Active Robotic Total Knee Arthroplasty (TKA): Initial Experience with the TSolution One® TKA System

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ABSTRACT

Several recent advances, including the use of robotic devices, have been explored to improve outcomes in total knee arthroplasty (TKA). The TSolution One® Total Knee Application (THINK Surgical, Inc., Fremont, CA, USA) introduces an active robotic device that supports an open implant platform and CT-based preoperative planning workflow, and requires minimal surgeon intervention for making bone cuts.

Our experience was part of a multi-center, prospective, non-randomized trial assessing the safety and effectiveness of this active robotic system for TKA. Each patient underwent a preoperative CT-scan, which was uploaded to proprietary planning software. The surgeon reviewed the software-generated 3D digital model, selected the appropriate implants and generated a final preoperative plan.

Intra-operatively, a standard medial parapatellar approach was used. The leg was then rigidly attached to the robot via fixation pins, and registration markers were placed in the tibia and femur. Landmark registration was

performed to inform the robot of the knee's position in space and to confirm the robot's ability to execute the preoperative plan. Next, the robot performed femoral and tibial cuts using a cutter in a sequential fashion along a defined cut-path. The robot was then removed from the operative field and the surgeon completed the procedure by removing marginal bone and performing final balancing and implantation in the usual fashion.

The TSolution One® Total Knee Application is a computer-assisted device that potentially allows a surgeon to make more accurate cuts and to determine optimal implant position based on the patient's specific anatomy. It is the only active robotic system currently available.

In this manuscript, we describe the operative technique and workflow involved in performing this surgery and offer insight on optimizing safety and efficiency as we introduce new technologies to the operating theater. We also present two cases performed by the senior author to further demonstrate technical aspects of the procedure.

INTRODUCTION

Total knee arthroplasty (TKA) is generally a highly successful procedure. However, malalignment and implant malposition continue to be significant causes of revision surgery.[1] The use of robotic devices may help to improve outcomes in TKA.

Robotic technology in various forms is currently used in many operating rooms, not only in orthopaedic surgery. For example, it is ubiquitous in many urologic, gynecologic, and abdominal surgeries, especially in academic medical centers.[2] Several robots have been developed for both unicondylar and TKA, with the goals of optimizing precision and accuracy in bony cuts.[3,4] Whereas some image-based robots take advantage of preoperative CT scans to plan bony cuts, others may use intraoperative mapping without the need for advanced preoperative images. Several approaches can be used in active, haptic, and passive systems to aid the surgeon in achieving accurate bone cuts and a balanced knee.[5] With active devices, the robot performs the bony cuts without direct contact between the surgeon and the cutting tool. Haptic systems allow for the surgeon to perform bony preparation using a cutting tool attached to a robotic arm which gives feedback regarding the correct position and trajectory of the cuts. Finally, in passive systems, the robotic arm places the cutting blocks and cuts are made directly by the surgeon using a standard saw-through-slot technique.[5]

The TSolution One® system (THINK Surgical, Fremont, CA, USA) is an active robotic milling system that uses a preoperative CT scan for planning and execution of automated bony cuts.[6] A high-speed burr is used for bony resection, which may eliminate errors that can occur with systems that use a saw blade, which is inherently flexible.[7,8] It is also an open-implant platform which allows the surgeon to choose from a variety of implant manufacturers. Early results with the active robot in a recent FDA IDE trial regarding the accuracy of implant positioning, alignment, and safety are encouraging. Here, we present our center's experience with 25 cases using the TSolution One ® system, focusing on preoperative planning and the operative technique. We present tips and tricks from our experience and present two cases that illustrate our approach.

Table I
Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Age >21	Previous open knee surgery on operative knee
Skeletally mature- Evidenced by closed physes	BMI> 40kg/m^2
Radiographic osteoarthritis Kellgren-Lawrence Grade3 or higher	◆Coronal deformity > 20deg ◆Flexion contracture > 15deg ◆Candidate for bilateral TKA ◆Active systemic infection, active local infection near knee, prior joint infection ◆Presence of hardware in ipsilateral lower extremity ◆Poor bone stock ◆Pathologic bone condition

TECHNIQUE

While robotic surgery is not yet nearly the standard of care in joint replacement, it has attracted the attention of many surgeons as possibly the next major advancement in the field.[9,10] As in most similar technologies in total joint replacement, the steps include preoperative imaging, which generates a virtual plan, intraoperative registration and execution of the plan with the assistance of the robotic device.

