Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

*Current Policy Effective Date: 3/1/24

(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 operating room (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, Inc.	12/02/2019	K191722	Computer-assisted Navigation for Orthopedic Surgery
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 Inc.	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
StealthStation™ S8 With Spine Software	Medtronic	5/01/2017	K170011	Computer-assisted Navigation for Orthopedic Surgery
NuVasive Next Generation NVM5® System	NUVASIVE Inc.	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
ExactechGPS®	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(R)-TPLAN(R) 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

MEDICAL POLICY STATEMENT

Computer-Assisted Musculoskeletal Surgical Navigation for use in orthopedic indications (spinal, cranial, and other musculoskeletal procedures) may be considered established for FDA-approved systems in accordance with their respective FDA-approved indications. The navigation is considered part of the primary procedure and is not separately reimbursed.

INCLUSIONARY AND EXCLUSIONARY GUIDELINES

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:

20985 61783 0054T 0055T

The above codes are not separately reimbursed

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

N/A

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 (CAN) 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 individuals 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.[4,5] 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.[4] 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).

A retrospective comparative study by Swartman et al (2021) investigated differences in conventional fluoroscopy-assisted percutaneous management (n=13) of acetabular fractures to

3-dimensional (3D) D-computer navigated management (n=24).[5,] Both groups demonstrated significant reduction in fracture gaps and steps post-intervention.

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 individuals 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.

Populations

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.[6] 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, the quality of evidence shows no clinically relevant difference between CAN and conventional surgery in the IKDC subjective scores. Pooled data of these trials showed a difference favoring CAN.

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.[7] 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, and the accuracy and consistency of tibial tunnel position can be improved by the use of CAN and the clinical laxity is more reliable.

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).[8] Blinded evaluation found more exact bone tunnel placement with CAN than the traditional arthroscopic technique.

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.[9] Evaluation by 3-dimensional computed tomography (CT) found no 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 et al (2006)	USA	1	Oct 2014 to Jan 2016	Patients (n=560) undergoing ACL reconstruction.	CAN (n=30)	Manual placement (n=30)
Hart et al (2008)	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 placement (n=40)
Meuffels et al (2012)	Netherlands	1	Jan 2007- to Nov 2009	Patients (n=100) patients ≥18 years of age and eligible for primary ACL reconstruction without additional posterior cruciate ligament PCL or lateral collateral ligament injury were included.	CAN (n=49)	Conventional (n=51)
Mauch et al (2007)	Germany	1	Dec 2003- to April 2004	Athletes aged 18- to 49 years (n=53) with ACL rupture and no complex injuries of knee with additional injury of PCL, injury of posterior lateral complex, or third-degree injury of intra-articular ligament.	CAN (n=24)	Manual placement (n=29)

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

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

Study	IKDC	Laxity < 2 mm	Lachman Test (0)	Lachman Test (2+)	Placement of the Femoral Tunnel	Tibial Tunnel Border
Plaweski et al (2006)						
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=.49	96.7%; p=.295	23 (76.7)	1 (3.3)		

Study	IKDC	Laxity < 2 mm	Lachman Test (0)	Lachman Test (2+)	Placement of the Femoral Tunnel	Tibial Tunnel Border
Manual (n=22 knees)					NR	mean ATB, 0.4 (0 to 3)
Mean Level A laxity level (n=22 knees)	mean, 1.5 mm at 200 N; p=.49	83%; p=.292	26 (87)	0 (0)		
Hart et al (2008)						
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.% (SD, 2.76)	Zone 2 location: 38 (95.0%)
Meuffels et al (2012)						
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 et al (2007)						
CAN	NR	NR	NR	NR	NR	21.2 mm (32.2%)
Manual	NR	NR	NR	NR	NR	19.4 mm

Study	IKDC	Laxity < 2 mm	Lachman Test (0)	Lachman Test (2+)	Placement of the Femoral Tunnel	Tibial Tunnel Border
						(29.7%)
p value	NR	NR	NR	NR	NR	.18

a/t value: ratio identifies anterior-posterior femoral tunnel placement; ATB: anterior tension band plate; CAN: computer-assisted navigation; IKDC: International Knee Documentation Committee; NR: not reported; Post-op: postoperative; RCT: randomized controlled trial; 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 Study Relevance Limitations in Key Randomized Controlled Trials Comparing Computer-Assisted Navigation with Manual Placement

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

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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[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.

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

	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Plaweski et al (2006)		1. Unclear whether patients were blinded.				3. Confidence intervals not reported. 4. Comparison of treatment effect not provided.
Hart et al (2008)	3. Randomization techniques are not described in any manner within the text.				1. Power calculations not reported.	3. Confidence intervals not reported.
Meuffels et al (2012)						
Mauch et al (2007)	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.

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.

CAN for Total Hip Arthroplasty (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 individuals 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.

Review of Evidence

Systematic Reviews

Kunze et al (2023) published a systematic review comparing surgical time, short-term adverse events, and implant placement accuracy between manual, robotic-assisted, and computer-navigated THA.[11,] Seven RCTs were identified comparing computer-assisted navigation and manual THAs. Table 6 outlines the studies included comparing computer-assisted THA and manual THA. Characteristics and results specific to computer-assisted navigation are shown in Tables 7 and 8, respectively. In brief, manual THA resulted in significantly shorter surgical times and a similar incidence of complications and revisions compared to computer-assisted THA. However, computer-assisted navigation THA led to increased precision in the placement of acetabular implants.

