

Computer-Assisted Surgical Navigation for Musculoskeletal Procedures (for New Mexico Only)

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[Instructions for Use](#)

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Related Policies
• Robotic Assisted Surgery Policy, Professional
• Surgery of the Hip (for New Mexico Only)
• Surgery of the Knee (for New Mexico Only)
• Surgery of the Shoulder (for New Mexico Only)

Application

This Medical Policy only applies to the state of New Mexico.

Coverage Rationale

Computer-assisted surgical navigation for musculoskeletal procedures of the pelvis and appendicular skeleton is unproven and not medically necessary due to insufficient evidence of efficacy.

The use of an intra-operative sensor for implant stability during knee replacement arthroplasty and for improved knee function post-operatively is unproven and not medically necessary due to insufficient evidence of efficacy.

Definitions

Refer to the federal, state, or contractual definitions that supersede the definitions below.

Appendicular Skeleton System: Includes the bones of the shoulder girdle, the upper limbs, pelvic girdle, and the lower limbs (Anderson et al., 2022).

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 (NIH, 2023).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarifications:

- Intra-operative use of a sensor for implant stability during knee replacement arthroplasty is considered incidental to the primary procedure being performed and is not eligible for separate reimbursement.
- The codes addressed within this policy are intended for navigational procedures for pelvic and appendicular musculoskeletal procedures; for cranial and spinal procedures, refer to CPT code 61781, 61782, or 61783.

CPT Code	Description
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)
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 (e.g., sensor)

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Description of Services

Computer-assisted navigation (CAN) also known as computer-assisted surgery (CAS) in musculoskeletal 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 CAN in musculoskeletal procedures is to increase surgical accuracy and reduce the chance of malposition.

CAN may be image-based or non-image-based. Image-based devices use preoperative computed tomography (CT) magnetic resonance imaging (MRI) scans, ultrasounds, or operative fluoroscopy to direct implant positioning. Newer non-image-based devices are characterized by the fact that it does not require preoperative and postoperative images for planning and guiding surgery. Instead for these procedures, joint kinetic information and bone morphology information are used for planning and to devise guiding maps. For orthopedics, these systems were originally developed for total knee arthroplasty (TKA) and total hip arthroplasty (THA) applications. (Kubicek, et al., 2019).

CAN involves three steps described below:

- **Data Acquisition:** Data can be acquired via fluoroscopic, CT, or magnetic resonance imaging (MRI)-guided, or imageless systems. This data is then used for registration and tracking.
- **Registration:** Registration refers to the ability of relating data (i.e., x-rays, CT, MRI, or patient's 3-D anatomy) to the anatomical position in the surgical field. Registration techniques may require the placement of pins or "fiducial 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 can then provide real time information of the position and orientation of the tools' alignment with respect to the bony anatomy of interest (Swank and Lehnert, 2005).

A sensor is an electronic device that measures physical properties such as temperature, pressure, distance, speed, torque, acceleration, force, flow, etc., and sends the information to an electronic processor. Smart sensor assisted can be used intraoperatively to provide objective assessment of ligament and soft tissue balancing whilst maintaining the sagittal and coronal alignment to achieve desired kinematic targets following total knee arthroplasty. It can also provide post-implantation data to monitor implant performance in natural conditions and patient's clinical recovery during rehabilitation. The ability of the sensors to measure multifarious data on patient's biological activities allows sensor technology to be used in the management of patient care (Iyengar et al., 2021).

Clinical Evidence

Hip/Pelvis

The evidence on the relative benefits of CAN with conventional or minimally invasive THA is inconsistent; quality randomized controlled trials (RCTs), and evidence for benefit of the technology on patient-centered outcome are lacking. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Zhou et al. (2024) conducted a multicenter RCT to evaluate the efficacy and safety of a novel surgical navigation system [visual treatment solution (VTS)] in acetabular prosthesis placement during total hip arthroplasty. Participants (n = 124) from three centers were randomly divided into an experimental group (VTS-assisted THA) and a control group (traditional surgical THA). After several subjects withdrew from both groups; 113 participants were included in the analysis (58 patients in the experimental group and 55 patients in the control group). The primary outcome measure was the proportion of the anteversion and inclination angles in the Lewinnek safe zone. The secondary evaluation indicators included the following: operation time, Western Ontario and McMaster University Osteoarthritis index (WOMAC) score, Harris score, and short-form-36 (SF-36) score three months after surgery; hip dislocation rate and safety. The results demonstrated the proportion of both anteversion and inclination angles in the safe zone was 93.1% in the experimental group and 50.9% in the control group; the difference was significant ($p < 0.01$). The average operation time was 112.5 min in the experimental group and 92.6 min in the control group; the difference was significant ($p < 0.01$). There were no significant differences in WOMAC score, Harris score, or SF-36 score between the experimental and control groups at 3 months after the operation ($p > 0.05$). The dislocation rate was 0% in the experimental group and 1.6% in the control group; the difference was not significant ($p > 0.05$). The authors concluded VTS-assisted THA can significantly improve the accuracy of acetabular prosthesis placement indicating good safety for this navigation system. However, there were no differences in short-term outcomes or dislocation rates between the two groups. The authors noted there is still debate on whether CAS can lead to better clinical outcomes. Limitations of the study include short term follow-up, controversial safety- margins, lack of different safety zones and the exclusion of spinal-pelvic parameters.

