Medicare Advantage Medical Policy

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(See policy history boxes for previous effective dates)

Title: Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure

DESCRIPTION / BACKGROUND

IMPLANT ALIGNMENT FOR KNEE ARTHROPLASTY

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

Computer-Assisted Navigation

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

In addition to reducing the risk of substantial misalignment, CAN devices may improve soft tissue balance and patellar tracking. CAN is also being investigated for operations with limited visibility such as placement of the acetabular cup in total hip arthroplasty (THA), 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 (ACL).

CAN devices 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 (OR), typically with infrared probes. For TKA, 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 surgical procedure, multiple surface points are taken from the distal femoral surfaces, tibial plateaus, and medial and lateral epicondyles. The femoral head center is typically calculated by kinematic methods that involve movement of the thigh through a series of circular arcs, with the computer producing a three-dimensional (3-D) model that includes the mechanical, transepicondylar, and tibial rotational axes. CAN systems direct the positioning of the cutting blocks and placement of the prosthetic implants based on the digitized surface points and model of the bones in space. The accuracy of each step of the operation (cutting block placement, saw cut accuracy, seating of the implants) can be verified, thereby allowing adjustments to be made during surgery.

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

Data Acquisition
Data can be acquired in three different ways: fluoroscopically, guided by CT scan or magnetic resonance imaging (MRI), or imageless systems. These data are then used for registration and tracking.

Registration
Registration refers to the ability of relating images (i.e., x-rays, CT scan, MRI or patients' 3-D anatomy) to the anatomical position in the surgical field. Registration techniques may require the placement of pins or "fiduciary markers" in the target bone. A surface-matching technique can also be used in which the shapes of the bone surface model generated from preoperative images are matched to surface data points collected during surgery.

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

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

iASSIST™ (Zimmer) is an accelerometer-based alignment system with the user interface built into disposable electronic pods that attach onto the femoral and tibial alignment and resection guides. For the tibia, the alignment guide is fixed between the tibial spines and a claw on the malleoli. The relationship 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

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 OR.

REGULATORY STATUS:

Because CAN is a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system, surgical navigation systems generally are subject only to 510(k) clearance from the U.S. Food and Drug Administration (FDA). As such, the 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 [PMA] 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.” FDA product code: haw.

Several navigation systems (e.g., PiGalileo™ Computer-Assisted Orthopedic Surgery System, PLUS Orthopedics; OrthoPilot® Navigation System, Braun; Navitrack® Navigation System, ORTHOsoft) have 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 intra-operatively (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”

FDA product code: HAW

In 2013, the VERASENSE™ Knee System from OrthoSensor™ and the iAssist™ Knee from Zimmer received 510(k) clearance from FDA. FDA product code ONN, OLO.

Several computer-assisted navigation devices cleared by the FDA are listed in the table below.

Table 1. Computer-assisted Navigation Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510 (k) No.	Indication
Vital Navigation System	Zimmer Biomet Spine,	12/02/19	K191722	Computer-assisted Navigation for Orthopedic Surgery

	Inc			
Stryker Navigation System With Spinemap Go Software Application, Fluoroscopy Trackers And Fluoroscopy Adapters. Spinemask Tracker	Stryker Corporation	02/14/2019	K183196	Computer-assisted Navigation for Orthopedic Surgery
NuVasive Pulse System	NuVasive Incorporated	6/29/2018	K180038	Computer-Assisted Navigation For Orthopedic Surgery
VERASENSE for Zimmer Biomet Persona	OrthoSensor Inc.	6/7/2018	K180459	Computer-Assisted Navigation For Orthopedic Surgery
NuVasive Next Generation NVM5 System	NuVasive Incorporated	3/16/2017	K162313	Computer-Assisted Navigation For Orthopedic Surgery
Stryker OrthoMap Versatile Hip System	Stryker Corporation	2/23/2017	K162937	Computer-Assisted Navigation For Orthopedic Surgery
JointPoint	JOINTPOINT Inc.	8/3/2016	K160284	Computer-Assisted Navigation For Orthopedic Surgery
Exactech GPS	Blue Ortho	7/13/2016	K152764	Computer-Assisted Navigation For Orthopedic Surgery
VERASENSE Knee System	OrthoSensor Inc.	4/15/2016	K150372	Computer-Assisted Navigation For Orthopedic Surgery
iASSIST Knee System	Zimmer CAS	9/11/2014	K141601	Computer-Assisted Navigation For Orthopedic Surgery
CTC TCAT®-TPLAN® Surgical System	Curexo Technology Corporation	8/18/2014	K140585	Computer-Assisted Navigation For Orthopedic Surgery
Digimatch Orthodoc Robodoc Encore Surgical System	Curexo Technology Corporation	5/27/2014	K140038	Computer-Assisted Navigation For Orthopedic Surgery
StealthStation S8 With Spine Software	Metronic	5/01/2017	K170011	Computer-assisted Navigation for Orthopedic Surgery

MEDICAL POLICY STATEMENT

Computer-assisted surgery for orthopedic procedures of the pelvis and appendicular skeleton is experimental/investigational. Its effectiveness and additional clinical utility have not been definitively determined. There are inadequate data to permit scientific conclusions regarding the usefulness of these devices.