Table 6. Comparison of RCTs Included in Systematic Reviews and Meta-Analyses for Computer-Assisted Navigation for THA

Study	Kunze et al (2022)
Leenders et al (2002)	●
Gurgel et al (2014)	●
Lass et al (2014)	●
Renkawitz et al (2015)	●
Parratte et al (2016)	●
Weber et al (2016)	●
Verdier et al (2016)	●

RCT: randomzied controlled trial; THA: total hip arthroplasty.
[a] Only articles comparing computer navigation and manual total hip arthroplasty procedures are included in table.

Table 7. Systematic Reviews and Meta-Analyses for Computer-Assisted Navigation for THA: Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration, mean
Kunze et al (2022)	2008-2019	7	Computer-assisted navigation THA compared to manual THA with at least 1-year follow-up.	598 (40 to 135)	RCT	4.3 yrs (range, 1 to 14.2 yrs)[a]

[a] Mean duration includes all studies included in systematic review, including robotic-assisted THA studies.
RCT: randomized controlled trial; THA: total hip arthroplasty

Table 8. Systematic Reviews and Meta-Analyses for Computer-Assisted Navigation for THA: Results

Study	Operation length, mins	All-cause complications	All-cause revisions	Acetabular implant positioning (% of acetabular cups placed in safe zone)
Kunze et al (2022)[11,]				
Total N	373 (3 studies)	NR (11 studies)	598 (7 studies)	178 (3 studies)
Manual THA	mean, 86.6 mins	Total=38 (6.6%)	Total=2	46/89 (52%)

Computer-assisted THA	mean, 95.7 mins	Total=5 (1.7%)	Total=3	70/89 (79%)
Pooled effect (95% CI)	SMD, 8.55 (3.49 to 13.60)	OR, 0.83 (0.23 to 2.99)	OR, 1.15 (0.30 to 4.42)	ES, 0.79 (0.69 to 0.86)
p-value	<.001	.781	.840	.02
I^2 (p)	--	--	--	*0%* (.29)

CI: confidence interval; ES: effect size; NR: not reported; OR: odds ratio; SMD: standard mean difference; THA: total hip arthroplasty.

Nonrandomized Studies

In a 2022 retrospective review, Sharma et al examined the use of computer assisted hip navigation and the rate of dislocations in patient undergoing THA. A retrospective review of 72 patients undergoing computer-navigated THA between February 2016 and May 2017 was performed. Demographics, indications for revision, type of procedure performed, and incidence of postoperative dislocation were collected for all patients. Clinical follow-up was recorded at 3 months, 1 year and 2 years. All 72 patients (48% female; 52% male) were included for analysis. The mean age was 70.4 ± 11.2 years and mean BMI was 26.4 ± 5.2 kg/m. Twenty two of 72 patients (31%) required a THA procedure due to instability resulting in dislocation. At 3 months, 1 year, and 2 years, there were no dislocations (0%). There was a significant reduction in dislocation rate after computer-navigated THA (0%) relative to that following primary THA in the same patient cohort (31%; $p < 0.05$).

A 2021 study by Agarwal et al compared the rate of revision between non-navigated and navigated primary THAs performed for osteoarthritis in Australia. The authors analyzed the effects of navigation on rate, reason, and type of revision. Hazard ratios (HRs) from Cox proportional hazard models, adjusted for age, sex, and head size, were utilized. Because of known prosthesis-specific differences in outcomes, the authors performed a further analysis of the 5 acetabular and femoral component combinations most commonly used with navigation. Computer navigation was utilized in 6,912 primary THAs for osteoarthritis, with the use of navigation increasing from 1.9% in 2009 to 4.4% of all primary THAs performed in 2019. There was no difference in the rate of all-cause revision between navigated and non-navigated THAs looking at the entire group. There was a lower rate of revision for dislocation in the navigation THA cohort. The cumulative percent revision for dislocation at 10 years was 0.4% (95% confidence interval [CI], 0.2% to0.6%) for navigated compared with 0.8% (95% CI, 0.8% to 0.9%) for non-navigated THAs (HR adjusted for age, sex, and head size, 0.46; 95% CI, 0.29 to 0.74; p = 0.002). In the 5 component combinations most commonly used with navigation, the rate of all-cause revision was significantly lower when these components were navigated compared with non-navigated. The cumulative percent revision at 10years for these 5 prostheses combined was 2.4% (95% CI, 1.6% to 3.4%) for navigated compared with 4.2% (95% CI, 4.0% to 4.5%) for non-navigated THAs (HR, 0.64; 95% CI, 0.48 to 0.86; p = 0.003).

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). The number of patients with a residual limb length discrepancy greater than 10 mm and/or a post-operative over-lengthening was significantly lower in the CAN group.