PREOPERATIVE PLANNING

Informed consent was obtained from eligible patients (Table I). Preoperative imaging consisted of full-length hip-to-ankle standing radiographs and CT scan of the operative limb. A CT scan was performed according to a strict protocol that required training of technologists and vetting of the facility to ensure accurate image capture. CT images were then analyzed and segmented by the manufacturer, who would then generate a standard preoperative plan using a proprietary preoperative planning software called TPLAN® (Fig. 1).

The standard preoperative plan was then sent to the surgeon for review (Fig. 2) using a dedicated computer station with TPLAN®. Virtual 3D models of the bone and implant appear on the screen,

which the surgeon can manipulate to visualize the bone, implant, anatomic axes, or all three simultaneously. The surgeon would first verify the location of the preselected bony landmarks (i.e., femoral head center, medial and lateral epicondyles, etc.) which are important for identification of the mechanical axes and for intraoperative registration, as some of the points selected in planning will need to be collected from the patient for initial registration.

The next steps are femoral and tibial planning. First, the surgeon selects the preferred implant; since this system is an open platform, more than one implant is available. At the time of publication, Zimmer (Zimmer Biomet, Warsaw, IN, USA), Corin (Corin Group, Tampa, FL, USA), DJO (DJO Global, Lewisville, TX, USA), Aesculap (Aesculap Implant Systems, LLC, Center Valley, PA, USA), and U2™ Knee System (United Orthopedic Corporation, New Taipei City, Taiwan) implants are available for this platform. Next, the surgeon can alter the resection depth, alignment, and implant placement in one-half degree or one-half millimeter increments based on alignment goals and the patient's anatomic axes. For example, the surgeon may choose between either mechanical alignment or kinematic alignment TKA, both of which were successfully performed in our study group.

One learning point that was noted during the study was that, when choosing between two tibial component sizes, in a surgeon's early experience, it was advisable to select the smaller size. Since the cutting depth is related to the size of the implant, while the resection plane would remain the same, less bone is removed near the perimeter of the implant. This allows the surgeon to gauge the protection of soft tissues, allowing more precise retractor placement. With experience, this may not be necessary. This concept is also applicable to the femoral side if standard versus narrow implants are available. This is one of the safety mechanisms in place to prevent soft tissue injury; in our series, this proved successful, as no such injuries were noted.

Once the surgeon is satisfied with the plan, it is finalized. The last step is approving the sequence of cuts where the surgeon decides whether or not to include femoral and/or tibial finishing steps in the sequence. As the study progressed and confidence in use of the device increased, this finishing step became more widely used in our surgeries.

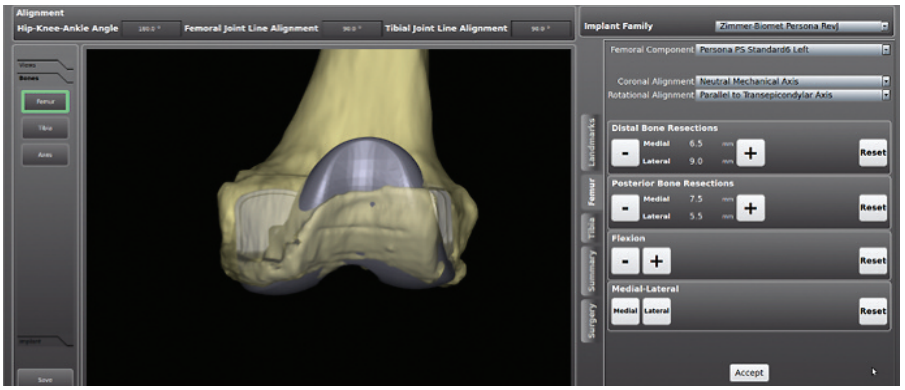

Figure 1. TPLAN© -Software used to create the pre-operative plan (THINK Surgical, Inc.)

SURGERY

Surgery involves standard exposure, fixation, registration, and robotic bone resection, followed by trialing, balancing, and implantation of the final prosthesis. One important value of an accurate pre-operative plan is that implant sizes are already determined to a high degree of accuracy and therefore fewer trays may need to be opened, reducing the amount of clutter in the operative field.

