Patient-Specific Instrumentation in Total Knee Arthroplasty: A Review

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Abstract

Recently, patient-specific approaches to total knee arthroplasty (TKA) have been introduced, in which preoperative imaging (plain radiographs, computed tomography, and magnetic resonance imaging) are used to manufacture cutting blocks specific to a patient's anatomy. Proposed benefits of patient-matched cutting blocks include a decrease in operative time, instrument trays required, and the ability to preoperatively plan a patient's component size, position, and alignment. In addition, an improvement in postoperative mechanical alignment is expected, without violation of the intramedullary canal. However, questions remain regarding patient outcomes and the cost-effectiveness associated with patient-specific cutting block technology. This article will review the evolution of surgical techniques in TKA, the development of patient-specific cutting blocks, surgical considerations, and the literature associated with this new technology.

Keywords
- ► total knee arthroplasty
- ► patient-specific instrumentation
- ► alignment
- ► cost-effectiveness

Recently, patient-specific approaches to total knee arthroplasty (TKA) have been introduced, in which preoperative imaging (plain radiographs, computed tomography [CT], and magnetic resonance imaging [MRI]) are used to manufacture cutting blocks specific to a patient's anatomy. Proposed benefits of patient-matched cutting blocks include a decrease in operative time, instrument trays required, and the ability to preoperatively plan a patient's component size, position, and alignment. In addition, an improvement in postoperative mechanical alignment is expected, without violation of the intramedullary (IM) canal. However, questions remain regarding patient outcomes and the cost-effectiveness associated with patient-specific cutting block technology. This article will review the evolution of surgical techniques in TKA, the development of patient-specific cutting blocks, surgical considerations, and the literature associated with this new technology.

An Evolution of Surgical Techniques

Although TKA has been a tremendously successful procedure in the management of degenerative joint disease, tibial and femoral component malalignment remains a significant concern. Berend et al has shown that a tibial varus alignment of >3 degrees increased the odds of implant failure and medial bone collapse by roughly 17 times, emphasizing the importance of accurate tibial component positioning on TKA survivorship.[1] Recently, Ritter et al, in a review of 6070 TKAs, noted that the risk of aseptic failure increased if the orientation of the tibial component was <90 degrees relative to the tibial axis, and the orientation of the femoral component was >8 degrees of valgus (failure rate 8.7%). In addition, they noted that "correction" of varus or valgus malalignment of the first implanted component by placement of the second component, to attain a neutral tibiofemoral alignment, was associated with increased failure rates, indicating that optimal positioning of both the femoral and tibial components is crucial.[2] With the increasing prevalence of total joint replacements performed in the United States, the projected increase in revision total knee surgery has been estimated to be 412% by the year 2030. Therefore, improved surgical techniques to prevent malalignment may prove cost-effective.[3]

Currently, the instruments most commonly used in TKA are an extramedullary (EM) alignment guide for the tibial resection, and an IM alignment guide for the distal femoral

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resection. These methods have been used for decades, are relatively simple to use, and are familiar to knee surgeons. Unfortunately, they have demonstrated a limited degree of accuracy. For overall lower extremity mechanical alignment, accuracy rates in obtaining an alignment within 3 degrees of neutral have been reported to be as low as 71% using these conventional techniques.[2,4] With regard to tibial component positioning, both IM and EM tibial alignment guides have shown limited accuracy, achieving a component position within 2 degrees of perpendicular to the mechanical axis in the coronal plane in only 72 to 85% and 65 to 88% of cases, respectively.[5,6]

The use of an IM guide for performing the distal femoral resection has shown better accuracy than EM tibial guides, however only 85.6 to 91% of components have been reported to be within 3 degrees of neutral to the mechanical axis in the coronal plane.[2,7] Inaccuracies using an IM system are likely due to several factors. First, it relies on assumptions regarding the difference between the femoral mechanical and anatomic axes. The distal femoral resection is performed at a fixed angle relative to the anatomic axis, with the goal of obtaining an alignment perpendicular to the femoral mechanical axis. However, significant variations exist among patients between the femoral mechanical and anatomic axes, as variations in the femoral offset and neck-shaft angle affect this relationship.[8] Also, the guide is dependent on a rigid fit of the IM rod in the femoral canal, which is rarely obtained, and on the position of the entrance hole through the distal femur in the IM canal, which can significantly alter the distal femoral mechanical angle.[8,11–13] Lastly, invasion of the IM canal has been implicated as a cause of increased pulmonary pressures and fat embolism,[9,10] as well as increased blood loss in TKA surgery,[11–13] thus raising additional safety concerns with this method.

