

Protocol

Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure

(70196)

Medical Benefit		Effective Date: 07/01/12	Next Review Date: 09/17
Preauthorization	No	Review Dates: 06/07, 07/08, 03/09, 03/10, 03/11, 03/12, 03/13, 03/14, 09/14, 09/15, 09/16	

Preauthorization is not required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Patients/individuals with: <ul style="list-style-type: none">• Orthopedic procedures that require alignment	Interventions of interest are: <ul style="list-style-type: none">• Computer-assisted orthopedic surgery	Comparators of interest are: <ul style="list-style-type: none">• Conventional/manual approaches for orthopedic surgery	Relevant outcomes include: <ul style="list-style-type: none">• Quality of life• Functional outcomes• Symptoms

Description

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

Summary of Evidence

Overall, the literature supports a decrease in variability of alignment with computer-assisted navigation (CAN), particularly with respect to the number of outliers. Although some observational data suggest that malalignment may increase the probability of early failure, recent randomized controlled trials with short- to mid-term follow-up have not shown improved health outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of available studies to detect changes in function, studies that assess health outcomes in a larger number of subjects with longer follow-up are needed. Potential uses of this procedure may be in gap balancing and the ability to decrease incision length without loss of accuracy in component alignment. Another area of potential benefit is pelvic tumor resection. Although evidence at this time has not adequately demonstrated improved health outcomes with this more resource-intensive combination, continued technology development in this area is expected.

Policy

Computer-assisted surgery for orthopedic procedures of the pelvis and appendicular skeleton is considered **investigational**.

Background

The goal of computer-assisted navigation (CAN) is to increase surgical accuracy and reduce the chance of malposition. For total knee arthroplasty (TKA), malalignment is commonly defined as a variation of greater than 3° from the targeted position. Proper implant alignment is believed to be an important factor for minimizing long-term wear, risk of osteolysis, and loosening of the prosthesis. In addition to reducing the risk of substantial malalignment, CAN may improve soft tissue balance and patellar tracking. CAN is also being investigated for 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, 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 3-dimensional (3D) model that includes the mechanical, transepicondylar, and tibial rotational axes. CAN systems direct the positioning of the cutting blocks and placement of the prosthetic implants based on 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 guided by imageless systems. These data are then used for registration and tracking.

Registration

Registration refers to the ability of relating images (i.e., radiographs, CT scan, MRI, or patients' 3D anatomy) to the anatomic position in the surgical field. Registration techniques may require the placement of pins or "fiducial markers" in the target bone. A surface-matching technique can 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.

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 FDA. As such, FDA does not require data documenting the intermediate or final health outcomes associated with CAN. (In contrast, robotic procedures, in which the actual surgery is robotically performed, are subject to the more rigorous requirement of the premarket approval application process.)

A variety of surgical navigation procedures have received FDA clearance through the 510(k) process with broad labeled indications. The following is an example; “The OEC FluoroTrak 9800 Plus provides the physician with fluoroscopic imaging during diagnostic, surgical and interventional procedures. The surgical navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images.”

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 intraoperatively (e.g., ligament tension, limb alignment). Examples of some surgical procedures include but are not limited to:

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

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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced

procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Hofstetter R, Slomczykowski M, Krettek C, et al. Computer-assisted fluoroscopy-based reduction of femoral fractures and antetorsion correction. *Comput Aided Surg.* 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. Suhm N, Jacob AL, Nolte LP, et al. Surgical navigation based on fluoroscopy--clinical application for computer-assisted distal locking of intramedullary implants. *Comput Aided Surg.* 2000; 5(6):391-400. PMID 11295852
5. 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
6. Meuffels DE, Reijman M, Scholten RJ, et al. Computer assisted surgery for knee ligament reconstruction. *Cochrane Database Syst Rev.* 2011(6):CD007601. PMID 21678367
7. Eggerding V, Reijman M, Scholten RJ, et al. Computer-assisted surgery for knee ligament reconstruction. *Cochrane Database Syst Rev.* 2014; 8:CD007601. PMID 25088229
8. 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
9. 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
10. 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
11. 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
12. Parratte S, Argenson JN. Validation and usefulness of a computer-assisted cup-positioning system in total hip arthroplasty. A prospective, randomized, controlled study. *J Bone Joint Surg Am.* Mar 2007; 89(3):494-499. PMID 17332097
13. Lass R, Kubista B, Olischar B, et al. Total hip arthroplasty using imageless computer-assisted hip navigation: a prospective randomized study. *J Arthroplasty.* Apr 2014; 29(4):786-791. PMID 24290738
14. 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