INCLUSIONARY AND EXCLUSIONARY GUIDELINES (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

20985 0054T 0055T

Rationale

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

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

For many orthopedic surgical procedures, optimal alignment is considered an important aspect of long-term success. For example, misplaced tunnels in 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.

COMPUTER-ASSISTED NAVIGATION FOR TRAUMA OR FRACTURE

Clinical Context and Therapy Purpose

The purpose of 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 patients who are undergoing orthopedic surgery for trauma or fracture.

The question addressed in this evidence review is: does the use of CAN improve the net health outcome when used for surgery for trauma fracture?

The following **PICO** were used to select literature to inform this review.

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

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

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

The existing literature evaluating computer assisted navigation as a treatment for patients who are undergoing orthopedic surgery for trauma or fracture has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Computer-assisted surgery has been described as an adjunct to pelvic, acetabular, or femoral fractures. For example, fixation of these fractures typically requires percutaneous placement of screws or guidewires. Conventional fluoroscopic guidance (i.e., C-arm fluoroscopy) provides imaging in only one plane. Therefore, the surgeon must position the implant in one 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 (OR) and radiation exposure. It is hoped the computer-assisted surgery would allow for minimally invasive fixation and provide more versatile screw trajectories with less radiation exposure. Therefore, computed-assisted surgery is considered an alternative to the existing image guidance using C-arm fluoroscopy.

Observational Study
Ideally, one would like controlled trials comparing OR time, radiation exposure, and long-term outcomes of those whose surgery was conventionally guided using C-arm versus image-guided using computer-assisted surgery. While several in vitro and review studies had been published,[1-3] a literature search at the time this policy was created identified only one clinical

trial of computer-assisted surgery in trauma or fracture cases.[4] Computer-assisted navigation (CAN) for internal fixation of femoral neck fractures has been described in a retrospective analysis consisting of 2 cohorts of consecutive patients (20 each, performed from 2001 to 2003 at 2 different campuses of a medical center) who underwent internal fixation with 3 screws for a femoral neck fracture.[5] Three of five measurements of parallelism and neck coverage were significantly improved by CAN; these included a larger relative neck area held by the screws (32% vs. 23%) and less deviation on the lateral projection for both the shaft (1.7 vs. 5.2 degrees) and the fracture (1.7 vs. 5.5 degrees, all respectively) screw angles. Slight improvements in anteroposterior screw angles (1.3 vs. 2.1 and 1.3 vs. 2.4 degrees, respectively) did not reach statistical significance. There were two reoperations in the CAN group and six in the conventional group. Complications (collapse, subtrochanteric fracture, head penetration, osteonecrosis) were lower in the CAN group (3 vs. 11, respectively).

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

CAN FOR ANTERIOR CRUCIATE LIGAMENT (ACL) OR POSTERIOR CRUCIATE LIGAMENT (PCL) RECONSTRUCTION

Clinical Context and Therapy Purpose
The purpose of 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 patients who are undergoing ligament reconstruction.

The question addressed in this evidence review is: does the use of CAN improve the net health outcome when used for orthopedic procedures, including surgery for trauma or fracture, ligament reconstruction?

The following **PICO** were used to select literature to inform this review.

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

Interventions
The therapy being considered is 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 the 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. These are performed by a physical therapist and primary care provider in an outpatient clinical setting.

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

The existing literature evaluating CAN as a treatment for patients who are undergoing ligament reconstruction has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, two years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Systematic Reviews
A Cochrane review from 2014 (Eggerding et al, 2014) assessed the effects of CAN in comparison with conventional operating techniques for ACL or PCL reconstruction.[5] Five randomized controlled trials (RCTs, 366 participants) on ACL reconstruction were included in the review; no studies involved PCL reconstruction. The quality of evidence ranged from moderate to very low. Pooled data showed no statistically or clinically significant differences in self-reported health outcomes (International Knee Documentation Committee [IKDC] subjective scores and Lysholm scores) at 2 years or more follow-up. A third trial included in this review found a small statistically significant difference in IKDC subjective scores. No significant differences were found for secondary outcomes, including knee stability, range of motion, and tunnel placement. Overall, there was insufficient evidence to advise for or against the use of CAN. Four of the 5 trials included in the Cochrane review are described next.

