Computer-Assisted Navigation for Orthopedic Surgery

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DESCRIPTION

Note: This medical policy addresses computer assisted navigation (CAN) for orthopedic procedures on the appendicular skeleton system. This policy does not address computer assisted navigation (CAN) when used for spinal or cranial procedures.

Additionally, robotic assistance is not discussed in this medical policy. Robotic assistance is considered integral to the primary procedure and is not separately reimbursed.

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 (knee and hip), and verification of intended implant placement.

The goal of computer-assisted navigation (CAN) is to increase surgical accuracy and reduce the chance of malposition. For total knee arthroplasty (TKA), malalignment is commonly defined as a variation of more than three degrees from the targeted position. Proper implant alignment is believed to be an important factor for minimizing long-term wear, risk of osteolysis, and loosening of the prosthesis. 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 reconstruction of the anterior cruciate ligament.

Computer-assisted navigation (CAN) may be image based or non-image based. Image based devices use preoperative computed tomography (CT) 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 (e.g., 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 medical and lateral epicondyles. The femoral head center is typically calculated by kinematic methods that involve movement of the thigh through a series of circular arcs, with the computer producing a three-dimensional (3D) 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 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.

Additionally, there are portable, handheld accelerometer-based navigation devices (e.g., HipAlign® or KneeAlign® OrthAlign Plus® by OrthAlign, Inc.) An accelerometer-based portable navigation system has been developed in the attempt to achieve the same precision of implant placement as with the large, conventional console navigation systems with the ease of use and enhanced convince.

Computer-assisted navigation (CAN) involves three steps: data acquisition, registration, and tracking.

- **Data Acquisition:** Data can be acquired in three different ways including fluoroscopic, computed tomographic (CT) or magnetic resonance imaging (MRI)-guided or guided by imageless systems. These data are then used for registration and tracking.
- **Registration:** Registration refers to the ability of relating images (i.e., radiographs, CT scan, MRI or an individuals’ 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 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 the tool alignment with respect to the bony anatomy of interest.

For many orthopedic surgical procedures, optimal alignment is considered an important aspect of long-term success. For example, misplaced tunnels in 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), 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. Intermediate outcomes include the number of procedures that achieve a predetermined level of acceptable alignment.

A kinetic balance sensor is an electronic wireless sensor used in knee replacement surgery to align and balance the knee. The single-use sensors are used during knee replacement surgery to record measurable data pertaining to the limb alignment, joint rotation, and soft tissue balance through a full range of motion. This computer-assisted technology can help the surgeon in determining intercompartmental loading during range of motion evaluation to help anticipate soft tissue abnormalities affected by joint position. Wirelessly recorded data assists the surgeon with optimal component placement to properly balance and position the knee. It is thought to help reduce the number of revisions performed due to instability and loosening of implant components.

Computer-Assisted Navigation for Trauma or Fracture

Clinical Context

The purpose of computer-assisted navigation (CAN) is to provide a treatment option that is an alternative to or an improvement of existing therapies, such as conventional/manual alignment methods, in individuals who are undergoing orthopedic surgery for trauma or facture.

Patients

The relevant population of interest are individuals who are undergoing orthopedic surgery for trauma or fracture.

Interventions
The therapy being considered is computer-assisted navigation (CAN). 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 bone for joint arthroplasty, and verification of intended implant placement.

Comparators
Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures, elastic bandaging, splints, and physical therapy.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

Timing
The existing literature evaluating CAN as a treatment for individuals who are undergoing orthopedic surgery for trauma or fracture has varying lengths of follow-up.

Setting
Individuals who are undergoing orthopedic surgery for trauma or fracture are actively managed by orthopedic surgeons in an outpatient or inpatient setting.

Computer-assisted navigation 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 (i.e., 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 navigation surgery may permit minimally invasive fixation and provide more versatile screw trajectories with less radiation exposure. Computer-assisted navigation 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 versus image guided using computer-assisted navigation. Based on review of the literature, there is limited literature on the use of computer-assisted navigation (CAN) for trauma or fractures. There is limited literature on the use of computer-assisted navigation for trauma or fractures. Additional controlled studies that measure health outcomes are needed to evaluate this technology for these indications.

Computer-Assisted Navigation (CAN) for Anterior or Posterior Cruciate Ligament Reconstruction (ACL or PCL)

Clinical Context
The purpose of computer-assisted navigation (CAN) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in individuals who are undergoing ligament reconstruction.

Patients
The relevant population of interest are individuals who are undergoing ligament reconstruction.

Interventions
The therapy being considered is computer-assisted navigation. 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 bone for joint arthroplasty, and verification of the intended implant placement.

Comparators
Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures, elastic bandaging, braces, and physical therapy.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

Timing
The existing literature on computer-assisted navigation as a treatment for individuals who are undergoing ligament reconstruction has varying lengths of follow-up.

Other studies performed prior to 2012 have found no significant improvement in the accuracy of tunnel placement when using computer-assisted navigation (CAN).

(2014) A cochrane review compared the effects of CAN with conventional operating techniques for anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) reconstruction. Five randomized controlled trials (RCTs; 366 participants) on ACL reconstruction were included in the updated review; no studies on 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 (IKDC) subjective scores and Lysholm Keen Questionnaire 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 computer-assisted navigation (CAN).

(2012) Meuffels et al. 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 tibial tunnel placement.

Section Summary: Computer-Assisted Navigation (CAN) for Anterior or Posterior Cruciate Ligament Reconstruction (ACL or PCL)
Based on review of the peer reviewed medical literature the evidence on computer-assisted navigation (CAN) for anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) reconstruction includes a systematic review of 5 RCTs. These RCTs, of moderate to low quality, did not consistently demonstrate 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.

