47,48,56}

ROSA® (active system – cutting guide/requires X-ray imaging)

ROSA® Knee System (Zimmer-Biomet, Warsaw, IN, USA) is an active, closed platform robotic arm that aids in placement of the cutting block and dynamic ligament balancing.⁶⁴ Preoperative full-length lower-extremity radiographs are converted intraoperatively to 3D images using X-Atlas™ software that has a reported accuracy of within 1 mm for the resection thickness and 0.4 mm for angle measurement.^{64,65} After bony registration, the native flexion and extension gaps are assessed to

determine depth of bony resection and planned implant positioning and alignment (Fig. 3). The plan is executed with the robotic arm locking the cutting jig in the desired position for manual bone resection with a conventional oscillating saw.^{64,65} This system received FDA clearance in 2019 and a strategic roll-out of the robot has limited further clinical studies.

Semi-active systems

Mako® (semi-active system – saw/requires CT imaging)

The Mako® robotic-arm closed platform system (Stryker Orthopaedics, Mahwah, NJ, USA) was introduced in 2005 and was acquired by Stryker Orthopaedics with Mako Surgical Corporation in 2013.⁶⁶ The CT-based TKA system integrates the robotic-arm-guided saw blade and the pre-operative plan with set implant position and alignment with anticipated bony resection thicknesses (Fig. 4). The intraoperative bony registration does not require rigid stabilization that may be needed in other robotic designs and allows for dynamic femur and tibia tracking.⁶⁷ After landmark registration, implant positions are adjusted on the computer software to target equal flexion and extension



Fig. 3 (A) ROSA for total knee arthroplasty. (B) ROSA's computer software for preoperative and intraoperative planning based on implant positioning and soft tissue tensioning. (C) ROSA arm attaching cutting block for femoral cut.

Source: Adapted from Zimmer-Biomet, Warsaw, IN, USA.

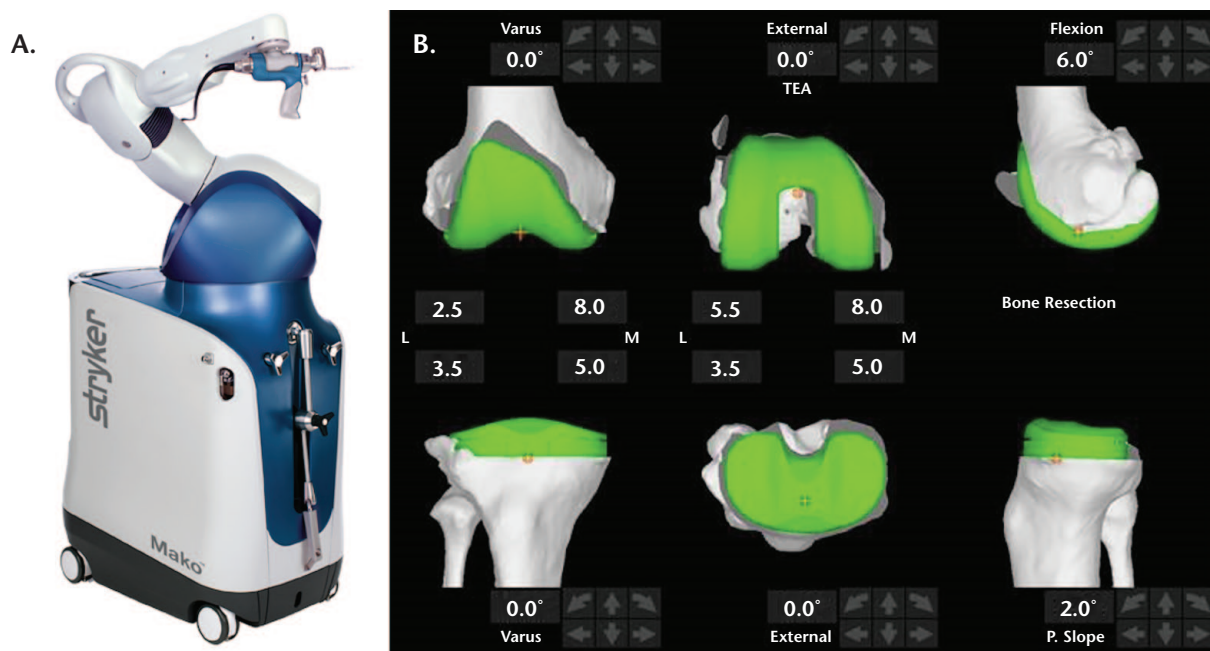


Fig. 4 (A) Mako robot for total knee arthroplasty. (B) Mako's computer software for preoperative templating that allows the surgeon to position the implant over the preoperative CT scan to obtain optimal positioning and alignment. The central numbers are the bony depth of resection in millimetres from the medial and lateral distal femur and posterior condyles.

Source: Adapted from Stryker Orthopedics, Mahwah, NJ, USA.

gaps and overall limb alignment. The robotic arm is used to perform bony cuts with haptic feedback if the saw deviates beyond the predetermined cutting zones.^{58,63,67}

Most of the literature evaluating RA-TKA efficacy involves Mako studies reporting radiological and clinical outcomes, surgical efficiency and cost-effectiveness as it was one of the earliest newer generation systems to receive FDA clearance for unicompartmental knee arthroplasty (UKA), TKA and THA.⁶⁸ Medium-term and long-term studies are warranted to continue to evaluate implant longevity, complications, functional outcomes and patient satisfaction after Mako TKA.