In 2022 ECRI provided a report assessing evidence for the HipAlign, a portable accelerometer-based navigation system intended to provide stereotaxic guidance in THA procedures. Another marketed version of this device is OrthoAlign Plus system. The focus of this report was on the HipAlign's safety and effectiveness, with comparison of HipAlign to conventional freehand THA techniques, and other THA guided alignment devices. The assessment analyzed one systematic review which included only three small studies, one of which was a randomized controlled trial along with four nonrandomized comparison studies. Although the evidence suggests the HipAlign aids cup alignment during THA, ECRI found the studies were inconclusive providing very low-quality evidence and reporting on surrogate outcomes which could not determine improvement of patient-oriented outcomes compared to conventional THA techniques or other alignment devices.

Kunze et al. (2022) conducted a meta-analysis and systematic review of randomized controlled trials (RCTs) to determine whether differences in surgical times, adverse events (AEs) and implant positioning existed between manual, robotic-assisted, and computer navigation THA at a minimum of one year follow-up. A total of 12 RCTs that included 1,139 patients were analyzed in this study. Seven RCTs compared computer navigation and manual THA and five compared robotic-assisted THA with manual THA. Manual THA was associated with significantly less surgical time in comparison to CAN (mean difference: 23.3 minutes) with no difference in all cause complications (CAN: 1.7%, manual: 6.6%, and robotic-assisted; 16.2%) or revisions (CAN: 1.0%, manual: 1.7%, and robotic-assisted: 4.8%). In three studies positioning of acetabular implant with CAN had significantly higher percentage of safe placement (79% versus 52% $p = 0.02$). Even though CAN increased precision placement of the acetabular implant, the study concluded manual THA results in significantly shorter surgical times and a similar incidence of complications and revisions compared with robotic-assisted and computer-assisted THA.

Lass et al. (2020) conducted a two-year follow-up prospective randomized study (Lass et al. 2014 discussed below) to compare computer-assisted to manual implantation techniques in THA. The study analyzed if computer-assisted surgery can improve the clinical and functional results and reduce dislocation rate shortly after THA. Although a significant difference was found in mean postoperative acetabular component anteversion and in outliers regarding inclination and anteversion ($p < 0.05$) between CAN and the manual placed group, no significant difference regarding clinical outcome or revision rates at short-term or 2-year follow-up were found. Therefore, further long-term follow-up of patient groups is needed.

In a 2019 clinical evidence assessment product brief, ECRI reported their findings regarding the Intellijoint® Hip surgical navigation system. In summary, there is no comparative data available to determine how well the Intellijoint Hip system works to reduce complications and risk of revision surgery compared to conventional freehand techniques, or how it compares with other navigation systems. There were only two small single-arm studies available, and both were at high risk of bias. High quality randomized controlled trials are needed, and none were identified.

Snijders et al. (2017) conducted a systematic review and meta-analysis to assess the precision (variance) and accuracy (deviation from the target) from all available high-quality randomized control trials to date on imageless navigation (NAV) versus freehand implantation of THA. The aim of this study has been to compare the precision and accuracy of the anteversion and inclination of the acetabular cup position after NAV implantation and after freehand implantation of THA. Six out of seven studies concluded a statistically significant difference in precision in anteversion between the NAV group

and the freehand group. Five out of seven studies concluded a statistically significant difference in precision in inclination. There is a significantly better accuracy for the NAV group than for the freehand group for anteversion ($p = 0.002$) and for inclination ($p = 0.01$). The authors concluded that this study showed that NAV placement is more precise and has an improved accuracy for anteversion and inclination than freehand placement of the acetabular cup. However, there is a lack of evidence to support an improved functional outcome and a reduction of complications and revisions.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS Clinical Practice Guidelines for surgical management of osteoarthritis (OA) of the hip states high-quality evidence supports that there are no specific risks and benefits to each surgical approach and that there is not a preferred surgical approach for patients with symptomatic OA of the hip undergoing THA (2022, updated 2024).