Computer-Assisted Navigation for Total Knee Arthroplasty (TKA)

Clinical Context
The purpose of computer assisted navigation (CAN) is to provide a treatment option that is an alternative to or an improvement to existing therapies, such as conventional/manual alignment methods, in individuals who are undergoing total knee arthroplasty (TKA) for verification of the intended implant placement.

Patients
The relevant population of interest are individuals who are undergoing TKA.

Interventions
The therapy being considered is computer assisted navigation (CAN). CAN in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures to include total knee arthroplasty (TKA). 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.

Comparators
Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/manual alignment methods include medical reduction procedures, elastic bandaging, splints/braces, and physical therapy.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes.

Timing
The existing literature evaluating CAN as a treatment for individuals who are undergoing TKA has varying lengths of follow-up, ranging from one – twelve years.

Setting
Individuals who are undergoing TKA are actively managed by orthopedic surgeons in an outpatient and inpatient surgical setting.

(2019) Per a Hayes Health Technology Assessment, Image-Based Computer-Aided Navigation for Total Knee Arthroplasty:

- CT image-based CAN for use in TKA may confer some alignment advantages with unclear clinical benefit over CONV navigation; however, evidence indicates no advantage with CT-based CAN over imageless CAN on alignment and function outcome measures. Fl-CAN is addressed by an inadequate quantity of evidence to inform conclusions. Evidence on complications is insufficiently reported to enable critical interpretation of its quality; a minority of included studies reported safety outcomes and it is unclear from published accounts whether no events occurred or if they were not reported.
    - CAN with imaging is noted to have increased surgical time and cost No clear advantage of using or supplementing image-based CAN as the choice method of CAN in TKA
    - CAN was not planned for selective use but image-based CAN may be more adventitious than imageless-CAN in identified atypical sitatuions (i.e. severe bony deformities).

(2019) Hsu et al. Reported it remains unclear if computer-assisted surgery (CAS) technique actually improves the clinical outcomes of total knee arthroplasty (TKA) and decreases the failure rate. The purpose of this retrospective study was to compare the functional results of TKA in a series of patients who underwent staged bilateral TKAs with CAS TKA in 1 knee and conventional TKA in the contralateral knee. From January 1997 to December 2010, we collected 60 patients who were randomly assigned to receive CAS TKA in 1 limb and conventional TKA in the other. The Brainlab Vector Vision navigation system was used for CAS TKA, and the DePuy press-fit condylar sigma guide system was used for conventional TKA. Patients were assessed before surgery, 3 months and 1 year after surgery, and annually thereafter. IKS criteria were used for radiographic evaluation. Clinical and functional evaluation using the scoring system of hospital for special surgery (HSS), international knee society (IKS), Western Ontario and McMaster University osteoarthritis index (WOMAC), and short form-36 (SF-36) were obtained on each knee, before surgery, and at each follow-up visit. Pertinent statistical methods were adopted for data analysis. Fifty-six patients were available for analysis and 44 of the patients were female. The mean duration of follow-up was 8.1 years. Less blood loss ($P=.007$) and longer operation time were noted for CAS TKAs when compared with conventional TKAs. Precise alignment and fewer outliers of the lower limb and prosthetic component positions were found for CAS TKAs ($P<.001$). There were no differences between the 2 groups before surgery and at the latest follow-up with regard to scores for HSS, IKS, WOMAC, and SF-36 as well as active range of motion. The clinical outcomes of CAS TKAs at the 8-year follow-up were similar to those of conventional TKAs despite the better radiographic alignment and fewer outliers achieved with navigation assistance.

(2018) Sasaki et al. completed a comparison of coronal prosthetic alignment after total knee arthroplasty using three computer-assisted navigation systems and noted recent advances in surgical tools such as navigation systems have contributed to accurate implantation in total knee arthroplasty. Although several navigation systems have been developed, reports regarding which navigation system has better accuracy are few. Therefore, this study aimed to compare the accuracy of postoperative coronal alignment among 3 navigation systems. A total of 90 knee prostheses were implanted for 90 patients with osteoarthritis. Thirty patients were enrolled in each of the following 3 navigation groups: Stryker Navigation System II (computed tomography–free navigation; Stryker, Mahwah, New Jersey); OrthoPilot version 4.2 navigation system (computed tomography–free navigation; B. Braun Aesculap, Tuttlingen, Germany); and VectorVision navigation system (computed tomography–based navigation system; BrainLAB, Munich, Germany). Thirty consecutive total knee arthroplasties performed via the conventional method without navigation were selected as a control group for comparison with the navigation groups. Postoperative coronal mechanical axis and femoral and tibial coronal component angles were compared among the groups using long-leg standing radiographs for the rate of outliers beyond 3°. The authors noted no differences were observed in the mean femoral and tibial component angles among the navigation and conventional groups. However, the proportion of outliers beyond 3° was higher in the conventional group than in the 3 navigation groups. No significant differences in the outlying values were found among the 3 navigation groups. These 3 navigation systems achieved equally accurate coronal mechanical alignment with fewer outliers. The navigation systems exhibited more precise implantation than the conventional method. Limitations include a small sample size and further high quality studies with long term FU are warranted to comprehensively evaluate the value of knee arthroplasty using three computer-assisted navigation systems

(2016) Aoude et al. completed a cohort study and mentioned earlier for THA, the American College of Surgeons National Surgical Quality Improvement Program database was used to identify patients who underwent a primary, unilateral TKA with or without CAS technology from 2011 to 2013. Multivariate analysis was conducted to compare the postoperative complications in patients whose surgery involved the use of CAS with those using conventional techniques. The authors identified 103,855 patients who had THA and TKA in the database. The rate of reoperation was higher in the CAS group for TKA. The authors concluded the use of CAS in TKA reduced the number of minor AEs in the first 30 days postoperatively. However, CAS was associated with an increased number of reoperations and superficial infections. These findings are limited by the observational design of the study with possible bias and confounding by indication or other important unmeasured confounding factors.

