Computer-Assisted Navigation for Orthopedic Procedure

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I. Description

Computer-assisted navigation (CAN) in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including fixation of fractures, ligament reconstruction, osteotomy, tumor resection, preparation of the bone for joint arthroplasty, and verification of the intended implant placement.

For individuals who are undergoing orthopedic surgery for trauma or fracture, ligament reconstruction, hip arthroplasty and periacetabular osteotomy, or total knee arthroplasty who receive CAN, the evidence includes randomized controlled trials and nonrandomized comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Overall, the literature supports a decrease in the variability of alignment with CAN, particularly with respect to the number of outliers. Although some observational data have suggested that malalignment may increase the probability of early failure, recent randomized controlled trials with short- to mid-term follow-up have not shown improved clinical outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of the available studies to detect changes in function using CAN, studies are needed that assess health outcomes using CAN in a larger number of subjects with longer follow-up to permit greater certainty on the impact of this technology. The evidence is insufficient to determine the effects of the procedure on health outcomes.

Background

IMPLANT ALIGNMENT FOR KNEE ARTHROPLASTY
For total knee arthroplasty, malalignment is commonly defined as a variation of more than 3 from the targeted position. Proper implant alignment is believed to be an important factor for minimizing long-term wear, the risk of osteolysis, and loosening of the prosthesis.

COMPUTER-ASSISTED NAVIGATION

The goal of computer-assisted navigation (CAN) is to increase surgical accuracy and reduce the chance of malposition.

In addition to reducing the risk of substantial malalignment, CAN may improve soft tissue balance and patellar tracking. CAN is also being investigated for surgical procedures with limited visibility such as placement of the acetabular cup in total hip arthroplasty, resection of pelvic tumors, and minimally invasive orthopedic procedures. Other potential uses of CAN for surgical procedures of the appendicular skeleton include screw placement for fixation of femoral neck fractures, high tibial osteotomy, and tunnel alignment during the reconstruction of the anterior cruciate ligament.

CAN devices may be image-based or non-image-based. Image-based devices use preoperative computed tomography scans and operative fluoroscopy to direct implant positioning. Newer non-image-based devices use information obtained in the operating room, typically with infrared probes. For total knee arthroplasty, specific anatomic reference points are made by fixing signaling transducers with pins into the femur and tibia. Signal-emitting cameras (eg, infrared) detect the reflected signals and transmit the data to a dedicated computer. During the surgery, multiple surface points are taken from the distal femoral surfaces, tibial plateaus, and medial and lateral epicondyles. The femoral head center is typically calculated by kinematic methods that involve the movement of the thigh through a series of circular arcs, with the computer producing a 3-dimensional model that includes the mechanical, transepicondylar, and tibial rotational axes. CAN systems direct the positioning of the cutting blocks and placement of the prosthetic implants based on the digitized surface points and model of the bones in space. The accuracy of each step of the operation (cutting block placement, saw cut accuracy, seating of the implants) can be verified, thereby allowing adjustments to be made during surgery.

Navigation involves 3 steps: data acquisition, registration, and tracking.

Data Acquisition
Data can be acquired in 3 ways: fluoroscopically, guided by computed tomography scan or magnetic resonance imaging or guided by imageless systems. These data are then used for registration and tracking.

Registration
Registration refers to the ability to relate images (ie, radiographs, computed tomography scans, magnetic resonance imaging, or patients' 3D anatomy) to the anatomic position in the surgical field. Registration techniques may require the placement of pins or "fiduciary markers" in the target bone. A surface-matching technique can also be used in which the shapes of the bone surface model generated from preoperative images are matched to surface data points collected during surgery.

Tracking
Tracking refers to the sensors and measurement devices that can provide feedback during surgery regarding the orientation and relative position of tools to bone anatomy. For example, optical or electromagnetic trackers can be attached to regular surgical tools, which then provide real-time information of the position and orientation of tool alignment concerning the bony anatomy of interest.