15. 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):873-883. PMID 18035952
16. 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):288-294. PMID 22886805
17. 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):591-597. PMID 16929435
18. 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):569-581. PMID 23385606
19. Blue Cross and Blue Shield Association Technology Evaluation Center. Computer-assisted navigation for total knee arthroplasty. *TEC Assessments 2007; Volume 22, Tab 10*. PMID 18411501
20. Bauwens K, Matthes G, Wich M, et al. Navigated total knee replacement. A meta-analysis. *J Bone Joint Surg Am*. Feb 2007; 89(2):261-269. PMID 17272438
21. Xie C, Liu K, Xiao L, et al. Clinical Outcomes After Computer-assisted Versus Conventional Total Knee Arthroplasty. *Orthopedics*. May 1, 2012; 35(5):e647-653. PMID 22588405
22. 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):938-944. PMID 24140274
23. Gothesen O, Espehaug B, Havelin LI, et al. Functional outcome and alignment in computer-assisted and conventionally operated total knee replacements: a multicentre parallel-group randomised controlled trial. *Bone Joint J*. May 2014; 96-B(5):609-618. PMID 24788494
24. Blyth MJ, Smith JR, Anthony IC, et al. Electromagnetic navigation in total knee arthroplasty-a single center, randomized, single-blind study comparing the results with conventional techniques. *J Arthroplasty*. Feb 2015; 30(2):199-205. PMID 25263246
25. 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):364-368. PMID 24703685
26. Lutzner 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):2241-2247. PMID 23851969
27. 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):1795-1802. PMID 24906519
28. Kim YH, Kim JS, Choi Y, et al. Computer-assisted surgical navigation does not improve the alignment and orientation of the components in total knee arthroplasty. *J Bone Joint Surg Am*. Jan 2009; 91(1):14-19. PMID 19122074
29. 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):2017-2024. PMID 23052635

30. 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):629-633. PMID 23140107
31. 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 1, 2013; 36(5):e627-632. PMID 23672916
32. 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):194-199. PMID 22323685
33. Huang NF, Dowsey MM, Ee E, et al. Coronal alignment correlates with outcome after total knee arthroplasty: five-year follow-up of a randomized controlled trial. *J Arthroplasty*. Oct 2012; 27(9):1737-1741. PMID 22868073
34. Choong PF, Dowsey MM, Stoney JD. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. *J Arthroplasty*. Jun 2009; 24(4):560-569. PMID 18534397
35. Czurda T, Fennema P, Baumgartner M, et al. The association between component malalignment and post-operative pain following navigation-assisted total knee arthroplasty: results of a cohort/nested case-control study. *Knee Surg Sports Traumatol Arthrosc*. Jul 2010; 18(7):863-869. PMID 19946667
36. Parratte S, Pagnano MW, Trousdale RT, et al. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. *J Bone Joint Surg Am*. Sep 15 2010; 92(12):2143-2149. PMID 20844155
37. Carter RE, 3rd, Rush PF, Smid JA, et al. Experience with computer-assisted navigation for total knee arthroplasty in a community setting. *J Arthroplasty*. Aug 2008; 23(5):707-713. PMID 18534523
38. Jenny JY, Miehlke RK, Giurea A. Learning curve in navigated total knee replacement. A multi-centre study comparing experienced and beginner centres. *Knee*. Mar 2008; 15(2):80-84. PMID 18262789
39. Pang HN, Yeo SJ, Chong HC, et al. Computer-assisted gap balancing technique improves outcome in total knee arthroplasty, compared with conventional measured resection technique. *Knee Surg Sports Traumatol Arthrosc*. Sep 2011; 19(9):1496-1503. PMID 21448662
40. Dutton AQ, Yeo SJ, Yang KY, et al. Computer-assisted minimally invasive total knee arthroplasty compared with standard total knee arthroplasty. A prospective, randomized study. *J Bone Joint Surg Am*. Jan 2008; 90(1):2-9. PMID 18171951
41. Luring C, Beckmann J, Haibock P, et al. Minimal invasive and computer assisted total knee replacement compared with the conventional technique: a prospective, randomised trial. *Knee Surg Sports Traumatol Arthrosc*. Oct 2008; 16(10):928-934. PMID 18633597
42. Bae DK, Song SJ, Yoon KH. Closed-wedge high tibial osteotomy using computer-assisted surgery compared to the conventional technique. *J Bone Joint Surg Br*. Sep 2009; 91(9):1164-1171. PMID 19721041
43. Fehlberg S, Eulenstein S, Lange T, et al. Computer-assisted pelvic tumor resection: fields of application, limits, and perspectives. *Recent Results Cancer Res*. 2009; 179:169-182. PMID 19230540