A 2012 meta-analysis by Xie et al. included 21 randomized trials (total N=2658 patients) that reported clinical outcomes with or without the use of computer assisted navigation (CAN). Most studies included in the review had short-term follow-up. Surgical time was significantly increased with CAN for total knee arthroplasty (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 at 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 a longer surgical times and few differences in clinical outcome measures at 1-year follow-up.

Portable Accelerometer-Based Navigation System in Total Knee Arthroplasty
(2021) Gao et al completed a study aimed to determine whether the accelerometer-based navigation (ABN) could improve the accuracy of restoring mechanical axis (MA), component positioning, and clinical outcomes compared to conventional (CON) total knee arthroplasty (TKA). A total of 301 consecutive patients (ABN: 27, CON: 274) were included. A 1:4 propensity score matching (PSM) was performed between the two groups according to preoperative demographic and clinical parameters. The postoperative MA, femoral coronal angle (FCA), femoral sagittal angle (FSA), tibial coronal angle (TCA) and tibial sagittal angle (TSA) were compared. Absolute deviations of aforementioned angles were calculated as the absolute value of difference between the exact and ideal value and defined as norms if within 3°, otherwise regarded as outliers. Additional clinical parameters, including the Knee Society knee and function scores (KSKS and KSFS) and range of motion (ROM), were assessed at final follow-up (FU) (mean FU was 21.88 and 21.56 months respectively for ABN and CON group). A secondary subgroup analysis and comparison on clinical outcomes were conducted between norms and outliers in different radiological parameters. A total of 98 patients/102 knees were analyzed after the PSM (ABN: 21 patients/24 knees, CON: 77 patients/78 knees). In the ABN group, the mean MA, FCA and TSA were significantly improved (p = 0.019, 0.006, < 0.001, respectively). Proportions of TKAs within a ± 3°deviation were significantly improved in all the postoperative radiological variables except for TCA (p = 0.003, 0.021, 0.042, 0.013, respectively for MA, FCA, FSA, and TSA). The absolute deviations of FSA and TSA were also significantly lower in the ABN group (p = 0.020, 0.048, respectively). No significant differences were found in either mean value, absolute deviation or outlier ratio of TCA between two groups. On clinical outcomes, there were no significant differences between two groups, although KSKS, KSFS and ROM (p < 0.01, respectively) dramatically improved compared to baseline. The subgroup analysis also demonstrated no statistical difference on clinical outcomes between the outliers and norms in varied radiological parameters. The author’s concluded the ABN could improve the accuracy and precision of mechanical alignment and component positioning without significant improvement of clinical outcomes. Further high quality studies with long term FU are warranted to comprehensively evaluate the value of the ABN.

(2020) Minoda et al. reported an accelerometer-based portable navigation system was recently introduced to improve prosthetic alignment during total knee arthroplasty (TKA). The purpose of this multicenter prospective randomized controlled trial (RCT) was to evaluate the effects of this accelerometer-based portable navigation system for achieving more accurate alignment during TKA in the clinical setting. One hundred patients with primary varus osteoarthritis of the knee were enrolled in this prospective RCT conducted in 5 hospitals. A navigation system was utilized in 50 patients (navigation group), and a conventional intramedullary femoral guide and an extramedullary tibial guide were utilized in 50 patients (conventional group). At 6 months postoperatively, weight-bearing radiographs were obtained of the whole operative leg. An experienced surgeon who was blinded to the treatment assignments then measured the alignment to 1 decimal place with use of computer software. Power analysis showed that 41 knees were required in each group. There were no complications as a result of the use of the accelerometer-based portable navigation system. Postoperative radiographs were obtained in 45 patients from each group. There were no significant differences in sex, age, height, body weight, body mass index, preoperative femorotibial angle, and operative time between groups. The absolute differences of the femoral prosthesis ($p = 0.01$), tibial prosthesis ($p < 0.01$), and hip-knee-ankle angle ($p < 0.01$) from a neutral mechanical axis were less in the navigation group compared with those in the conventional group. Alignment outliers (>2° away from the neutral mechanical axis) of the tibial prosthesis and hip-knee-ankle angle were less in the navigation group (9% and 27%, respectively) compared with those in the conventional group (31% and 49%; $p = 0.01$ and $p = 0.04$, respectively). The authors concluded an accelerometer-based portable navigation system provides more accurate prosthetic and limb alignment in the coronal plane than conventional techniques, without extended operative time or an increased rate of complications. The results of this study may help orthopaedic surgeons decide whether or not to use an accelerometer-based portable navigation system. Limitations included a small sample size and follow up of 6 months timeframe.

(2019) Shigemura et al. noted precise implant alignment is a crucial prognostic factor in total knee arthroplasty (TKA). Portable navigation systems (PN-TKA) were reported to be better than the conventional technique (CON-TKA). We hypothesized that PN-TKA offered greater radiologic precision than CON-TKA in mechanically aligning components. We investigated whether (1) it improved global mechanical alignment, and (2) optimized component placement with respect to the tibial and femoral mechanical axes. A systematic literature review compared PN-TKA versus CON-TKA. PubMed, Web of Science and Cochrane Library search retrieved ten studies. Their data were pooled using RevMan 5.3. Odds ratios (OR) for dichotomous data were calculated with 95% confidence intervals (CIs) for each outcome. Statistical heterogeneity was assessed as I2 using a standard $\chi 2$ test. I2 > 50% denoted significant heterogeneity requiring a random effects model; otherwise, a fixed effects model was applied. There were significantly fewer outliers for mechanical axis (I2 = 24%, OR = 0.62, 95% CI = 0.42–0.91, $p = 0.02$) and coronal femoral component angle (I2 = 58%, OR = 0.31, 95% CI = 0.13–0.73, $p = 0.007$) using PN-TKA; however, no significant difference was observed for coronal tibial component angle outliers (I2 = 0%, OR = 0.66, 95% CI = 0.38–1.15, $p = 0.14$). The authors noted although PN-TKA appeared to improve global alignment, it had no effect on coronal tibial alignment, which is a key factor in predicting the long-term success of component fixation. There thus appeared to be no definite advantage of PN-TKA over CON-TKA.

