Orthopaedic Advances

Patient-specific Instruments for Total Knee Arthroplasty

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Abstract

The use of patient-specific instruments for total knee arthroplasty shifts computer navigation for bone landmark registration and implant positioning from the intraoperative to the preoperative setting. Each system requires preoperative MRI or CT, with specifications determined by the instrument manufacturer. The marketed advantages of patient-specific instruments include greater accuracy in coronal alignment with fewer outliers, no need for instrumentation of the intramedullary canal, reduced surgical time, lower hospital costs, and improved clinical outcomes. The few published results of these instruments suggest minimal gains obtained in hospital logistics variables and minimal evidence of improvement in either alignment or patient outcomes. Disadvantages of patient-specific instruments include increased costs for imaging and instrument fabrication as well as increased preoperative time required for surgical planning and reviewing the instrument plans, and the learning curve for the surgeon to work with the engineers and use these instruments intraoperatively. It is also necessary to have a set of standard instruments available in case the patient-specific instruments do not work properly. Additional data are required before deciding whether these instruments should be recommended.

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Total knee arthroplasty (TKA) is a successful and cost-effective surgical intervention that provides pain relief, enhanced mobility, and improved quality of life for patients with end-stage knee arthritis.[1,2] The demand for TKA has increased in the past decade and was projected to double between 2005 and 2016.[3] Patient-specific instruments and cutting blocks for TKA were introduced with the goals of providing improved patient outcomes and cost-effectiveness.

Restoration of a neutral mechanical axis has long been a recommendation for TKA.[4] Recently, some have questioned the clinical relevance of the relationship between alignment status and implant failure where alignment is marked by a mechanical axis of ≤3° and outliers by a mechanical axis of >3°.[5]

Computer-assisted TKA was popularized in the late 1990s to improve alignment, reduce the incidence of outliers, and improve long-term survival. Optical trackers and computer software were used intraoperatively to register bony landmarks, usually after placement of rigid pins into the distal femur and proximal tibia, to guide precise femoral and tibial bone resections. The use of computer-assisted TKA has decreased dramatically, however, due to high capital costs, increased surgical time, difficulty registering bony landmarks, fractures due to pin insertion, and

Table 1

Patient-specific Instruments and Custom Implants for Total Knee Arthroplasty

Manufacturer	System Trade Name	Implant	Imaging Required	Method
Biomet	Signature	Vanguard	MRI or CT	Pin guides
ConforMIS	iTotal CR	iTotal G2	CT	Custom jigs
DePuy	TruMatch	P.F.C. Sigma	CT	Pin guides with metal cutting slot
Smith & Nephew	Visionaire	Journey, Legion	MRI and radiographs	Pin guides with nylon cutting slot
Wright Medical Technology	Prophecy	Advance	MRI or CT	Pin guides with metal cutting slot
Zimmer	PSI	NexGen, Natural, Persona	MRI	Pin guides for standard jigs

the learning curve involved for the surgical technique.[6,7]

Patient-specific instruments and standard and custom cutting blocks were introduced with the goals of achieving consistent alignment, avoiding intramedullary instrumentation, and simplifying operating room procedures. Patient-specific instruments shift the work of computer navigation from the intraoperative setting to the preoperative period.

A preoperative CT scan or magnetic resonance image is submitted by the surgeon using a manufacturer-specific protocol, and single-use instruments are fabricated for the femoral and tibial resections of one specific patient. The proposed benefits of this method include cost savings resulting from operating room efficiencies (ie, decreased operating room and turnover times due to fewer numbers of instrument trays to open, clean, and resterilize), improved implant alignment, avoidance of systemic emboli, and improved patient outcomes. Disadvantages include increased costs from the imaging study and fabrication of instruments; preoperative time inputs of the patient, surgeon, and office staff; the potential for error in size or placement; and the learning curve inherent in adopting new technology.

Patient-specific Instrumentation

The first iteration of patient-specific cutting jigs was introduced by OtisMed in the first decade of the 21st century.[8] Results of the OtisMed instruments are presented for historical purposes only. That system is no longer available.