Minimally Invasive THA

Systematic Reviews

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

Curley et al (2023) published a systematic review evaluating the techniques and outcomes of intraoperative computer assisted modalities for periacetabular osteotomy (PAO). Three databases (PubMed, CINAHL/EBSCOHost and Cochrane) were searched for clinical studies reporting on computer-assisted modalities for PAO. Exclusion criteria included small case series (<10 patients), non-English language and studies that did not provide a description of the computer-assisted technique. Data extraction included computer-assisted modalities utilized, surgical techniques, demographics, radiographic findings, perioperative outcomes, patient-reported outcomes (PROs), complications and subsequent surgeries. Nine studies met the inclusion criteria, consisting of 208 patients with average ages ranging from 26 to 38 years. Intraoperative navigation was utilized in seven studies, patient-specific guides in one study and both modalities in one study. Three studies reported significantly less intraoperative radiation exposure ($P < 0.01$) in computer assisted versus conventional PAOs. Similar surgical times and estimated blood loss ($P > 0.05$) were commonly observed between the computer assisted and conventional groups. The average post-operative lateral center edge angles in patients undergoing computer assisted PAOs ranged from 27.8° to 37.4°, with six studies reporting similar values ($P > 0.05$) compared to conventional PAOs. Improved PROs were observed in all six studies that reported preoperative and post-operative values of patients undergoing

computer assisted PAOs. Computer-assisted modalities for PAO include navigated tracking of the free acetabular fragment and surgical instruments, as well as patient-specific cutting guides and rotating templates. Compared to conventional techniques, decreased intraoperative radiation exposure and similar operative lengths were observed with computer assisted PAOs, although these results should be interpreted with caution due to heterogeneous operative techniques and surgical settings.

Imai et al (2020) compared outcomes after computer assisted PAO and conventional PAO performed for hip dysplasia (DDH). Ninety-one patients (98 hips) were enrolled in this study. In each case, DDH was treated with either conventional PAO, in which the angle and direction of the osteotomy was determined by intra-operative X-ray examination, or with computer assisted PAO, which used the 3D navigation system. Forty hips underwent conventional PAO and 58 hips underwent computer assisted PAO. Japanese Orthopaedic Association hip scores improved significantly from 70.0 points pre-operatively to 90.7 points post-operatively in patients with conventional PAO, and from 74.5 points pre-operatively to 94.2 points post-operatively in patients with computer-assisted PAO. In all patients with computer assisted PAO, the post-operative AHI and VCA angle were within the radiographic target zone. Some patients with conventional PAO had post-operative AHI and VCA angle outside of the target zone. A total hip arthroplasty (THA) was performed on five of the 98 PAO hips (5.1%) after an average follow-up period of 5.4 years. None of 58 hips (0%) with computer-assisted PAO was revised.

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.

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 individuals 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).

Table 9. Characteristics of Systematic Reviews and Meta-Analyses Investigating TKA

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Xie et al (2012)	PubMed and EMBASE through August 2011	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 et al (2014)	PubMed, EMBASE, Scopus, and CENTRAL through December 2012	20	Included 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 (46-166)	RCT	3 mos and 12-32 mos

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

Table 10. Results of Systematic Reviews and Meta-Analyses Investigating TKA

Study	Knee Society Score				Operative Time	
Xie et al (2012)						
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- to 32 Months**	**3 Months**	**12- to 32 Months**		
Rebal et al (2014)						

Study	Knee Society Score				Operative Time	
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 TKA groups.

Three trials comparing computer-assisted navigation and conventional surgery reported on outcomes at 4 to 5 years follow-up (N=67 to 107). Blakeney et al (2014) reporting 46-month follow-up for 107 patients [19] found a trend toward higher scores on the Oxford Knee Questionnaire with computer-assisted navigation, with a mean score of 40.6 for the computer-assisted navigation group compared with 37.6 and 36.8 in extramedullary and intramedullary control groups, respectively. There were no significant differences in the 12-Item Short-Form Health Survey Physical Component or Mental Component Summary scores. The trial was underpowered, and the clinical significance of this trend for the Oxford Knee Questionnaire is unclear. Lutzner et al (2013), reporting on 5-year follow-up for 67 of 80 patients[20] found a significant decrease in the number of outliers with computer-assisted navigation (3 vs. 9; p=.048) but no significant differences between groups on the Knee Society Score or Euroqol quality of life questionnaire. At 10-years post-surgery, a follow-up study (Beyer et al 2021) of 50 patients originally included in the Lutzner et al 2013 study showed no significant differences in the number of outliers between groups, patient-reported outcomes from the Knee Society Score of Euroqol quality of life questionnaire, and no differences in revision risk.[21] Cip et al (2014) found a significant decrease in malalignment with computer-assisted navigation, but no significant differences in implant survival or consistent differences in clinical outcome measures between the navigated (n=100) and conventional (n=100) total knee arthroplasty groups at minimum 5-year follow-up.[22]