Navio® surgical system (semi-active system – burring/image free)

Blue Belt Technologies (Plymouth, MN, USA) introduced and received FDA clearance for Navio® Surgical System (Smith & Nephew, Memphis, TN, USA) for UKA and patellofemoral arthroplasty (PFA) in 2012. Shortly after being acquired by Smith & Nephew in 2016, the robotic platform acquired FDA approval for TKA in 2017.¹⁶ Navio is a closed platform, semi-autonomous, hand-held end-cutting burr that allows the surgeon to perform predefined bone cuts using imageless registration digital-based reference points (Fig. 5).⁵⁸ Similar to Mako, preset boundaries prevent excessive resection while the robotic tool alters the burr speed and retracts the burr tip to prevent errors; however, a potential lag time between burr tip retraction

and speed change may pose problems.^{16,58} The imageless system eliminates preoperative imaging cost and associated radiation exposure.

Although there are few studies on Navio UKA demonstrating improved alignment without any difference in revision rates,^{54,69} there are currently no reports, to our knowledge, on short or long-term data for Navio TKA. Currently, there is an ongoing prospective randomized controlled trial evaluating conventional versus Navio TKA with an estimated completion date of December 2022.⁷⁰

OMNIBotic® (semi-active system – cutting guide/requires CT imaging)

OMNIBotic® (Corin, Tampa, FL, USA) closed platform system, previously known as PRAXIM Robotic-assisted navigation, was FDA approved for TKA in 2017. After intraoperative registration, the OMNIBot robotic cutting guide is mounted onto the bone, similar to the ROSA (Zimmer-Biomet, Warsaw, IN, USA). The BalanceBot is used in conjunction with the cutting guide and is the first and only robotic soft tissue balancer available on the market (Fig. 6).⁷¹ The robotic lamina spreader measures soft tissue tension throughout the range of motion after the tibial cut and prior to any femoral cuts.⁷¹ The robot consists of two autonomous motorized actuators with integrated force sensors.^{71,72} The soft tissue tension data help plan femoral component rotation and position that optimizes symmetric flexion and extension gaps with minimal soft tissue