Knee

The evidence suggests that the main difference found between TKA with and without CAN is increased surgical time with CAN. Few differences in clinical and functional outcomes were seen at up to 12 years post procedure. The evidence is inconclusive to determine the effects of the technology on overall health outcomes.

Kim et al. (2024) conducted a systematic review and meta-analysis aimed to investigate the clinical and radiological outcomes following primary TKA using CAN surgery in patients with extra-articular deformity (EAD). The authors searched Medline, Embase, and the Cochrane Library for studies investigating surgical outcomes of using the navigation system for TKA to treat patients with EAD. From 14 studies, 539 knees with EAD that underwent navigation TKA were enrolled. Knee ROM, outcome scores at final follow-up [Knee Society Score (KSS) and Knee Functional Score (KFS)], and pre- and postoperative mechanical hip-knee-ankle (mHKA) angle using lower extremity scanogram was investigated. The meta-analysis was based on the single-arm method, and all data were pooled using a random-effects model. Following meta-analyses, the mean knee ROM changed from 87.0° [95% confidence interval (CI), 75.9° - 98.1°] preoperatively to 109.4° (95% CI, 97.9° - 120.8°) postoperatively. The adjusted KSS was 93.45 points (95% CI, 88.36-98.54 points), and the adjusted KFS was 91.57 points (95% CI, 86.80-96.33 points) in knees with EAD that underwent CAS-TKA. As a radiological outcome, the mHKA angle changed from 169.53° (95% CI, 166.90° - 172.16°) preoperatively to 178.81° (95% CI, 178.31° - 179.30°) postoperatively. The authors concluded that CAS-TKA yielded positive clinical results and demonstrated satisfactory alignment of the lower limb's mechanical axis. CAS-TKA showed promise for primary TKA procedures, demonstrating favorable clinical and radiological outcomes even in complex cases involving EAD. This study has some limitations. First, the meta-analysis on clinical and radiological outcomes was only performed for participants who underwent primary TKA using CAS. Only three comparative studies were found, which were not enough for pair-wise meta-analysis. The second limitation is that most of the studies included were conducted in Asia, which could introduce regional bias. Third, RCTs could not be included due to the lack of level I studies. In the future, further investigations from multiple, prospective RCTs are needed.

Sheridan et al. (2023) conducted a systematic review and meta-analysis to compare radiographic, clinical and functional outcomes between conventional TKA (C-TKA) and navigated computer-assisted methods (N-TKA). Seventeen eligible prospective RCTs were included in the meta-analysis. There was a cumulative total of 2201 TKAs (1063 in the conventional group and 1138 in the navigated group) included in the data extraction. Radiographic outcomes included postoperative coronal, sagittal and axial component alignment. Clinical outcomes included all-cause revision and aseptic revision. Functional outcomes were analyzed when reported. The results demonstrated there was no difference in short-term clinical survivorship (all-cause, $p = 0.649$; aseptic, $p = 0.79$) or in functional outcomes reported between the N-TKA and C-TKA groups. There was a clinically significant reduction in the mean operative time in the conventional group relative to the navigated group. The mean conventional operative time was 87 min ($\sigma = 16.6$, 95% CI 76.4–98.8) compared to 97.6 min ($\sigma = 16.9$, 95% CI 86.2–109.1) in the navigated group ($p = 0.17$). Radiological outcomes showed normal coronal mechanical alignment of the tibial ($p < 0.001$) and femoral ($p = 0.001$) components were achieved more frequently with N-TKA. Normal sagittal mechanical alignment of the tibial component was achieved significantly more with N-TKA ($p < 0.010$). The authors concluded although navigated TKA achieves superior radiographic alignment, operative times are longer and functional outcomes are similar. Future prospective studies are required due to limited short-term follow-up on clinical outcomes.