The goal of improving alignment in TKA led to the development of computer-assisted surgery (CAS) techniques. CAS systems most commonly consist of a large computer console, with the use of additional incisions and pins in the tibia and femur for placement of tracking arrays. Numerous comparative studies have demonstrated improved precision and accuracy of implant positioning in TKA compared with conventional IM and EM alignment guides.[4,14–16] Mason et al performed a meta-analysis of 29 studies comparing CAS to conventional alignment techniques, and demonstrated that overall mechanical axis malalignment of greater than 3 degrees occurred in only 9.0% of CAS versus 31.8% of conventional TKA patients.[4] However, despite the improved alignment obtained with computer-assisted surgical techniques, CAS systems have not become a panacea, as less than 3% of TKAs are performed using CAS in the United States.[15] Increased capital costs, operative times, and the associated learning curve with the use of CAS techniques have continued to limit its widespread acceptance. Recently, a portable navigation device has been implemented for the tibial resection, which consists of a small, $2 \times 4 \times 2$ inch display console attached to an EM jig similar to conventional techniques. This device avoids the use of large consoles and extra pin sites, while providing a level of familiarity to surgeons accustomed to the use of conventional, EM guides. Preliminary results have been encouraging, but additional, comparative studies are required to prove its efficacy.[17–19]

Patient-Specific Cutting Guides

The objective of combining the advantages of computer-assisted surgical techniques, while eliminating its significant disadvantages, has led to the development of patient-specific cutting guides in TKA.[20] With this technology, a preoperative image of the knee is obtained (most commonly CT or MRI), along with selected images of the hip and ankle. Computer software is used to generate a three-dimensional (3D) model of the patient's anatomy, and the proposed bony resections to obtain both the desired coronal and rotational alignment are templated. 3D models of the femoral and tibial components are next created to determine their optimal size, position, and alignment. The surgeon is then able to view an image of the patient's knee with the proposed bony resections completed, and with the final implants in place (►**Fig. 1A–E**). The preoperative plan is then sent to the surgeon who can review and alter the plan as necessary. Once approved, rapid prototyping technology is used to fabricate disposable, custom-cutting guides (►**Fig. 2A, B**). These guides fit on the patient's native anatomy, and can be used to determine accurate pin positioning for the use of standard resection instruments of the implant manufacturer, or can be used as the actual cutting guides depending on the manufacturer.[20] As noted above, the cutting guides do not only set the appropriate coronal orientation, but also set the depth of resection, rotation, slope, and anteroposterior position based on the preoperative template. The patient-specific blocks are disposable, allowing for fewer instrument trays to be used intraoperatively, and for the procedure to be performed in a more accurate and efficient manner.

The implementation of this technology requires several changes in preoperative planning when compared with conventional techniques in TKA. First, the surgical planning process is moved into the early preoperative time period, as at least 3 weeks are required to fabricate these cutting blocks. In addition, 3D imaging studies such as MRI or CT are required preoperatively, which have not typically been performed in the past before a TKA. Also, the surgeon must collaborate with the manufacturer in determining and approving a preoperative plan for the surgery, while coordination is also required to ensure that the guides are ready and available at the day of the procedure. However, as noted by Lombardi et al, while this process is relatively new in TKA, this technology has had previous applications.[20] Preoperative 3D reconstructed CT scans have been used to assist with the planning and placement of pedicle screws in spine surgery,[21] and 3D models have been used to fabricate custom implants in revision total hip arthroplasty.[20,22,23]

