

Technology for surgery

O-scanner: Real-time imaging in the OR

Imagine scrubbing in for a spine case without lead aprons. Imagine taking a scan of the spine at the beginning of surgery that gives images so precise further imaging isn't needed during the case. These are advantages of the new O-shaped portable computed tomography (CT) scanners, which provide real-time 3-D imaging in the OR.

These include the O-Arm Imaging System from Medtronic, the only such device cleared for marketing by the Food and Drug Administration (FDA), and the Dominion Vi 3D Imaging Scanner from Imaging3, which is investigational. An older technology is the Arcadis Orbic 3D by Siemens.

Donald Myers, MD, chief of neurosurgery at Community Regional Medical Center, Fresno, California, who has used the O-Arm for about a year, told *OR Manager*, "It is the next-generation advance—it provides intraoperative CT scanning with the convenience and mobility of a C-arm."

Traditionally, spinal surgery patients have had preoperative imaging procedures such as CT scans, MRIs, and x-rays to provide diagnostic information to the surgeon. Conventional x-rays taken during surgery with a C-arm verify placement of surgical implants such as pedicle screws. But x-rays show only one-dimensional views, which means the trajectory of the screw could be off in 2 other planes. The O-Arm shows 3 planes during surgery and can verify accurate placement before closing.

"There is nothing else like the view we get of the spine in the OR with the O-Arm," says Dr Myers. "There is no way to duplicate it with previous technology."

O-Arm with navigation

The O-Arm can function in a stand-alone mode but is most useful when linked with a computerized navigation system, such as the Medtronic Stealth, which functions like a global positioning system (GPS).

The navigation system converts the 3-D image from the O-Arm into a computerized image, which is projected onto a monitor to guide the surgeon in placing instruments and implants in real time.

Using reflective spheres as markers on drills and other instruments, the navigation system can generate images to show the surgeon exactly where the instruments extend inside the patient's body. This enables the surgeon to insert pedicle screws precisely, for example.

"If a pedicle screw is inserted in a suboptimal manner in a 4 mm pedicle, it may crack or break," says Dr Myers. "We get one good shot at putting a screw in exactly the right spot. There's nothing like the O-Arm to help us do it."

Clear, accurate image

One O-Arm can be used in multiple cases at the same time, but if navigation is also needed, it requires 2 navigation systems, notes Julie Blatnik, RN, BSN, CNOR, program director for spine care for HealthEast Care System, Maplewood, Minnesota. Medtronic recommends cases start about 45 minutes apart, but the O-Arm is mobile and can be moved from room to room for scans at the beginning and ending of cases.



The Medtronic O-Arm portable CT scanner.

Special focus: Imaging

HealthEast purchased an O-Arm last spring.

"The image is very clear and accurate up to 0.3 millimeter," says Blatnik.

Some surgeons use the O-Arm alone without navigation just at the end of surgery before closing to confirm screw placement, spine decompression, alignment, and any surgical changes before leaving the OR. According to Medtronic, about 80% are using it with Stealth navigation.

There is also potential to use the O-Arm linked to navigational guidance at the skull base and in the brain. Medtronic anticipates that within the next year it will have algorithms and new software that might allow using it in the head, says Dr Myers.

The O-Arm is not cleared as a diagnostic imaging CT device, and the patient cannot be charged for it from that standpoint. The FDA submission is expected in 2009 or 2010, notes Blatnik.

Surgeons work faster

In addition to accurate imaging, Blatnik says the O-Arm allows surgeons to work faster and have the patient under anesthesia a shorter time. The O-Arm with Stealth can reduce a minimally invasive 2-level spinal fusion from 2 to 3 hours to about 1½ hours. This is after training is conducted, and staff are comfortable with the equipment.

Dr Myers says the O-Arm doesn't necessarily save him a great deal of time, but it allows him to be more accurate.

The big advantage for the OR staff is they don't need to wear lead aprons for the entire case. Usually, only 1 or 2 spins are done at the beginning and end of the case. The staff can step behind a lead shield or leave the room for the spins. In contrast, with a C-arm, images are taken throughout the case, which requires the staff to wear lead aprons. The anesthesiologist can don a lead apron for the spin.

Draping the O

Draping for the O-shaped scanner is similar to the C-arm. The device is shaped like a C-arm when open and can be draped similarly before closing it over the patient.