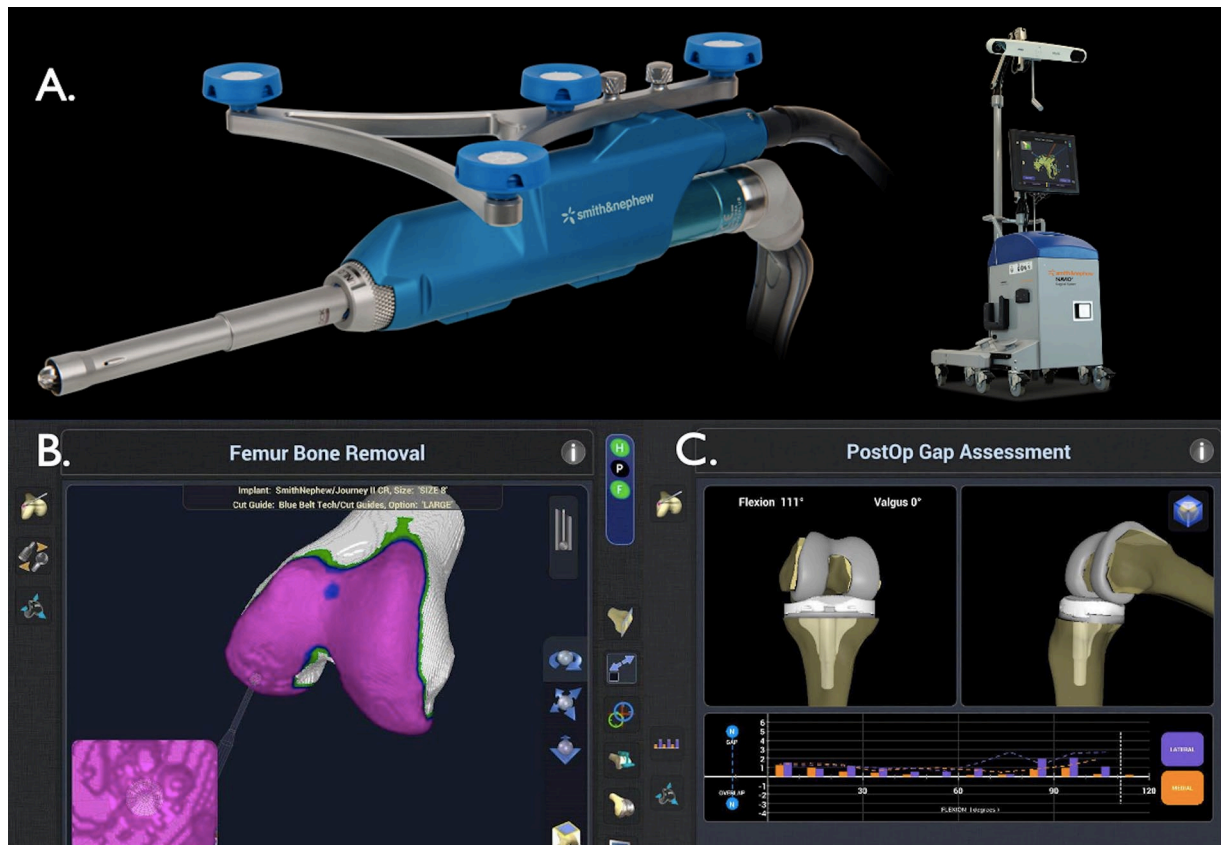


Fig. 5 (A) Navio and its computer software for total knee arthroplasty. (B) Burring for femoral component preparation. (C) Intraoperative gap assessment while trialling implants.

Source: Adapted from Smith & Nephew, Memphis, TN, USA.



Fig. 6 BalanceBot robotic soft tissue balancer (formerly OMNIBotics active spacer).

Source: Adapted from Siddiqi A, Smith T, Mcphilemy JJ, Ranawat AS, Sculco PK, Chen AF. Soft-tissue balancing technology for total knee arthroplasty. *JBJs Rev* 2020;8:e0050.

releases. The main robotic-assisted systems currently used are summarized in Table 2.

Learning curve

The RA-TKA learning curve is critical to understand the impact on surgical workflow and duration. Kayani et al⁷³

reported on the RA-TKA learning curve by assessing surrogate operative and radiological markers in 60 conventional TKAs followed by 60 RA-TKA, and found the learning curve was seven cases for operative times ($p = 0.01$) and surgical team anxiety levels ($p = 0.02$). There was no learning curve effect for achieving planned femoral and tibial positioning ($p < 0.001$) and limb alignment ($p < 0.001$) without additional risk of postoperative complications. Similarly, Sodhi et al⁷⁴ found the operative times for RA-TKA were increased for an initial 20 cases in two fellowship-trained arthroplasty surgeons but comparable to conventional TKA afterwards in both surgeons. Although operative times are increased in the learning phase of RA-TKA, surgical workflow appears to be comparable to traditional TKA after proficiency has been achieved.⁶⁰

Clinical outcomes

Regardless of the improved accuracy of robotic-assisted TKA, it is important to determine whether the improved precision impacts functional outcomes and implant survivorship. Although robotic technology has been present for over a decade with an increasing market penetration,

Table 2. Main robotic-assisted TKA systems in the United States.

Name	Manufacturer	Introduction year	Platform	Indication	FDA clearance	Type	Technique	Image	Current Status
TSolution-One	THINK Surgical Inc. Fremont, CA	2015	Open	THA, TKA	THA: 2015 TKA: 2019	Active	Milling	CT	Currently used
ROSA	Zimmer Biomet Warsaw, IN	2018	Closed	TKA	2019	Active	Cutting guide	XR	Limited release
Mako	Stryker Mahwah, NJ	2005	Closed	UKA PFA TKA THA	2015	Semi-active	Saw burr	CT	Currently used
Navio	Smith & Nephew Memphis, TN	2012	Closed	UKA PFA TKA	2017	Semi-active	Burring	Image Free	Currently used
OMNIBotic BalanceBot	Corin Tampa, FL	2004	Closed	TKA	2017	Semi-active	Cutting guide	CT	Currently used
Orthotaxy	DePuy Synthes Warsaw, IN	–	Closed	UKA TKA	–	Semi-active	Saw	N/A	Awaiting product launch
CORI	Smith & Nephew Memphis, TN	–	Closed	UKA TKA	–	Semi-active	Burring	Image free	Awaiting product launch; TKA release planned fall 2020

Note. UKA, unicompartmental knee arthroplasty; PFA, patellofemoral arthroplasty; TKA, total knee arthroplasty; THA, total hip arthroplasty; CT, computed tomography; NJ, New Jersey; TN, Tennessee; FL, Florida; CA, California; IN, Indiana; XR, X-ray.

there are relatively few medium-term or long-term studies assessing the impact of robotic assistance on these outcome measures. However, comparative short-term findings are promising.^{46,75–80} In a retrospective study, Siebert et al⁵⁷ compared 70 RA-TKA patients versus 50 conventional TKA patients and observed reduced post-operative soft tissue swelling in the robotic cohort. Peri-articular soft tissue preservation with minimal releases and decreased surrounding tissue injury in RA-TKA may limit local inflammatory response resulting in decreased pain and postoperative swelling.^{60,81–83} Similarly, Kayani et al⁸⁴ found RA-TKA patients to have less postoperative pain, decreased perioperative analgesia requirements, and reduced physical therapy duration compared to conventional TKA.