VERASENSE (OrthoSense) is a single-use device that replaces the standard plastic tibial trial spacer used in total knee arthroplasty. The device contains microprocessor sensors that quantify load and contact position of the femur on the tibia after resections have been made. The wireless sensors send the data to a graphic user interface that depicts the load. The device is intended to provide quantitative data on the alignment of the implant and soft tissue balancing in place of intraoperative "feel."

iASSIST (Zimmer) is an accelerometer-based alignment system with a user interface built into disposable electronic pods that attach onto the femoral and tibial alignment and resection guides. For the tibia, the alignment guide is fixed between the tibial spines and a claw on the malleoli. The relation between the electronic pod of the digitizer and the bone reference is registered by moving the limb into abduction, adduction, and neutral position. Once the information has been registered, the digitizer is removed, and the registration data are transferred to the electronic pod on the cutting guide. The cutting guide can be adjusted for varus/valgus alignment and tibial slope. A similar process is used for the femur. The pods use the wireless exchange of data and display the alignment information to the surgeon within the surgical field. A computer controller must also be present in the operating room.

Due to the lack of any recent studies on pelvic tumor resection, these sections of the Rationale were removed from this evidence review in 2016.

REGULATORY STATUS
Because CAN is a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system, surgical navigation systems generally are subject only to 510(k) clearances from the U.S. Food and Drug Administration (FDA). As such, FDA does not require data documenting the intermediate or final health outcomes associated with CAN. (In contrast, robotic procedures, in which the actual surgery is robotically performed, are subject to the more rigorous requirement of the premarket approval application process.)

A variety of surgical navigation procedures have been cleared for marketing by FDA through the 510(k) process with broad labeled indications. For example, The OEC FluoroTrak 9800 plus is marketed for locating anatomic structures anywhere on the human body.

Several navigation systems (eg, PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, ORTHOsoft) have received FDA clearance specifically for total knee arthroplasty. The FDA-cleared indications for the PiGalileo™ system are representative. This system "is intended to be used in computer-assisted orthopedic surgery to aid the surgeon with bone cuts and implant positioning during joint replacement. It provides information to the surgeon that is used to place surgical instruments during surgery using anatomical landmarks and other data specifically obtained intraoperatively (eg, ligament tension, limb alignment). Examples of some surgical procedures include but are not limited to:

- Total knee replacement supporting both bone referencing and ligament balancing techniques
- Minimally invasive total knee replacement."

FDA product code: HAW.

In 2013, the VERASENSE™ Knee System (OrthoSensor) and the iASSIST™ Knee (Zimmer) were cleared for marketing by FDA through the 510(k) process. FDA product codes: ONN, OLO.

II. Criteria/Guidelines

Computer-assisted surgery for orthopedic procedures of the pelvis and appendicular skeleton is not covered as it is not known to be effective in improving health outcomes.

III. Administrative Guidelines

The following CPT codes are not covered:

CPT Code	Description
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less (List separately in addition to code for primary procedure)
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image guidance based on CT and MRI images. (List separately in addition to code for primary procedure)

IV. Scientific Background

This evidence review was created in February 2004 and has been updated regularly using the MEDLINE database. The most recent literature update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events

and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For many orthopedic surgical procedures, optimal alignment is considered an important aspect of long-term success. For example, misplaced tunnels in the anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) reconstruction or malalignment of arthroplasty components are some of the leading causes of instability and reoperation. In total hip arthroplasty (THA), the orientation of the acetabular component of the THA is considered critical, while for total knee arthroplasty (TKA), alignment of the femoral and tibial components and ligament balancing are considered important outcomes. Ideally, one would prefer controlled trials comparing the long-term outcomes, including stability and reoperation rates.

TRAUMA OR FRACTURE

Computer-assisted surgery has been described as an adjunct to pelvic, acetabular, or femoral fractures. For example, fixation of these fractures typically requires percutaneous placement of screws or guidewires. Conventional fluoroscopic guidance (ie, C-arm fluoroscopy) provides imaging in only 1 plane. Therefore, the surgeon must position the implant in 1 plane and then get additional images in other planes in a trial-and-error fashion to ensure that the device has been properly placed. This process adds significant time in the operating room and radiation exposure. Computer-assisted surgery may permit minimally invasive fixation and provide more versatile screw trajectories with less radiation exposure. Therefore, computed-assisted surgery is considered an alternative to the existing image guidance using C-arm fluoroscopy.