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

Hart et al (2008) compared biomechanical radiographic and functional results in 80 patients randomized to ACL reconstruction using CAN (n=40) or to the standard manual targeting technique (n=40).[7] Blinded evaluation found more exact bone tunnel placement with CAN, but no overall difference in biomechanical stability or function between groups.

Other studies have found no significant improvement in the accuracy of tunnel placement when using CAN. In 2012, the authors of the 2011 Cochrane review reported a double blind controlled trial with 100 patients who were randomly assigned to either conventional or computer-assisted surgery.[8] Evaluation by 3-dimensional computed tomography (CT) found no significant difference between the 2 groups for either the accuracy or the precision of the femoral and tibial tunnel placement.

Table 2. Summary of Characteristics of Key RCTs Comparing CAN with Manual Placement for Anterior or Posterior Cruciate Ligament Reconstruction

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Plaweski (2006)[6]	USA	1	2014-2016	Patients (n=50)	CAN (n=26)	Manual (n=24)
Hart (2008)[7]	Czech Republic	1	NR	Patients (n=80) undergoing ACL reconstruction for chronic rupture of the ACL/ only chronic ACL-insufficiency knees were included in the study (> 6 mo after injury). Other inclusion criteria were no other prior or simultaneous intra-articular surgical procedure; no cartilage degeneration of meniscal tear; and a normal contralateral knee. Ages ranged from 16 to 39 years with a mean of 29.4. Mean body weight was 74 kg.	CAN (n=40)	Manual (n=40)
Meuffels (2012)[8]	Netherlands	1	2007-2009	Patients (n=100) patients who were 18 years of age or older and eligible for primary ACL reconstruction without any additional posterior cruciate ligament or lateral collateral ligament injury were included. Exclusion criteria were insufficient grasp of the Dutch or English language and inability or unwillingness to comply with regular postoperative follow-ups; Participants were randomized according to a computer-generated procedure (block randomization utilizing a variable block size;	CAN (n=49)	Conventional (n=51)
Mauch (2007)[9]	Germany	1	2003-2004	53 athletes underwent anterior cruciate ligament reconstruction surgery with arthroscopic press-fit technique.	CAN (n=24)	Manual (n=29)

RCT: randomized controlled trial; CAN: computer-assisted navigation; NR: not reported; ACL: anterior cruciate ligament.

Table 3. Summary of Key RCTs Comparing CAN with Manual Placement for Anterior or Posterior Cruciate Ligament Reconstruction

Study	IKDC	Laxity Less Than 2 mm	Lachman Test (0)	Lachman Test	Placement of the Femoral Tunnel	Tibial Tunnel Border
Plaweski (2006)[6]						

CAN (n=26 knees)					NR	Mean ATB, -0.2 (5 to +4)
Mean Level A Laxity Level (n=26 knees)	Mean, 1.3 mm at 200 N; p=0.49	96.7%; p=0.295	23 (76.7)	1 (3.3)		
Manual					NR	Mean ATB, 0.4 (0 to 3)
Mean Level A Laxity Level (n=22 knees)	Mean, 1.5 mm; p=0.49 at 200 N	83%; p=0.292	26 (87)	0 (0)		
Hart (2008)[7]						
CAN (n=40)	Mean post-op Improvement: 76.5 points; SD, 10.3; p<.01	Mean difference in anterior laxity compared with contralateral (healthy) knee: 1.43 mm (range, 0 to 4 mm)	12 (30%)	14 (35%)	Ideal *a/t* value: 24.8%Mean, 25.5% (SD, 1.63)	Zone 2 location: 39 (97.5%)
Manual (n=40)	Mean post-op Improvement: 73.1 points; SD, 11.8; p<.01	Mean difference in anterior laxity compared with contralateral (healthy) knee: 1.24 mm (range, -2 to 5 mm)	18 (45%)	10 (25%)	Ideal *a/t* value: 24.8%Mean, 27.% (2.76)	Zone 2 location: 38 (95.0%)
Meuffels (2012)[8]						
CAN	NR	NR	NR	NR	Mean 39% of the proximal distance on the intracondylar axis	Distance from most medial edge: 42.7% ±3.6%
Manual	NR	NR	NR	NR	mean 39.7% of the proximal distance on the intracondylar axis	Distance from most medial edge: 42.6% ±5.7%
Mauch (2007)[9]						
CAN	NR	NR	NR	NR	NR	21.2 mm (32.2%)
Manual	NR	NR	NR	NR	NR	19.4 mm (29.7%)
p-value	NR	NR	NR	NR	NR	p=0.18

RCT: randomized controlled trial; CAN: computer-assisted navigation; IKDC: International Knee Documentation Committee; SD: standard deviation.