Another study comparing 30 conventional TKA with 30 RA-TKA demonstrated that RA-TKA had reduced medial soft tissue injury in passively correctable ($p < 0.05$) and fixed varus deformities ($p < 0.05$), more accurate femoral and tibia bone cuts ($p < 0.05$), and less macroscopic soft tissue injury (MASTI) compared with conventional TKA (Fig. 7).⁸⁵ This decreased swelling after RA-TKA may be an implication of greater initial postoperative range of motion compared to conventional TKA. A multicentre study found that patients undergoing RA-TKA experienced a significant 4.5-fold decrease in manipulation under anaesthesia rates ($p = 0.032$).⁸⁶ Subsequently, a systematic review and meta-analysis of five studies with 323 RA-TKAs and 251 traditional TKAs, Ren et al⁸⁷ reported improved Knee Society Score (KSS) functional scores and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores in the robotic group at six-month follow-up.

However, improved implant positioning and alignment with robotic TKA have not rendered any difference in medium-term to long-term functional outcomes

compared to conventional TKA.⁶⁰ Song et al⁴⁷ and Liow et al⁸⁸ both reported no difference in Hospital for Special Surgery (HSS), WOMAC, Oxford Knee Score (OKS) and KSS scores between robotic TKA and traditional TKA at minimum two-year follow-up. Similarly, recent long-term studies found no difference in HSS, WOMAC, OKS or Short-Form 12 (SF-12) scores at minimum 10-year follow-up.^{89,90} A recent prospective, randomized controlled trial also found no differences between RA-TKA and conventional TKA in terms of functional outcome scores, aseptic loosening, overall survivorship and complications at minimum 10-year follow-up.⁹¹ Current studies regarding clinical outcomes after RA-TKA are summarized in Table 3.

Cost analysis

In today’s cost-conscious healthcare environment that has transitioned towards value-based care, the future of robotics in TJA depends heavily on the value it provides and its associated cost-effectiveness. Robotic technology is associated with substantial installation and maintenance costs in addition to preoperative imaging, increased operating times during the learning phase, and computer software updates.⁶⁰ Depending on the hospital contracts, each robotic device may range in cost from \$400,000 to \$1.5 million.⁶⁰ The upfront expenditure may be partly offset with cost savings from reduced analgesia consumption, decreased hospital length of stay (LOS), readmission rates and greater home discharges for robotic TKA.⁶⁰

In a Markov model analysis, Moschetti et al⁹² found robotic UKA to be more cost-effective compared to traditional UKA if case volume exceeded 94 cases per year, two-year failure rates were below 1.2%, and total system costs were less than \$1.4 million and not cost-effective in low to medium-volume centres. Similarly, another Markov

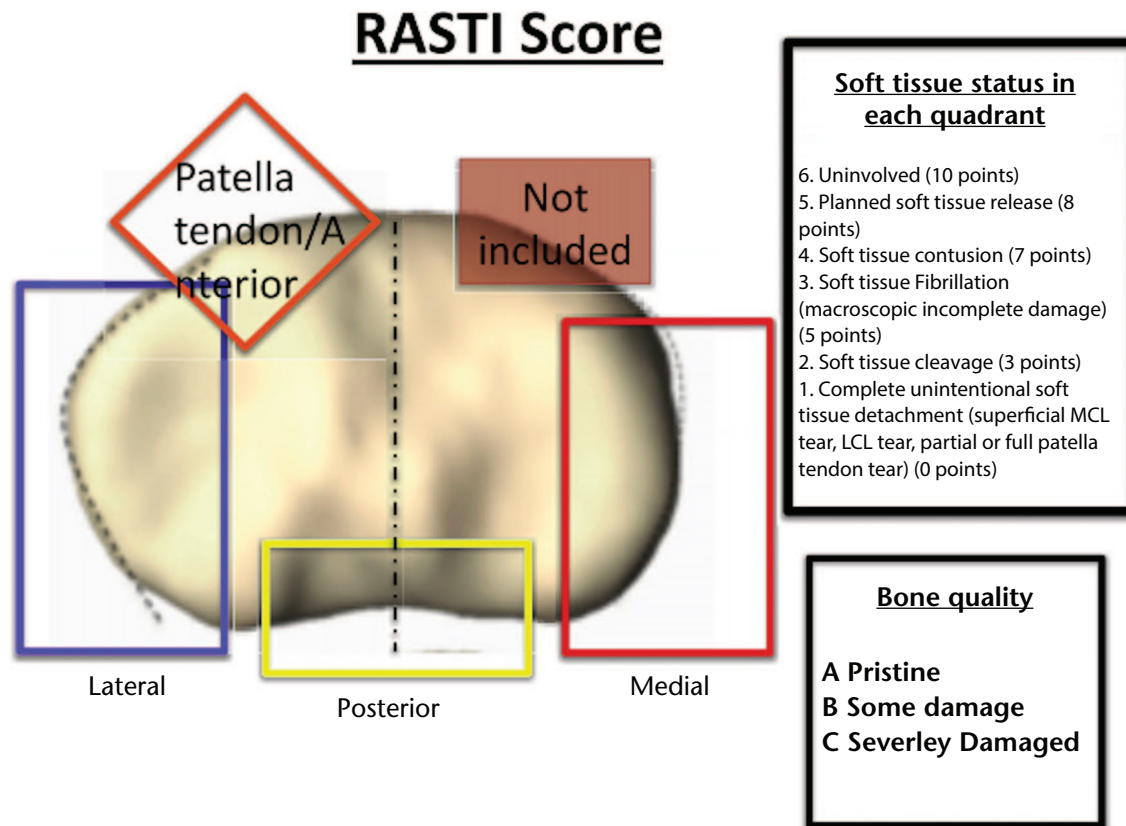


Fig. 7 Diagrammatic representation of the macroscopic soft tissue injury (RASTI) score showing tibial plateau in the axial plane.