Section Summary: Computer Assisted Navigation for Total Knee Arthroplasty (TKA)

Relatively few randomized controlled trials (RCTs) have evaluated computer-assisted navigation (CAN) for knee procedures. Although there was early interest in this technology, further studies are needed to validate study findings. There is inconsistent evidence from these small trials on whether CAN improves alignment with conventional or minimally invasive total knee arthroplasty (TKA). Overall, improved health outcomes have not been demonstrated with computer-assisted navigation (CAN) for any knee procedures.

Computer-Assisted Navigation for Total Hip Arthoplasty (THA) and Periacetabular Osteotomy

Clinical Context

The purpose of computer-assisted navigation (CAN) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual alignment methods, in individuals undergoing total hip arthroplasty (THA), periacetabular osteotomy or total hip resurfacing.

Patients

The relevant population of interest are individuals who are undergoing total hip arthroplasty (THA), periacetabular osteotomy or total hip resurfacing.

Interventions

The therapy being considered is computer-assisted navigation (CAN). 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 bone for joint arthroplasty, and verification of the intended implant placement.

Comparators

Comparators of interest include conventional/manual alignment methods. Treatment by means of conventional/alignment methods including medical reduction procedures, and physical therapy.

Outcomes

The general outcomes of interest are symptoms, morbid events, and functional outcomes.

Timing

The existing literature evaluating computer-assisted navigation (CAN) as a treatment for individuals who are undergoing total hip arthroplasty (THA), periacetabular osteotomy or total hip resurfacing has varying lengths of follow-up.

Setting
Individuals who are undergoing total hip arthroplasty (THA), periacetabular osteotomy or total hip resurfacing are actively managed by orthopedic surgeons in an outpatient and inpatient surgical setting.

(2011) A study by Manzotti et al. compared leg length restoration in a matched-pair study. Forty-eight patients undergoing total hip arthroplasty (THA) with computer assisted navigation (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.

(2007) Parratte and Argenson randomized patients to computer assisted navigation (CAN) (n=30) or freehand cup positioning (n=30) for total hip arthroplasty (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 computed tomography (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.

Minimally Invasive Total Hip Arthroplasty (THA)
It has been proposed that computer assisted navigation (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 total hip arthroplasty (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 total hip arthroplasty (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 post-surgery.

Periacetabular Osteotomy
(2006) In a trial by Hsieh et al., 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 computer assisted navigation (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 Replacement
(2013) Stiehler et al. reported on short-term radiographic and functional outcomes from a randomized comparative trial of total hip replacement (THR) using computer assisted navigation (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 degrees) 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.

Portable Accelerometer-Based Navigation System in Total Hip Arthroplasty
(2021) Asai et al. completed an in vitro study on the pelvic tilt reduces the accuracy of acetabular component placement when using a portable navigation system (PNS). PNS enables surgeons to place the acetabular component accurately. While the margin of the error for the cup abduction and anteversion was larger than the values obtained from a computed tomography-based navigation system. We hypothesized that the accuracy of the PNS might be affected by pelvic tilt. A bone substitute model of the pelvis was used in this in vitro study. We set the acetabular component using PNS. The acetabular component angle was set after changing the sagittal, coronal, and axial pelvic tilt. The difference was calculated between the angle displayed on the PNS display and the actual angle of the acetabular component. The difference in inclination angle was defined as ΔRI, and the difference in the anteversion angle was defined as ΔRA. We evaluated the trends in this ΔRI and ΔRA due to the pelvic tilt. In this in vitro study, the placement of the acetabular component was accurate in the neutral position; ΔRI was 0.5 ± 0.7° and ΔRA was 1.0 ± 0.7°. Sagittal pelvic tilt and axial pelvic tilt increased both the ΔRA and ΔRI (P = .017). Coronal tilt increased ΔRI but did not change ΔRA. The authors

concluded while the PNS may enable surgeons to place accurate component placement in the neutral position, its accuracy decreased by pelvic tilt. The surgeons should use a solid pelvic lateral positioner for reducing discrepancies in pelvic tilt when using the PNS in the lateral decubitus position. Additionally, the authors stated that this study had several drawbacks. First, they did not examine factors that affect the placement of the acetabular component, e.g., soft tissue, because they used a pelvic model. Second, the impaction energy needed to fit the acetabular component could deform the pelvic model and wooden board, which may have resulted in the variations. Third, these researchers only examined a single direction of pelvic tilt and did not evaluate the combination of axial, sagittal, and coronal pelvic tilt that could occur intra-operatively. Fourth, these investigators set the acetabular component in the left acetabulum only, which might have affected the results because both operators were right-handed. However, the result would be reversed regarding left and right tilt and rotation if these investigators set it in the right acetabulum. Finally, these researchers only examined combinations with the pelvis, and any correlation with spinal alignment was unknown.