The purpose of the limitations tables (see Tables 4 and 5) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the

conclusions on the sufficiency of evidence supporting the position statement.

Table 4. Summary of Design and Conduct Limitations in Key RCTs Comparing CAN with Manual Placement

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Completeness of Follow-up	Power[e]	Statistical[f]
Plaweski (2006)[6]		1.Unclear whether patients were blinded				3.Confidence intervals not reported. 4.Comparison of treatment effect not provided.
Hart (2008)[7]	3. Randomization techniques are not described in any manner within the text.				1. Power calculations not reported.	3. Confidence intervals not reported.
Meuffels (2012)[8]						
Mauch (2007)[69]	4. Drawing lots is a weak method of allocation.	1, 2, 3. Blinding is not mentioned at all.			1. Power calculations not reported.	3. Confidence intervals not reported.

CAN: computer-assisted navigation; RCT: randomized controlled trial.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Table 5. Summary of Relevance Limitations in Key RCTs Comparing CAN with Manual Placement

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Plaweski (2006)[6]	3.Limited demographic information provided.				
Hart (2008)[7]	3. The study setting and source of study participants is missing (as is the referral pattern)--this could create referral-filter bias				
Meuffels (2012)[8]	3.Study population is incompletely characterized.	2. Fidelity of intervention protocol: There is a lack of consistency as to the best			

		method for performing the intervention (positioning of a single-bundle ACL reconstruction) among surgeons in the field.		
Mauch (2007)[9]	1,4. Intended use population is unclear. Limited to athletes.		5,6.Clinically significant difference not prespecified or mentioned.	1,2.Follow-up was 4 days, not long enough to determine intermediate-or long-term outcomes.

RCT: randomized controlled trial; CAN: computer-assisted navigation; CT: computed tomography; ACL: anterior cruciate ligament.The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

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

CAN for THA and Periacetabular Osteotomy

Clinical Context and Therapy Purpose
The purpose of 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 patients who are undergoing THA and periacetabular osteotomy.

The question addressed in this evidence review is: does the use of CAN improve the net health outcome when used for THA and periacetabular osteotomy?

The following **PICO** were used to select literature to inform this review.

Populations
The relevant population of interest are individuals who are undergoing THA and periacetabular osteotomy.

Interventions
The therapy being considered is 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 the 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, and physical therapy. These are performed by a physical therapist and primary care provider in an outpatient clinical setting.

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

The existing literature evaluating CAN as a treatment for patients who are undergoing THA and periacetabular osteotomy has varying lengths of follow-up, ranging from 6-40 months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Randomized Controlled Trials
In a 2007 study, Paratte and Argenson randomized patients to CAN for THA (n=30) or freehand cup positioning (n=30) by an experienced surgeon.[10] The mean additional time for the computer-assisted procedure was 12 minutes. There was no difference between the computer-assisted group and the freehand-placement group with regard to the mean abduction or anteversion angles measured by CT. A smaller variation in the positioning of the acetabular component was observed in the CAN group; 20% of cup placements were considered to be outliers in the CAN group compared with 57% in the freehand-placement group. In a randomized trial of 125 patients, Lass et al (2014) compared the acetabular component position between CAN versus the conventional freehand technique.[11] CT scans identified higher accuracy for acetabular component anteversion, deviation from the target position for anteversion, and in outliers from the target for inclination and anteversion. The operation time was 18 minutes longer for CAN. Functional outcomes were not assessed.

Nonrandomized Studies
A 2011 study by Manzotti et al compared leg length restoration in a matched-pair study.[12] Forty-eight patients undergoing THA with CAN were compared with patients who were matched for age, sex, arthritis level, preoperative diagnosis, and preoperative leg length discrepancy and underwent conventional freehand THA using the same implant in the same period. The mean preoperative leg length discrepancy was 12.17 mm in the THA-CAN group and 11.94 in the standard THA group. Surgical time was increased by 16 minutes (89 vs. 73 min, respectively). There was a significant decrease in both the mean postoperative leg length discrepancy (5.06 vs. 7.65 mm) and in the number of cases with a leg length discrepancy of equal to or greater than 10 mm (5 vs. 13 patients – all respectively). Outcomes at 40-month follow-up (range, 7 to 77 months) were not significantly different for the Harris Hip Score (88.87 vs. 89.73) or the 100-point normalized Western Ontario and McMaster Universities (WOMAC) Arthritis Index (9.33 vs. 13.21 – all respectively; p=0.0503). Longer follow-up with a larger

number of subjects is needed to determine whether THA-CAN influences clinical outcomes.