In 2021 ECRI provided a report assessing evidence for the KneeAlign a palm-sized CAN system intended to aid in calculating cutting block alignment relative to the mechanical axis for distal femur and proximal tibia resection cuts during knee arthroplasty. This report compared the clinical outcomes using KneeAlign with outcomes of conventional knee arthroplasty and other navigation techniques. Although the evidence suggests using KneeAlign improves implant alignment compared with conventional TKA, the studies were inconclusive with too few data on outcomes of interest and

did not demonstrate whether KneeAlign improves knee function and patient-oriented outcomes compared with traditional methods for implant alignment or other navigation techniques.

Lee et al. (2020) conducted a meta-analysis to compare mid-to long-term clinical outcomes (such as knee scoring and functional results) and radiological outcomes (such as normal alignment of the limb axis or component) between computer navigated TKA and conventional TKA. The study analyzed seven randomized controlled trials where no significant difference was found in radiologic outcomes and clinical outcomes in the two techniques. It remains unclear which TKA technique yields better results in terms of mid-to long-term clinical and radiological outcomes.

Matar et. al (2020) conducted a systematic review and meta-analysis of 403 randomized controlled trials with a total of 47,675 patients in TKA summarizing the available high-quality evidence of healthcare interventions. The studies were classified according to intervention groups; surgical approach, tourniquet use, minimally invasive, patient specific instrumentation, knee design, fixation, mobile bearing, navigation, polyethylene, technique, patella resurfacing, drain, closure and other. The largest subgroup intervention was navigation with 50 RCTs and 5,936 patients. The analyzed evidence of 40 of the 50 navigation-related RCTs reported no significant differences in outcomes; 35 RCTs compared navigation and computer-assisted technique with conventional TKA and 5 RCTs compared different aspects of navigation surgery. Ten RCTs reported significant findings, however those findings were mainly with improved radiological outcomes with no difference in clinical outcomes (9 RCTs). Only one RCT reported improved clinical outcomes in favor of navigation. The overall results concluded a standard conventional TKA with surgical approach familiar to the surgeon using standard well-established components, with or without a tourniquet and without surgical drain leads to satisfactory long-term outcomes. [Authors Cip 2018, Song 2016, and Harvie 2012, previously cited in this policy, are included in the Matar (2020) systematic review and meta-analysis].

A Hayes Comparative Effectiveness Review (2019, updated 2022) on image-based computer-aided navigation (CAN) for total knee arthroplasty performed a comprehensive search using PubMed and Embase for studies reported from 2012 through March 2019. The evidence was comprised of:

- One RCT comparing fluoroscopic-based CAN (FI-CAN) with conventional (CONV) in patients undergoing total Knee arthroplasty (TKA)
- Two RCTs and three nonrandomized prospective studies comparing computed tomography (CT)-based CAN (CT-CAN) with CONV TKA
- Two RCTs and two nonrandomized prospective studies comparing CT-CAN and imageless CAN

The review found that the key disadvantages of image-based CAN relative to imageless CAN include greater expense, more time for preoperative planning, longer duration of surgery, and increased patient radiation exposure. CT image-based CAN for use in TKA may confer some alignment advantages with unclear clinical benefit over conventional navigation; however, evidence indicates no advantage with CT-based CAN over imageless CAN on alignment and function outcome measures. Fluoroscopic 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 not reported.

Panjwani et. al (2019) conducted a systematic review and meta-analysis comparing functional outcomes for TKA of CAN systems versus conventional technique with a minimum two-year follow-up. The review included a total of 18 studies with 3,060 knees of which 1,538 underwent TKA with CAS and 1,522 underwent conventional TKA. The evidence suggests restoration of mechanical axis during TKA has been associated with better outcomes however, the evidence with regards to whether CAS-TKA improves patient function and/or longevity of TKA is unclear. The study concluded that there is limited evidence that CAS-TKA improves functional outcomes at 5- to 8-year follow-up. More prospective studies with larger sample size and longer-term follow-up are required to support the trend toward better functional outcomes with CAS.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS Clinical Practice Guidelines for surgical management of osteoarthritis of the knee states that there is “strong evidence” to support not using intraoperative navigation in TKA because there is no difference in outcomes or complications (2016, updated 2023).

Other Pelvis and Appendicular Skeletal Indications

Computer-assisted musculoskeletal navigation has been primarily investigated as an adjunct to surgery of the appendicular skeletal system. Most of the research has focused on its use in the knee and hip. There is only very preliminary literature regarding its use in the upper extremity (shoulder and elbow) and axial skeleton (spine). Evidence

suggests that, although CAN for trauma, fractures, or other pelvis and appendicular skeleton conditions may improve the precision of bone cutting and alignment of prosthetic devices, the impact on improved clinical outcomes is unclear. Additional controlled studies that measure health outcomes are needed to evaluate this technology for these indications. Further analysis is needed to evaluate the impact of this approach on patient outcomes.

