Applying Computer-Assisted Navigation Techniques to Total Hip and Knee Arthroplasty

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Abstract

Appropriate implant alignment is a major goal of total joint arthroplasty. Obtaining appropriate alignment typically involves making intraoperative decisions in response to visual and tactile feedback. Integrated computer-based systems provide the option of continuous real-time feedback and offer the potential to decrease intraoperative errors while enhancing the surgical learning experience. Computer-assisted orthopedic surgery helps the surgeon perform both intraoperative and postoperative technical audits of implant alignment. Improving implant alignment can be correlated with improved long-term clinical outcomes. However, despite emerging data, many surgeons remain wary of computer-assisted orthopedic surgery.

major goal of total joint arthroplasty is to obtain appropriate implant alignment. This typically involves making intraoperative decisions in response to visual and tactile feedback.¹ Feedback is facilitated by various intraoperative jigs, guides, and examinations. Integrated computer-based systems provide the option of continuous real-time feedback and offer the potential to decrease intraoperative errors while enhancing the surgical learning experience. Computer-assisted feedback helps the surgeon perform both intraoperative and postoperative technical audits

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of alignment measurements, which can then be correlated with improved long-term clinical outcomes. Current computer-assisted orthopedic surgery (CAOS) systems for use in total joint arthroplasty can be broadly categorized into active and passive.2 Passive systems are further subdivided into image-free navigation systems and image-based navigation systems. The former have gained in popularity recently, as they are less technically demanding. As exciting and promising as these new techniques are, this technology has yet to be universally accepted in the operating room.

Computer-Assisted Orthopedic Surgery in Total Knee Arthroplasty

Conventional total knee arthroplasty (TKA) has been reported to result in an approximate survivorship of 95% at 10 years.3 Soft-tissue balancing and restoration of component and limb alignment in the coronal, sagittal, and axial planes are important determinants of component survivorship in TKA.^{1,4-6} Suboptimal alignment has been associated with several complications, including increased polyethylene wear, instability, component loosening, and complications related to the extensor mechanism.2,7-18 Technical errors increase the need for early revision TKA, and these errors do not decrease with experience.¹⁹

The potential for an alignment error is present during each of the various steps during TKA. Conventional TKA uses intramedullary or extramedullary alignment systems to optimize coronal alignment.²⁰⁻²² Alignment rods may be incorrectly placed—reported to be as much as 8.3° off the anatomic axis of the femur—leading to axial misalignment and femoral component flexion.23,24 During conventional TKA, sagittal tibial and femoral component alignment (flexion/extension) is determined by referencing the osseous crest of the tibia or the cortex of the femur by visual inspection.²⁵ Axial (rotational) alignment of the femoral component is determined using various bony references (eg, posterior condylar axis, Whiteside's line, transepicondylar axis).10,26-28 Similarly, axial alignment of the tibial component is determined using various bony references (eg, tibial tuberosity, medial border of second ray). However, studies have shown that visual and jig-related measurements vary significantly and may not replicate the desired alignment.^{1,29,30}

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Figure 1. During image-free computer-assisted total knee arthroplasty, the surgeon uses a handheld probe to perform registration (A), and the computer workstation uses infrared technology to detect registration data (B).

Postoperative analyses of alignment after conventional TKA demonstrate unacceptable alignment in 25% to 37% of cases.19,31,32 Accuracy of femoral intramedullary alignment instruments has been reported to be in the range of 80% to 90% in case series.33-36 Similar accuracy rates have been reported for tibial extramedullary alignment instrumentation.²¹ Malalignment of more than 3° of varus or valgus has been reported to result in a prosthetic failure rate between 20% and 56% .^{1,7,37,38} Computer-assisted TKA (CA-TKA) obviates use of inaccurate mechanical alignment guides and has the added advantage of decreasing operative blood loss, postoperative hematoma, fat embolism, and cardiac complications.39-42