Ideally, investigators would conduct controlled trials comparing operating room time, radiation exposure, and long-term outcomes of those whose surgery was conventionally guided using C-arm vs image-guided using computer-assisted surgery. While several in vitro and review studies had been published, when this evidence review was created in 2004, only a single clinical trial of computer-assisted surgery in trauma or fracture cases was identified. Computer-assisted navigation (CAN) for internal fixation of femoral neck fractures was retrospectively analyzed in 2 cohorts of consecutive patients (20 each, performed from 2001 to 2003 at 2 different campuses of a medical center) who underwent internal fixation with 3 screws for a femoral neck fracture. Three of 5 measurements of parallelism and neck coverage were significantly improved by CAN; they included a larger relative neck area held by the screws (32% vs 23%) and less deviation on the lateral projection for both the shaft (1.7° vs 5.2°) and the fracture (1.7° vs 5.5°) screw angles, all respectively. Slight improvements in anteroposterior screw angles (1.3° vs 2.1° and 1.3° vs 2.4°, respectively) were not statistically significant. There were 2 reoperations in the CAN group and 6 in the conventional group. Complications (collapse, subtrochanteric fracture, head penetration, osteonecrosis) were lower in the CAN group (3 vs 11, respectively).

Section Summary: Trauma or Fracture

There is limited literature on the use of CAN for trauma or fractures. Additional controlled studies that measure health outcomes are needed to evaluate this technology.

ANTERIOR OR POSTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

A Cochrane review (2014) compared the effects of CAN with conventional operating techniques for ACL or PCL reconstruction. Five RCTs (total N=366 participants) on ACL reconstruction were

included in the updated review; no studies involved PCL reconstruction. The quality of evidence ranged from moderate to very low. Pooled data showed no statistically or clinically relevant differences in self-reported health outcomes (International Knee Documentation Committee subjective scores and Lysholm Knee Scale scores) at 2 or more years of follow-up. No significant differences were found for secondary outcomes, including knee stability, range of motion, and tunnel placement. Overall, there was insufficient evidence to advise for or against the use of CAN. Four of the 5 trials included in the Cochrane review are described next.

Plaweski et al (2006) reported on a trial that randomized 60 patients to manual or computer-assisted guidance for tunnel placement with follow-up at 1, 3, 6, 12, 18, and 24 months. There were no differences between groups in measurements of laxity. However, there was less variability in side-to-side anterior laxity in the navigated group (eg, 97% were within 2 mm of laxity in the navigated group vs 83% in the conventional group at an applied force of 150 N). There was a significant difference in the sagittal position of the tibial tunnel (distance from the Blumensaat line, 0.4 mm vs -1.2 mm, respectively), suggesting possible impingement in extension for the conventional group. At the final follow-up (24 months), all knees had normal function, with no differences observed between groups.

Hart et al (2008) compared biomechanical radiographic with functional results in 80 patients randomized to ACL reconstruction using CAN (n=40) or to the standard manual targeting technique (n=40). The blinded evaluation found more exact bone tunnel placement with CAN, but no overall difference in biomechanical stability or function between groups.

Other studies have found no significant improvement in the accuracy of tunnel placement when using CAN. Meuffels et al (2012) reported on a double-blind controlled trial that randomized 100 patients to conventional or computer-assisted surgery. Evaluation by 3-dimensional computed tomography (CT) found no significant difference between groups for the accuracy or the precision of the femoral and tibial tunnel placement.

Mauch et al (2007) reported on a trial that randomized 53 patients to manual or computer-assisted ACL reconstruction by 3 experienced surgeons. Tunnel placement and range variance did not differ between groups, suggesting that experienced surgeons can achieve the same positioning as CAN.

Section Summary: Anterior or Posterior Cruciate Ligament Reconstruction
The evidence on CAN for ACL or PCL reconstruction includes a systematic review of 5 RCTs. These RCTs, of moderate to low quality, did not consistently demonstrated more accurate tunnel placement with CAN. No studies have shown an improvement in functional outcomes or need for revision when CAN is used for ACL or PCL reconstruction.

HIP ARTHROPLASTY AND PERIACETABULAR OSTEOTOMY
Few RCTs have evaluated CAN for hip procedures.