Numerous potential advantages exist with the use of patient-specific guides when compared with conventional alignment techniques, and computer-assisted navigation. First, the surgeon is able to formulate a preoperative plan before the surgery, and essentially "navigate" the procedure

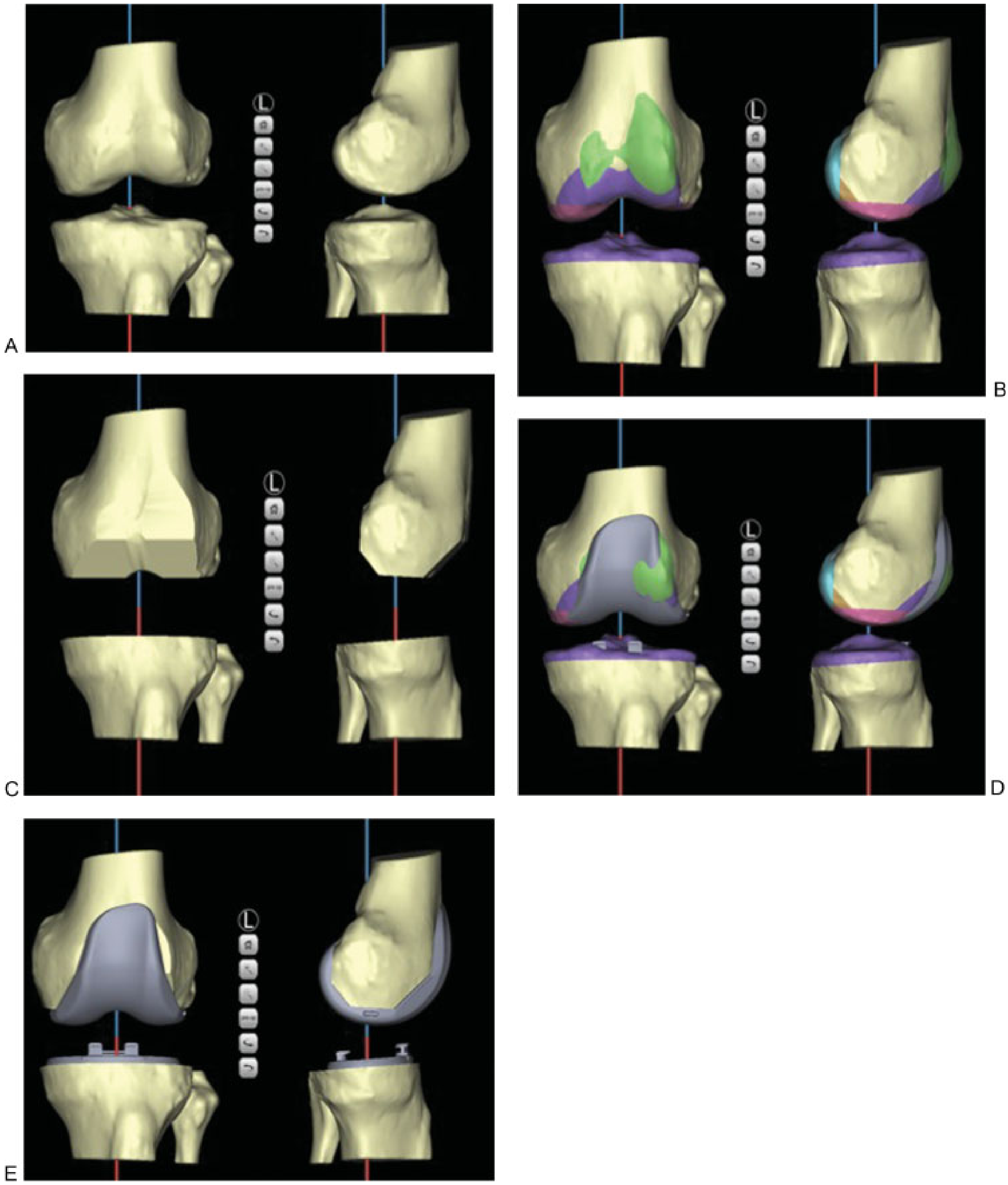

Figure 1 Images of a preoperative surgical plan created for the use of patient-specific cutting blocks based on a preoperative magnetic resonance imaging scan: (A) A 3D model of the patient's anatomy is created, and (B) the proposed areas of bone resection are templated. (C) This surgeon is able to view the model after the proposed resections have been performed, and (D) also after the implants are superimposed on the proposed resections. (E) The final image demonstrates the implants in their final position.