The patient is brought to the operating suite after a surgical technician performs preliminary diagnostics on the

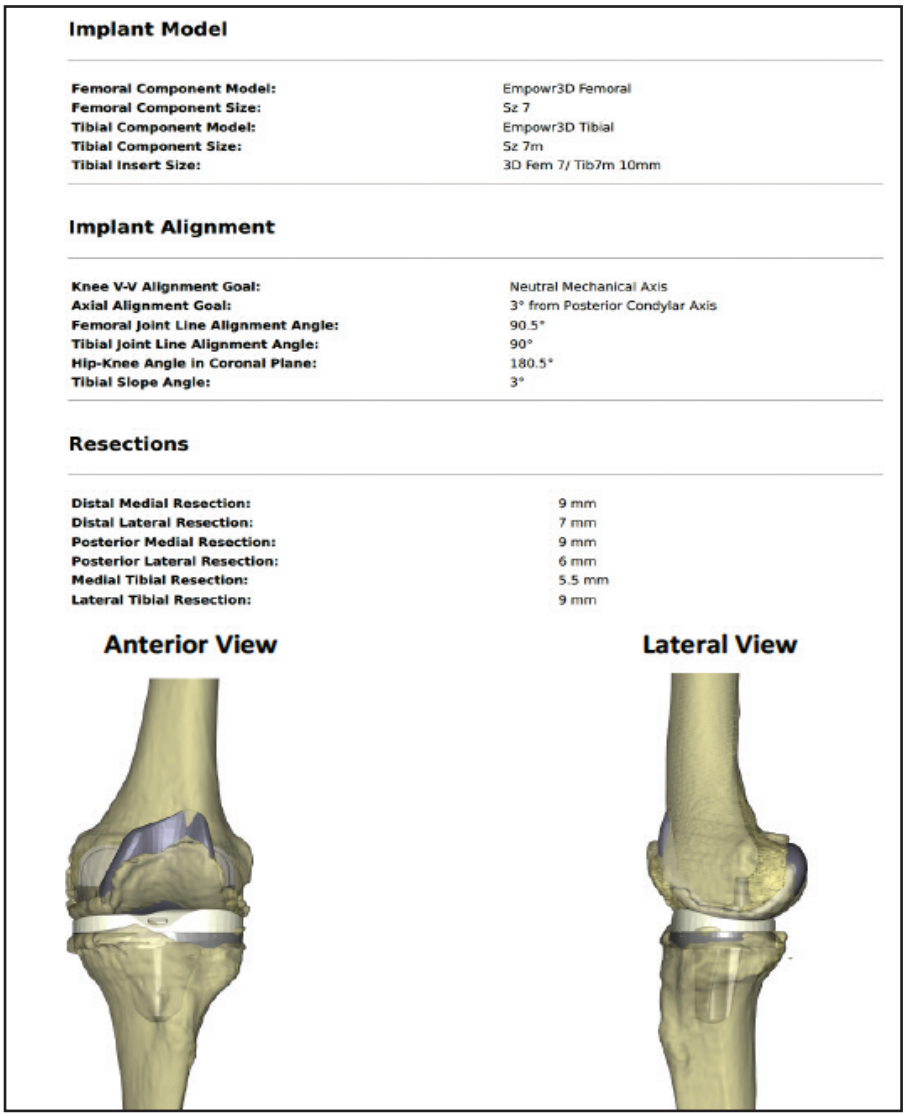

Figure 2. Pre-operative plan highlights implant selection, resection depths and alignment, and provides visualization of implanted components relative to the bone.

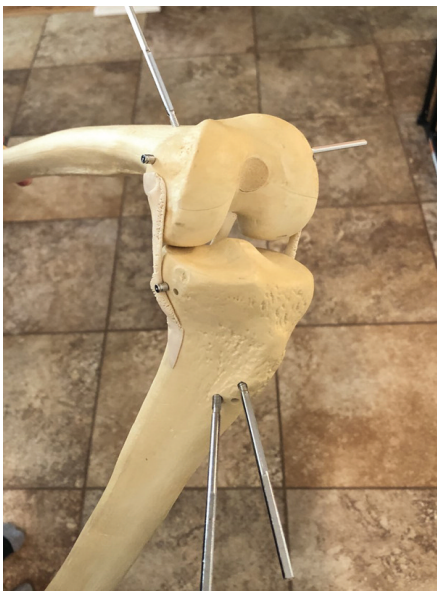

Figure 3. Fixation and registration: Sawbones (Pacific Research Laboratories, Vashon, WA, USA) demonstration with pins and tacks in place.

