Protocol

Computer-Assisted Navigation for Orthopedic Procedure

(70196)

Medical Benefit		**Effective Date**: 07/01/12	**Next Review Date**: 09/19
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, 09/17, 09/18	

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
Individuals: • Who are undergoing orthopedic surgery for trauma or fracture	Interventions of interest are: • Computer-assisted navigation	Comparators of interest are: • Conventional/manual alignment methods	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes
Individuals: • Who are undergoing ligament reconstruction	Interventions of interest are: • Computer-assisted navigation	Comparators of interest are: • Conventional/manual alignment methods	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes
Individuals: • Who are undergoing hip arthroplasty and periacetabular osteotomy	Interventions of interest are: • Computer-assisted navigation	Comparators of interest are: • Conventional/manual alignment methods	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes
Individuals: • Who are undergoing total knee arthroplasty	Interventions of interest are: • Computer-assisted navigation	Comparators of interest are: • Conventional/manual alignment methods	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes

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

For individuals who are undergoing orthopedic surgery for trauma or fracture, ligament reconstruction, hip arthroplasty and periacetabular osteotomy, or total knee arthroplasty (TKA) who receive CAN, the evidence includes randomized controlled trials (RCTs) and nonrandomized comparative studies. Relevant outcomes are symptoms, morbid events, and functional outcomes. Overall, the literature supports a decrease in the variability of alignment with CAN, particularly with respect to the number of outliers. Although some observational data

have suggested that malalignment may increase the probability of early failure, recent RCTs with short- to mid-term follow-up have not shown improved clinical outcomes with CAN. Given the low short-term revision rates associated with conventional procedures and the inadequate power of the available studies to detect changes in function using CAN, studies are needed that assess health outcomes using CAN in a larger number of subjects with longer follow-up to permit greater certainty on the impact of this technology. The evidence is insufficient to determine the effects of the procedure on health outcomes.

POLICY

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

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.

In addition to reducing the risk of substantial malalignment, CAN may improve soft tissue balance and patellar tracking. CAN is also being investigated for surgical procedures with limited visibility such as placement of the acetabular cup in total hip arthroplasty, resection of pelvic tumors, and minimally invasive orthopedic procedures. Other potential uses of CAN for surgical procedures of the appendicular skeleton include screw placement for fixation of femoral neck fractures, high tibial osteotomy, and tunnel alignment during the reconstruction of the anterior cruciate ligament.

CAN devices may be image-based or non-image-based. Image-based devices use preoperative computed tomography scans and operative fluoroscopy to direct implant positioning. Newer non-image based devices use information obtained in the operating room, typically with infrared probes. For total knee arthroplasty, specific anatomic reference points are made by fixing signaling transducers with pins into the femur and tibia. Signal-emitting cameras (e.g., infrared) detect the reflected signals and transmit the data to a dedicated computer. During the surgery, multiple surface points are taken from the distal femoral surfaces, tibial plateaus, and medial and lateral epicondyles. The femoral head center is typically calculated by kinematic methods that involve the movement of the thigh through a series of circular arcs, with the computer producing a 3-dimensional 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 ways: fluoroscopically, guided by computed tomography scan or magnetic resonance imaging or guided by imageless systems. These data are then used for registration and tracking.

Registration

Registration refers to the ability to relate images (i.e., radiographs, computed tomography scans, magnetic resonance imaging, or patients' 3D anatomy) to the anatomic position in the surgical field. Registration techniques may require the placement of pins or "fiduciary markers" in the target bone. A surface matching technique can 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 then provide real-time information of the position and orientation of tool alignment concerning the bony anatomy of interest.

VERASENSE (OrthoSense) is a single-use device that replaces the standard plastic tibial trial spacer used in total knee arthroplasty. 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 soft tissue balancing in place of intraoperative "feel."

iASSIST (Zimmer) is an accelerometer-based alignment system with a 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 relation between the electronic pod of the digitizer and the bone reference is registered by moving the limb into abduction, adduction, and neutral position. Once the information has been registered, the digitizer is removed, and the registration data are transferred to the electronic pod on the cutting guide. The cutting guide can be adjusted for varus/valgus alignment and tibial slope. A similar process is used for the femur. The pods use the wireless exchange of data and display the alignment information to the surgeon within the surgical field. A computer controller must also be present in the operating room.

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) clearances 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 process.)

A variety of surgical navigation procedures have been cleared for marketing by the FDA through the 510(k) process with broad labeled indications. For example, The OEC FluoroTrak 9800 plus is marketed for locating anatomic structures anywhere on the human body.

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 total knee arthroplasty. The 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 (OrthoSensor) and the iASSIST™ Knee (Zimmer) were cleared for marketing by the FDA through the 510(k) process. FDA product codes: 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.

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