CAOS was developed to address the limitations inherent in mechanical instrumentation systems and to reduce the number of cases of unacceptable alignment.39,43,44 CA-TKA can facilitate more accurate prosthesis component implantation by digital mapping using anatomic landmarks and kinematic analyses. CA-TKA was first performed in France in 1997 and is now performed worldwide. Although CAOS systems were licensed for use in the United States only in 2001, several early series with short-term follow-up suggest that they may improve the accuracy of component alignment in TKA.39,45-50

Image-Free Navigation Surgical Techniques

There are several types of image-free navigation systems.45,50 One of the major advantages of these systems is that the patient is spared the radiation and the cost of preoperative imaging. In addition, a comparison of image-based and image-free CA-TKA found no difference in coronal alignment of the tibial or femoral components.⁵¹ The working principle involves intraoperative anatomic mapping and kinematic analysis of the limb, which is then matched to a computer database to facilitate creation of a virtual joint model that closely matches the patient's anatomy. Infrared beacons/emitters/arrays (lightemitting diodes) are secured to specific bony landmarks using bicortical pins placed into the femoral and tibial shafts (some older systems used an additional pin in the anterior superior iliac spine).^{39,47,50} Other systems use passive markers in the form of retroreflective spheres or disks (Figure 1). Registration is then enabled, involving input of the marked anatomic landmarks into the computer, whereby continuous information is relayed to an infrared localizing system that tracks the beacons. The hip center is determined, in most systems, by cinematic algorithmic methods. This involves rotating the hip to determine its center with reference to the radius of rotation. Kinematic registration involves cycling the hip and knee joint through various arcs of motion while the computer calculates the center of the hip and knee joint. Vector digitization or surface mapping of the intra-articular surfaces of the femur and tibia involves specific anatomical landmarks: femoral intercondylar notch, femoral condyles, tibial plateau, epicondyles, Whiteside's line, medial and lateral malleoli, and distal tibiofibular joint.^{39,47} These data facilitate determination of the center of the ankle and the rotational axes of the femur and tibia. The rotational axis of TKA implants is based on the mean readings of the transepicondylar axis and Whiteside's line. The computer completes the registration process by determining the overall mechanical axes in the coronal and sagittal planes. The computer uses these various inputs to determine overall deviation of the limb from the optimal mechanical axes. Surface digitization allows identification of defects in the femoral condyle and the tibial plateau—information that is used to determine the resection level without altering the joint line. During subsequent CA-TKA steps, the jigs are set with reference to the correction values provided by the computer. Some systems permit continuous information feedback to ensure that cuts match predetermined values. Other knee navigation systems offer additional information, such as soft-tissue balancing information, database suggestions for component sizing, and steps to take to avoid femoral notching. Throughout the surgical procedure, the software can be managed using a handheld pointer, or a coordinator can manually select menu items on a touchscreen.47

Outcomes

Initial studies to evaluate the possible advantages of CA-TKA were performed with cadavers. Authors of one such study, which compared CA-TKA with conventional TKA, found that femoral component rotation (via the Perth computed tomography [CT] protocol), femoral component flexion, posterior tibial slope, and femoraltibial component matching were significantly improved with use of CA-TKA.⁵² Thus, it was proposed that CA-TKA may reduce the number of component positioning outliers, those patients whose alignment results are outside the acceptable range.

Results similar to those found with cadavers have since been noted with patients. In one case-control study, authors found that the navigation group had a larger number of optimal results in mechanical axis alignment as measured by postoperative radiographs.46 In another case-control study, postoperative radiographs showed 23 of 30 globally optimal results in navigation group but only 8 of 30 in conventional group (global optimal implantation was defined as being within the desired range for mechanical femorotibial angle as well as coronal and sagittal orientations of the femoral and tibial components).49 Authors of a study comparing conventional TKA and CA-TKA in cohorts matched for body weight, age, sex, diagnosis, and preoperative deformities reported increased precision in femoral and tibial component placement and fewer outliers with computerassisted assessment of component positioning in four axes: mechanical axes, coronal tibial component angle, coronal femoral component angle, and sagittal femoral component angle.⁵⁰