(2021) Shigemura et al. completed a systemic review and meta analysis noting. Precise implant alignment is a crucial prognostic factor for successful outcomes following total hip arthroplasty (THA). A portable accelerometer-based navigation (PN) device may achieve the same accuracy as that achieved by the computer-assisted navigation surgery technique, with the convenience of a conventional technique. Although the usefulness of PN in THA (PN-THA) has been reported, whether it is more accurate than performing THA with a conventional technique (CON-THA) remains controversial. The difference in surgical time between PN-THA and CON-THA is also unclear. Therefore, we conducted a systematic review and meta-analysis of studies comparing results of PN-THA with those of CON-THA. We focused on the following question: is PN-THA superior to CON-THA in terms of radiological parameters and surgical time?

A literature search was conducted in PubMed, Web of Science, and Cochrane Library, to identify studies that met the following inclusion criteria: randomized controlled trials (RCT) or non-RCT, studies involving patients who underwent PN-THA and patients who underwent CON-THA, studies including data on radiological parameters and surgical outcomes. Author names, publication year, country, study design, surgical approach, demographic characteristics of the participants (diagnosis, gender, age, and body mass index), and surgical outcomes (the radiological parameters and the surgical time) were extracted. We calculated the mean differences (MDs) for continuous data with 95% confidence intervals (CIs) for each outcome. $p<0.05$ was considered significant. Three studies were included in this meta-analysis. The meta-analysis showed that absolute deviation of the postoperative measured angles from the target position for the cup anteversion was significantly smaller in PN-THA than in CON-THA (MD=-1.70, 95% CI=-2.91 to -0.50, [p=0.005]). There was no significant difference in the absolute deviation of the postoperative measured angles from the target position for cup abduction between the groups (MD=-1.82, 95% CI=-4.32-0.67, [p=0.15]). The surgical time was significantly longer in PN-THA than in CON-THA (MD=8.58, 95% CI=4.05-13.10, [p=0.0002]). The authors noted this systematic review and meta-analysis of studies comparing the results of PN-THA with those of CON-THA showed that the PN-THA is advantageous for precise cup implantation compared to CON-THA, although PN-THA has a longer surgical time compared to CON-THA. It should also be noted that all 3 studies discussed post-operative cup position but not clinical outcomes.

(2020) Hayashi et al. reported accurate orientation of acetabular and femoral components is important during THA. In recent years, several navigation systems have been developed. In a prospective, cohort study, these researchers examined the orientation accuracy of cups inserted using a disposable accelerometer-based portable navigation system for THAs. They analyzed 63 hips with navigation prospectively and 30 hips without navigation retrospectively as historical control. Subjects underwent THA via the mini anterolateral approach in the supine position using an accelerometer-based portable navigation system. These investigators compared the pre-operative target angles, intra-operative cup angles using navigation records, post-operative angles using post-operative CT data, measurement errors of cup angles, and clinical parameters such as sex, treated side, age at surgery, and BMI. The average absolute error (post-operative CT-navigation record) was 2.7 ± 2.1° (inclination) and 2.7 ± 1.8° (anteversion), and the absolute error (post-operative CT-pre-operative target angle) was 2.6 ± 1.9° (inclination) and 2.7 ± 2.2° (anteversion). The absolute error between post-operative CT and target angle with navigation was significantly lower than the error without navigation (inclination; $p = 0.025$, anteversion; $p = 0.005$). Cup malalignment (absolute difference of inclination or anteversion between post-operative CT and pre-operative target angle of over 5°) was significantly associated with BMI value (odds ratio [OR]: 1.3, 95 % CI: 1.1 to 1.7). The absolute measurement error of cup inclination and anteversion was significantly correlated with patients' BMI (inclination error: correlation coefficient = 0.53, $p < 0.001$, anteversion error: correlation coefficient = 0.58, $p < 0.001$). The authors concluded that the clinical accuracy of accelerometer-based portable navigation was precise for the orientation of cup placement, although accurate cup placement was affected by high BMI. This was the first study to report the accuracy of accelerometer-based portable navigation for THA in the supine position.

(2019) Kamenaga et al. examined the accuracy of cup orientation and learning curve of the disposable accelerometer-based portable navigation system for THA in the supine position. A total of 75 patients who underwent THA through the anterolateral supine approach (ALS) with an accelerometer-based portable navigation system for the supine position (HipAlign) between July 2017 and October 2018 were analyzed in this study. These researchers compared the intra-operative cup angles using navigation records with the post-operative angles using post-operative CT data. All participants were categorized into the following groups according to the course of 3 discrete, sequential operative time periods: 1 to 25 (initial group), 26 to 50 (intermediate group), and 51 to 75 (recent group). These investigators compared the accuracy of cup inclination and anteversion among the 3 groups. The time required for navigation and the operative time of all patients were measured. The average absolute error in measurement (post-operative CT-navigation record) was 2.6° ± 2.7° (inclination) and 2.8° ± 2.7° (anteversion). There were no significant differences among the 3 groups. The average time needed for navigation and the operative time were 365.1 ± 90.3 seconds and 76.1 ± 1.6 minutes, respectively. The required time for HipAlign navigation and operative time were constant in most patients, except for those of the initial 5 cases. The authors concluded that the accelerometer-based portable navigation system provided good accuracy of cup orientation, had a short learning curve, and required a minimal surgical time for THA in supine position. These researchers stated that the main drawback of this study was the absence of a control group that used other navigation systems; thus, they should compare the accuracy of cup orientation and learning curve of single surgeon between the accelerometer-based portable navigation and other navigation in the future trials.