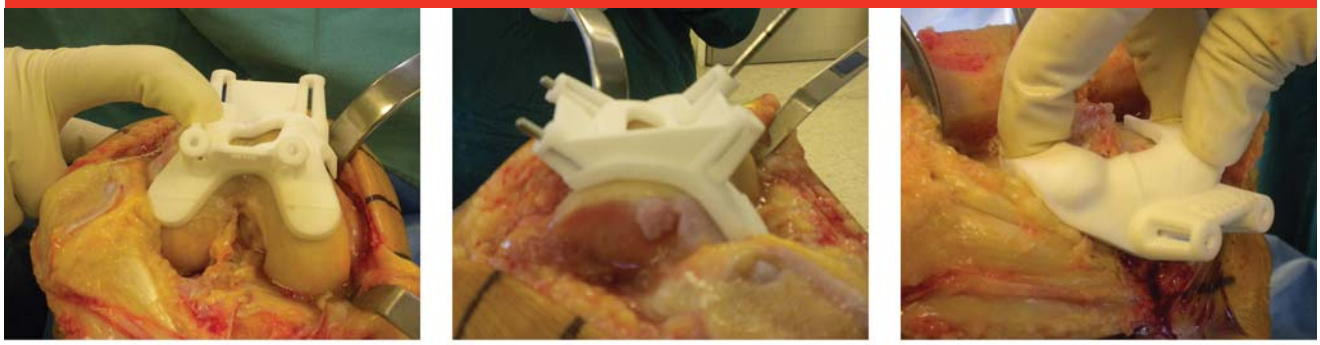
The OtisMed system was designed to restore kinematic alignment rather than anatomic alignment. Kinematic knee motion was referenced to a single flexion-extension axis of the distal femur, passing through the center of cylindrically shaped posterior femoral condyles.[9] This transcylindrical axis guides knee motion in the normal knee, and it can be difficult to locate in the arthritic knee. Using the arthritic knee magnetic resonance image, custom cutting guides were generated to align the femoral and tibial components to the prearthritic transcylindrical axis rather than to the transepicondylar and coronal mechanical axes.

Howell et al[8] reported the initial experience of one surgeon who used the OtisMed custom guides in 48 knees. Forty-five of the femoral and tibial cutting guides fit securely. The poor fit of the three femoral and tibial guides was retrospectively determined to be due to technician error in aligning the MRI. One tibial resection was repeated. The sizes of the implanted components matched the planned femoral and tibial components in every knee using the OtisMed guides. Spencer et al[9] compared results using OtisMed custom guides in 21 patients with a matched cohort of 30 previous TKAs performed using conventional instruments. Postoperative CT scans demonstrated average alignment of 1.2° varus ± 2.4° (range, 4° varus to 6° valgus). Two knees in the OtisMed cohort were considered to be outliers. The differences in mean alignment between the groups were not significant.

To our knowledge, there are currently six orthopaedic implant manufacturers that offer patient-specific instruments and one that manufactures custom implants to accompany these instruments (Table 1). Although each manufacturer has its own proprietary software, the procedures used in planning and fabrication are similar.

First, the surgeon must obtain advanced imaging (ie, MRI or CT) of the surgical extremity in addition to standard radiographs. ConforMIS and DePuy require a preoperative

Figure 1



A B C

A, Intraoperative frontal view photograph of a patient-specific femoral cutting guide placed on the distal femur. **B,** Intraoperative side view photograph of a patient-specific femoral cutting guide pinned to the distal femur. Following removal of the guide, conventional instruments were placed onto the pins or pin sites. **C,** Intraoperative photograph of a patient-specific tibial cutting guide pinned atop the proximal tibia. That component was removed and replaced by a tibial cutting jig placed onto the pins.