Pan et al. (2022) conducted a small RCT for patients (10 in the navigation group and 10 in the traditional group) admitted for arthroscopic capsulolabral repair surgery. Penetration rates were compared between the groups divided into four zones of the glenoid. The penetration rate in zone 3, the most inferior region of the glenoid, showed 40.9% in the traditional group and 15.7% in the navigation group ($p = 0.077$) demonstrating a trend toward improved accuracy of anchor placement with the aid of the navigation system; however, this was not statistically significant. In addition, there was no difference in American Shoulder and Elbow Surgeons Shoulder Scores before and six months after surgery. Although this study showed a trend toward decreased penetration rate in O-arm navigated capsulolabral repair surgeries and decreased risk of implant misplacement, the difference was not statistically significant possibly due to small sample size. In conclusion further large-scale studies are needed to confirm the possible benefit of navigation systems.

Ansari et al. (2021) conducted a retrospective cohort study analyzing data from 2011 to 2018, to determine the effect of spinal CAN on short-term clinical outcomes following posterior cervical fusion. A total of 12,578 patients were identified and separated into cohorts (689 CAN and 11,889 were non-CAN) rates of 30-day unplanned readmission, reoperation, and other complications were evaluated. In addition, a separate subgroup comparison of patients was established who were undergoing C1-C2 or occiput C2 fusion. After adjusting for baseline differences there was no significant distinction in the 30-day complication, readmission, or revision rates; however, patients receiving CAN experienced longer operations and had higher total relative value units associated with care. At the occipitocervical junction there were more hardware revisions, but this effect did not reach statistical significance. In conclusion, the use of CAN does not seem to affect 30-day postoperative complications, readmissions or need for revision surgery. The use of CAN is more common in procedures where anatomy may be variable and navigation may be more of assistance, given the lack of differences in complication rates despite increased operation length. The overall opinion of the authors states surgeons should embrace CAN at their own discretion in cases expected to be of high operative complexity.

TKA Sensors

The evaluation of the peer-reviewed medical literature for the use of an intra-operative sensor for implant stability during TKA and for improved knee function post-operatively shows evidence is lacking. Further high-quality RCTs are needed to determine the safety, efficacy, and impact on clinical outcomes.

Tran et al. (2025) conducted a systematic review and meta-analysis comparing the clinical outcomes and complications between sensor-assisted and manual balancing techniques in total knee arthroplasty. Data was collected and analyzed from 14 articles consisting of four RCTs (667 knees, 334 sensor-guided, 333 manual). The results demonstrated no significant improvement in functional scores for sensor-guided balancing compared to manual techniques (SMD 0.10; 95% CI -0.15–0.34; $I^2 = 57\%$). No significant differences were observed in complication rates (OR 0.84; 95% CI 0.46–1.54; $I^2 = 0\%$) or postoperative range of motion (MD 1.20; 95% CI -0.26–2.65; $I^2 = 0\%$). The authors concluded sensor-guided balancing in TKA does not provide statistically significant improvements in functional outcomes, complication rates or postoperative range of motion compared to manual balancing. The authors noted as the technology matures further high-quality, long-term trials are conducted, the role of intraoperative sensors in optimizing outcomes for TKA will become clearer. The study limitations include variability in time-frame follow-up creating result inconsistency, short-term follow-up outcomes, high heterogeneity in function outcomes and publication bias.

Feng et al. (2023) conducted a systematic review aimed at analyzing the application of gait analysis in combination with wearable sensor technologies in post-TKA rehabilitation. The study included 25 articles (823 patients) receiving multiple techniques of TKA with gait evaluation from one week to five years post-operatively. Follow-up time points began at six weeks, three months, six months and one year, however few studies lasted for more than one year. The results showed inconsistencies in patient characteristics, sensor data and protocols with varied methodologies. Gait analysis using wearable sensors and patient-reported outcome measures (PROMs) showed differences in controlled environments, daily life, and when comparing different surgeries. The authors concluded wearable sensors can be used to monitor post-TKA gait function in unsupervised mode and on remote basis, providing additional clinical measurement methods and diagnostic approaches. However, more cohort longitudinal studies are warranted to further confirm the benefits of this remote technology in clinical practice. The limitations of the articles included in this systematic review are small sample size, varied methodologies, and limited parameters for measurement accuracy.