Section Summary: Computer-Assisted Navigation for Total Hip Arthoplasty (THA), Periacetabular Osteotomy
Relatively few randomized controlled trials (RCTs) have evaluated computer-assisted navigation (CAN) for hip procedures. Although there was early interest in this technology, further studies are needed to validate study findings. There is inconsistent evidence from these small trials on whether CAN improves alignment with conventional or minimally invasive total hip arthroplasty (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 computer-assisted navigation (CAN) for any hip procedures.

Effect of Computer-Assisted Navigation (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 computer assisted navigation (CAN), but little to no functional difference between the CAN and conventional TKA groups.

(2020) Antonios et al. completed a population-based survivorship study of computer-navigated versus conventional total knee arthroplasty. The goal of computer navigation in total knee arthroplasty (TKA) is to improve the accuracy of alignment. However, the relationship between this technology and implant longevity has not been established. The purpose of this study was to analyze survivorship of computer-navigated TKAs compared with traditionally instrumented TKAs. The PearlDiver Medicare database was used to identify patients who underwent a primary TKA using conventional instrumentation versus computer navigation between 2005 and 2014. Conventional and computer-navigated cohorts were matched by age, sex, year of procedure, comorbidities, and geographic region. Kaplan-Meier curves were generated to estimate survivorship with aseptic mechanical complications, periprosthetic joint infection, and all-cause revision as end points. During the study period, 75,709 patients who underwent a computer-navigated TKA were identified and matched to a cohort of 75,676 conventional TKA patients from a cohort of 1,607,803 conventional TKA patients. No difference existed in survival between conventional instrumentation (94.7%) and navigated TKAs (95.1%, P = 0.06) at 5 years. A modest decrease was found in revisions secondary to mechanical complications associated with navigation (96.1%) compared with conventional instrumentation (95.7%, P = 0.02) at 5 years. No differences in revision rates because of periprosthetic joint infection were observed (97.9% versus 97.9% event-free survival, P =

0.30). In a subgroup of Medicare patients younger than 65 years of age, use of computer navigation was associated with a decrease in all-cause revision (91.4% versus 89.6% event free survival, P = 0.01) and revision secondary to mechanical complications (89.6% versus 87.8% event-free survival, P = 0.01) at 5 years. The authors concluded among the Medicare patients no notable difference existed in TKA survival associated with the use of computer navigation at the 5-year follow-up. Use of computer navigation was associated with a slight decrease in revisions secondary to mechanical failure. Although improved survivorship was associated with patients younger than 65 years of age who had a navigated TKA, generalizability of these findings is limited given the unique characteristics of this Medicare subpopulation.

(2018) Cip et al. in a prospective randomized comparative trial reported on twelve- year follow-up of navigated computer assisted versus conventional total knee arthroplasty. One hundred conventional TKAs (group CONV) were compared with 100 computer-assisted TKAs (group NAV) after a mean follow-up of 12 years postoperatively. A long-leg weight-bearing X-ray was performed for measuring mechanical axis of the limb, lateral distal femoral angle, and medial proximal tibial angle. Tibial slope, patella alpha angle, and radiolucent lines were also observed. Clinical investigation included evaluation of 4 different scores: Insall Knee Score, Western Ontario and MacMaster University Index score, Hospital for Special Surgery Knee Score, and visual analog scale. Based on a follow-up rate of at least 75%, no difference in TKA survival was found 12 years postoperatively: 91.5% in group CONV vs 98.2% in group NAV (P = .181). Since 5-year follow-up, no additional TKA revision had been performed in both groups. Group CONV showed a nonsignificant higher inaccuracy of neutral lower limb axis (1.8° ± 1.4°) compared to group NAV (1.6° ± 1.7°, P = .700). All X-ray assessments were not significant different within both study groups (P ≥ .068). Clinical examination showed no differences in evaluations (P ≥ .204). All collected outcome score results were similar (P ≥ .222). The authors concluded, Twelve- years postoperatively, no differences were found in terms of long-term survival, implantation accuracy, clinical outcome, or score results.

(2016) Beal et al. reported while the clinical benefits of computer-aided surgery or PSI may not be actualized as it was intended, surgeons should not be wary of new technologies. It is with the adoption and subsequent critical evaluation of technology that innovation can occur. Despite equivocal success in the average patient, both navigation and PSI have shown to be of benefit in extra-articular deformity cases, or in cases in which conventional techniques cannot be applied, such as a patient with intramedullary implants already in place. Thienpont et al. reported restored limb alignment and improved functional scores in patients without access to the intramedullary canal who underwent TKA with PSI (Knee, 2013). Several others have similarly reported success using navigation in cases where deformity or prior hardware limited traditional instrumentation. Extra-clinical benefits, moreover, may not have yet been well defined for these technologies. The preoperative imaging of PSI, for example, can provide a wealth of anthropometric data for research purposes, in particular the rotational alignment of the distal femur. Navigation similarly opens the door to an array of research, teaching, and surgical documentation opportunities. While navigation and customized implants have found recent interest in the knee arthroplasty marketplace, in a broad sense and in their current forms, these technologies have yet to reach their full potential in improving outcomes and patient experience.

(2016) Dyrhovden et al. compared survivorship and the relative risk of revision at 8-year follow-up for 23,684 cases from the Norwegian Arthroplasty Register. Overall prosthesis survival and risk of revision were similar for the 2 groups, although revisions due to malalignment were reduced with computer assisted navigation (CAN) (RR=0.5; 95% CI, 0.3 to 0.9; p=0.02). There were no significant differences between the groups for other reasons for revision (e.g., aseptic loosening, instability, peri-prosthetic fracture, decreased range of motion). At 8 years, the survival rate was 94.8% (95% CI, 93.8% to 95.8%) in the CAN group and 94.9% (95% CI, 94.5% to 95.3%) for conventional surgery.