To add to these initial promising results, authors of a randomized prospective clinical trial of 70 patients compared image-free CA-TKA with conventional TKA and found that CA-TKA improved standing alignment, femoral and tibial varus/valgus alignment, femoral and

tibial rotation, and tibial slope as determined with postoperative CT and long-leg radiography.³⁹ In addition, CA-TKA required no femoral intramedullary drilling, and blood loss was approximately 200 mL less in this group. In another study, researchers randomly assigned 120 patients to either conventional TKA or image-free CA-TKA and demonstrated optimal anatomical lateral tibiofemoral alignment in the CA-TKA group.⁴⁸ In one of the largest prospective studies, 315 patients were randomly assigned to 1 of 3 groups: conventional TKA, CA-TKA with Stryker 2.0 software (Stryker Orthopedics, Mahwah, New Jersey), and CA-TKA with Stryker 3.1 software.⁵³ Using each method, the authors attempted to obtain limb alignment within 3° of biomechanical neutral. Ninety-nine percent of patients in the CA-TKA with Stryker 3.1 software group achieved this desired alignment, compared with 93% of patients in the CA-TKA with Stryker 2.0 software group and 80% of patients in the conventional TKA group. The authors also found nearly identical tourniquet times for the CA-TKA groups and the conventional TKA group (71 and 74 minutes, respectively). These additional data help to dispel the popular notion that CAOS means longer operating times.

Most early prospective studies addressed alignment only in the long axis (coronal and sagittal planes).⁴⁴ As rotational alignment is a significant predictor of successful TKA clinical outcomes, investigators needed to verify the contribution of computer assistance to this parameter as well.⁵⁴ Results of one such prospective study demonstrated improved flexion angle of components, posterior tibial slope, and mechanical axis as well as enhanced rotational alignment in image-free navigation group patients.⁴⁷ Data from other studies also have indicated significant improvement in femoral and tibial rotation.³⁹

CA-TKA may be most useful in reducing the number of outliers in component alignment.⁵² In a prospective study of 192 knees, only 2 tibial components (1%) had more than 3° of varus or valgus.⁵⁵ In another prospective study, researchers found a decrease in outliers for both tibial and femoral component alignment.⁵⁰ Authors of a recent meta-analysis reported alignment outlier reduction rates of 87% (femoral components) and 80% (tibial components) in evaluation of limb mechanical axis and coronal position of implants.⁵⁶ Although results from at least one study dispute this claim, the overwhelming majority of studies show a reduction in component outliers with use of CA-TKA.57

Evaluating soft-tissue release requirements during TKA is another possible application for CAOS. Softtissue release is often performed without precise knowledge as to whether it will help balance the knee. In one study, investigators considered the indications to be the inability to restore the mechanical axis before bony resection, and any incongruity between lateral and medial joint space after tibial osteotomy but before femoral osteotomy.58 Given these indications, only 10

Figure 2. Computer monitor during computer-assisted total hip arthroplasty shows virtual pelvic model that facilitates control of cup abduction and anteversion.

of 93 patients (10.8%) required soft-tissue release, and all 93 patients demonstrated satisfactory postoperative alignment and balance.

However, reports are contradictory regarding the clinical significance of improved implant alignment using CA-TKA. Whereas some authors have asserted that postoperative alignment may not be a determinant of failure, others have indicated that malalignment increases the risk for prosthetic failure.1,7,37,59-61 Data have shown that flexion of the femoral component can be associated with loss of extension and knee stiffness.⁶² Femoral malrotation increases the likelihood of patella maltracking, femoral condylar liftoff leading to flexion instability, accelerated polyethylene wear, component loosening, implant failure, and eventual need for revision.16,63-66 More accurate posterior slope cuts in the tibia improve overall knee kinematics, resulting in better soft-tissue balancing and satisfactory range of motion.⁶⁷ Accurate joint line restoration is also important in improving range of motion.⁶⁸ Given these examples, increased precision through use of CAOS should be expected to increase overall component survivorship.⁵⁰ Data supporting the need for correct alignment of TKA components appear to be adequate, but the argument hinges on how precise those data need be. Long-term studies will determine whether the small but statistically significant improvements in component alignment reported in many series will affect implant survival.