Though Dr Myers notes this draping technique is adequate, he worries about contamination when the O-Arm is opened again and removed from the field. The area where the O-Arm closes is not draped.

He places an extra drape over the patient for the spin, cutting the drape down the middle and letting it fall to each side after the O-Arm is taken from the field.

If the O-Arm stays in place for the entire procedure, the usual clear plastic drape is enough, he says.

Costs and benefits

Before purchasing an O-Arm, find out what surgeons intend to use it for, cautions Blatnik. Some surgeons want to use it as a glorified C-arm, though it is not designed to be used in that way. This exposes the patient to large amounts of radiation. A single spin of the O-Arm entails significantly higher radiation exposure for the patient and staff than a standard C-arm, though a standard C-arm typically involves multiple shots during a case.

The technology is expensive at nearly \$1 million for the O-Arm and Stealth together, and \$20,000 should be added for marketing and education, Blatnik advises.

Minimally invasive instrumentation will add another \$89,000 to the price, in addition to disposables such as percutaneous leads and dilating tubes. A reusable set of dilating tubes is about \$20,000.

Use of this high-tech scanner does not bring additional reimbursement. In fact, some payers question its necessity. Blatnik recommends working with the hospital's contracting department and payers to establish guidelines or pass-throughs for use of the device.

"The only thing your organization can gain financially is market share or increased volume," she says. "If use of the device isn't going to expand volume or market share, are you willing to spend a million-plus dollars just to have a new technology?"

Dr Myers sees the O-Arm as a technology whose time has come, saying, "The time is right for intraoperative and small mobile CT scanners. All the major neuro and spine programs either have this technology, or they're planning to acquire it."

Training for staff

Radiologic technologists are trained by Medtronic to operate the O-Arm. Dr Myers has a radiologic tech to perform the spin even though he and the other surgeons have fluoroscopy operator supervisor licenses and technically don't need to.

At HealthEast, radiologic techs set up the O-Arm and perform the spin. HealthEast surgeons receive training on how to use the O-Arm, but it is not a certification course, says Blatnik. Typically, Medtronic staff are in the room for support. HealthEast is looking into separate physician credentialing for this technology if used with navigation for minimally invasive spinal procedures.

The scanner market

The Medtronic system currently is the only O-Arm with FDA clearance. The Dominion Vi Imaging Scanner by Imaging3 received FDA approval for investigational use in April 2008 and anticipates full FDA clearance by the end of the year, notes Jennifer Van Pelt, MA, senior research analyst and strategic technology planning specialist with Hayes Incorporated, a health technology research and consulting company (www.hayesinc.com).

The Dominion is described by Imaging3 as a multifunction device that can cross over to other modalities such as mammography and digital radiography.

"The fact that there may be a competing system introduced to the market soon is important for OR managers and administrators to know," says Van Pelt. "They need to look at both systems to see which system will fit their needs best in terms of the clinical application they are going to use it for."

Though the O-shaped devices may have more advanced features, they haven't been proven to improve patient outcomes, she notes.

The Siemens Arcadis Orbic 3D is also a C-arm with 3-D imaging capabilities, notes Jason Launders, senior project officer, medical physicist for ECRI Institute, an independent nonprofit organization (www.ecri.org). The Orbic is slower in generating an image than the O-Arm, taking up to a minute compared with less than 30 seconds for the O-Arm.

The Orbic is equipped with a multimodality workstation but does not include a surgical navigation system, which is where Medtronic has the advantage, says Launders.

A third-party system can be integrated with Orbic via Navilink, he says.

"The spine is the best use for the O-Arm because that is where you can do the most harm. The 3-D data set is a huge advantage for the O-Arm, even though it takes more radiation to create the 3-D image," he says. ♦

—Judith M. Mathias, RN, MA

Reference

Holly L T, Foley K T. Image guidance in spine surgery. *Orthop Clin N Am*. July 2007;38:451-461.

Resources

O-Arm Imaging System

Medtronic, Minneapolis, Minn
[www.medtronicnavigation.com/
procedures/intraoperative/o-arm.jsp](http://www.medtronicnavigation.com/procedures/intraoperative/o-arm.jsp)

Arcadis Orbic 3D

Siemens, Munich, Germany
www.medical.siemens.com
Look under Healthcare, Products & Solutions, Detection and Diagnosis, Surgery
Systems, C-arms, Arcadis Orbic.

Dominion Vi Imaging System

Imaging3 Inc, Burbank, Calif
www.imaging3.com