Follow-up from 4 randomized trials were published between 2013 and 2016; they assessed mid-term functional outcomes following computer assisted navigation (CAN) for total knee arthroplasty (TKA). Blakeney et. al. (2014) reported 46-month follow-up for 107 patients from a randomized trial of CAN versus 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.

Section Summary
Based on review of the peer reviewed medical literature a large number of RCTs have compared outcomes between total knee arthroplasty (TKA) with computer-assisted navigation (CAN) and conventional TKA without CAN. Results are consistent in showing a reduction in the proportion of outliers greater than 3 degrees in alignment. Results up to 12-years postoperatively have not shown that these differences in alignment lead to improved patient outcomes.

Kinetic Balance Sensor in Total Knee Arthroplasty (TKA)
A systematic review examined the Verasense (OrthoSensor, Inc.) for use during total knee arthroplasty (TKA). The literature search identified 3 eligible studies (n=54 to 158 patients) that evaluated the effect of Verasense-assisted-TKA (VSA-TKA) on clinical outcomes. Overall, a very-low-quality body of evidence did not allow for definitive conclusions to be drawn regarding the efficacy, comparative effectiveness, or safety of VSA-TKA. The authors concluded there was no evidence to support the use of Verasense over other soft-tissue balancing procedures, such as manual balancing. All eligible studies reviewed i evaluated the use of the sensor-embedded device after conventional manual alignment; therefore, no conclusion can be drawn regarding the efficacy of VSA-TKA.

(2019) MacDessi et al. in a randomized controlled trial (RCT) compared patients undergoing total knee arthroplasty assigned to kinematic alignment (KA) versus mechanical alignment (MA) to determine whether KA protocols resulted in better quantitative knee balance. According to the authors, the results of this study provide persuasive evidence that restoration of the patient's constitutional alignment within a restrictive kinematic safe zone significantly improved knee balance, reduced knee balancing procedures, and may more closely restore native soft-tissue tension when compared with MA. Despite these findings, the study failed to show group difference in functional patient-centered outcomes. Further high-quality randomized trials with long-term follow-up to evaluate efficacy, safety, and subsequent revision risk are needed to confirm the validity and efficacy of this approach, as well as its clinical significance on relevant outcomes.

(2018) Cho et al. reported on the objective quantification of ligament balancing using Verasense-assisted-TKA (VSA-TKA) in measured resection and modified gap balance total knee arthroplasty (TKA). They observed significant decrease in both medial and lateral compartments pressure after TKA in a case series of 84 patients who underwent TKA using the orthosensor. Using the orthosensor, patients could obtain 94% quantified balanced knee, consequently. Between the techniques, measured resection TKA showed less balanced knee in the initial pressure measurement and also required more additional procedures compared to modified gap balancing TKA. The authors suggested that regardless of TKA surgical methods, additional procedures could be needed for adequate "patient-specific" ligament balancing. Furthermore, with the consistent data of the orthosensor acquired during appropriate ligament balancing, a surgeon could eventually reduce the complications associated with soft tissue imbalance in the future. However, findings are limited by lack of comparison group, lack of functional outcomes, and short follow-up.

(2017) Gustke et al. reported on a multicenter case series examining the intraoperative data of 129 patients receiving sensor assisted total knee arthroplasty (TKA). The study found that loading across the joint decreased, overall and became more symmetrical after releases were performed. On average, between 2 and 3 corrections were made (up to 8) in order to achieve ligament balance. The authors concluded that objective data from sensor output may assist surgeons in decreasing loading variability and, thereby, decreasing ligament imbalance and its associated complications. One or more authors on this study reported a potential conflict of interest with this work. Additionally, the findings are limited by lack of comparison group and limited duration of follow-up.

Section Summary

Based on review of the peer reviewed medical literature the use of intra-operative kinetic balance sensor for implant stability during total knee arthroplasty (TKA) is unproven and further evidence with high-quality randomized controlled trials (RCTs) are needed to determine the safety, efficacy, and impact on clinical outcomes. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Summary of Evidence
For individuals who are undergoing orthopedic surgery for trauma or fracture, ligament reconstruction, total hip arthroplasty (THA) and periacetabular osteotomy, or total knee arthroplasty (TKA) who receive computer-assisted navigation (CAN), the evidence includes systematic reviews, randomized controlled trials (RCTs) and nonrandomized comparative studies. Overall, the literature supports a decrease in 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 RCTs with 12 years of follow-up have not shown improved clinical outcomes with computer-assisted navigation (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, further 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 this technology on net health outcomes.

Also, no studies have been identified that directly compared any surgical navigation systems to each other. Therefore, no clinical evidence is available to determine whether any system works better than another system. In 2016, the American Academy of Orthopaedic Surgeons (AAOS) issued a guideline on surgical management of osteoarthritis of the knee that included the following regarding surgical navigation; "Strong evidence supports not using intraoperative navigation in total knee arthroplasty (TKA) because there is no difference in outcomes or complications. The work group recognizes that there are scenarios where computer navigation theoretically could be considered, such as malunions, intramedullary implants, or in training scenarios, but the evidence is insufficient to make a recommendation."

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons (AAOS)
(2016) The American Academy of Orthopaedic Surgeons (AAOS) current guideline for surgical management of osteoarthritis of the knee states the following regarding the use of intraoperative navigation: "strong evidence supports not using intraoperative navigation in total knee arthroplasty (TKA) because there is no difference in outcomes or complications." (*Accessed June 2022*)

Regulatory Status
Because computer-assisted navigation (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) clearance from 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 received FDA clearance through the 510(k) process with broad labeled indications. The following is an example;

- "The OEC FluoroTrak 9800 Plus provides the physician with fluoroscopic imaging during diagnostic, surgical and interventional procedures. The surgical navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images."