In 2022 Sun and colleagues conducted a meta-analysis to evaluate if sensor-guided balancing improves postoperative clinical outcomes compared to conventional gap balancing technique. Nine studies (randomized and non-randomized controlled trials) were assessed identifying 2,147 patients. When compared with manual gap balancing, sensor-guided

gap balancing resulted in less manipulation under anesthesia ($p = 0.02$), however, higher rates of intraoperative procedures ($p = 0.0003$). There was no statistically significant improvement in terms of function, operative time, mechanical axis, and rate of reoperation when contrasting the two groups. In conclusion, when comparing conventional manual gap balancing techniques more sensor-guided gap balancing procedures are being performed and resulted in reduction in the rate of manipulation under anesthesia but more extensive, high-quality RCTs are required to verify these findings further.

Wood et al. (2021) conducted a prospective double-blind randomized controlled trial of 152 patients (76 sensor-guided experimental and 76 control cases) electing primary TKA to determine a difference in TKA soft tissue balance. This study focused on the standard gap balancing (tensiometer) approach versus using a sensor-guided device. The sensor-guided experimental group had adjustments made to achieve a balanced knee within 15 pounds of intercompartmental pressure variance and secondary outcomes differentiating clinical outcome scores at 6 months and 1 year postoperative. Within the control group, 36% of knees were unbalanced based on average coronal plan intercompartmental difference > 15 pounds, compared to only 5.3% within the experimental group ($p < .001$). In addition, there were no significant differences in 1-year postoperative flexion and patient satisfaction at one year was comparable with 81% controls and experimental cases ($p = .992$). In conclusion the use of sensor-guided knee balancer device provided additional feedback during TKA however, it was unable to demonstrate improved clinical outcomes or patient satisfaction compared to conventional gap balancing technique.

MacDessi et al. conducted a 2020 RCT comparing patients undergoing TKA 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.

Cho et al. (2018) 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. The findings are limited by lack of comparison group, lack of functional outcomes, and short follow-up.

ECRI (2018, updated 2020) assessed 4 non-randomized comparison studies that reported the results on 1,491 patients regarding the use of the VeraSense Knee System for soft tissue balancing during TKA. The evidence is inconclusive due to very low-quality comparative data. Ongoing clinical trials reporting knee function and patient satisfaction at up to one year follow up may address evidence gaps.

Gustke et al. (2017) conducted a multicenter case series examining intraoperative data of 129 patients who had TKA surgery with sensor assistance. The study found that loading across the joint decreased, overall and became more symmetrical after releases were performed. On average, between two and three corrections were made (up to eight) 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. Of note, 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.

Gustke et al. (2014) conducted a multicenter case series of intra-operative kinetic balance sensors with 176 participants undergoing TKA performed with the use of the VERASENSE™ Knee System. The authors found that participants with balanced joints were more likely to have favorable clinical outcomes. While power analyses did confirm that comparisons could be reasonably made, an equal proportion of patients in each group would have been more favorable. Controlled trials with longer follow-up are needed to demonstrate that use of intra-operative kinetic balance sensors for implant stability during knee replacement arthroplasty results in improved clinical outcomes. Study limitations included the lack of a control group and the number of unbalanced patients which was much smaller than balanced patients.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgical navigation systems require U.S. Food and Drug Administration (FDA) clearance, but generally are subject only to 510(k) clearance since CAS is considered analogous to a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system. As such, the FDA does not require data documenting the intermediate or final health outcomes associated with CAS.

A variety of CAN devices for orthopedic surgery have been approved by the FDA through the 510(k) process, including but not limited to:

- CTC TCAT®-TPLAN® Surgical System
- Digimatch Orthodoc Robodoc Encore Surgical System
- ExactechGPS
- iASSIST Knee System
- Intellijoint® Navigation System (Hip and Knee)
- JointPoint
- KneeAlign
- NuVasive Next Generation NVM5 System
- NuVasive Pulse System
- OrthAlign Plus System
- Stryker Navigation System with Spinemap Go Software
- Stryker OrthoMap Versatile Hip System
- Verasense for Zimmer Biomet Persona
- Verasense Knee System
- Vital Navigation System

For additional information on approved FDA surgical navigations systems, search the following site by device name: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm>. (Accessed September 2, 2025)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2026	Supporting Information <ul style="list-style-type: none">Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current informationArchived previous policy version CS167NM.B

Instructions for Use

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