Total Hip Arthroplasty
Parratte and Argenson (2007) randomized patients to CAN (n=30) or freehand cup positioning (n=30) for THA by an experienced surgeon. The mean additional time for the computer-assisted procedure was 12 minutes. There was no difference between the computer-assisted group and

the freehand-placement group with regard to the mean abduction or anteversion angles measured by CT. A smaller variation in the positioning of the acetabular component was observed in the CAN group; 20% of cup placements were considered to be outliers in the CAN group compared with 57% in the freehand-placement group. In a randomized trial of 125 patients, Lass et al (2014) compared the acetabular component position for CAN and the conventional freehand technique. CT scans identified higher accuracy for acetabular component anteversion, less deviation from the target position for anteversion, and fewer outliers from the target for inclination and anteversion. Surgical time was 18 minutes longer for CAN. Functional outcomes were not assessed.

A study by Manzotti et al (2011) compared leg length restoration in a matched-pair study. Forty-eight patients undergoing THA with CAN were compared with patients who were matched for age, sex, arthritis level, preoperative diagnosis, and preoperative leg length discrepancy and underwent conventional freehand THA using the same implant in the same period. The mean preoperative leg length discrepancy was 12.17 mm in the CAN group and 11.94 mm in the standard group. Surgical time was increased by 16 minutes in the CAN group (89 minutes vs 73 minutes). There was a significant decrease in both the mean postoperative leg length discrepancy (5.06 mm vs 7.65 mm) and the number of cases with a leg length discrepancy of 10 mm or more (5 patients vs 13 patients), all respectively. Outcomes at 40-month follow-up (range, 7-77 months) did not differ significantly for the Harris Hip Score (88.87 vs 89.73) or the 100-point normalized Western Ontario and McMaster Universities Arthritis Index score (9.33 vs 13.21; p=0.050), all respectively. Longer follow-up with a larger number of subjects is needed to determine whether CAN influences clinical outcomes.

Minimally Invasive THA
It has been proposed that CAN might overcome the difficulties of reduced visibility of the surgical area associated with minimally invasive procedures. A review by Ulrich et al (2007) summarized studies that compared outcomes from minimally invasive THA using CAN with standard THA. Seventeen studies were described in this evidence-based review, including 9 prospective comparisons, 7 retrospective comparisons, and 1 large (N=100) case series. Reviewers concluded that alignment with minimally invasive CAN appears to be at least as good as standard THA, although the more consistent alignment must be balanced against the expense of the computer systems and increased surgical time.

Short-term outcomes of minimally invasive THA approach with CAN (n=35) compared with conventional posterolateral THA (n=40) was reported by Reininga et al (2013). This randomized comparison found no group differences in the recovery of gait at up to 6 months postsurgery.

Periacetabular Osteotomy
In a trial by Hsieh et al (2006), 36 patients with symptomatic adult dysplastic hip were randomized to CT-based navigation or the conventional technique for periacetabular osteotomy. An average of 0.6 intraoperative radiographs were taken in the navigated group compared with 4.4 in the conventional group, resulting in a total surgical time that was 21 minutes shorter for CAN. There were no differences between groups for correction in femoral head coverage or functional outcomes (pain, walking, range of motion) at 24 months.

Total Hip Resurfacing
Stiehler et al (2013) reported on short-term radiographic and functional outcomes from a randomized comparative trial of THR using CAN and conventional THR in 75 patients. For most of the radiographic measures, there were no significant differences between the CAN and conventional THR groups. There were fewer outliers (≥5°) for the femoral component with CAN (11%) compared with conventional placement (32%). At 6-month follow-up, there were no differences between groups in the final Western Ontario and McMaster Universities score or Harris Hip Score. The CAN group did show a greater percentage improvement in the Western Ontario and McMaster Universities scores and Harris Hip Score due to differences between groups at baseline.

Section Summary: Hip Arthroplasty and Periacetabular Osteotomy
Relatively few RCTs have evaluated CAN for hip procedures. Although there was early interest in this technology, no recent RCTs have been identified. There is inconsistent evidence from these small trials on whether CAN improves alignment with conventional or minimally invasive THA. One RCT found improved alignment when CAN was used for hip resurfacing, but there was little evidence of improved outcomes at short-term follow-up. Overall, improved health outcomes have not been demonstrated with CAN for any hip procedures.