Figure 4. Bone islands: Sawbones (Pacific Research Laboratories) demonstration of bone islands left in place after cuts are made.

robot. Anesthesia is then applied, which at our institution includes a single-shot short-acting spinal along with adductor and IPAK (Interspace between the Popliteal Artery and Knee capsule) blocks in conjunction with multimodal pain management. The patient's leg is placed in a sliding knee-positioning device and a standard medial parapatellar approach is then performed.

PEARLS ON EXPOSURE: First, during exposure, it is important not to remove any osteophytes, since the patient's bony anatomy is the basis for the preoperative plan and may well be part of intraoperative registration. Further, some surgeons may elect to cut the patella first, prior to positioning of the knee in flexion. With this sequence, there is less tension on the lateral soft tissue, making the resected patella easier to retract out of the way of the burr. Finally, the ACL and selectively the PCL along with as much meniscus as possible are excised to help sublux the tibia and ensure that the burr does not get bound up in soft tissue.

Next, the tibia and femur are firmly attached to the robot via ex-fix type pins. These pins can be placed percutaneously or within the incision, based on the surgeon's preference.

PEARLS ON PIN PLACEMENT: While we did not experience any pin- or device-related complications in our series, placement of such pins in robotics and as previously used in navigation can certainly result in serious morbidity. including fracture, pin-site drainage/infection, pain and wound issues.[11-15] This robotic device requires one registration and one fixation pin to be placed into both the tibia and femur. Proper spacing of pins, at least one to two fingerbreadths apart, and engagement but not penetration of the second cortex provide sufficient fixation while limiting the risk of fracture. Also, it is critical to place pins in such a way that they are clear of the cut-path of the burr. This is especially important on the tibial side in tibial finishing; the pin needs to be inserted distal enough to avoid contact during milling of the keel.

Once these pins are in place, registration tacks are inserted in the femur and the tibia. The combination of the leg holder and external fixation provides rigid fixation of the knee, which is required with an active robot. Along with the registration pin, the tacks serve as a two-step re-registration if excess motion is detected during the robotic portion of the case, which stops the burr from progressing. Bone motion monitors (BMM) are the final preparation step and are sharply malleted into the tibia and femur. These sensors are able to detect bone-motion greater than 1 mm as the robotic arm is cutting, and will halt the cutting device within 2mm of motion, for safety and to avoid error (Fig. 3).

REGISTRATION: A sharp stylus is used to register the patient's anatomic landmarks based on on-screen instructions. This vital step aligns the virtual preoperative plan with the patient's actual anatomy intraoperatively and allows the robotic arm to locate the knee precisely in space. As this is a CT-based preoperative planning model, articular cartilage must be pierced so the stylus tip contacts subchondral bone to correlate with the plan appropriately. While this step is familiar to surgeons who have performed navigation in the past, even for the inexperienced surgeon, it is a skill that can be perfected rather quickly after several attempts.

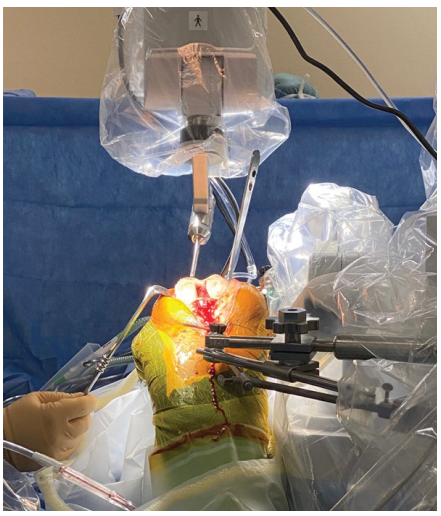

Figure 5. Burring with minimal retractors in place.