as with CAS techniques, except this is done in the preoperative period rather than intraoperatively. This allows the surgeon to start the surgery with knowledge regarding the size and location of the bony resections for each portion of the knee, as well as implant sizing and rotation information. Preoperative knowledge of the planned thickness of bony resections can prove useful, as the surgeon can intraoperatively determine if the surgery is proceeding as planned. Second, improved alignment should be obtained with the use of patient-specific cutting blocks, when compared with conventional alignment techniques. As noted earlier, conventional alignment techniques (EM tibial and IM femoral guides) have demonstrated a limited degree of accuracy, and the precision provided by patient-specific technology

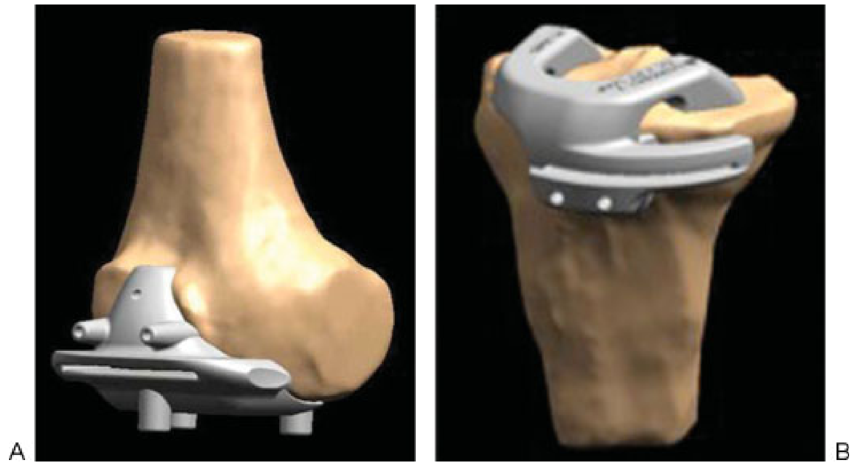

Figure 2 3D computer-generated images of the patient-specific cutting blocks fabricated for both the femur (A) and tibia (B), and their placement on the patient's native anatomy. In this system (Visionaire, Smith & Nephew Inc., Memphis, TN), the bony resections are performed through the specific cutting guides.

should significantly reduce the number of outliers as with CAS techniques. Third, due to the use of 3D imaging preoperatively, patient-specific cutting blocks should be able to improve rotational component alignment, even when compared with CAS techniques. Obtaining accurate rotational alignment with the use of CAS techniques has been difficult, as the anatomic landmarks entered into the system intraoperatively are rarely of high enough accuracy to effectively assess component rotation.[24] Preoperative MRI or CT scans allow for the accurate assessment of landmarks such as the epicondylar axis, trochlear sulcus, tibial tubercle, and tibial crest, which can be used for determining component rotation and is incorporated in the cutting blocks. Fourth, the use of patient-specific technology should lead to a more efficient surgery, as operative times should be shorter as the number of steps are decreased. In addition, there is a potentially decreased surgical set up time, as fewer instrument trays are required, and thus sterilization costs should also decrease. Lastly, as with CAS techniques, patient-specific cutting blocks avoid violation of the IM canal, and thus could potentially lead to decreased pulmonary complications and perioperative blood loss.[11,25]