Four additional trials comparing computer-assisted and conventional surgery reported outcomes after 8 to 12 years follow-up (N=60 to 200). Hsu et al (2019) reported similar clinical and functional outcomes with the 2 procedures after a mean 8.1-year follow-up, although computer-assisted navigation achieved better radiographic alignment and fewer outliers.[23] They suggested that TKA 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. Song et al (2016) also reported on a reduction in the number of outliers with computer-

assisted navigation (7.3% vs. 20%; p=.006), with no significant differences in clinical outcomes at 8-year follow-up.[24] The trial, which assessed 80 patients (88 knees) was powered to detect a 3-point difference in Knee Society Score results. Cip et al (2018) published the results of a prospective randomized trial (N=200) comparing conventional TKA with computer-assisted TKA with a mean follow-up of 12 years postoperatively.[25] The trial was aimed at determining the long-term outcomes of computer-assisted navigation 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 computer-assisted navigation group (98.2%) at 12 years (p=.181). In a single-blinded, prospective RCT, Farhan-Alanie et al (2023) compared conventional TKA (n=98) with computer-assisted TKA (n=101), with a mean follow-up of 10 years.[26] Over the 10-year period, there were 23 deaths (22.8%) in the computer-assisted group and 30 deaths (30.6%) in the conventional cohort. At the 10-year follow-up, the authors found no difference in revision rates (4.0% computer-navigation vs 6.1% conventional; p=.429) or clinical outcomes, including Oxford Knee Scores, American Knee Society Scores, or mental and physical scores on the 36-item Short-Form survey between groups.

Comparative Studies

Results from observational studies have generally been consistent with the systematic reviews and RCTs.[27-32] 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.[31] 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 (e.g., 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.[32] 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).

A retrospective comparison cohort study by Webb et al (2021) compared conventional TKA cases (n=219,880) to computer navigated TKA cases (n=5243) that occurred from 2008 through 2016 and were documented in the American College of Surgeons National Surgical Quality Improvement Program database.[33] In univariate analysis of unmatched cohorts, rates of composite serious morbidities and death or serious morbidity were significantly higher in the conventional TKA group than the computer navigated group (8.47% vs. 7.54%; p=.016). In multivariable regression analysis, computer navigated TKA was found to be significantly associated with lower rates of serious morbidity (odds ratio [OR], 0.83; p=.001), death or serious morbidity (OR, 0.82; p<.001) and length of stay (OR, 0.86; p=.024). Propensity score

matching identified 4811 case pairs of conventional versus computer navigated TKA. Propensity-matched analyses demonstrated no significant difference in mortality, length of operation time, length of stay, or rates of reoperation or readmission. The composite rate of complications was 18% less in the computer navigated group compared to the conventional TKA group (p=.009).

Aletto et al (2021) evaluated the functional outcomes of computer navigated TKA through the Knee Society Score (KSS) and Tegner Lysholm Knee Scoring Scale (TLKSS). Between September 2007 and February 2013, 180 patients (200 knees; 109 females and 71 males; mean age: 64 years) undergoing computer assisted TKA were recruited. Plain radiographs and CT scans were performed post-operatively to evaluate alignment. The clinical outcomes were measured using the KSS and TLKSS pre-operatively and after 6, 12 and 36 months. The mean follow-up duration was 2.5 years. The mean tourniquet time was 72 ± 13.4 min, and patients received an average of 0.6 ± 0.82 units of blood after surgery. The average preoperative KSS functional score of 44.6 ± 13.7 improved to 80.4 ± 16.4 after 2 years. The average preoperative TLKSS improved to 71.4 ± 13.5 after 2 years. The mechanical axis was within ±3° in all patients. No axial malalignments were observed on TC Scan. Three patients (1.6% of cases) required revision.

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 individuals 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 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

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 below, 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; risk ratio [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).

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),[38] 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)[39] 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.[40] 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 11. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Laine et al (2000)	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)	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)	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

Table 12. Summary of Key Randomized Controlled Trial Results

Study; Trial	Mean Insertion Time	Pedicle Screw Perforation	Radiation Exposure
Laine et al (2000)	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)	n=33 (478 screws)	n=33 (478 screws)	--
Computer-assisted	2.4 (SD 0.7) minutes per	2.1% (5/242)	Not reported

navigation	screw		
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)	--	--	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

SD: standard deviation.

Table 13. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Laine et al (2000)				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)				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)				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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[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 14. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Laine et al (2000)[34]					1. Power calculations	

					not reported	
Rajasekaran et al (2007)[35.]					1. Power calculations not reported	
Villard et al (2014)[36.]	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.

Other Indications

The use of computer-assisted navigation for the treatment of spinal tumors has been reported in uncontrolled case series and case reports.[41-43] 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.

SUMMARY OF EVIDENCE

For individuals who are undergoing orthopedic surgery for trauma or fracture and receive computer-assisted navigation, the evidence includes one retrospective studies, 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.

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 all knees had normal function, as well as the accuracy and consistency of tibial tunnel position can be improved by the use of CAN. In addition, the clinical laxity is more reliable.

For individuals who are undergoing hip arthroplasty and periacetabular osteotomy (PAO) and receive computer-assisted navigation, the evidence includes systematic reviews of older RCTs, 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 showed a significant reduction in dislocation rate after computer-navigated THA relative to that following primary THA. There is evidence that computer navigation THA led to better precision in the placement of acetabular implants. In all patients with computer assisted PAO, the post-operative AHI and VCA angle were within the radiographic target zone. Some patients with conventional PAO had post-operative AHI and VCA angle outside of the target zone.

