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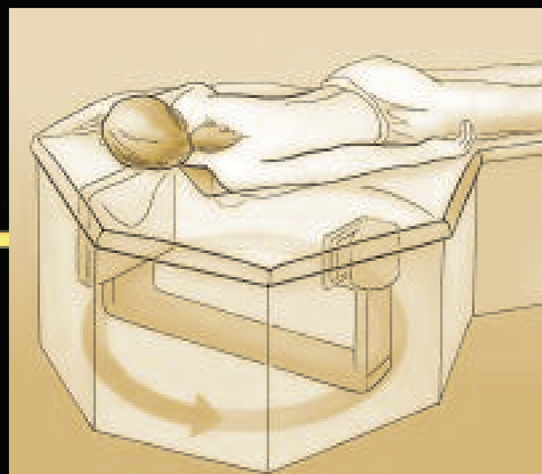

Dedicated breast CT enters new phase of clinical testing

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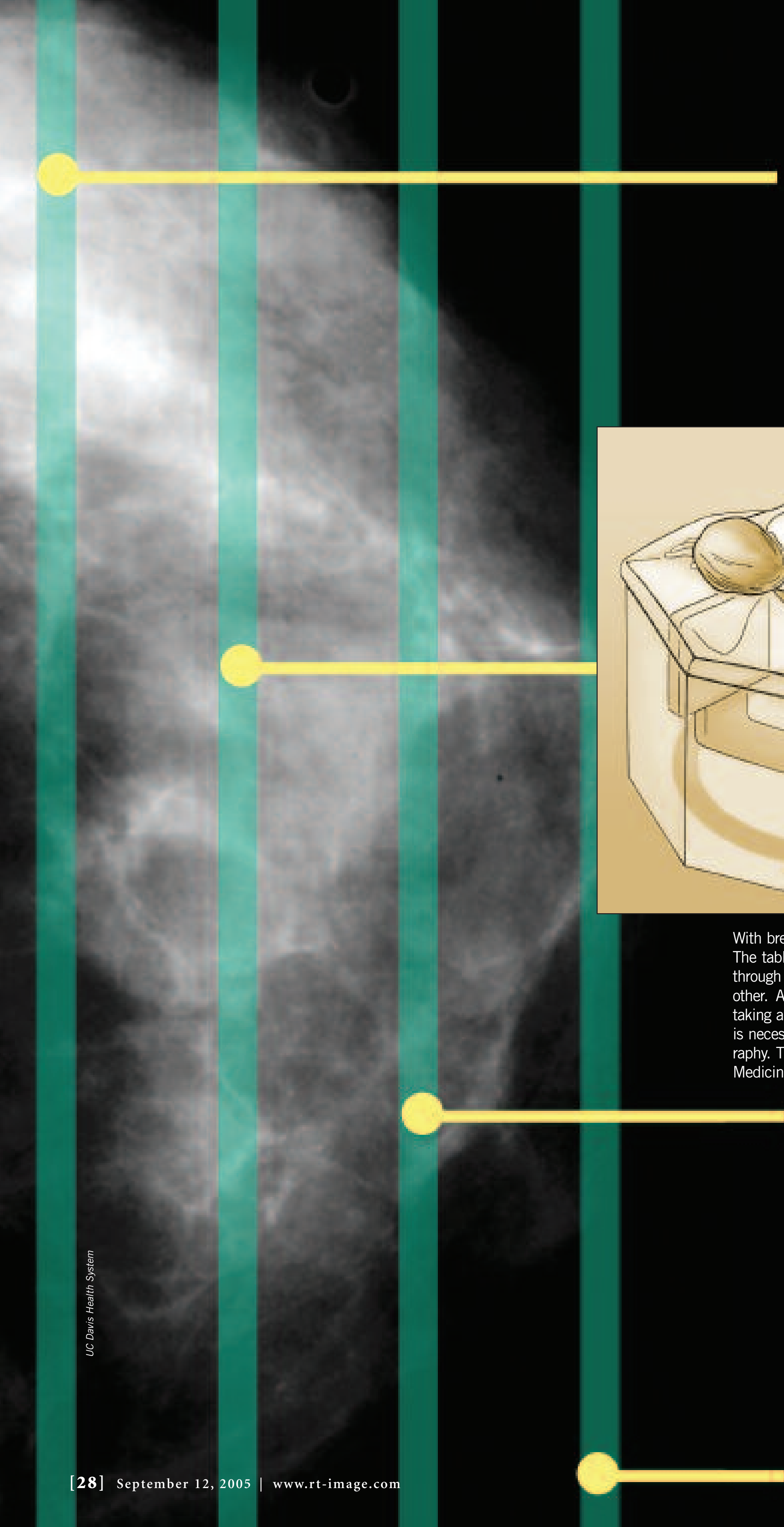

