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By Dan Harvey

— Image courtesy of Naviscan PET Systems

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Specialty PET System — Positron Emission Mammography Improves Resolution

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Once a research tool, positron emission mammography (PEM) entered the realm of clinical application roughly three years ago, taking a primarily adjunct role. However, with its high-resolution, organ-specific PET scanners, PEM may soon find itself in a larger role.

"This technology has the potential to detect breast cancers as small as 2 millimeters," says Lorraine Tafra, MD, director of the Anne Arundel Medical Center Breast Center in Annapolis, Md., the first U.S. facility to implement PEM technology. "Currently, we have no technology that allows us to do that. If we can pick up cancers that small, we will probably be able to cure most breast cancers."

But that early screening role is down the road, Tafra concedes. In the meantime, the technology is proving valuable in treating patients already diagnosed with breast cancer because it provides what is probably the most accurate image of breast cancer available, she says. "In a nutshell, it offers both improved sensitivity and specificity for the imaging of breast cancer," Tafra says.

PEM builds on the ability of FDG (fluorodeoxyglucose)-PET to identify and characterize malignant breast tumors. While it operates like PET, it can isolate and enhance breast images better than PET scans, enabling physicians to study molecular abnormalities inside tumor cells.

Compared with whole-body PET scanners, PEM scanners can better image small breast lesions and provide better localization. Besides improved spatial resolution and higher sensitivity for radiation, it provides reduced attenuation and higher coincident counts for image production.

But the resolution is the key, says Paul Grayson, chairman and CEO of Naviscan PET Systems, a manufacturer and marketer of compact, high-resolution PET scanners. The company has developed the PEM Flex PET Scanner, an organ-specific PET device optimized to image breast cancer, which can potentially lead to detection at an earlier, more curable stage.

The 2-Millimeter Threshold

The product's resolution and flexible configuration are currently used to improve treatment planning. The system boasts resolution between 1.5 and 2 millimeters, the highest resolution offered by any biochemical breast imaging modality. Studies have shown that the PEM Flex system's sensitivity and specificity for characterizing suspicious lesions are both greater than 90%. Furthermore, the system has a positive predictive value of 92% for identifying breast cancer.

Grayson explains that the remarkable resolution results from proximity and breast immobilization. "By bringing the detector heads right next to the immobilized breast, we reduce the noise and increase the number of radioactive counts captured," he says.

"Detector plates are placed close together, which impacts the accuracy and the size of lesion you can detect," says Tafra, who has used Naviscan's PEM Flex technology for more than two years. "With a whole-body PET scanner, plates are usually a foot apart. With PEM, the plates can come together within a couple of centimeters. The resulting resolution takes you down to a 2-millimeter tumor."

This kind of resolution is unprecedented in molecular imaging, says Naviscan President Thomas Watlington. "The lowest limit for imaging lesions with whole-body PET is about 1 centimeter," he says.

Such resolution, combined with functional imaging capability that molecular imaging technology provides, improves lesion characterization compared with other modalities. “Anatomical breast imaging modalities, such as MR and CT, are not particularly good at distinguishing between the benign and malignant state, and mammography has poor specificity,” says Watlington.

The resolution is so good that PEM can image ductal carcinoma in situ (DCIS), which is difficult to identify with modalities such as mammography and breast MRI. Noninvasive DCIS represents more than 30% of reported breast cancers. “Such detection can permit a less invasive surgical procedure to be applied in cases that might otherwise be judged to be more severe,” says Watlington.

Overcoming Challenges

Right now, PEM is used as an adjunct to current breast imaging techniques, says Watlington. “In concert with existing modalities, PEM should reduce [the] number of biopsies, improve surgical planning, and better detect any recurrent disease, at least on the local level,” he says.

Due to challenges inherent in other modalities, many ultimately unnecessary biopsies are performed. The developers hope the improved image accuracy can reduce the superfluous biopsies.

PEM is currently being used for patients with newly diagnosed breast cancer who are facing surgery. Before surgery is undertaken, PEM provides physicians with one more imaging analysis to help determine whether there is multifocality and multicentricity.

At the Comprehensive Breast Center at St. Joseph Hospital in Orange, Calif., Naviscan’s PEM Flex system has been used in a research setting and more recently in commercial application. “It is enormously helpful to us in making sure we don’t miss multifocal or multicentric disease,” says Jay Harness, MD, the center’s medical director.

Multifocality, Harness explains, means that there is more than one location of cancer along a dual system in a radial pattern. Multicentricity means that the cancer is in completely different locations, either in the same breast or the other breast.

“The difference is really important because, in most cases, multifocality means someone can have breast conservation, where multicentricity is a contraindication to breast conservation,” Harness says.