Minimally Invasive THA
It has been proposed that CAN devices may overcome the difficulties of reduced visibility of the surgical area associated with minimally invasive procedures. A 2007 review by Ulrich et al summarized studies that compared outcomes from minimally invasive THA-CAN and standard THA.[13] Seventeen studies were described in this evidence-based review, including 9 prospective comparisons, 7 retrospective comparisons, and 1 large (n=100) case series. The review 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 current expense of the computer systems and increased surgical time.

Randomized Controlled Trials
Short-term outcomes of minimally invasive THA approach with CAN (n=35) compared with conventional posterolateral THA (n=40) was reported by Reninga et al in 2013.[14] This randomized comparison found no group differences in the recovery of gait at up to 6 months after surgery.

Periacetabular Osteotomy
A 2006 study by Hsieh et al, randomly assigned 36 patients with symptomatic adult dysplastic hip to either CT-based navigation or the conventional technique for periacetabular osteotomy.[15] 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 operative time that was 21 minutes shorter for CAN. There were no differences between the groups for correction in femoral head coverage or for functional outcomes (pain, walking, range of motion) at 24 months.

Total Hip Resurfacing
In 2013, Stiehler et al reported short-term radiographic and functional outcomes from a randomized comparative trial of CAN-THR (total hip resurfacing) in 75 patients.[16] For most of the radiographic measures, there was no significant difference between the CAN and conventional THR groups. There were fewer outliers (≥5°) for the femoral component with CAN (11%) compared with conventional placement (32%). At 6-month follow-up, there were no differences between groups in the final WOMAC or Harris Hip Score. The CAN group did show a greater percentage improvement in the WOMAC and Harris Hip Score due to differences between the groups at baseline.

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

CAN for TOTAL KNEE ARTHROPLASTY (TKA)

Clinical Context and Therapy Purpose
The purpose of 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 patients who are undergoing TKA.

The question addressed in this evidence review is: does the use of CAN improve the net health outcome when used for TKA?

The following **PICO** were used to select literature to inform this review.

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

Interventions
The therapy being considered is computer-assisted navigation.

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

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. These are performed by a physical therapist and primary care provider in an outpatient clinical setting.

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

The existing literature evaluating CAN as a treatment for patients who are undergoing TKA has varying lengths of follow-up, ranging from one-eight years. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

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.

Review of Evidence
A 2012 meta-analysis, Xie et al, included 21 randomized trials (total N=2658 patients) that reported clinical outcomes with or without the use of CAN.[17] Most studies included in the review had short-term follow-up. As was found in the 2007 TEC Assessment, surgical time was significantly increased with CAN for TKA, but there was no significant difference between approaches in total operative blood loss, the Knee Society Score (KSS), or range of motion.

Rebal et al (2014) conducted a meta-analysis of 20 RCTs (total N=1713 knees) that compared imageless navigation technology with conventional manual guides.[18] 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.

Table 6. Characteristics of Systematic Reviews and Meta-Analyses Investigating TKA

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Xie (2012)[17]	1966-2011 PubMed 1984-2011 EMBASE	21	Included 2658 patients. Among these 1376 were randomly allocated to the computer-assisted TKA group and 1282 to the conventional group	2658 (25-120)	RCT	NR
Rebal (2014)[18]	2004-2009	20	a combined 869 knees in the computer-assisted groups, and 844 knees in the control groups for a total of 1,713 knees analyzed	1713 knees	RCT	3 mos and 12-32 mos

RCT: randomized controlled trial; NR: not reported; TKA: total knee arthroplasty.

Table 7. Results of Systematic Reviews and Meta-Analyses Investigating TKA

Study	Knee Society Score				Operative Time	
Xie et al (2012)[17]						
Mean standard difference	4.47				14.68	
95% CI	-1.05 to 9.99				11.74 to 17.62	
P-value	.36				<.0001	
	CAN		**Conventional**		**CAN (min)**	**Conventional (min)**
	3 Months	**12-32 Months**	**3 Months**	**12-32 Months**		
Rebal et al (2014)[18]						
Mean	68.5	53.1	58.1	45.8	101.6	83.3
95% CI			1.13 to 19.78	2.87 to 11.90		11.84 to 24.60
P-value			.03	<.01		<.01

CAN: computer-assisted navigation; CI: confidence interval; min: minutes.

Effect of CAN on Mid- to Long-term Outcomes

Randomized Controlled Trials

RCTs comparing outcomes at 4 to 12 years follow-up generally have shown a reduction in the

number of outliers with computer assisted navigation, but little to no functional difference between the computer assisted navigation and conventional total knee arthroscopy groups. Hsu et al (2019) reported such results with their randomized study of 60 patients who underwent computer assisted navigation total knee arthroscopy on one knee and conventional total knee arthroscopy on the other.[22] At a mean follow-up of 8.1 years, investigators saw similar clinical and functional outcomes with the 2 procedures, although computer assisted navigation achieved better radiographic alignment and fewer outliers. They suggested that total knee arthroscopy with computer assisted navigation may not provide an advantage to the typical osteoarthritis patient, but it may benefit certain patients, such as those with severe deformity of the knee joint, extra-articular deformities, and severe femoral bowing. The study was limited by its solely Asian patient population, single center, and small sample size.