However, potential disadvantages do exist with the use of patient-specific cutting blocks. With CAS techniques, it has been shown that the accuracy of anatomic landmarking is crucial to the final accuracy or output of the system, and the same rule holds true with patient-specific technology. Preoperative deformities such as a large flexion contracture of the knee may distort the accuracy of the MRI or CT scan, and thus the points digitized during creation of the 3D model may be compromised. In addition, selection or digitization of the anatomic landmarks is susceptible to human error, as points such as the epicondyles and trochlear sulcus are manually selected by engineers for each respective manufacturer. A second disadvantage is that a significant amount of time is required to obtain the appropriate preoperative imaging, formulate the intraoperative plan, and to fabricate the cutting blocks. Thus, surgeries may need to be delayed during this process. In addition, while the use of patient-specific technology should increase operating room efficiency and sterilization costs, it is unclear whether these costs offset those of the preoperative studies and manufacturing costs to fabricate the actual cutting blocks. While the cost of the preoperative MRI is typically less than a standard MRI, as a radiologist is not required to interpret the study, the cost of the MRI can still be between $500 and $1000 depending on the institution at which it is performed. In addition, if a preoperative CT scan is required, there is the downside of increased radiation exposure. While the cost of fabrication of the cutting blocks varies per company, this could potentially lead to an increase in approximately $400 per cutting block fabricated. However, it is important to note that while all of the advantages and disadvantages of patient-specific technology previously noted appear to be of sound principle, as this is a new technology, the data supporting these results in the literature is scarce.

Surgical Technique

As noted earlier, preoperative planning is performed before fabrication of the patient-specific cutting guides, and thus is done well ahead of the actual surgical procedure. The surgeon's standard exposure for TKA is performed, as no specific adaptations are required for use of these instruments. The prepackaged implants are either opened immediately before the surgical procedure (if the manufacturer provides them sterilized), or are opened with the remaining instrument trays if the hospital is required to perform the sterilization. Of note, it is essential that all soft tissue be removed from the bone at any contact point with the instruments, but that osteophytes are preserved. The preoperative plan is formulated taking osteophytes into consideration, but not soft tissue, and thus the presence of soft tissue can affect the accuracy of the cutting blocks.

The femoral cutting block is placed on the distal femur, and is pinned in place (►**Fig. 3**). As noted earlier, depending on the manufacturer, the cutting blocks can be used either as a pin

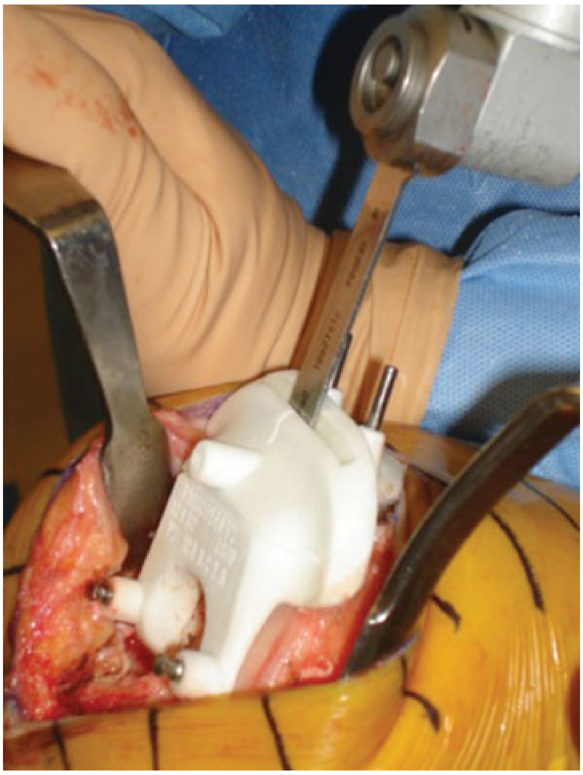

Figure 3 Intraoperative image of a patient-specific cutting block in place for performing the distal femoral resection. The saw blade is in the slot through which the resection is performed, and pins anteriorly have been placed to set the femoral component rotation and translation in the anteroposterior axis.

guide for placement of the manufacturer's standard cutting blocks, or the distal femoral resection can be performed through the block itself. The femoral cutting blocks also have pin guides to set component rotation, and translation in the anteroposterior plane. The surgeon can then elect to