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. However, computer assisted TKA allows reproducible alignment and kinematics, reducing outliers, provides ligament balancing and ensures good short term outcomes in terms of Knee Society functional score and Tegner Lysholm Knee Scoring Scale. Literature shows results to be equal to or not inferior to conventional methods.

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. .

ONGOING AND UNPUBLISHED CLINICAL TRIALS

One currently unpublished trial that might influence this review is listed in Table 15.

Table 15. 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 Dec 2022
NCT02717299	Making Sense Out of Total Knee Sensor Assisted Technology: A Randomized Control Trial	78	Apr 2021 (recruitment status unknown)
NCT04960345	Comparison of Accuracy and Clinical Outcomes Between Brainlab Knee 3 Computer-assisted Navigation Systems and Conventional Instruments in TKA: a Prospective Cohort Study	188	Dec 2023
Unpublished			

NCT01469299[a]	Prospective Study Measuring Clinical Outcomes of Knee Arthroplasty Using the VERASENSE™ Knee System	285	Dec 2016 (updated 01/11/17)
NCT03668756	Comparison of Computer-Assisted Navigation and Conventional Instrumentation for Bilateral Total Knee Arthroplasty: The Functional Outcome of Mid-Term Follow-up Study	56	Aug 2018
NCT02190435[a]	Computer-Assisted Navigation for Intramedullary Nail Fixation of Intertrochanteric Femur Fractures	65	Jan 2016
NCT03817632a	Prospective, Multicenter, Observational, Comparative Clinical Trial on the Equivalence of Two Different OrthoPilot® Navigation System Generations Applied for Computer-assisted Total Knee Arthroplasty	217	Oct 2022

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.

American Academy of Orthopedic Surgeons

The American Academy of Orthopedic Surgeons updated guidelines in 2022 on surgical management of osteoarthritis of the knee.[44,] Related to computer-assisted surgical navigation, the guidelines state there is no difference in outcomes, function, or pain between computer-navigation and conventional techniques for total knee arthroplasty (strength of evidence: strong; strength of recommendation: moderate), and make no specific recommendation related to its use. The guidelines note that the advantages of surgical navigation remain unclear.

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:

Wisconsin Physicians Service Insurance Corporation has published a Local Coverage Determination on this topic.

Stereotactic Computer Assisted Volumetric and/or Navigational Procedure (LCD ID L29586), Original Effective Date 8/16/09, Retired 12/01/2015

Recent advances in technology have led to numerous advances in imaging technology, more specifically for the purposes of this LCD, imaging as related to surgical procedures. This LCD is intended to cover those uses of stereotactic computer assisted volumetric and or navigational procedures which could correctly be identified by the use of CPT codes 61781, 61782 and 61783, add-on codes, recognized for payment by Medicare, when their use is considered medically reasonable and necessary.

Payment is limited to stereotactic computer assisted volumetric and or navigational procedures for any one or more of the following indications;

1. Where there is clinical data to support its use.
2. When used in conjunction with most intracerebral procedures, excluding routine shunt procedures.
3. When used for the following extracranial otorhinolaryngological/head and neck procedures;
    a. Revision endoscopic sinus surgery
    b. Frontal or sphenoid sinus surgery when there is documented loss of or altered anatomic and marks, congenital deformities or severe trauma
    c. Significantly distorted sinus anatomy of developmental, postoperative or traumatic origin
    d. Extensive sino-nasal polyposis of sufficient severity to create a need for the precision localization and navigation assistance
    e. Pathology involving the frontal, posterior ethmoid or sphenoid sinuses
    f. Disease abutting the skull base, orbit, optic nerve or carotid artery
    g. Lateral skull base surgery where navigational planning and assistance is required
    h. CSF rhinorrhea or conditions where there is a skull base defect
    i. Transsphenoidal surgery
    j. Benign and malignant sino-nasal neoplasms of sufficient size or high-risk location

Use of CPTs 61781, 61782 and 61783 with 20985, 0054T and 0055T or other such CPT codes have been determined to be **NOT** appropriate in cases where screws and/or other hardware are applied to the spine. All spinal procedures will be considered inappropriate for its separate payment, due to the lack of compelling literature support, and such claims will be denied as not proven effective. To date, we have seen no such compelling literature.

In addition, there is currently no convincing literature to support the use of any other clinically available devices for use in performing joint replacement surgery, either knee or hip. Though it does appear that the technology allows arguably more precise positioning of the joint replacement hardware, there is no long-term data supporting the assertion that this improves patient outcomes or long-term viability of the repair as compared to traditional methods of performing these procedures. Therefore, CPT codes 20985, 0054T and 0055T, or other such CPT codes will be denied as not proven effective.