Much of the CA-TKA literature focuses on radiographic alignment rather than clinical outcome—a situation that derives from the recent introduction of the technology and the lack of studies with long-term patient follow-up. Results of a prospective evaluation of 52 CA-TKA patients at 6-month follow-up showed poor clinical outcomes associated with comorbidities and with poor preoperative knee function, particularly flexion deformity (however, there was no comparison with conventional TKA). 69 Authors of a retrospective

case-control study found no significant clinical difference between 30 conventional TKA patients and 30 CA-TKA patients at a mean follow-up of 5.4 years but did find improved maintenance of coronal alignment in the CA-TKA group.⁷⁰ With the goal of CA-TKA being better clinical outcomes, some would argue improved maintenance of lower limb alignment to be of no consequence. In a prospective randomized study of 73 TKAs with 20 months of follow-up, the differences between conventional TKA and CA-TKA patients in postoperative Knee Society Scores and EuroQuol (quality-of-life) questionnaire results were insignificant.⁷¹ The authors suggested that any differences between conventional TKA and CA-TKA will not be realized until many years later, when any malaligned components will begin to show accelerated wear. Investigators have yet to study alignment with respect to component wear and clinical outcomes over longer patient follow-ups.

Computer-Assisted Orthopedic Surgery in Total Hip Arthroplasty

A critical determinant of survivorship in total hip arthroplasty (THA) is component alignment. The 3 key alignment parameters are abduction and anteversion of acetabular cup, postoperative leg-length, and femoral offset. Optimal positioning produces maximal hip range of motion, stability, and a desirable wear rate for a polyethylene bearing.72-75 In the increasingly more common minimally invasive surgery, reduced surgical exposure can increase the risk for component malpositioning, and in response some surgeons have indicated a desire for more accurate means of prosthesis placement.^{76,77} CAOS hardware and software systems have been developed in an effort to improve optimal implant position which, in turn, is expected to improve postoperative outcomes. CAOS makes it possible to combine preoperative planning with intraoperative surgical implementation. It allows the position of surgical equipment to be displayed in real time with three-dimensional representation of the bony structure. System software also allows the surgeon to predict results of technical maneuvers. In being able to address the "blind spots" attributed to limited surgical exposure, CAOS complements minimally invasive surgery. It may also be helpful when combined with larger surgical approaches.78

Outcomes

The common methods used in conventional acetabular cup component positioning include use of internal (anatomic) or external (jig) guides. Alignment guides can be inaccurate when used for cup placement; during surgery, they cannot compensate for anatomic variations in the pelvis and pelvic motion. Hence, a dynamic sensor that continuously tracks pelvic alignment during surgery may help to optimize acetabular cup positioning (Figure 2). Ideal cup placement in the "safe zone," as defined by Lewinnek and colleagues, involves 40° of abduction

(with an SD of 10°) and 15° of anteversion (with an SD of 10°).79 Retrospective evaluation of acetabular cup anteversion found that, in 59 of 74 patients (80%), the acetabular cup was outside the safe zone with regard to anteversion when the implant was aligned using mechanical guides.80 These outliers are clinically relevant. They are associated with femoroacetabular impingement, decreased range of motion, dislocations, and accelerated component wear.74,81 Results of a prospective study demonstrated that acetabular cups oriented with more than 45° of abduction, compared with cups oriented less than 45°, underwent a 50% increase in linear wear per year and a 44% increase in volumetric wear per year.⁸² Accelerated component wear, along with the other problems associated with malaligned cups, significantly increase the revision rate and should be minimized with more accurate acetabular cup placement.

In an investigation of the accuracy of cup positioning in CA-THA, 10 surgeons placed 150 acetabular implants in plastic models in 3 different ways: freehand, with mechanical alignment guides, or with computer assistance.83 Results showed that, compared with the freehand and mechanical alignment guide methods, CAOS led to improvements in reproducibility and accuracy of cup positioning during CA-THA. In a prospective study, researchers compared the accuracy of component positioning with and without CAOS in 150 THAs demonstrated a statistically significant improvement in acetabular cup placement in the CA-THA group, with none of the acetabular cups placed outside the safe zone.⁸⁴ The authors concluded that CAOS helped the surgeon place the acetabular component with less variability in abduction angle. More importantly, no cups were placed in the more extreme positions.