Cip et al (2018) published the results of a prospective randomized trial in which 100 conventional TKAs were compared with 100 computer-assisted TKAs with a mean follow-up of 12 years postoperatively.[23] The trial was aimed at determining the long-term outcomes of CAN for TKA as a tool to expedite long-term survival based on improved postoperative implantation. The follow-up rate was 75%. No difference in long-term TKA survival was found between the conventional group (91.5%) and the CAN group (98.2%) at 12-years (p=.181).
Follow-up from 4 randomized studies were published in 2013 to 2016 that assessed mid-term functional outcomes following CAN for TKA. Blakeney et al reported 46-month follow-up of 107 patients from a randomized trial of CAN versus conventional surgery.[24] 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 was no significant difference in the 12-Item Short-Form Health Survey Physical Component or Mental Component Scores. The study was underpowered, and the clinical significance of this trend for the Oxford Knee questionnaire is unclear.

Comparative Studies
Results from observational studies have generally been consistent with the systematic reviews and RCTs.[25,26,27,28,29,30,] The longest of these observational studies, conducted by Dyrhovden et al (2016), assessed survivorship and the relative risk of revision at 8-year follow-up for 23,684 cases from the Norwegian Arthroplasty Register for patients treated with computer-assisted navigation or conventional surgery.[29,] Overall prosthesis survival and risk of revision were similar for both groups, although revisions due to malalignment were reduced with computer-assisted navigation (relative risk, 0.5; 95% confidence interval [CI], 0.3 to 0.9; p=0.02). There were no significant differences between groups for other reasons for revision (eg, aseptic loosening, instability, periprosthetic fracture, decreased range of motion). At 8 years, the survival rate was 94.8% (95% CI, 93.8% to 95.8%) in the computer-assisted navigation group and 94.9% (95% CI, 94.5% to 95.3%) for conventional surgery.

In the largest observational study, Antonios et al (2020) compared Medicare data from 75,709 patients who underwent a computer navigated total knee arthroplasty with a matched cohort of 75,676 Medicare patients who underwent conventional total knee arthroplasty.[30,] There was no statistically significant difference in 5-year event-free survival in all-cause revisions between groups (95.1% vs. 94.7%; P=0.06) However, there was a small difference in revisions due to mechanical complications (96.1% vs. 95.7%; P=0.02) but not in revisions due to periprosthetic joint infection (97.9% vs. 97.9%; P=0.30).

Section Summary: CAN for TKA
A large number of RCTs have compared outcomes between TKA with CAN and conventional TKA without CAN. Results are consistent in showing a reduction in the proportion of outliers greater than 3° in alignment. Results up to 12 years postoperatively have not shown that these differences in alignment lead to improved patient outcomes.

Computer-Assisted Navigation for Spine Surgery
The purpose of computer-assisted navigation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional/manual methods, in patients who are undergoing spine surgery, particularly spinal fusion surgery for radiculopathy and correction of spinal deformities (e.g. scoliosis). Spinal fusion may include the use of pedicle screws. Pedicle screws are a type of bone screw that, along with rods, is used to secure the vertebrae in a fixed position following fusion. Pedicle screws may be removed once healing has occurred, or they can be left in place. Pedicle screw placement accuracy is critical, as misplacement can cause a variety of complications, including pain and weakness or perforation leading to damage to surrounding nerves, soft tissues and bones.
The question addressed in this evidence review is: Does the use of computer-assisted navigation improve the net health outcome when used for spine surgery?

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who are undergoing spine surgery. This can include patients undergoing cervical, thoracic or lumbar pedicle screw placement in association with spinal fusion surgery, due to trauma or for correction of spinal deformities, or patients undergoing spinal tumor resection.

Interventions
The therapy being considered is computer-assisted navigation. Computer-assisted navigation in orthopedic procedures describes the use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including tumor resection and pedicle screw placement.

Comparators
Comparators of interest include conventional/manual surgical methods, such as fluoroscopically-guided freehand surgery.

Outcomes
The general outcomes of interest are symptoms, morbid events, and functional outcomes. Many studies report pedicle screw perforation (breach or encroachment into surrounding tissues, bones or organs) as a measure of procedural success. However, because not all screw perforations lead to symptoms or morbid events, revision surgeries would be a more relevant measure of clinical outcomes.