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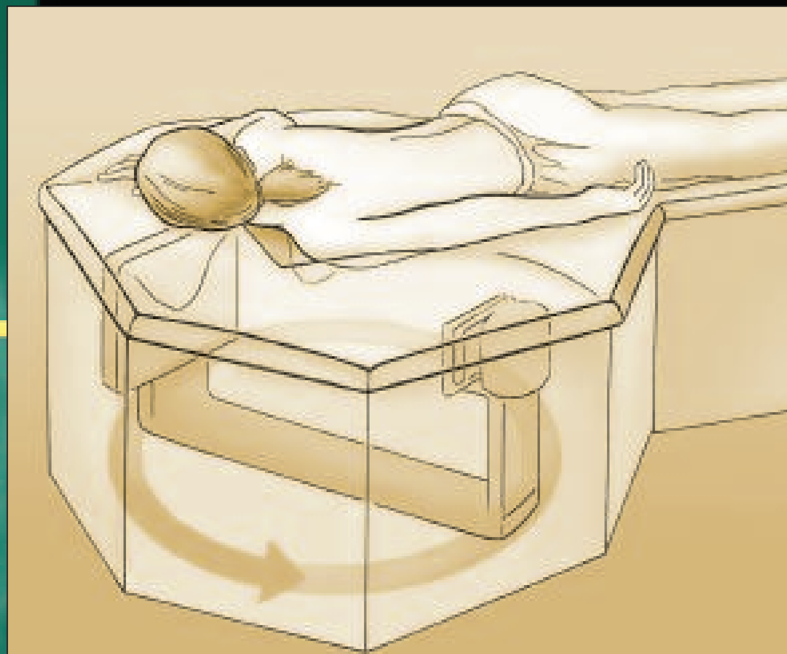


With breast CT, a woman lies face down on a padded table. The tabletop has a depression with a circular opening in it, through which the woman positions first one breast, then the other. A CT machine under the table scans each breast, taking about 17 seconds per breast. No breast compression is necessary. Radiation levels are the same as in mammography. The breast CT was developed at UC Davis School of Medicine and Medical Center.

Getting a Better View

Dedicated breast CT enters new phase of clinical testing

By Jennifer Patterson Lorenzetti

For many years, CT scanning has been dismissed as an option for detecting breast cancer, due mostly to concerns about radiation exposure. But recently, researchers at the University of California (UC) Davis are putting those concerns to rest, opening up the possibility of more comfortable imaging procedures with more accurate scanning results, with a scanner that changes the orientation of traditional breast cancer screening.

Limitations of Mammography

X-ray mammography is currently the primary screening test for breast cancer, and it is easy to see why. A mammogram, which takes only a few minutes and requires the patient to tolerate only a reasonable radiation dose, is up to 85 percent sensitive in detecting breast cancer. In fact, mammography has been credited with helping to reduce the mortality statistics from breast cancer through its help in early detection.