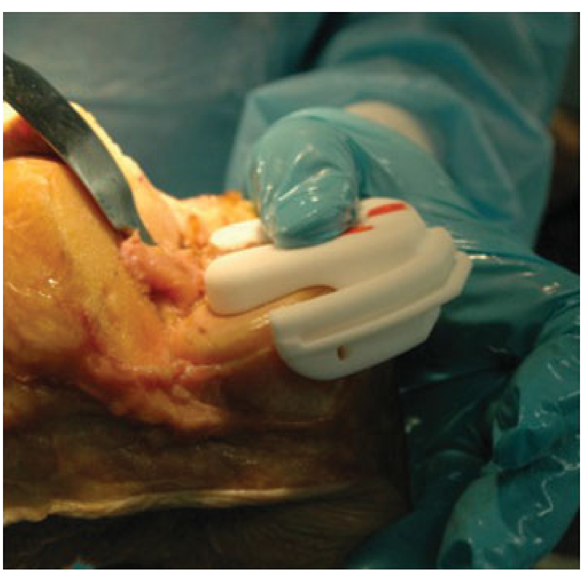

Figure 4 Intraoperative image of a patient-specific cutting block placed for performing the tibial resection.

perform the anteroposterior cuts using their standard cutting block, or first proceed with preparation of the tibia (depending on the surgeon's preference). The tibial cutting block is then placed in a similar fashion, again taking care to remove any soft tissue remaining on the bony surface, but preserving any osteophytes (►**Fig. 4**). Once the distal femoral and tibial resections have been performed, the extension gap can be assessed and ligament balancing can be performed as with the conventional methods.

Literature Review

Patient-matched cutting blocks were first introduced by OtisMed Corporation (Alameda, CA), which was subsequently purchased by Stryker Orthopaedics (Mahwah, NJ) in 2009. However, the initial results using this technology were mixed. Klatt et al first reported on four patients who underwent TKA using the OtisKnee system. An imageless computer navigation system was used to check the recommended custom cuts of the OtisKnee system, and the authors determined that the custom guides recommended component alignments that were more than 3 degrees off of the mechanical axis, thus raising concerns regarding the accuracy of the technique.[26] However, it is important to note that initially, the concept behind the OtisMed design was to restore a patient's mechanical alignment back to their "baseline," and not necessarily to achieve a neutral alignment. For example, if a patient's "normal" alignment was believed to be 3 degrees of varus, then the OtisMed design attempted to restore an alignment of 3 degrees of varus postoperatively. This concept was eventually abandoned, and the goal of a neutral alignment using patient-specific cutting blocks was adopted. Howell et al retrospectively reviewed 48 patients who underwent TKA utilizing the OtisKnee system, and demonstrated shorter operative times and excellent short-term functional outcomes when compared with conventional techniques. The average postoperative mechanical alignment based on CT scans was 1.4 ± 2.8 degrees of valgus, but they did note that 3% of the tibial guides and 3% of the femoral guides did not fit securely on the bony surfaces in their series.[27] Retrospectively, it was determined that the technician creating the preoperative plan did not align the MRIs correctly, highlighting that human error can still occur with the use of patient-specific techniques. However, despite these mixed results, the principles of patient-specific cutting blocks were sound, and several companies currently offer this technology (►**Table 1**).

The orthopaedic community appears fairly willing to implement this technology, as the proposed advantages and ease of use of this technique are encouraging. Mont et al performed a survey of 50 orthopaedic surgeons, and noted that 10 surgeons were already using patient-specific technology, and 29 of the remaining 40 were willing to try the new technique if made available to them. However, the two main reasons cited by surgeons not interested in using the technique were concerns regarding the costs, and also the scarce amount of clinical data in the literature.[28]

With regard to postoperative alignment using patient-specific technology, Spencer et al reported the results of

Table 1 Table Noting Several Manufacturers that Offer Patient Specific Technology (CR, cruciate retaining; PS, posterior stabilized). "Drill Guide" Refers to the Patient Specific Block Being Used for Pin Placement Only, after which the Manufacturer's Conventional Block is then Applied. "Cutting Block" Means that the Resection Is Performed through the Custom Block