Review of Evidence

Pedicle Screw Insertion For Spinal Fusion or Deformity Correction

Randomized Controlled Trials

Three RCTs have compared pedicle screw insertion by computer-assisted navigation with conventional surgical techniques (Table 8). None of the trials reported health outcomes or post-surgical follow-up (Table 9). In the largest RCT, conducted by Laine et al (2000),[31] computer-assisted navigation was associated with longer surgical time than conventional surgery and fewer instances of pedicle screw perforation. A second, smaller RCT conducted by Rajasekaran et al (2007)[32] found pedicle screw placement using computer-assisted navigation associated with shorter placement time and a lower rate of pedicle perforation relative to fluoroscopically-guided placement. The third trial (n=21) compared the risk of patient and surgical team radiation exposure with pedicle screw placement using computer-assisted navigation with freehand, fluoroscopically-guided screw placement.[33] The trial found significantly higher radiation exposure to the surgical team during freehand screw insertion (p<.01) with no difference between intervention groups and cumulative patient radiation dose. Tables 10 and 11 summarize key study relevance and design and conduct limitations.

Table 8. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Laine et al (2000)[31]	Finland	1	1998-1999	Patients undergoing thoracolumbar or lumbosacral fusion	Pedicle screw placement using computer-assisted navigation; n=41	Conventional pedicle screw placement; n=50
Rajasekaran et al (2007)[32]	India	1	Not reported	Patients with scoliosis (40°to 80°) or kyphosis (≤90°) undergoing spinal deformity correction of the thoracic spine	Pedicle screw placement using computer-assisted navigation; n=17	Pedicle screw placement using fluoroscopic guidance; n=16
Villard et al (2014)[33]	Germany	1	Not reported	Patients undergoing lower thoracic and lumbar posterior transforaminal interbody fusion	Pedicle screw placement using computer-assisted navigation; n=10	Pedicle screw placement using fluoroscopic guidance as needed; n=11

NR: not reported.

Table 9. Summary of Key RCT Results

Study; Trial	Mean Insertion Time	Pedicle Screw Perforation	Radiation Exposure
Laine et al (2000)[31]	n=91 (496 screws)	n=91 (496 screws)	--
Computer-assisted navigation	40.0 (SD 16) minutes total insertion time	4.6% (10/219)	Not reported
Conventional placement	28.7 (SD 17) minutes total insertion time	13.4% (37/277)	Not reported
p value	p=.001	p=.006	--
Rajasekaran et al (2007)[32]	n=33 (478 screws)	n=33 (478 screws)	--
Computer-assisted navigation	2.4 (SD 0.7) minutes per screw	2.1% (5/242)	Not reported
Conventional placement	4.6 (SD 1.1) minutes per screw	22.9% (54/236)	Not reported
p value	p<.001	p<.001	--
Villard et al (2014)[33]	--	--	n=21 patients
Computer-assisted navigation	Not reported	Not reported	888 (SD 449) cGy•cm^2
Conventional placement	Not reported	Not reported	1884 (SD 881) cGy•cm^2
p value	--	--	p=.73

Table 10. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Laine et al (2000)[31]				1, 2. The study reported on pedicle screw perforation but not clinical outcomes.	1, 2. Follow-up was insufficient to assess benefits and harms
Rajasekaran et al (2007)[32]				1, 2. The study reported on pedicle screw perforation but not clinical outcomes.	1, 2. Follow-up was insufficient to assess benefits and harms
Villard et al (2014)[33]				1, 2. The study reported on radiation exposure but not clinical outcomes.	1, 2. Follow-up was insufficient to assess benefits and harms

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Laine et al (2000)[31]					1. Power calculations not reported	
Rajasekaran et al (2007)[32]					1. Power calculations not reported	
Villard et al (2014)[33]	3. Allocation concealment is unclear	1, 2. Not blinded to treatment assignment or outcome assessment				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1, Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Systematic Reviews

Numerous systematic reviews of mostly retrospective observational studies have assessed pedicle screw placement using computer-assisted navigation, however, evidence on health outcomes from the reviews is limited.[34,35,36,37,] In a 2018 review conducted by Staartjes et al, comparing computer-assisted navigation (n=1779 pedicle screws) and freehand placement (n=1809 pedicle screws) and the need for intraoperative revision, there was a nonsignificant trend favoring freehand placement based on an imprecise risk estimate (OR 1.46, 95% CI, 0.30 to 7.17; I^2=88%).[36,] The same review found the need for postoperative revision was significantly lower with computer-assisted navigation versus freehand placement (OR 0.31, 95% CI, 0.21 to 0.46; I^2=0%). Another review, conducted by Perdomo-Pantoja et al (2019)[37,] reported similar rates of screw placement accuracy with computer-assisted navigation (95.5%) and other placement methods (90.5% to 93.1%). Consistent with the RCT evidence discussed above, an older review by Shin et al (2012)[35,] found a lower risk of pedicle screw perforation with computer-assisted navigation (6%; 287/4814) versus conventional, non-navigated screw placement (15%; 556/3725; RR 0.39, 95% CI, 0.31 to 0.49; I^2=49%). The review found no difference between navigated and non-navigated screw placement on operative time (-3.06 minutes, 95% CI, -35.60 to 29.48), estimated blood loss (-91.6 mL, 95% CI, -185.95 to 3.24), or overall revision rate per screw insertion (1.44% vs. 2.03%; p=.11)