Harness, who is also president-elect of the American Society of Breast Surgeons, adds that the PEM Flex system serves as a legitimate substitute for patients who cannot undergo breast MRI for reasons including medical implants, claustrophobia, or obesity. “Our experience demonstrates that it is equivalent to MRI and in some instances even easier to do,” he says.

PEM is particularly helpful in cases involving women with dense breast tissue that can make tumors hard to spot. In such patients, mammography has limitations in specificity and sensitivity. In such patients, whole breast ultrasound and breast MRI represent alternatives. Ultrasound provides good anatomical information about where in the breast a tumor is located, but density still poses a challenge. In patients with dense breasts, MRI may be the more viable alternative as it achieves a higher sensitivity. But it has a lower specificity. “We believe that a challenge with MRI is that its specificity is lower than what we achieve with PEM, which means that it has a higher false positive rate, which can lead to unnecessarily invasive surgery and misdiagnosis,” says Grayson.

He indicates that another alternative is the wait-and-see approach. “You can wait to see if the tumor gets large enough so that you can see it on a standard mammogram or that something that could be palpated or seen with ultrasound,” he explains.

Of course, that approach runs the risk of delaying treatment in a patient subsequently shown to have a breast carcinoma which, in turn, increases the chance of axillary lymph node metastasis.

As far as surgery, the PEM technology can significantly influence decisions and procedures, says Watlington. It can help physicians avoid mastectomies, inappropriate lumpectomies, or the need to reexcise positive margins obtained after lumpectomy. “It can improve the quality of surgical decisions because it is very good at staging and determining the local extent of disease,” he says.

Well-tolerated Procedure

PEM involves the injection of the radiopharmaceutical FDG. A patient needs to fast for four hours before the procedure. Afterward, a serum blood sample is taken to determine blood glucose level. Then FDG is injected intravenously. Tumor cells will take up much more glucose than normal cells, and PEM imaging will reveal the FDG concentrations that suggest malignancy.

The imaging is acquired one hour after the FDG injection, when the patient’s body has had enough time to absorb the radiopharmaceutical. Images are obtained in a manner similar to mammography. Both breasts are imaged, with mediolateral oblique and craniocaudal views taken. Each view takes approximately 10 minutes to accomplish; thus imaging requires roughly 40 to 45 minutes.

During the imaging, the PEM detectors are positioned close to the breast. As a result, image acquisition is much more efficient. In addition, with only a small attenuation of counts, the spatial resolution is greatly improved compared with whole-body PET imaging.

During imaging, the breast is immobilized but requires only slight compression. “Patients report that they can tolerate the procedure very well because of this reduced amount of compression,” Harness says. “It is nowhere near as severe as the compression involved in a standard mammogram.”

The purpose of compression in a mammography procedure, Grayson says, is to reduce the thickness of tissue clinicians need to x-ray, which increases the sensitivity by decreasing the background noise. But during a PEM procedure, the compression is more for isolation purposes. “You’re isolating the breast so that it doesn’t move because the imaging window is minutes, not seconds,” he explains. “So, only light compression for immobilization is necessary.”

The PEM Flex system includes an articulating arm with two parallel detectors at the end, which allows for flexibility in imaging of any small body part, although the system is designed for breast imaging. PEM scanners include advanced lutetium oxyorthosilicate crystal components and a compact design that make it ideal for the imaging the breast or appendages such as the head, hand, or foot.

The viewing station is combined into a highly mobile, small footprint with a camera and detectors. Situated on casters, it can be easily rolled into and out of a room. “Its mobility offers a tremendous convenience because it allows the camera to be wheeled into a standard imaging room, next to a large, whole-body system, for example, and to be used in concert with that larger system,” says Watlington.

Looking to the Future

Naviscan is developing its own radiopharmaceutical, based on a B-12 derivative, that it anticipates will enhance the characteristics and properties of the PEM Flex system. “We believe that this new agent, combined with PEM technology, will be equivalent to or better than FDG and it will dramatically lower radioisotopic exposure for the patient,” says Grayson.

The company is also developing an accessory for the camera that would permit a PEM-guided biopsy for localization. The new feature would allow clinicians to deploy any number of existing biopsy systems with the PEM Flex camera. “You could precisely locate the lesion and guide the biopsy exactly to that point in the breast,” Watlington says. “In real time, you would be able to confirm, through the image, the success of the excision.”

Beyond those new developments, Naviscan anticipates that several other disease processes could be imaged by this technology. The company is exploring its use to image thyroid and prostate cancer as well as arthritis, particularly in the hands. “All of that is somewhere in the future,” says Watlington.

As utilization and research proceeds, the developers hope PEM technology will not only improve decisions related to staging but also measure the effectiveness of therapy. Specifically, neo-adjuvant therapy involving a course of chemotherapy followed by surgery could be better managed.

*— Dan Harvey is a freelance writer based in Wilmington, Del., and a frequent contributor to **Radiology Today**.*