(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

- Computer-Aided Detection Mammography (Retired)
- Dynamic Posturography (retired)

References

1. Hofstetter R, Slomczykowski M, Krettek C, et al. Computer-assisted fluoroscopy-based reduction of femoral fractures and antetorsion correction. Comput Aided Surg. Feb 2000;5(5):311-325. PMID 11169877
2. Schep NW, Broeders IA, van der Werken C. Computer assisted orthopaedic and trauma surgery. State of the art and future perspectives. Injury. May 2003;34(4):299-306. PMID 12667784
3. Slomczykowski MA, Hofstetter R, Sati M, et al. Novel computer-assisted fluoroscopy system for intraoperative guidance: feasibility study for distal locking of femoral nails. J Orthop Trauma. Feb 2001;15(2):122-131. PMID 11232651
4. Liebergall M, Ben-David D, Weil Y, et al. Computerized navigation for the internal fixation of femoral neck fractures. J Bone Joint Surg Am. Aug 2006;88(8):1748-1754. PMID 16882897
5. Swartman B, Pelzer J, Beisemann N, et al. Fracture reduction and screw position after 3D-navigated and conventional fluoroscopy-assisted percutaneous management of acetabular fractures: a retrospective comparative study. Arch Orthop Trauma Surg. Apr 2021; 141(4): 593-602. PMID 32519074
6. Eggerding V, Reijman M, Scholten RJ, et al. Computer-assisted surgery for knee ligament reconstruction. Cochrane Database Syst Rev. Aug 4 2014;8(8):CD007601. PMID 25088229
7. Plaweski S, Cazal J, Rosell P, et al. Anterior cruciate ligament reconstruction using navigation: a comparative study on 60 patients. Am J Sports Med. Apr 2006;34(4):542-552. PMID 16556753
8. Hart R, Krejzla J, Svab P, et al. Outcomes after conventional versus computer-navigated anterior cruciate ligament reconstruction. Arthroscopy. May 2008;24(5):569-578. PMID 18442690
9. Meuffels DE, Reijman M, Verhaar JA. Computer-assisted surgery is not more accurate or precise than conventional arthroscopic ACL reconstruction: a prospective randomized clinical trial. J Bone Joint Surg Am. Sep 5 2012;94(17):1538-1545. PMID 22832975
10. Mauch F, Apic G, Becker U, et al. Differences in the placement of the tibial tunnel during reconstruction of the anterior cruciate ligament with and without computer-assisted navigation. Am J Sports Med. Nov 2007;35(11):1824-1832. PMID 17878429

11. Kunze KN, Bovonratwet P, Polce EM, et al. Comparison of Surgical Time, Short-term Adverse Events, and Implant Placement Accuracy Between Manual, Robotic-assisted, and Computer-navigated Total Hip Arthroplasty: A Network Meta-analysis of Randomized Controlled Trials. J Am Acad Orthop Surg Glob Res Rev. Apr 01 2022; 6(4). PMID 35472191
12. Manzotti A, Cerveri P, De Momi E, et al. Does computer-assisted surgery benefit leg length restoration in total hip replacement? Navigation versus conventional freehand. Int Orthop. Jan 2011; 35(1): 19-24. PMID 19904533
13. Ulrich SD, Bonutti PM, Seyler TM, et al. Outcomes-based evaluations supporting computer-assisted surgery and minimally invasive surgery for total hip arthroplasty. Expert Rev Med Devices. Nov 2007; 4(6): 873-83. PMID 18035952
14. Reininga IH, Stevens M, Wagenmakers R, et al. Comparison of gait in patients following a computer-navigated minimally invasive anterior approach and a conventional posterolateral approach for total hip arthroplasty: a randomized controlled trial. J Orthop Res. Feb 2013; 31(2): 288-94. PMID 22886805
15. Hsieh PH, Chang YH, Shih CH. Image-guided periacetabular osteotomy: computer-assisted navigation compared with the conventional technique: a randomized study of 36 patients followed for 2 years. Acta Orthop. Aug 2006; 77(4): 591-7. PMID 16929435
16. Stiehler M, Goronzy J, Hartmann A, et al. The First SICOT Oral Presentation Award 2011: imageless computer-assisted femoral component positioning in hip resurfacing: a prospective randomised trial. Int Orthop. Apr 2013; 37(4): 569-81. PMID 23385606
17. Xie C, Liu K, Xiao L, et al. Clinical Outcomes After Computer-assisted Versus Conventional Total Knee Arthroplasty. Orthopedics. May 2012; 35(5): e647-53. PMID 22588405
18. Rebal BA, Babatunde OM, Lee JH, et al. Imageless computer navigation in total knee arthroplasty provides superior short term functional outcomes: a meta-analysis. J Arthroplasty. May 2014; 29(5): 938-44. PMID 24140274
19. Blakeney WG, Khan RJ, Palmer JL. Functional outcomes following total knee arthroplasty: a randomised trial comparing computer-assisted surgery with conventional techniques. Knee. Mar 2014; 21(2): 364-8. PMID 24703685
20. Lützner J, Dexel J, Kirschner S. No difference between computer-assisted and conventional total knee arthroplasty: five-year results of a prospective randomised study. Knee Surg Sports Traumatol Arthrosc. Oct 2013; 21(10): 2241-7. PMID 23851969
21. Beyer F, Pape A, Lützner C, et al. Similar outcomes in computer-assisted and conventional total knee arthroplasty: ten-year results of a prospective randomized study. BMC Musculoskelet Disord. Aug 18 2021; 22(1): 707. PMID 34407776
22. Cip J, Widemschek M, Luegmair M, et al. Conventional versus computer-assisted technique for total knee arthroplasty: a minimum of 5-year follow-up of 200 patients in a prospective randomized comparative trial. J Arthroplasty. Sep 2014; 29(9): 1795-802. PMID 24906519
23. Hsu RW, Hsu WH, Shen WJ, et al. Comparison of computer-assisted navigation and conventional instrumentation for bilateral total knee arthroplasty: The outcomes at mid-term follow-up. Medicine (Baltimore). Nov 2019; 98(47): e18083. PMID 31764842
24. Song EK, Agrawal PR, Kim SK, et al. A randomized controlled clinical and radiological trial about outcomes of navigation assisted TKA compared to conventional TKA: long-term