Other Indications

The use of computer-assisted navigation for the treatment of spinal tumors has been reported in uncontrolled case series and case reports.[38,39,40,] Although the use of computer-assisted navigation appears safe for tumor resection based on these reports, evidence is too limited to draw any conclusions regarding the effect of computer-assisted navigation on health outcomes.

Section Summary - Computer-Assisted Navigation for Spine Surgery

Evidence from RCTs and larger observational studies found that computer-assisted navigation was associated with lower rates of pedicle screw perforation compared with other surgical placement methods. Evidence on clinical outcomes, including long-term health outcomes, is lacking.

SUMMARY OF EVIDENCE

For individuals who are undergoing orthopedic surgery for trauma or fracture and receive computer-assisted navigation, the evidence includes one retrospective clinical trial, reviews, and in vitro studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Functional outcomes were not included in the clinical trial, although it did note fewer complications with computer-assisted navigation versus conventional methods. The evidence is insufficient to determine the effects of the technology on net health outcomes.

For individuals who are undergoing ligament reconstruction and receive computer-assisted navigation, the evidence includes a systematic review of 5 randomized controlled trials (RCTs) of computer-assisted navigation versus conventional surgery for anterior and posterior cruciate ligament. Relevant outcomes are symptoms, morbid events, and functional outcomes. Trial results showed no consistent improvement of tunnel placement with computer-assisted navigation, and no trials looked at functional outcomes or need for revision surgery with computer-assisted navigation. The evidence is insufficient to determine the effects of the

technology on net health outcomes.

For individuals who are undergoing hip arthroplasty and periacetabular osteotomy and receive computer-assisted navigation, the evidence includes older RCTs, a systematic review, and comparison studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Evidence on the relative benefits of computer-assisted navigation with conventional or minimally invasive total hip arthroscopy is inconsistent, and more recent RCTs are lacking. The evidence is insufficient to determine the effects of the technology on net health outcomes.

For individuals who are undergoing total knee arthroscopy and receive computer-assisted navigation, the evidence includes RCTs, systematic reviews of RCTs, and comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. The main difference found between total knee arthroscopy with computer-assisted navigation and total knee arthroscopy without computer-assisted navigation is increased surgical time with computer-assisted navigation. Few differences in clinical and functional outcomes were seen at up to 10 years post-procedure. The evidence is insufficient to determine the effects of the technology on net health outcomes.

For individuals who are undergoing spine surgery and receive computer-assisted navigation, the evidence includes RCTs, comparative observational studies, and systematic reviews of those observational studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Computer-assisted navigation for pedicle screw insertion was consistently associated with lower rates of screw perforation relative to other screw insertion methods, but evidence on clinical outcomes such as revision rate is inconsistent or lacking, including long-term outcome follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

One currently unpublished trial that might influence this review is listed in Table 12.

Table 12. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03628378	Outcomes in Free-hand Versus Sensor-guided Balancing in Total Knee Arthroplasty: a Randomized Controlled Trial	130	Mar 2021
NCT02717299	Making Sense Out of Total Knee Sensor Assisted Technology: A Randomized Control Trial	78	Apr 2021
Unpublished			
NCT01469299a	Prospective Study Measuring Clinical Outcomes of Knee Arthroplasty Using the VERASENSE™ Knee System	285	Dec 2016 (updated 01/11/17)

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

SUPPLEMENTAL INFORMATION

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, Blue Cross Blue Shield Association received input from 3 academic medical centers while this policy was under review in 2011. The input was mixed regarding

whether CAN is considered investigational. One reviewer provided additional references regarding use of CAN for high tibial osteotomy and pelvic tumor resection. These topics were subsequently added to the policy.

Government Regulations

National: There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Local:

There is no current Local Coverage Determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Dynamic Posturography

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2021, the date the research was completed.

Medical Policy History

Policy Effective Date	Comments
1/1/2022	Medical policy established
3/1/2022	Rationale updated, references #31-40 added. No change in policy status.

Next Review Date: 4th Qtr. 2022