Source: Adapted from Kayani B, Konan S, Pietrzak JRT, Haddad FS. 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;33:2496–2501.

decision analysis showed robotic UKA to be cost-effective in terms of quality-adjusted life years (QALY) at centres with greater than 200 annual cases a LOS less than two days.⁹³ Although there are no Markov model cost-analysis RA-TKA studies, many models are theoretical as prospective outcome studies are needed to substantiate the role of robotics.

Wide acceptance of new technologies should be coupled with the anticipated short and long-term benefits, outcomes and reduction in postoperative complications beyond the cost of the robotic technology. Revision TKA has an annual burden of \$2.3 billion in hospital charges with the burden on the healthcare system to surpass \$13 billion by 2030.⁹⁴ In an era of value-based care and bundled payments, Cool et al⁹⁵ evaluated 90-day episode-of-care costs associated with 519 RA-TKA versus propensity score matched 2,595 manual TKA amongst Medicare patients. Overall, 90-day episode-of-costs were \$2,391 less costly for RA-TKA ($p < 0.0001$) driven by fewer readmission (5.2% versus 7.8%) and greater home discharges (56.7% versus 46.7%).⁹⁵ However, the study highlights that as diagnosis-related group payments vary by hospital, the ability to determine claims costs versus true

hospital facility costs are difficult to elucidate across the overall population.

Currently, these short-term outcome studies suggest that the initial capital investment has the potential to be offset by improved PROMs, LOS, readmission rates, and home discharge. However, since there are no long-term RA-TKA studies demonstrating distinct advantages and cost-savings over conventional techniques, insurance companies do not always authorize RA-TKA including preoperative advanced imaging as medical necessities.⁹⁶ Though RA-TKA has shown short-term success, longer-term evaluation of implant survivorship, patient satisfaction, and rates of revision arthroplasty will determine the value of robotic technology in TKA. Cost-effectiveness and the value added with robotic procedures remains a dynamic and important factor as the field of robotics in arthroplasty continues to evolve.

Ergonomic health

Operating room physical stresses are known potential causes of musculoskeletal overuse injuries amongst surgeons, especially those who perform arthroplasty, due

Table 3. Clinical outcomes after robotic-assisted total knee arthroplasty.

Study	Year	Studies (#)	System	Robotic cases (#)	Conventional cases (#)	Follow-up in months	Conclusions	Level of evidence	Grade of recommendation
Song et al ⁴⁷	2013	1	ROBODOC	50	50	41	No differences in postoperative ROM, WOMAC scores, and HSS knee score.	1	A
Liow et al ²⁸	2014	1	ROBODOC	31	29	6	At 6-month follow-up, there was no overall difference in terms of clinical outcome measures, except in SF-36 vitality scores, where the robot-assisted group reported higher vitality scores.	1	A
Liow et al ⁸⁸	2017	1	ROBODOC	31	29	24	Both robotic and conventional TKA displayed significant improvements in majority of the functional outcome scores at 2 years. Despite having a higher rate of complications, the robotic-assisted group displayed a trend towards higher scores in SF-36 QoL measures, with significant differences in SF-36 vitality (p = 0.03), role emotional (p = 0.02) and a larger proportion of patients achieving SF-36 vitality MCID (48.4% vs. 13.8%, p = 0.009). No significant differences in KSS, OKS or satisfaction/expectation rates were noted.	1	A
Kim et al ⁹¹	2020	1	ROBODOC	975	990	120	At a minimum follow-up of 10 years, there were no differences between robotic-assisted TKA and conventional TKA in terms of functional outcome scores, aseptic loosening, overall survivorship, and complications. Considering the additional time and expense associated with robotic-assisted TKA, we cannot recommend its widespread use.	1	A
Kayani et al ¹⁰⁷	2018	1	Mako	40	40	1	Robotic-arm assisted TKA was associated with reduced postoperative pain (p < 0.001), decreased analgesia requirements (p < 0.001), decreased reduction in postoperative haemoglobin levels (p < 0.001), shorter time to straight leg raise (p < 0.001), decreased number of physiotherapy sessions (p < 0.001) and improved maximum knee flexion at discharge (p < 0.001) compared with conventional jig-based TKA. Median time to hospital discharge in robotic TKA was 3.2 days compared with 4.4 days in conventional TKA (p < 0.001).	2	B
Khlopas et al ⁷⁶	2020	1	Mako	150	102	3	This prospective, non-randomized, open-label, multicentre comparative cohort study found robotic TKA patients to have equal or greater improvements in 9 out of 10 of the Knee Society Scoring System components assessed at 3 months postoperatively, though not all findings were statistically significant.	2	B
Ren et al ⁸⁷	2019	7	ROBODOC CASPAR	315	262	16–120	Seven studies with a total of 577 knees undergoing TKA were included. Compared with conventional surgery, active robotic TKA showed better outcomes in precise mechanical alignment (p < 0.05) and implant position, with lower outliers (p < 0.05), better functional score (WOMAC functional score) and less drainage (p < 0.05).	2	B
Siebert et al ⁵⁷	2002	1	CASPAR	70	50	–	The mean difference between preoperatively planned and postoperatively achieved tibiofemoral alignment was 0.8 degrees (0–4.1 degrees) in the robotic group vs. 2.6 degrees (0–7 degrees) in a manually operated historical control group of 50 patients. The authors observed reduced postoperative soft tissue swelling in the robotic cohort.	3	B
Park et al ⁴²	2007	1	ROBODOC	32	30	45	Roughly 70% of conventional TKA gives a MA alignment of less than ± 3° as compared to more than 90% with navigation TKA. Six of the 32 active robotic TKA procedures had short-term complications including superficial infection, patellar tendon ligament rupture, patella dislocation, supracondylar fracture and patellar fracture and common peroneal injury.	3	B
Song et al ⁴⁸	2011	1	ROBODOC	15	15	16	Radiographic results showed significantly more postoperative leg alignment outliers of conventional sides than robotic-assisted sides (mechanical axis, coronal inclination of the femoral prosthesis, and sagittal inclination of the tibial prosthesis). Robotic-assisted sides had non-significantly better postoperative knee scores (HSS, WOMAC, side preference) and ROMs.	3	B