CT scan. Zimmer and Smith & Nephew require a magnetic resonance image. Biomet and Wright Medical Technology accept either CT scans or magnetic resonance images. Each manufacturer describes a specific protocol for patient positioning that is required to avoid errors in the fit of the patient-specific instruments. A CT scan, which does not visualize articular cartilage, may be less accurate than MRI for the fabrication of patient-specific instruments. Although this step is not necessary for fabrication, at many medical centers or imaging facilities, radiologists read the scans and submit professional charges for interpreting these images. The imaging studies are then submitted to the manufacturer, along with surgeon preferences for overall alignment, femoral and tibial resection angles, and default component sizes.

Engineers at the instrument manufacturer generate a computer simulation of the knee anatomy based on the submitted imaging and surgeon preferences, and desired bone resections are planned using proprietary software. The resulting plan is sent to the surgeon for review and modification based on factors such as fixed deformity, flexion contracture, and ligament insufficiency. Following surgeon approval, femoral and tibial cutting blocks or pin guides are fabricated and sent to the surgeon's hospital, usually in an operating room–ready sterile instrument pack. The time from surgeon approval to delivery of the custom instruments varies, but it is quoted anecdotally as being between 3 and 6 weeks.

The contents of the instrument pack are manufacturer-specific. Several of the manufacturers send guides that sit on the anterior distal femur and proximal tibia for pin placement into the femur (Figure 1, A and B) and tibia (Figure 1, C). Standard manufacturer-provided cutting jigs are then placed onto these pins or pin holes. Other manufacturers send instruments that are pinned onto the distal femur and proximal tibia; these instruments have cutting slots through which a standard saw blade is used. ConforMIS provides both custom cutting jigs and custom components.

These patient-specific instruments will not perform ligament balancing and releases in knees with fixed deformities. This remains the responsibility of the surgeon and is crucial to the success of this operation. Anecdotally, the presence of preexisting metal plates or screws located at or near the knee joint can cause radiographic artifact, which may preclude the use of patient-specific instruments. For these reasons, patients with posttraumatic knee arthritis and severe preoperative deformities have often been excluded from studies of patient-specific instruments.[8,9] The other crucial aspects of TKA—tibial component rotation, implant fixation, and patella preparation—are performed by the surgeon using conventional techniques.

Results With Patient-specific Instruments

Alignment

Few studies have reported on the clinical and radiographic results of contemporary patient-specific instruments. The initial results with the OtisMed instruments have been described elsewhere.[8-10]

Conteduca et al[11] used intraoperative computer navigation to evaluate alignment in a study of 12 patients treated with the Visionaire system (Smith & Nephew). Unacceptable

coronal plane alignment (ie, ≥2° from anatomic) was reported in 1 of 12 femoral and 2 of 12 tibial resections. In the sagittal plane, the error rate was higher, with 7 of 12 tibial cuts malaligned and 3 of 12 femoral resections malaligned. The sample size in this study was small, and the results may not be representative.

In a prospective randomized study, Noble et al[12] compared the postoperative alignment of 15 TKAs performed with the Visionaire instruments with 14 TKAs performed with conventional instruments. Based on evaluation of full-length AP radiographs, a significant improvement in coronal alignment was reported with patient-specific instruments (1.7° versus 2.8°; $P = 0.03$). The authors did not mention cutting block fitting, bone resection adjustment, or soft-tissue balancing in this study.

In a retrospective review of 569 TKAs performed with Signature (Biomet) patient-specific instruments and 155 TKAs performed with conventional instruments, Ng et al[13] reported better alignment, that is, passage of the mechanical axis through the middle one third of the knee, with the patient-specific instruments (88% patient-specific and 78% conventional; $P < 0.001$). There were fewer hip-knee angle outliers (ie, alignment >3°) with patient-specific instruments (9% patient-specific and 22% conventional; $P = 0.018$). However, there were similar rates of outliers when evaluating either the tibial component independently (10% patient-specific instruments and 7% conventional; $P = 0.21$) or the femoral component independently (22% patient-specific instruments and 18% conventional; $P = 0.14$). A major deficiency of this study is that it was nonrandomized. In addition, it may have been biased in favor of patient-specific instruments, given the disparity in number of surgeries performed with patient-specific instruments compared with conventional instruments.