follow-up. Knee Surg Sports Traumatol Arthrosc. Nov 2016; 24(11): 3381-3386. PMID 26831857

25. Cip J, Obwegeser F, Benesch T, et al. Twelve-Year Follow-Up of Navigated Computer-Assisted Versus Conventional Total Knee Arthroplasty: A Prospective Randomized Comparative Trial. J Arthroplasty. May 2018; 33(5): 1404-1411. PMID 29426792
26. Farhan-Alanie OM, Altell T, O'Donnell S, et al. No advantage with navigated versus conventional mechanically aligned total knee arthroplasty-10 year results of a randomised controlled trial. Knee Surg Sports Traumatol Arthrosc. Mar 2023; 31(3): 751-759. PMID 36166095
27. Kim YH, Park JW, Kim JS. Computer-navigated versus conventional total knee arthroplasty a prospective randomized trial. J Bone Joint Surg Am. Nov 21 2012; 94(22): 2017-24. PMID 23052635
28. Hoppe S, Mainzer JD, Frauchiger L, et al. More accurate component alignment in navigated total knee arthroplasty has no clinical benefit at 5-year follow-up. Acta Orthop. Dec 2012; 83(6): 629-33. PMID 23140107
29. Yaffe M, Chan P, Goyal N, et al. Computer-assisted versus manual TKA: no difference in clinical or functional outcomes at 5-year follow-up. Orthopedics. May 2013; 36(5): e627-32. PMID 23672916
30. Hoffart HE, Langenstein E, Vasak N. A prospective study comparing the functional outcome of computer-assisted and conventional total knee replacement. J Bone Joint Surg Br. Feb 2012; 94(2): 194-9. PMID 22323685
31. Dyrhovden GS, Fenstad AM, Furnes O, et al. Survivorship and relative risk of revision in computer-navigated versus conventional total knee replacement at 8-year follow-up. Acta Orthop. Dec 2016; 87(6): 592-599. PMID 27775460
32. Antonios JK, Kang HP, Robertson D, et al. Population-based Survivorship of Computer-navigated Versus Conventional Total Knee Arthroplasty. J Am Acad Orthop Surg. Oct 15 2020; 28(20): 857-864. PMID 31934926
33. Webb ML, Hutchison CE, Sloan M, et al. Reduced postoperative morbidity in computer-navigated total knee arthroplasty: A retrospective comparison of 225,123 cases. Knee. Jun 2021; 30: 148-156. PMID 33930702
34. Gelalis ID, Paschos NK, Pakos EE, et al. Accuracy of pedicle screw placement: a systematic review of prospective in vivo studies comparing free hand, fluoroscopy guidance and navigation techniques. Eur Spine J. Feb 2012; 21(2): 247-55. PMID 21901328
35. Shin BJ, James AR, Njoku IU, et al. Pedicle screw navigation: a systematic review and meta-analysis of perforation risk for computer-navigated versus freehand insertion. J Neurosurg Spine. Aug 2012; 17(2): 113-22. PMID 22724594
36. Staartjes VE, Klukowska AM, Schröder ML. Pedicle Screw Revision in Robot-Guided, Navigated, and Freehand Thoracolumbar Instrumentation: A Systematic Review and Meta-Analysis. World Neurosurg. Aug 2018; 116: 433-443.e8. PMID 29859354
37. Perdomo-Pantoja A, Ishida W, Zygourakis C, et al. Accuracy of Current Techniques for Placement of Pedicle Screws in the Spine: A Comprehensive Systematic Review and Meta-Analysis of 51,161 Screws. World Neurosurg. Jun 2019; 126: 664-678.e3. PMID 30880208