TOTAL KNEE ARTHROPLASTY
Alignment of a knee prosthesis can be measured along several different axes, including the mechanical axis, and the frontal and sagittal axes of both the femur and tibia.

Systematic Reviews
A TEC Assessment (2007) evaluated CAN for TKA. Nine studies from 7 RCTs were reviewed. Selection criteria for the RCTs included having at least 25 patients per group and comparing limb alignment and surgical or functional outcomes following TKA with CAN or conventional methods. Also reviewed were cohort and case series that evaluated long-term associations between malalignment of prosthetic components and poor outcomes. In the largest of the cohort studies, which included more than 2000 patients (3000 knees) with an average of 5-year follow-up, 41 revisions for tibial component failure (1.3% of the cohort) were identified. The relative risk for age was estimated at 8.3, with a greater risk observed in younger, more active patients. For malalignment (defined as >3° varus or valgus), the relative risk was estimated to be 17.3.

Pooled data from the prospective RCTs showed:

- A significant decrease in the percentage of limbs considered to be outliers (eg, >3° of varus or valgus from a neutral mechanical axis) with CAN.
- Surgical time increased by 10 to 20 minutes in all but 1 study. CAN-associated reduction in blood loss was less consistent, with only some of the studies showing a decrease in blood loss of 100 to 200 mL.
- RCTs that assessed function (up to 2 years of follow-up) did not find evidence of improved health outcomes. However, the studies were not adequately powered to detect functional differences, and data on long-term follow-up were not available.

Based on the deficiencies in the available evidence (eg, potential for bias in observational studies, lack of long-term follow-up in the RCTs), TEC reviewers concluded that it was not possible to determine whether the degree of improvement in alignment reported in the RCTs led to meaningful improvements in clinically relevant outcomes such as pain, function, or revision surgery.

A meta-analysis by Xie et al (2012) included 21 randomized trials (total N=2658 patients) that reported on clinical outcomes with or without the use of CAN. Most trials included in the review had short-term follow-up. As was found in the 2007 TEC Assessment, surgical time was significantly increased with CAN for TKA, but there was no significant difference between approaches in total operative blood loss, the Knee Society Score (KSS), or range of motion. Rebal et al (2014) conducted a meta-analysis of 20 RCTs (total N=1713 knees) that compared imageless navigation technology with conventional manual guides. Nine studies were considered to have a low risk of bias due to the blinding of patients or surgical personnel. Fifteen studies were considered to have a low risk of bias due to evaluator blinding. The improvement in KSS was statistically superior in the CAN group at 3 months (4 studies; 68.5 vs 58.1, p=0.03) and 12 to 32 months (5 studies; 53.1 vs 45.8, p<0.01). However, these improvements did not achieve the minimal clinically significant difference, defined as a change of 34.5 points.

More recent studies (2014, 2015) have also found longer surgical times and few differences in clinical outcome measures at 1-year follow-up.

Effect of CAN on Mid- to Long-Term Outcomes
Most studies comparing outcomes at mid- to long-term generally have shown a reduction in the number of outliers with CAN, but little to no functional difference between the CAN and conventional TKA groups.

Follow-up from 4 randomized trials was published between 2013 and 2016; they assessed mid-term functional outcomes following CAN for TKA. Blakeney et al (2014) reported on 46-month follow-up for 107 patients from a randomized trial of CAN vs conventional surgery. There was a trend toward higher scores on the Oxford Knee Questionnaire with CAN, with a mean score of 40.6 for the CAN group compared with 37.6 and 36.8 in extramedullary and intramedullary control groups. There were no significant differences in the 12-Item Short-Form Health Survey Physical Component or Mental Component Summary scores. The trial was underpowered, and the clinical significance of this trend for the Oxford Knee Questionnaire is unclear.