(continued)

Table 3 (continued)

Study	Year	Studies (#)	System	Robotic cases (#)	Conventional cases (#)	Follow-up in months	Conclusions	Level of evidence	Grade of recommendation
Clark et al ⁸⁰	2013	1	OMNIBotic	52	29	1	Robotic navigation times were, on average, 9.0 minutes shorter compared to computer navigation. The average absolute intraoperative malalignment was 0.5° less in the robotic procedures compared to the computer-navigation procedures. Patients in the robotic TKA group tended to be discharged 0.6 days earlier compared to patients in the computer-navigated TKA.	3	B
Yang et al ⁸⁹	2017	1	ROBODOC	71	42	120	Clinical outcomes and long-term survival rates were similar between the two groups. Regarding the radiological outcomes, the robotic TKA group had significantly fewer postoperative leg alignment outliers (femoral coronal inclination, tibial coronal inclination, femoral sagittal inclination, tibial sagittal inclination, and mechanical axis) and fewer radiolucent lines than the conventional TKA group.	3	B
Marchand et al ¹⁰⁸	2017	1	Mako	20	20	6	The mean physical function scores for the manual and robotic cohorts were 9 ± 5 and 4 ± 5, p=0.055, respectively. The mean total patient satisfaction scores for the manual and robotic cohorts were 14 points and 7 points, p<0.05, respectively. The results from this study highlight the potential of the Mako to improve short-term pain, physical function, and total satisfaction scores.	3	B
Kayani et al ⁸⁵	2018	1	Mako	30	30	–	Patients undergoing RA-TKA had reduced medial soft tissue injury in both passively correctible (p < 0.05) and fixed varus deformities (p < 0.05); more accurate femoral (p < 0.05) and tibial (p < 0.05) bone resection cuts; and improved macroscopic soft tissue injury (MASTI) scores compared to conventional TKA (p < 0.05).	3	B
Cho et al ⁹⁰	2019	1	ROBODOC	155	196	132	All clinical assessments showed excellent improvements in both robotic and conventional TKA cohorts (all p < 0.05), without any significant differences between the groups (p > 0.05). The conventional TKA group showed a significantly higher number of outliers compared with the robotic TKA group (p < 0.05). The cumulative survival rate was 98.8% in robotic TKA and 98.5% in the conventional group (p = 0.563).	3	B
Cool et al ⁹⁵	2019	1	Mako	519	2595	3	Overall 90-day episode-of-care costs were US\$2,391 less for robotic TKA (p < 0.0001). Over 90% of patients in both cohorts utilized post-acute services, with robotic TKA accruing fewer costs than manual TKA. Savings were driven by fewer readmissions and an economically beneficial discharge destination.	3	B
Malkani et al ⁸⁶	2020	1	Mako	188	188	24	Patients undergoing RA-TKA experienced a significant, 4.5-fold decrease in rates of MUA (p = 0.032). Given that MUAs can be a marker of knee stiffness following total knee arthroplasty, the lower rate indicates that study cohort patients had less knee stiffness and, therefore, greater initial postoperative ROM than the control cohort.	3	B
Marchand et al ²⁵	2019	1	Mako	53	53	12	The RA-TKA cohort had significantly improved mean total (6 ± 6 vs. 9 ± 8 points, p=0.03) and physical function scores (4 ± 4 vs. 6 ± 5 points, p=0.02) when compared with the manual cohort. The mean pain score for the RA-TKA cohort (2 ± 3 points [range, 0–14 points]) was also lower than that for the manual cohort (3 ± 4 points [range, 0–11 points]) (p=0.06). RA-TKA was found to have the strongest association with improved scores when compared with age, gender, and BMI. This study suggests that RA-TKA patients may have short-term improvements at minimum 1-year postoperatively.	3	B
Sultan et al ⁴⁶	2019	1	Mako	43	39	1.5	RA-TKA patients had smaller mean differences in posterior condylar offset ratio which has been previously shown to correlate with better joint ROM at one year following surgery. In addition, these patients were less likely to have values outside of normal Insall-Salvati Index, which means they are less likely to develop patella baja, leading to restricted flexion and overall decreased ROM.	3	B