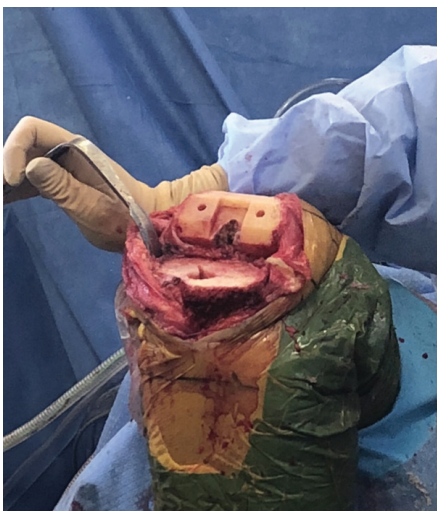

Figure 6. Completed cuts including femoral and tibial finishing

PREPARATION FOR CUTTING: This device allows for very minimal instrumentation as resection guides and traditional cutting jigs are completely eliminated from the procedure. It is suggested to have a right-angle retractor and possibly a lateral Hohmann retractor to protect the medial and lateral soft tissue during burring of the bone. A rongeur is useful for removing loose bone fragments as the procedure progresses so that the burr does not bind up in them.

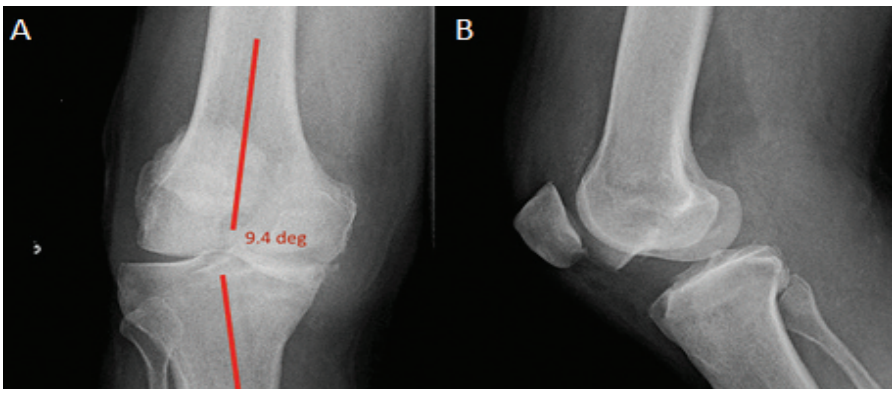

Figure 7. Pre-operative imaging in Patient 1. (A) Antero-posterior radiograph of the right knee demonstrating a 9.4 degree varus deformity. (B) Lateral radiograph of the right knee.