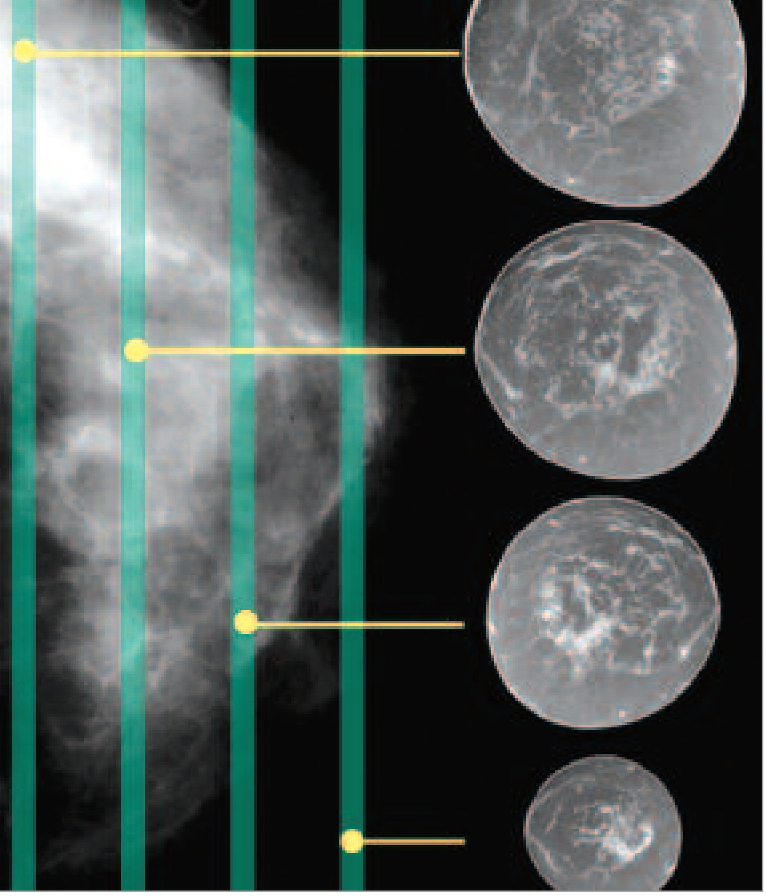
But for all of its benefits, mammography has its limitations. Women with dense breasts, including those who are younger, those who have had their breasts enhanced with implants, and those taking hormone replacement therapy, have much less success with mammography than do other patients with more adipose, or fatty, breasts. In fact, data suggests that mammography will be able to find a 4-millimeter tumor about 60 percent of the time in a woman with low-density breasts. In order to have the same level of sensitivity in a woman with dense breasts, the tumor must have reached 17 millimeters, which corresponds to about 1.7 additional years of tumor growth.

In addition, the discomfort that many women experience from the necessary breast compression during mammographic screening is enough to make some women hesitant to undergo mammography. Studies show that more than 90 percent of women experience "low to moderate" pain from the required compression. Eliminating compression could make more women amenable to mammography and would make the procedure more comfortable for all.

So the search is on for even better ways to scan for breast cancer. Any new solution would have to meet some pretty stiff requirements. It would have to be more sensitive than traditional mammography, including improved sensitivity in patients with dense breasts, in order to facilitate early detection of cancer. And, it would have to screen in a manner that is more comfortable to the patient in terms of necessity of compression, while also being no more risky than mammography in terms of patient exposure to radiation. In pursuit of such a solution, John M. Boone, PhD, professor of radiology and biomedical engineering at UC Davis, is pursuing a new twist on a familiar technology: CT scanning. His new configuration of a dedicated breast CT machine has reached clinical testing, with hopes for widespread future application.

A New Angle on CT Scanning

The idea of using CT scanning for breast cancer detection is nothing new. Researchers have considered the use of this technology for at least three decades, but the idea has traditionally been dismissed due to concerns about the cost effectiveness, and, more seriously, the radiation dose. Many earlier studies of CT scans of the breast involved traditional scanner configurations, in which the image was acquired transversely and the X-ray beam penetrated the chest cavity. This exposes a large amount of non-breast tissue to radiation. Additionally, movement of the patient's



body due to cardiac or respiratory activity has the potential to reduce image quality.

Boone has turned the geometry of the CT scan on its side. With the help of a table that allows for scanning of the breast in a pendant (or hanging down) geometry similar to that used in digital breast biopsy systems, Boone is able to control exposure to radiation while increasing patient comfort and harnessing the greater screening power of CT. He has developed a prototype breast CT scanner in collaboration with UC Davis radiology professors Karen K. Lindfors, MD, and J. Anthony Siebert, PhD, and also UC San Diego radiology professor Thomas R. Nelson, PhD.

The dedicated breast CT scanner looks quite different from a standard mammography machine. Instead of requiring the patient to stand upright and place her breast on a plate for compression, the breast CT machine makes use of a table similar in appearance to those used by massage therapists. The patient lies on the table in a prone position with her breast hanging through a cutout in the table. Gravity will do most of the work of keeping the breast stationary and roughly cylindrical in shape, although Boone is considering the addition of a gentle breast restraint to guarantee the breast's immobility during the scan.

To ensure that an adequate amount of chest wall is imaged along with the breast, the X-ray tube and flat panel detector are positioned just under the table. The patient is partially shielded from radiation by the table itself. The scans take approximately 17 seconds per breast.

The most noticeable response from current study participants, thus far, is the increased comfort of the CT scan compared to mammography. Boone reports that the women in the study "uniformly say it's great not to have compression." Boone continually tweaks the table design in response to patient feedback, adding padding for comfort or decreasing it to avoid uncomfortable neck positioning. "We hope after a couple of design iterations to have a very comfortable table," he says.