A randomized controlled trial of 26 hips compared cup anteversion angle and inclination angle, as well as postoperative Harris Hip Scale (HHS) scores after CA-THA vs conventional THA.⁸⁵ The goals were anteversion of 15° and inclination of 45°. In the CA-THA group, mean (SD) anteversion was 15.4°(1.4) and mean (SD) inclination was $45.5^{\circ}(1.3)$. In the conventional THA group, anteversion was 13.9° (7.6) and mean (SD) inclination was 43.7° (6.4). The difference in inclination values was statistically significant. In addition, mean postoperative HHS score was 95 (range, 85-110) in the CA-THA group, with an excellent result in 11 hips and a good result in 2 hips, vs 92 (range, 75-110) in the conventional THA group, with an excellent result in 9 hips, a good result in 3 hips, and a fair result in 1 hip. This difference in HHS scores was statistically significant and, therefore, showed clinical and radiographic benefits to CA-THA.

In a 2009 meta-analysis, authors examined cup orientation after conventional THA vs CA-THA in 400 patients from 5 studies and concluded that CAOS is of benefit, and the difference is mainly in the reduction of outliers beyond the safe zone.⁸⁶ A decrease in overall cup orientation variability was noted in the CA-THA group. The authors mentioned that the clinical relevance of cup orientation is difficult to assess because all the complications of the cup outliers also can be attributed to incorrect placement of the other components. Authors of another meta-analysis reached a similar conclusion after analyzing 3 randomized clinical trials with a total of 250 patients. In the CA-THA group, 15 of 140 hips (10.7%) were outside the safe zone; in the conventional THA group, 46 of 110 hips (41.8%) were outside the safe zone.87 These meta-analyses provided compelling data that suggest CAOS is a useful adjunct in THA.

Restoration of leg-length is another aspect that has a significant impact on THA component survivorship and on patient satisfaction after surgery. Length inequality creates abnormal force transmission across the implant surface and has been shown to contribute to implant loosening.⁸⁸ In addition, length inequality increases the risk for stiffness, instability, neuropathy, pain, gait asymmetry, knee and back pain, heterotopic ossification, and litigation.89 Although there is no absolute tolerable discrepancy, 6 mm has been proposed as the maximum amount of leg-length difference that is clinically acceptable. 90 CA-THA has been proposed as a method to assist surgeons in achieving this small margin of error, and results of a cadaver study, in which a pinless navigation system was used, showed that this technology is able to accurately estimate leg-length when measured against CT scan.⁹¹ In a retrospective study of 344 hips, authors examined the reliability of intraoperative computer-assisted measurements of leglength by reviewing the intraoperative leg-length data and comparing them against postoperative radiographs. The mean (SD) intraoperative leg-length change was 6.6 (4.1) mm, and this value was consistent with values obtained by measuring the changes from postoperative radiographs. The authors concluded that CAOS provides reliable leg-length measurements. ⁹² Results of a similar study design showed that OrthoPilot THA 2.0 software (Aesculap AG, Tuttlingen, Germany) accurately assessed leg length changes to within 5 mm in 83% of 107 THAs.⁹³ In another retrospective study, authors compared leg length discrepancies greater than 10 mm after conventional THA and CA-THA in 96 patients (48 patients in each group).⁸⁹ Five CA-THA patients and 13 conventional THA patients fell outside the 10 mm cutoff, and this difference was statistically significant. Clinically, however, the groups did not differ significantly in their scores on the HHS or the Western Ontario McMaster Arthritis Index. In a study of 82 CA-THA cases, 81 of 82 hips (99%) maintained leg length changes to within the accepted standard of 6 mm, and the mean change was only 2.5 mm.⁹⁴