Lutzner et al (2013) reported on 5-year follow-up for 67 of 80 patients randomized to CAN or conventional TKA. There was a significant decrease in the number of outliers with CAN (3 vs 9, p=0.048), but no significant differences between groups on the KSS or EuroQoL questionnaire for quality of life. Cip et al (2014) found a significant decrease in malalignment with CAN, but no significant differences in implant survival or consistent differences clinical outcome measures between the navigated (n=100) and conventional (n=100) TKA groups at minimum 5-year follow-up. Song et al (2016) also reported on a reduction in the number of outliers with CAN (7.3% vs 20%, p=0.006), with no significant differences in clinical outcomes at 8-year follow-up. The trial, which assessed 80 patients (88 knees) was powered to detect a 3-point difference in KSS results.

Other comparative study designs have found no significant differences in clinical outcomes following CAN. In a comparative study by Kim et al (2009), which assessed 160 bilateral TKAs performed by experienced surgeons in Asia, differences in alignment measures between the conventionally prepared knee and the knee prepared with CAN assistance were minimal. In 2012, this group reported longer term follow-up (mean, 10.8 years) on 520 patients who underwent CAN for 1 knee and conventional TKA for the other knee (randomized). There were no significant differences between groups for knee function or pain measures. Kaplan-Meier survivorship at 10.8 years was 98.8% in the CAN knee and 99.2% for the conventional knee. Two additional nonrandomized comparative studies (2012, 2013) found an improvement in alignment with CAN, but no difference in clinical or functional outcomes at 5-year follow-up compared with conventional TKA.

Hoffart et al (2012) used an alternate allocation design with 195 patients to compare functional outcomes following CAN-assisted TKA with conventional instrumentation. An independent observer performed the pre- and postoperative assessments. After 5 years, complete clinical scores were only available for 121 (62%) patients. There was no significant difference in the frequency of malalignment between groups. The CAN group had a better mean KSS as well as mean function and knee scores. Mean pain scores did not differ between groups. Study limitations included the high loss to follow-up and lack of subject blinding.

Dyrhovden et al (2016) assessed survivorship and the relative risk of revision at 8-year follow-up for 23,684 cases from the Norwegian Arthroplasty Register for patients treated with CAN or conventional surgery. Overall prosthesis survival and risk of revision were similar for both groups, although revisions due to malalignment were reduced with CAN (relative risk, 0.5; 95% confidence interval, 0.3 to 0.9; p=0.02). There were no significant differences between groups for other reasons for revision (eg, aseptic loosening, instability, periprosthetic fracture, decreased range of motion). At 8 years, the survival rate was 94.8% (95% confidence interval, 93.8% to 95.8%) in the CAN group and 94.9% (95% confidence interval, 94.5% to 95.3%) for conventional surgery.

Section Summary: Total Knee Arthroplasty
A large number of RCTs have assessed outcomes for TKA using CAN or conventional TKA without CAN. Results are consistent in showing reductions in the proportion of outliers greater than 3° in alignment. Results up to 10 years postoperatively have not shown that these differences in alignment lead to improved patient outcomes.

SUMMARY OF EVIDENCE
For individuals who are undergoing orthopedic surgery for trauma or fracture, ligament reconstruction, hip arthroplasty and periacetabular osteotomy, or TKA who receive CAN, the evidence includes randomized controlled trials and nonrandomized comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Overall, the literature supports a decrease in the variability of alignment with CAN, particularly with respect to the number of outliers. Although some observational data have suggested that malalignment may increase the probability of early failure, recent randomized controlled trials with short- to mid-term follow-up have not shown improved clinical outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of the available studies to detect changes in function using CAN, studies are needed that assess health outcomes using CAN

in a larger number of subjects with longer follow-up to permit greater certainty on the impact of this technology. The evidence is insufficient to determine the effects of the procedure on health outcomes.

SUPPLEMENTAL INFORMATION

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 academic medical centers while this policy was under review in 2011. Input was mixed on whether computer-assisted navigation is considered investigational. One reviewer provided additional references on high tibial osteotomy and pelvic tumor resection.

PRACTICE GUIDELINES AND POSITION STATEMENTS
No guidelines or statements were identified.

U.S. PREVENTIVE SERVICES TASK FORCE **RECOMMENDATIONS**
Not applicable.

MEDICARE NATIONAL COVERAGE
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
One currently unpublished trial that might influence this review is listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01469299[a]	Prospective Study Measuring Clinical Outcomes of Knee Arthroplasty Using the VERASENSE™ Knee System	285	Dec 2016 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

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