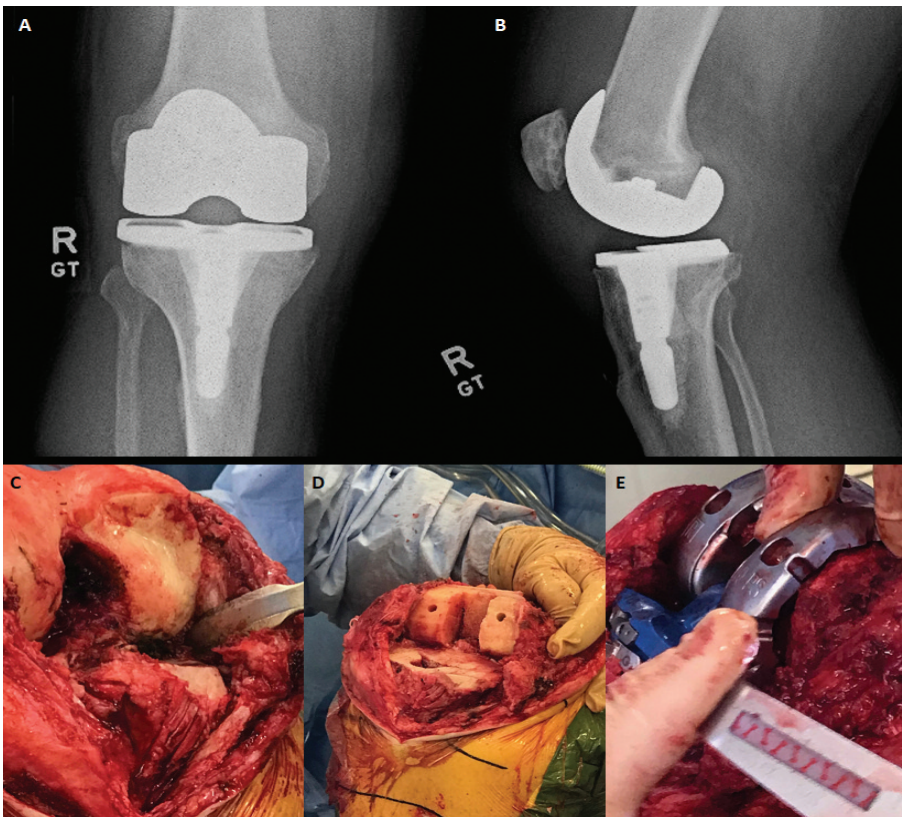

Figure 8. Post-operative and intra-operative images in Patient 1. (A) Antero-posterior radiograph of the right knee post TKA demonstrating correction of varus deformity. (B) Lateral radiograph post TKA. (C) Intra-operative image demonstrating large medial femoral condyle defect. (D) Intra-operative image after femoral cuts have been made by the robot (E) Intra-operative imaging demonstrating the fit of the femoral component given the large medial femoral condyle defect.

Table II
Patient 1

64-year-old male with varus knee	
Initial Alignment	9.4 deg varus
Difference in alignment as planned (CT)	0.4 deg more varus than planned

The cut-path for the burr takes into account the surrounding soft tissue, such as the medial collateral ligament, patellar tendon and posterior knee, and has been designed to avoid injury by leaving a bony margin of 1-2 mm in the periphery of the cut (Fig. 4). The surgeon removes this residual bone once the cuts are complete and predictably shields the soft tissue. In our study, no soft tissue injuries were seen with the device.

ROBOTIC CUTTING: Once registration is complete, the robotic arm enters the operative field and the cuts are performed in a predetermined sequence with a high-speed burr. The surgeon or surgical assistant can stop the cutting process if needed by pushing a button on a connected handheld device. Minimal surgeon intervention is needed during this step, other than minor retraction and rongeuring of loose bone (Figs. 5,6).

POST-CUTTING: At the completion of the cuts, pins and tacks are removed and the robot is removed from the operative field. The surgeon then removes the peripheral residual bone and performs standard trialing and balancing. Once the surgeon is satisfied, final implantation is undertaken.

CASE EXAMPLES

PATIENT 1: A 64-year-old well-controlled diabetic male presented to the clinic with a severely arthritic right knee. He was already known to the practice, having undergone successful left TKA three years previously, but continued to suffer from debilitating pain and dysfunction of his right knee. X-rays showed severe osteoarthritis changes, 9.4 degree varus deformity with bone loss of the medial femoral condyle and to a lesser degree the medial tibial plateau (Fig. 7). He was indicated for TKA and consented to be part of the study after failing to respond to nonoperative treatments including physical therapy and intraarticular injections.

His degree of deformity along with bone loss were concerning, but at that point in the study, our team had gained enough experience and confidence in the device that we chose to undertake this case robotically. In planning of this case, it was presumed that the burr would perform an air-cut of the medial femoral condyle and that there would be a residual defect. However, since his planned femoral size was on the large end of the spectrum, we felt that cement would suf-

ficiently fill the gap and obviate the need for a metal augment. On the tibial side, an extra degree of "Gentleman's varus", as has been described recently in the literature,[16] was planned in the hope of limiting the need for a medial release.

The surgery proceeded as planned, with bone loss on the femur noted and cement augmentation being sufficient (Fig. 8). No medial soft-tissue release was needed to balance the knee, which we believe would have been very likely necessary if conventional TKA had been performed in this case. This case demonstrated how difficult challenges can be addressed to result in a successful TKA. One additional benefit of robotics over conventional surgery in this case was that traditional cutting guides would not have had adequate bone to rest on and therefore could have introduced error, while the robotic arm was able to cut the bone with precision despite the bone loss. This patient's accuracy data are presented in Table II. The patient experienced contact dermatitis from the adhesive dressing, but this resolved uneventfully and was not believed to have been related to the robotic device.