Computer-Assisted Navigation Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
CTC TCAT (R) – TPLAN (R) Surgical System	Curexo Technology Corporation	2014	K140585	Computer-assisted navigation for orthopedic surgery
DigiMatch ROBODOC Surgical System	CUREXO Technology Corporation	2014	K140038	Computer-assisted navigation for orthopedic surgery
ExactechGPS	Blue Ortho	2016	K152764	Computer-assisted navigation for orthopedic surgery
HipAlign	OrthAlign, Inc.			Portable Accelerometer-Based Navigation System for total hip arthroplasty.
iASSIST Knee System	Zimmer Biomet	2014	K141601	Computer-assisted navigation for orthopedic surgery. It is an accelerometer-based alignment system with a user interface built into disposable electronic pods that attach onto the femoral tibial alignment and resection guides. For the tibia, the alignment guide is fixed between the tibial spines and 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.
HipAlign®	OrthAlign, Inc.			Based Navigation System for, total hip arthroplasty.
Intellijoint® Navigation System	Intellijoint Surgical Inc.	2019	K191507	Computer-assisted navigation for orthopedic surgery
JointPoint	JointPoint Inc.	2016	K160284	Computer-assisted navigation for orthopedic surgery
KneeAlign / KneeAlign 2 System	OrthAlign, Inc.	2017	K13038	Portable Accelerometer-Based Navigation System for total knee arthroplasty, total hip arthroplasty: Anterior/posterior and unicompartmental knee arthroplasty: Tibial transverse resection
Navitrack® Navigation System				It has received FDA clearance specifically for TKA. 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 (e.g., 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."
NuVasive Next Generation NVM5 System	NuVasive Incorporated	2017	K162313	Computer-assisted navigation for orthopedic surgery
NuVasive Pulse System	NuVasive Incorporated	2019	K180038	Computer-assisted navigation for orthopedic surgery
OrthAlign Plus®	OrthAlign, Inc.	2020	K200642	Portable Accelerometer-Based Navigation System for total knee arthroplasty, total hip arthroplasty: Anterior/posterior and unicompartmental knee arthroplasty: Tibial transverse resection.
OrthoMap Versatile Hip System	Stryker Corporation	2017	K162937	Computer-assisted navigation for orthopedic surgery
OrthoPilot® Navigation System				It has received FDA clearance specifically for TKA. 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 (e.g., 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.”
ORTHOsoft				It has received FDA clearance specifically for TKA. 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 (e.g., 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.”
PiGalileo™ Computer-Assisted Orthopedic Surgery System				It has received FDA clearance specifically for TKA. 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 (e.g., 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.”
PLUS Orthopedics				It has received FDA clearance specifically for TKA. 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 (e.g., 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.”
Stryker Navigation System with Spinemap Go Software Application, Fluoroscopy Trackers and Fluoroscopy Adapters Spinemask Tracker	Stryker Corporation	2019	K183196	Computer-assisted navigation for orthopedic surgery
VERASENSE Knee System	OrthoSensor Inc.	2016	K150372	Computer-assisted navigation for orthopedic surgery as it is a single use device that replaces that standard plastic tibial trial spacer used in TKA. It 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 the graphic user interface that depicts the load. The device is intended to provide quantitative data on the alignment of the implant and on soft tissue balancing in place of intraoperative "feel."
VERASENSE for Zimmer Biomet Persona	OrthoSensor Inc.	2018	K180459	Computer-assisted navigation for orthopedic surgery
Vital Navigation System	Zimmer Biomet Spine, Inc	2019	K191722	Computer-assisted navigation for orthopedic surgery

PRIOR APPROVAL

Not applicable.

POLICY

Note: This medical policy addresses computer assisted navigation (CAN) for orthopedic procedures on the appendicular skeleton system. This policy does not address computer assisted navigation (CAN) when used for spinal or cranial procedures.

Additionally, robotic assistance is not discussed in this medical policy. Robotic assistance is considered integral to the primary procedure and is not separately reimbursed.

Orthopedic Procedure(s)
Computer-assisted musculoskeletal surgical navigation (CAN) as an adjunct for orthopedic procedure(s) of the appendicular skeleton is considered **investigational.** There is insufficient evidence to support a conclusion concerning the effects of this technology on net health outcomes.

Intra-Operative Kinetic Balance Sensor
The use of intra-operative kinetic balance sensor including but not limited to the Verasence Knee System and iASSIST Knee System for implant stability during total knee replacement is considered **investigational,** because there is insufficient evidence to support a conclusion concerning the effects of this technology on net health outcomes.

Policy Guidelines

Definitions

- **Appendicular skeleton system**: includes the bones of the shoulder girdle, the upper limbs, pelvic girdle, and the lower limbs.
- **Musculoskeletal system**: provides form, support, stability, and movement to the body. It is made up of the bones of the skeleton, muscles, cartilage, tendons, ligaments, joints, and other connective tissue that supports and binds tissues and organs together.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 20985 Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure)
- 27599 Unlisted procedure femur or knee (*may be utilized for the Verasence Knee System or iASSIST Knee System*)
- 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/MRI images (List separately in addition to code for primary procedure)

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POLICY HISTORY

Date	Reason	Action
July 2022	Annual Review	Policy Renewed
July 2021	Annual Review	Policy Revision
July 2020	Annual Review	Policy Renewed
July 2019	Annual Review	Policy Renewed
July 2018	Annual Review	Policy Revised
July 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
August 2015	Annual Review	Policy Renewed
September 2014	Annual Review	Policy Renewed
October 2013	Annual Review	Policy Renewed
December 2012	Annual Review	Policy Renewed
December 2011	Annual Review	Policy Renewed
December 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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