Company Product	Regulatory status	Block Type	Vendor Manufacturing Site, Delivery time	Sterilization	Implant options	Image protocol	
Biomet Signature	510k cleared	Mechanical	Drill guides	Meterialize Belgium 4 wks	Nonsterile: only flashed once	CR/PS	Full leg MRI or CT
DePuy TruMatch	510k cleared	Mechanical	Cutting block	DePuy US-on site 4–6 wks	Shipped sterile	CR/PS	Full Leg CT
Steyker ShapeMatch	510k cleared	mechanical	Cutting block	Otis Med US-On site Was 3 wks	Nonsterile: only flashed once	CR	Full leg MRI ot CT
Wright Prophecy	510k cleared	Mechanical or Anatomic	Cutting block or drill guide	Wright US-on site unknown	Nonsterile	CR/PS	Full leg MRI or CT
Zimmer patient specific instruments	510k cleared	Mechanical	Drill guides	Materialize Belgium 4 wks	Nonsterile	CR/PS	Full leg MRI
Smith & Nephew	510k cleared	Mechanical	Cutting block	Smith & Nephew US-on site 3 wks	Shipped Sterile Flashed up to 3 x	CR/PS	MRI of knee joint and Full length X-Ray

21 patients who underwent TKA using an MRI-based cutting block system. They noted a mean decrease in operative time of 14% compared with a cohort of patients with conventional knee replacements, and reported an average postoperative deviation of 1.2 degrees of varus from the mechanical axis in their cohort, which was comparable to CAS techniques.[29] In the largest series reported in the literature, Ng et al retrospectively reviewed 569 TKAs performed with patient-specific cutting guides to 155 TKAs performed with conventional tibial EM and femoral IM guides. They noted the overall mechanical axis to pass through the central third of the knee in 88% of the cases in which patient-specific guides were used, versus 78% of manually instrumented cases. In addition, there were fewer TKAs aligned outside of 3 degrees of a neutral mechanical axis with the use of patient-specific guides (9%) versus manual instrumentation (22%). Thus, the authors concluded that patient-specific positioning guides assist in achieving a neutral mechanical axis, with a significant reduction in outliers compared with conventional techniques.[30]

While results regarding postoperative alignment with the use of patient-specific guides have been encouraging, the implementation of this method has not yet been proven to be cost-effective. Watters et al analyzed the procedure-related costs of using patient-specific technology versus both conventional, and computer-assisted surgical techniques. They compared 12 consecutive cases in which patient-specific technology was used, to 12 consecutive conventional cases and 12 consecutive CAS cases. They accounted for potential differences in operative time, preparation and turnover time, sterilization and cleaning costs, and the additional cost of the patient-specific approach (including preoperative imaging and fabrication of the guides) and of the imageless computer navigation technology. Based on their cost analysis, they concluded that the patient-specific approach was not cost saving on a per-case basis compared with conventional methods, but was less costly compared with intraoperative CAS techniques. However, they did note that per intervention, the patient-specific approach provides the institution with an additional 28 minutes of operating room time, and thus an increased operative caseload may be possible, potentially increasing the cost-effectiveness of patient-specific technology.[31] In addition, Slover et al performed a cost-effectiveness analysis of custom total knee cutting blocks using a Markov decision model, and concluded that the routine use of custom cutting blocks would not be cost-effective unless it resulted in a significantly reduced revision rate.[32]

Future Directions

As patient-specific technology in TKA is still a relatively new concept, it is not surprising that the clinical data for both postoperative radiographic and functional results, and cost-effectiveness of this technology, remain limited. Patient-specific technology attempts to both improve postoperative alignment, and also operating room efficiency. Currently, only the cutting blocks are disposable for each case, but the next evolution may be to use a complete set of disposable instruments that would include cutting blocks, trials, and polyethylene inserts for each patient, which could improve the cost-effectiveness of this technology. Future studies must focus on randomized controlled trials comparing the clinical outcomes of patient-specific cutting guides to both conventional and CAS techniques. In addition, it remains to be seen whether hospitals and surgeons can capitalize on the proposed increase in surgical and operating room efficiency, and whether these benefits will offset the increased costs associated with patient-specific designs.

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