Nunley et al[14] retrospectively compared the outcomes of TKA using conventional instruments (50 patients) with TKA using patient-specific instruments (Biomet Signature and OtisMed; 50 patients each). They measured postoperative femorotibial angle, hip-knee axis, and passage of the zone of the mechanical axis (ZMA) through the central zone of the knee and found a significantly higher occurrence of alignment outliers—particularly valgus—in the OtisMed group than in either of the other two cohorts. The OtisMed instruments had an outlier rate of 64% in the ZMA evaluation (32 of 50 knees), compared with 32% with the Vanguard instruments and 40% with conventional instruments ($P = 0.0008$ and $P = 0.0012$, respectively). There was no statistically significant difference in outlier rate between the Vanguard patient-specific instruments and the conventional instruments.

In a separate study of 200 consecutive knees comparing patient-specific (n = 100) and conventional (n = 100) instruments, Barrack et al[15] reported that conventional instruments were superior to patient-specific instruments in restoring the hip-knee angle (mean, 0.5° and 1.7°, respectively; $P < 0.01$) but that patient-specific instruments more closely reproduced the femorotibial angle target of 5° valgus (mean, 5.5° and 3.7°, respectively; $P < 0.001$). No significant differences were found in the frequency of femorotibial outliers. There was a trend toward more outliers with patient-specific instruments with regard to hip-knee angles and ZMA passing through the central zone.

Operating Room Logistics

One marketed benefit of patient-specific instruments is simplification of the procedure and potential for shorter surgical and operating room turnover times, with cost savings for the hospital. In theory, these improvements could permit the surgeon to complete an additional arthroplasty in a given surgical day. Noble et al[12] reported that overall surgical time was 6.7 minutes shorter with patient-specific instruments compared with conventional instruments (121.4 and 128.1 minutes, respectively). Watters et al[16] compared 12 patients treated with the patient-specific Vanguard system with 12 patients treated with conventional instruments using computer navigation. Surgical time was 13 minutes shorter with the patient-specific instruments. In a retrospective review of 114 patients, Nunley et al[17] reported similar tourniquet times with patient-specific and conventional instruments (56.2 and 61.0 minutes, respectively) but a significant decrease in overall time in the operating room with patient-specific instruments (137.2 versus 125.1 minutes; $P = 0.028$). The available data seem to support a small decrease in surgical time with the use of patient-specific instruments.

Barrack et al[15] analyzed the instrument tray processing requirements associated with patient-specific instruments and conventional instruments (100 cases per cohort). Postoperative tray collection, manual washing of trays and instruments, and tray reassembly took significantly less time with the patient-specific instruments, with savings of approximately 90 minutes in overall processing time. At the one hospital studied, labor and instrument savings were approximately $31 per tray. Coupled with the 11 fewer minutes in surgical time and an associated savings of approximately $200 per case, the total net savings was $628 per case with patient-specific instruments. However, that hospital

cost savings was outweighed by the costs of preoperative imaging ($400 to $1,250) and instrument fabrication ($950).

Patient Outcomes

The most important data required before the widespread adoption of any new technology is whether it improves clinical patient outcomes or reduces complications, and there are few data reporting such outcomes with patient-specific instruments. Noble et al[12] reported a statistically significant reduction in hospital stay in patients treated with patient-specific instruments (59.2 versus 66.9 hours; $P = 0.043$), as well as decreased intraoperative blood loss. No one has yet assessed whether these instruments provide improved implant survival, patient satisfaction, or function. To our knowledge, no studies have reported the rates of systemic fat or marrow embolization with the use of patient-specific instruments.

Problems With Patient-specific Instruments

Intraoperative Changes

Even with the use of CT or MRI in fabricating patient-specific instruments, there is a possibility of alignment error or component size mismatch between the bone resections suggested by these instruments and that desired intraoperatively. In two of the four cases reported by Klatt et al,[10] the instruments (OtisMed) were abandoned due to perceived misdirection of the resections. Howell et al[8] reported that several of the OtisMed instruments used on their patients did not fit properly until osteophytes were removed; they also noted that revision of bone resection was occasionally required. The need to remove osteophytes could potentially affect the bone resections, alignment, and ligament balancing.