Femoral offset is another THA parameter to be optimized to minimize postoperative complications and maximize patient satisfaction. Femoral offset helps correct hip biomechanics and restore proper hip abductor function; incorrect offset can result in hip instability, accelerated component wear, and decreased hip range of motion.⁹⁴ Results of a cadaver study that used a pinless navigation system showed that this technology can accurately estimate femoral offset as measured against CT scans.⁹¹ The importance of maintaining natural offset was recently quantified when it was suggested that failing to restore offset to within 5 mm was associated with a 33% increase in linear polyethylene wear and a 32% increase in volumetric wear.82 Results of a retrospective study showed that, in 73% of 107 CA-THA cases, femoral offset was within 10 mm. 93 Mean offset was 1.2 mm, but it was associated with a 17.8 mm standard deviation. In addition, a different group of surgeons maintained femoral offset within 6 mm in 78 (95%) of 82 CA-THA cases.94

Complications Associated With Computer- Assisted Orthopedic Surgery

Although case series of image-free navigation systems have not provided sample sizes sufficient to establish accurate complication rates, the literature so far suggests that such systems are safe and do not affect postoperative pain or function.45 In 2 articles, authors reported tracker loosening or dislodgement caused by poor fixation in osteoporotic bone. $47,50$ Insertion of tracker pins poses risks, including fracture and infection, and a few case reports have described femoral or tibial fractures after pin insertion for CA-TKAs.⁹⁵⁻⁹⁷ Given the number of TKA cases, however, this risk seems low. One globally reported difference is that, compared with conventional TKA, image-free navigation increases tourniquet time 10 minutes to 20 minutes, during registration.^{39,50} Consideration of this phenomenon should be balanced with the fact that image-free navigation equipment is continually being refined and that, as experience with these new systems increases, operative time will likely decrease. Authors of a recent article reported on the learning curve for using an image-free navigation system when performing $CA-THA⁹⁸$. The first 30 surgeries were classified as being performed during the learning curve, and the second 30 after the learning curve. The first 30 cases showed significant differences between intraoperative and postoperative cup orientation, but the second 30 cases showed no such difference. A decrease in the percentage of outliers was also noted in the second group. Mean navigation time—time in excess of conventional THA operating time—was 13.2 minutes during the learning curve but only 4.8 minutes after the learning curve. The authors thought that this nominal increase in operating time is justified by surgeons' ability to achieve better cup orientation.

Perspectives on Computer-Assisted Orthopedic Surgery

The role of CAOS in fracture fixation already has been established, as virtual modeling reduces radiation exposure for both patient and surgeon. It also facilitates development of psychomotor skills and planning of innovative techniques. In conventional TKA and THA, preoperative radiographic data and intraoperative visual cues are used in the optimal fixation of prosthetic components. In the knee, radiographic methods are subject to error, as they do not assess cumulative error in the coronal, sagittal, and axial planes.³⁹ As a result, radiographs have inaccuracies of 1.6° (long) and 1.9° (short).^{99,100} Intraoperative computer assistance eliminates this inaccuracy. Over the short term, CAOS improves overall alignment in hip and knee arthroplasty.39,48,52,86,87 Results of a recent study showed that these alignment improvements may hold for other orthopedic procedures as well. Researchers examined the accuracy of oscillating saw cuts on simulated bone in a comparison of freehand, robot-assisted, and computernavigated freehand techniques.¹⁰¹ Mean cut location was 5.2 mm with freehand, 2.8 mm with computer-navigated freehand, and 1.7 mm with robot-assisted—indicating that any orthopedic procedure that involves an oscillating bone saw may benefit from computer assistance.

Many surgeons are wary about the usefulness of CAOS.102,103 They identify increased initial cost, increased operating time, increased patient irradiation (with some techniques), questionable radiographic benefit, and no proven long-term difference as reasons for further investigation of CAOS before universal acceptance. To point out that CAOS is not as useful a tool as initially proclaimed, detractors speak about multifactorial reasons for poor postoperative outcomes—not just component alignment—and about problems inherent to TKA (eg, saw blade deflection).¹⁰⁴

TKA and THA are very successful orthopedic procedures, so implant positioning improvements related to improved clinical outcomes will be difficult to prove over the short and middle term. However, as surgery continues to move in the direction of minimally invasive techniques, the need for uniform proper component alignment in light of fewer visual cues may spark more widespread interest in this technology.

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