PATIENT TWO: A 72-year-old healthy and previously active female with a severely arthritic left knee was indicated for robotic total knee replacement. She consented to participate in the study after failing to respond to nonoperative treatment involving home exercises and over-the-counter medications. Standing radiographs showed a 17-degree valgus deformity (Fig. 9). The patient underwent successful robotic TKA with no need for lateral valgus soft tissue release or lateral patellar release (Fig. 10). Her accuracy data are presented in Table III. The valgus knee often presents unique challenges in both alignment and soft tissue balance, which in this case were managed successfully with the robot device.

DISCUSSION

Patients who undergo traditional TKA currently have a satisfaction rate of 82%-89%.[17,18] One of the drawbacks of the traditional technique is the error introduced at each step; i.e., jig placement based on anatomic landmarks, cutting guides, etc. While the error introduced by a single cut may be negligible, areas such as the distal femur may accumulate significant error, since multiple cuts are required. Errors introduced by a cutting guide and oscillating saw alone can be up to 1.1 degrees in the coronal plane and 1.8 degrees in the sagittal plane.[7]

Robot-assisted surgery potentially decreases the error that may be introduced by creating more accurate cuts based on pre-operative plans. The TSolution One ®TKA application is one of several robot-assisted TKA systems currently available. However, it has several unique features that set it apart from others. For example, TSolution One ® is the only open platform currently available. This offers flexibility in that a hospital can use implants from different manufacturers and does not obligate a surgeon to change from his or her preferred system. It is also the only fully active robot, which may offer improved precision over traditional TKA.[19,20] Rather than being a substitute for the surgeon, it is simply another tool which

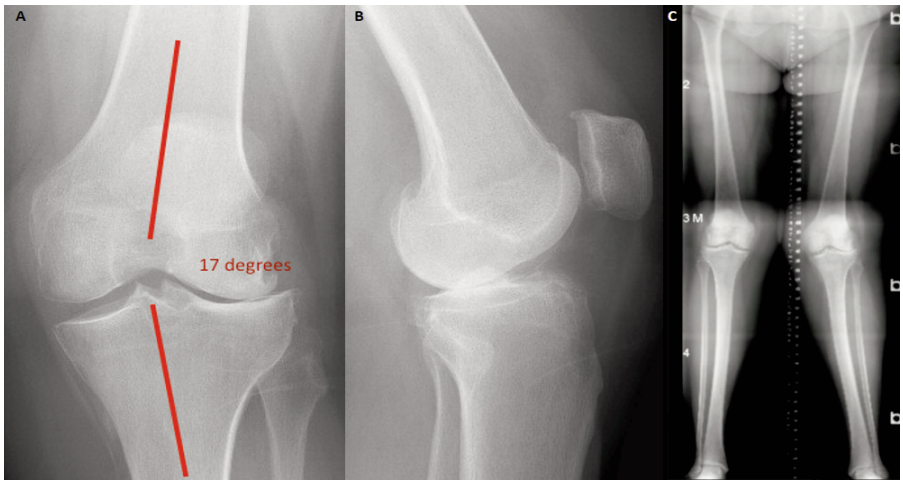

Figure 9. Pre-operative imaging in Patient 2. (A) Antero-posterior radiograph of the left knee demonstrating a 17 degree valgus deformity. (B) Lateral radiograph of the left knee. (C) Mechanical axis series demonstrating valgus deformity of the left knee.