(continued)

Table 3 (continued)

Study	Year	Studies (#)	System	Robotic cases (#)	Conventional cases (#)	Follow-up in months	Conclusions	Level of evidence	Grade of recommendation
Khlopas et al ⁷⁶	2020	1	Mako	150	102	3	At 4 to 6 weeks postoperatively and at 3 months, RA-TKA patients were also found to have larger improvements in walking and standing, standard activities, advanced activities, functional activities total score, pain with walking, total symptoms score, satisfaction score, expectations score when compared with manual TKA patients.	3	B
Bellemans et al ⁴³	2007	1	CASPAR	25	–	66	Results demonstrate excellent implant positioning and alignment was achieved within the 1° error of neutral alignment in all three planes in all cases. Despite this technical precision, the excessive operating time required for the robotic implantation, the technical complexity of the system, and the extremely high operational costs have led the authors to abandon the robotic system.	4	C
Marchand et al ⁸⁰	2018	1	Mako	330	–	–	All 132 knees with initial varus deformity of less than 7° were corrected to neutral (mean 1°, range –1–3°). A total of 82 knees (64%) with 7° or greater varus deformity were corrected to neutral (mean 2°, range 0–3°). However, roughly 30% of patients with severe deformity who were not corrected to neutral were still corrected within a couple of degrees of neutral. There were seven knees with 7° or greater valgus deformity, and all were corrected to neutral (mean 2°, range 0–3°). This study demonstrated that all knees were corrected in the appropriate direction within a few degrees of neutral, and no knees were overcorrected.	4	C
Sodhi et al ⁷⁴	2018	1	Mako	20	20	–	<i>Surgeon 1:</i> First and last robotic cohort operative times were 81 and 70 minutes (p<0.05). Mean operative times for the first 20 robotic-assisted cases and manual cases were 81 versus 68 minutes (p<0.05). Mean operative times for the last 20 robotic-assisted cases and manual cases were 70 versus 68 minutes (p>0.05). <i>Surgeon 2:</i> First and last robotic cohort operative times were 117 and 98 minutes (p<0.05). Mean operative times for the first 20 robotic-assisted cases and manual cases were 117 versus 95 (p<0.05). Mean operative times for the last 20 robotic-cohort cases and manual cases were 98 versus 95 (p>0.05). The data from this study effectively create a learning curve for the use of robotic-assisted TKA. As both surgeons completed their total cases numbers within similar time frames, these data imply that within a few months, a board-certified orthopaedic joint arthroplasty surgeon should be able to adequately perform robotic TKA without adding any operative times.	4	C
Sodhi et al ⁷⁷	2019	1	Mako	3	–	–	Three cases (femoral and tibial fracture malunion, proximal tibial fracture nonunion, healed tibial plateau fracture) of patients who underwent RA-TKA in the setting of preoperative extra-articular deformities were identified. Utilizing preoperative CT scans with a 3D plan for robotic-arm assisted surgery allowed for appropriate assessment of the deformity preoperatively and execution of a plan for a balanced and aligned total knee arthroplasty. The study reported excellent results utilizing RA-TKA in these complex cases.	4	C
Marchand et al ⁷⁸	2019	1	Mako	335	–	1	For 98% of prostheses, RA-TKA software predicted within 1 implant size the actual tibial or femoral implant size used. The mean length of stay was found to be 2 days. No patients suffered from superficial skin infection, pin site infections or fractures, soft tissue damage, and no robotic cases were converted to manual TKA due to intraoperative complications. A total of 8 patients (2.2%) were readmitted; however, none were directly related to robotic use. The robotic software and use of a preoperative CT substantially helped with intraoperative planning and accurate prediction of implant sizes.	4	C

(continued)

Table 3 (continued)

Study	Year	Studies (#)	System	Robotic cases (#)	Conventional cases (#)	Follow-up in months	Conclusions	Level of evidence	Grade of recommendation
Khlopas et al ⁸³	2017	1	Mako	6	6	–	During bone resections, the tibia in RA-TKA procedures did not require subluxation, which may reduce ligament stretching or decrease complication rates. Potential patient benefits for short-term recovery and decreased morbidity to reduce operative complications should be studied in a clinical setting. Since RA-TKA uses a stereotactic boundary to constrain the sawblade, which is generated based on the implant size, shape, and plan, and does not have the ability to track the patient's soft tissue structures, standard retraction techniques during cutting are recommended. Therefore, the retractor placement and potential for soft tissue protection needs to be further investigated. RA-TKA has the potential to increase soft tissue protection when compared to manual TKA.	5	I
Parratte et al ⁶⁵	2019	1	ROSA	15	15	–	15 cadaveric specimens were used with 15 knees undergoing TKA with computer navigation and 15 knees undergoing robotic TKA with ROSA. The target angles obtained from the intraoperative planning were then compared to the angles of the bone cuts performed using the robotic system and measured with the computer-assisted system considered to be the gold standard. All angle mean differences were below 1° and standard deviations below 1°. For all 6 angles, the mean differences between the target angle and the measured values were not significantly different from 0 except for the femoral flexion angle which had a mean difference of 0.95°. The mean hip-knee-ankle axis difference was $-0.03^\circ \pm 0.87^\circ$. All resection mean differences were below 0.7 mm and standard deviations below 1.1 mm.	5	I
Hamppe et al ⁸¹	2019	1	Mako	12	12	–	Significantly less damage occurred to the PCLs in the RA-TKA versus the manual TKA specimens ($p < 0.001$). RA-TKA specimens had non-significantly less damage to the deep medial collateral ligaments ($p = 0.149$), iliotibial bands ($p = 0.580$), poplitei ($p = 0.248$), and patellar ligaments ($p = 0.317$). The remaining anatomical structures had minimal soft tissue damage in all manual TKA and RA-TKA specimens. These findings are likely due to the enhanced preoperative planning with the robotic software, the real-time intraoperative feedback, and the haptically bounded saw blade, all of which may help protect the surrounding soft tissues and ligaments.	5	I