38. Laine T, Lund T, Ylikoski M, et al. Accuracy of pedicle screw insertion with and without computer assistance: a randomised controlled clinical study in 100 consecutive patients. Eur Spine J. Jun 2000; 9(3): 235-40. PMID 10905443
39. Rajasekaran S, Vidyadhara S, Ramesh P, et al. Randomized clinical study to compare the accuracy of navigated and non-navigated thoracic pedicle screws in deformity correction surgeries. Spine (Phila Pa 1976). Jan 15 2007; 32(2): E56-64. PMID 17224800
40. Villard J, Ryang YM, Demetriades AK, et al. Radiation exposure to the surgeon and the patient during posterior lumbar spinal instrumentation: a prospective randomized comparison of navigated versus non-navigated freehand techniques. Spine (Phila Pa 1976). Jun 01 2014; 39(13): 1004-9. PMID 24732833
41. Arand M, Hartwig E, Kinzl L, et al. Spinal navigation in tumor surgery of the thoracic spine: first clinical results. Clin Orthop Relat Res. Jun 2002; (399): 211-8. PMID 12011712
42. Van Royen BJ, Baayen JC, Pijpers R, et al. Osteoid osteoma of the spine: a novel technique using combined computer-assisted and gamma probe-guided high-speed intralesional drill excision. Spine (Phila Pa 1976). Feb 01 2005; 30(3): 369-73. PMID 15682022
43. Smitherman SM, Tatsui CE, Rao G, et al. Image-guided multilevel vertebral osteotomies for en bloc resection of giant cell tumor of the thoracic spine: case report and description of operative technique. Eur Spine J. Jun 2010; 19(6): 1021-8. PMID 20069317
44. American Academy of Orthopaedic Surgeons. Surgical management of osteoarthritis of the knee. 2022. https://www.orthoguidelines.org/topic?id=1041. Accessed November 2023.
45. Sharma AK, Cizmic Z, Carroll KM, et al. Computer navigation for revision total hip arthroplasty reduces dislocation rates. Indian J Orthop. Jun 2022; 56(6):1061-1065.
46. Agarwal S, Eckhard L, Walter W, et al. The use of computer navigation in total hip arthroplasty is associated with a reduced rate of revision for dislocation: a study of 6,912 navigated THA procedures from the Australian Orthopaedic Association National Joint Replacement Registry. J Bone Joint Surg Am. Oct 2021; 103(20):1900-1905.
47. Curley AJ, Bruning RE, Padmanabhan S, et al. Periacetabular osteotomy with intraoperative computer assisted modalities: a systematic review. J Hip Preserv Surg. Apr 2023; 10(2):104-118.
48. Imai H, Kamada T, Miyawaki J, et al. Outcomes of computer assisted periacetabular osteotomy compared with conventional osteotomy in hip dysplasia. Int Orthop. June 2020; 44(6):1055-1061.
49. Aletto C, Zara A, Notarfrancesco D, Maffulli N. Computer assisted total knee arthroplasty: 2.5 years follow-up of 200 cases. Surgeon. Dec 2021; 19(6):e394-e401.
50. Blue Cross Blue Shield Association. Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure. Medical Policy Reference Manual. Policy #7.01.96, Issue 7:2012, original policy date 2/25/04, last review date May 2023.
51. HAYES Directory Assessment. Computer-Aided Total Hip Arthroplasty. Lansdale, PA: HAYES, Inc. December 7, 2012, last updated October 2016.
52. HAYES Directory Assessment. Imageless Computer-Aided Navigation for Total Knee Arthroplasty. Lansdale, PA: HAYES, Inc. December 23, 2012, last updated November 2016.
53. HAYES Clinical Research Response. Verasense (Orthosensor Inc.) for use during total knee replacement. Lansdale, PA: HAYES Inc. December 2015.

54. HAYES Technology Brief Verasense (Orthosensor Inc.) for use during total knee replacement. Lansdale, PA: Hayes Inc. September 15, 2016. Archived October 2019.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
8/26/05	8/26/05	9/15/05	Joint policy established
7/1/07	5/10/07	4/15/07	Routine maintenance
7/1/08	5/17/08	5/1/08	Routine maintenance, codes updated
9/1/09	6/16/09	6/16/09	Codes updated; policy statement unchanged
11/1/11	8/16/11	8/16/11	Routine maintenance; added codes 0054T and 0055T effective 1/1/09
9/1/13	6/19/13	6/26/13	Routine maintenance; updated references, rationale and information in the “Government Regulations” section.
5/1/15	2/17/15	2/27/15	Routine maintenance. No change in policy status.
5/1/16	2/16/16	2/16/16	Routine maintenance. No change in policy status.
3/1/17	12/13/16	12/13/16	Routine policy maintenance, updated references/rationale, Hayes and clinical trials. No change in policy statement.
3/1/18	12/12/17	12/12/17	Routine policy maintenance, updated rationale, added references 26 & 32, removed some references. No change in policy status.
3/1/19	12/11/18		Routine policy maintenance, no change in policy status.

3/1/20	12/17/19		Rationale updated, referenced #19 added, several outdated references removed. No change in policy status.
3/1/21	12/15/20		Rationale updated, reference #22. Code 0396T deleted effective 1/1/2021. No change in policy status.
3/1/22	12/14/21		Rationale updated, references #31-40 added. No change in policy status.
3/1/23	12/20/22		Updated rationale section added reference #31. No change in policy status.
3/1/24	1/4/24		Policy status changed to established. Use of CAN is not separately reimbursed. Added code 61783 as established. Rationale updated, references updated, some removed some added (5,11,21,26,33,44-49). Codes 20985, 61783, 0054T & 0055T now established. Vendor managed: Turning Point. (ds)

Next Review Date: 4th Qtr. 2024

BLUE CARE NETWORK BENEFIT COVERAGE

POLICY: COMPUTER-ASSISTED MUSCULOSKELETAL SURGICAL NAVIGATIONAL ORTHOPEDIC PROCEDURE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Per policy
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A