Stronach et al[18] reported multiple intraoperative problems with the Vanguard patient-specific instruments in 66 consecutive knees. An average 2.4 intraoperative changes per knee were required, including modifications in bone resection, alignment, and implant sizes. The cutting blocks did not fit properly on the femur in 8 knees (12.1%) and on the tibia in 3 knees (4.5%). The patient-specific instruments correctly predicted the implant size ultimately chosen by the surgeon in only 23% of femurs and 47% of tibias. Most of the femoral size changes consisted of downsizing relative to the template (76%), whereas 36% of the tibial components were upsized and 15% were downsized relative to the template. For the 95 intraoperative changes made by the surgeon that could be evaluated radiographically (74 component size changes and 21 alignment changes), 82 (86.3%) were considered improvements over the templated size and alignment in post hoc analysis. For comparison, a recent study of preoperative templating using only standard radiographs predicted the exact size of 165 of 200 femoral components (82.5%) and 159 of 200 tibial components (79.5%).[19]

Economic Concerns

Analysis of the economic tradeoffs involved in choosing patient-specific instruments may be simplistically viewed as a comparison between the increased input costs for the additional imaging study and manufacture of single-use guides and the savings found in the operating room and subsequent clinical improvements (eg, lower rates of implant failure and revision). Two studies have examined the cost-effectiveness of patient-specific instruments.

Slover et al[20] estimated an increased cost of patient-specific instruments of $2,500 per case—$1,000 for the imaging study and $1,500 for instrument fabrication. Their determination of cost-effectiveness was based on whether these instruments improve clinical outcomes and reduce the rate of revision surgery sufficient to warrant that cost. Using Markov modeling, a decrease in the 20-year revision rate of approximately 50% relative to conventional instruments would be necessary for this tradeoff to be cost-effective. This reduction is highly unlikely with the known success of TKA.

Watters et al[16] examined the procedure-related cost of TKA performed using conventional instruments with computer navigation and of TKA performed with patient-specific instruments. They assumed a per-procedure added cost of $925 for patient-specific instruments. The cost of imaging was not considered in this study. In calculating operating room savings, this study reported two sources of cost savings. First, patient-specific instruments saved 13 minutes of operating room time per case, valued at $7.77 per minute ($101.01 per case). Second, fewer trays required processing after each case, netting a savings of approximately $290 per case. Therefore, the cost of patient-specific instruments that could be recovered in the operating room was $391 per case. Two other studies estimated time savings per case of 7 to 12 minutes using patient-specific instruments.[12,17] Barrack et al[15] estimated total savings of $322 per case in hospital personnel and overhead costs, although that savings was negated by the additional $1,500 expense for imaging and the cutting guide.

Taking into account the additional cost for instrument fabrication, imaging costs, and possible radiologist fees, patient-specific instruments rep-

resent a net cost increase to the healthcare system relative to conventional instruments for routine TKA.

Summary

Patient-specific instruments for TKA reintroduce computer navigation in the preoperative setting. The potential advantages of these instruments have not been conclusively proved. Disadvantages include added costs for imaging and instrument fabrication, as well as the possible intraoperative inaccuracy of fit and subsequent modifications to templated plans. Currently available data suggest modest gains in alignment and operating room time savings, but these are outstripped by increased costs for additional imaging and instrument manufacturing. Whether clinical outcomes will justify this additional expense requires further investigation. Additional data are required before these patient-specific instruments or custom components for TKA can be recommended for routine or widespread use.

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References

Evidence-based Medicine: Levels of evidence are described in the table of contents. In this article, references 6, 7, and 12 are level I studies. Reference 11 is a level II study. References 1, 5, 13-15, 17, and 18 are level III studies. References 2, 4, 8-10, 16, 19, and 20 are level IV studies.

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