Note. TKA, total knee arthroplasty; (#), number; ROM, range of motion; KSS, Knee Society score; WOMAC, Western Ontario and McMaster Universities osteoarthritis index; SF-36, Short Form-36; RA-TKA, robotic-assisted TKA; PCL, posterior cruciate ligament; HSS, Hospital for Special Surgery; QoL, quality of life; MCID, minimal clinically important difference; OKS, Oxford Knee Score; MA, mechanical axis; MUA, manipulation under anesthesia; BMI, body mass index; CT, computed tomography

to ergonomically challenging postures.⁹⁶ Other studies have reported neck injuries to be one of the highest incidences amongst arthroplasty surgeon work-related injuries.^{97,98} In a cadaver study, movement and electromyography (EMG) sensors were secured to two surgeons performing manual TKA and RA-TKA to monitor shoulder and low back movements and muscle activities. Overall, there were more high-risk shoulder than lower back activities in both manual and RA-TKA. Highest risk tasks for shoulder and low back stimulation were during bone cut preparation and cutting, with a higher risk for manual TKA compared to RA-TKA.⁹⁶ RA-TKA can further help reduce physical stress on an individual's neck by providing an

eye-level computer display to improve cervical and thoracic spine posture.⁹⁹ Robotic technology requires less demanding physical work with more ergonomic friendly postures which may prove to have a beneficial impact on long-term physical health.⁹⁹ However, studies specifically evaluating medium and long-term impact on surgeon health are warranted to determine robotic technology's additional value.

Limitations

Many robotic devices are compatible with a limited number of implant designs, and different application systems

need to be purchased for THA, UKA and TKA. Additionally, RA-TKA may require additional incisions for insertion of the femoral and tibial registration pins to enable optical motion-capture tracking, and image guidance that increases patient radiation exposure.⁶⁰ Despite improvement of workflow and efficiency, there are inherent time delays both preoperatively for implant templating and intraoperative plan adjustment. This is especially relevant as every 20-minute increase in operative time is associated with nearly a 25% increased risk of subsequent periprosthetic joint infection.¹⁰⁰ Furthermore, similar to CAN, robotic systems can require percutaneous pins for optical tracking arrays which creates stress risers and risk for periprosthetic fractures, especially if placed in diaphyseal bone.¹⁰¹ Inadvertent pin placement can also theoretically cause neurovascular laceration.¹⁰¹ It is, therefore, critical that optical array pins be placed meticulously in metaphyseal bone without extensively breaching the second cortex. Finally, although robotic platforms are designed to make precise bone cuts without deviation from the planned template, some systems such as the older ROBODOC did not routinely recognize periarticular soft tissue, as studies have reported a 5% incidence of patella tendon rupture.¹⁰² Although newer designs have evolved to become more cognizant of surrounding soft tissues, it is still imperative to place retractors in the appropriate position to prevent any iatrogenic ligamentous or neurovascular compromise.

Conclusion

Robotic TKA has shown improved reproducibility and precision in mechanical alignment restoration with improvement in early functional outcomes and 90-day episode-of-care cost savings compared to conventional TKA; however, its added value is still to be determined. Technology-assisted TKA helps execute a preoperative templated plan while minimizing variation and maximizing reliability and reproducibility compared to conventional methods. Therefore, the usefulness of robotic platforms is the decreased variability in execution of an action, not necessarily to improve the expected outcome from an already well executed procedure.¹⁰³ In today's paradigm shift towards increased emphasis on quality of care while curtailing costs, providing value-based care is the primary goal for healthcare systems and clinicians.¹⁰⁴ As robotic technology continues to develop, longer-term studies evaluating implant survivorship and complications will determine whether the initial capital is offset with improved outcomes. More importantly, evaluation of patient functional outcomes, satisfaction and overall surgeon health will determine whether robotic technology has added value in TKA.

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ICMJE CONFLICT OF INTEREST STATEMENT

AS reports consultancy for the Zimmer Biomet robot discussed in the paper, outside the submitted work.

MRB reports consultancy for Stryker Orthopaedics, outside the submitted work.

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