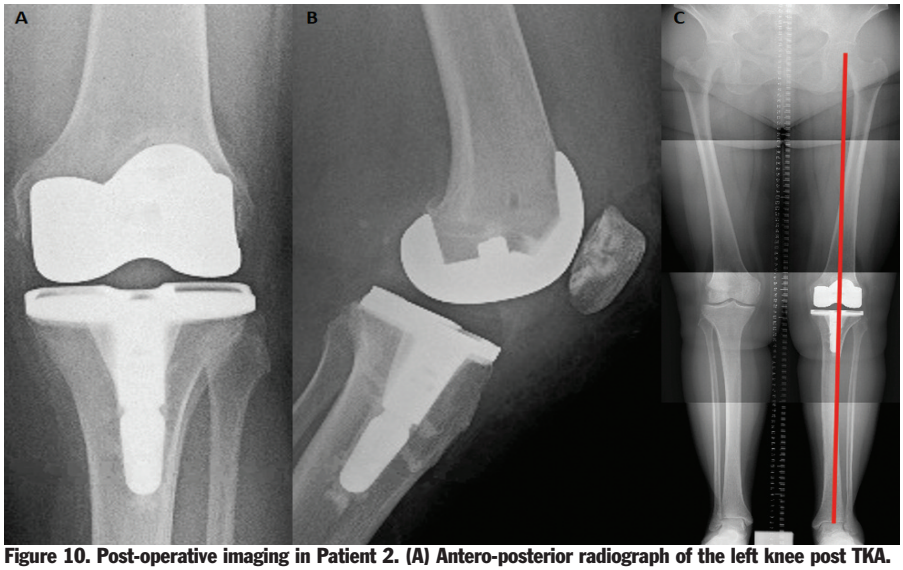

Figure 10. Post-operative imaging in Patient 2. (A) Antero-posterior radiograph of the left knee post TKA. (B) Lateral radiograph of the left knee post TKA. (C) Post-operative mechanical axis demonstrating correction of valgus deformity.

Table III
Patient 2

72-year-old female with valgus knee	
Initial Alignment	17 deg valgus
Difference in alignment as planned (CT)	0.1 deg more valgus than planned

keeps the art of medicine in the hands of the surgeon for final balancing and implantation. It has been well-established that outcomes of TKA are related to surgeon experience and volume.[21,22] This device provides a very standardized approach for the surgeon in performing TKA and may well help elevate performance regardless of surgeon volume, while simultaneously personalizing the cuts to the patient's specific anatomy.

The TSolution One® recently received FDA clearance following an IDE trial and is available for use in the United States. Its predecessor, ROBODOC® (THINK Surgical, Inc.), has been used in more than 8000 cases since 2000.[23] Song et al. published a prospective trial involving 100 patients; half underwent manual TKA and the other half underwent robotic TKA.[19] They found an improved postoperative mechanical axis with fewer outliers in alignment in postoperative studies as well as improved PCL tension in the robotic group, with decreased blood loss. Subsequent studies by Liow et al. achieved similar results.[6] There were no coronal-plane outliers in the robotic group, compared to 19.4% outliers in the manual group. They also reported less joint line shift outliers and less femoral notching.[6]

Conversely, Liow et al. also reported a 10% robot abort rate due to technical errors and a 6.5% rate of soleal vein thrombosis that may be attributable to the positioner.[6] The increased procedure time for robotic setup is associated with increased rates of infection.[4,24] In our study, safety was assured by proper pin placement, appropriate retraction and consistent technique. In our center, we had one device-related adverse event (arthrofibrosis requiring manipulation under anesthesia),which was possibly associated with the device or the TKA procedure. The results from other centers in our FDA IDE trial demonstrate favorable outcomes and accuracy, which are currently being tabulated and prepared for publication in the near future.

Currently, hospital systems are being challenged by the coronavirus disease 2019 (COVID-19) pandemic, and all elective orthopedic cases have been cancelled.[25-28] While recent trends demonstrate increased rates of adoption of technology and a three-fold increase in the use of technology from 2008 to 2015, decisions to add new technology in the context of new infection protocols is paramount. Additional operating room foot traffic and operative time have been associated with increased rates of surgical site infection.[29,30] However, we hope that the greater accuracy and precision provided by robotic technology can help to improve outcomes, resulting in fewer revisions and higher patient satisfaction while improving efficiency. In a post-COVID-19 world, new technologies will need to prove their worth, which can hopefully be achieved by further studies.

CONCLUSION

The TSolution One® is a viable entrant in the US market for robot-assisted knee arthroplasty. Adherence to proper technique and increased understanding of the nuances of robotics will continue to ensure good outcomes. Only time will tell if introduction of this technology will improve our care of knee arthroplasty patients, especially post-COVID-19. STI

AUTHORS' DISCLOSURES

YK, BS, SK, RL and WL were investigators for THINK Surgical, Inc.'s (Fremont, CA) FDA IDE Trial. They are also consultants for THINK and have received institutional support. YK and BS are stockholders in THINK. YK, BS, and WL are members of the speakers' bureau. VC is an employee of THINK and holds stock options. JC, TA and RL declare that they have no conflicts of interest.

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