The CT scan takes some 300 image slices and then uses Boone's homegrown software to form a 3-D picture of the breast. The software will allow the radiologist to examine the breast in any plane, critical for more accurate scanning. Radiologists will "not [be] bothered by underlying or overlying anatomy," Boone says. This should allow for more flexibility and sensitivity than that found with the traditional two-view, 2-D mammography images.

The assembly of this multitude of slices should allow radiologists to dig more deeply in their hunt for small tumors. "It's the difference between taking a picture of a crowd from across the street, versus circling the crowd and shooting hundreds of separate photos along the way, each photo only two or three people deep. Your chances of finding a particular person in the crowd are going to be a lot better with more photos," Boone says.

It is still early in Boone's clinical trial, so there is no scientific data yet about the accuracy of the dedicated breast CT. However, his early impressions of the resulting scans have been very positive. "The gut level response from the images is 'wow,'" he says.

If this "wow" turns out to be a confirmed improvement in breast imaging, it will do so at no greater radiation risk than that from traditional mammography. "The radiation dose is the same as with two-view mammography," Boone says. In fact, because the dose of radiation is more homogeneous across the entire breast, some theories suggest that the risk may be even less than from mammography.

Additionally, table design can play a role in shielding non-breast tissue from radiation exposure. The use of steel instead of aluminum in certain parts of the table can provide more radiation shielding than the aluminum used for the frame.

(Opposite page, left) The breast CT scanner developed at UC Davis School of Medicine and Medical Center produces about 300 individual images per breast. Each image is a virtual "slice" through the breast. Four such "slices" are shown; the green lines indicate where each image was taken. UC Davis researchers hope to show that breast CT can detect breast cancer earlier than mammography. (Center) To ensure that an adequate amount of chest wall is imaged along with the breast, the X-ray tube and flat panel detector are positioned just under the table. (Above right) John M. Boone with the dedicated breast CT machine. With the help of a table that allows for scanning of the breast in a pendant geometry similar to that used in digital breast biopsy systems, Boone is able to control exposure to radiation while increasing patient comfort and harnessing the greater screening power of CT.

Now and Beyond

For the current Phase II clinical study, Boone is starting small. Presently, he has enrolled two-dozen volunteers and patients in his study. Ten of these were healthy candidates, while the remaining were patients at UC Davis ages 40 to 80 with BIRAD 4 and 5 mammograms indicating a high likelihood of cancer. Over a two-year period, he plans to enroll about 190 women. Women who participate in the trial will have the breast CT exam and a needle biopsy to test any suspicious tissue.

If this trial confirms that the breast CT detects tumors as well as mammography does, the next step is an even larger trial to determine if CT can detect tumors earlier than mammography. Such a trial could be underway in two to three years.

Conducting such studies takes time, which means that the dedicated breast CT may not reach commercial availability for quite some time. "It would be aggressive to say five years," says Boone, noting that there are non-scientific issues such as sorting out the ownership of patents that need to be solved in addition to scientific questions. "The approval process takes time," he adds.

At this point, it is too soon to predict which populations of women will be the best candidates for breast CT. "Our assumption is that it is for all women," Boone says, explaining that the possible increased sensitivity could make it a candidate to replace mammography for breast cancer screening. The increased sensitivity could have a tangible impact on patients' lives. Some estimates suggest that breast CT may be able to routinely detect breast lesions that range in size from 3 to 5 millimeters. If 5-millimeter tumors were routinely detectible, Boone estimates an overall reduction in breast cancer mortality of 8.7 percent. If the 3-millimeter tumors were routinely detected, 15-year survival rates would improve by 11.2 percent compared to mammography, which would result in a survival rate of nearly 98 percent.

However, cost issues may make the technique most practical for populations in which mammography is least effective, such as women with dense breasts, or in populations for which early detection is at a premium, like women with a genetic predisposition to breast cancer.

Boone does not plan to rest with the pursuit of more effective screening. He has also announced the receipt of funding from the California Breast Cancer Research Program to build a PET/CT scanner. This will elevate breast imaging from simple screening to "quantitative assessment to the response to therapy," Boone says, allowing for post-therapy assessments of possible residual tumors.

With the possibility of earlier detection and more accurate scanning on the horizon, breast cancer could well become a health scare, but no longer a possible death sentence.

Jennifer Patterson Lorenzetti is a freelance technology writer in Centerville, Ohio, and owner of Hilltop Communications. Questions and comments can be directed to editorial@rt-image.com.