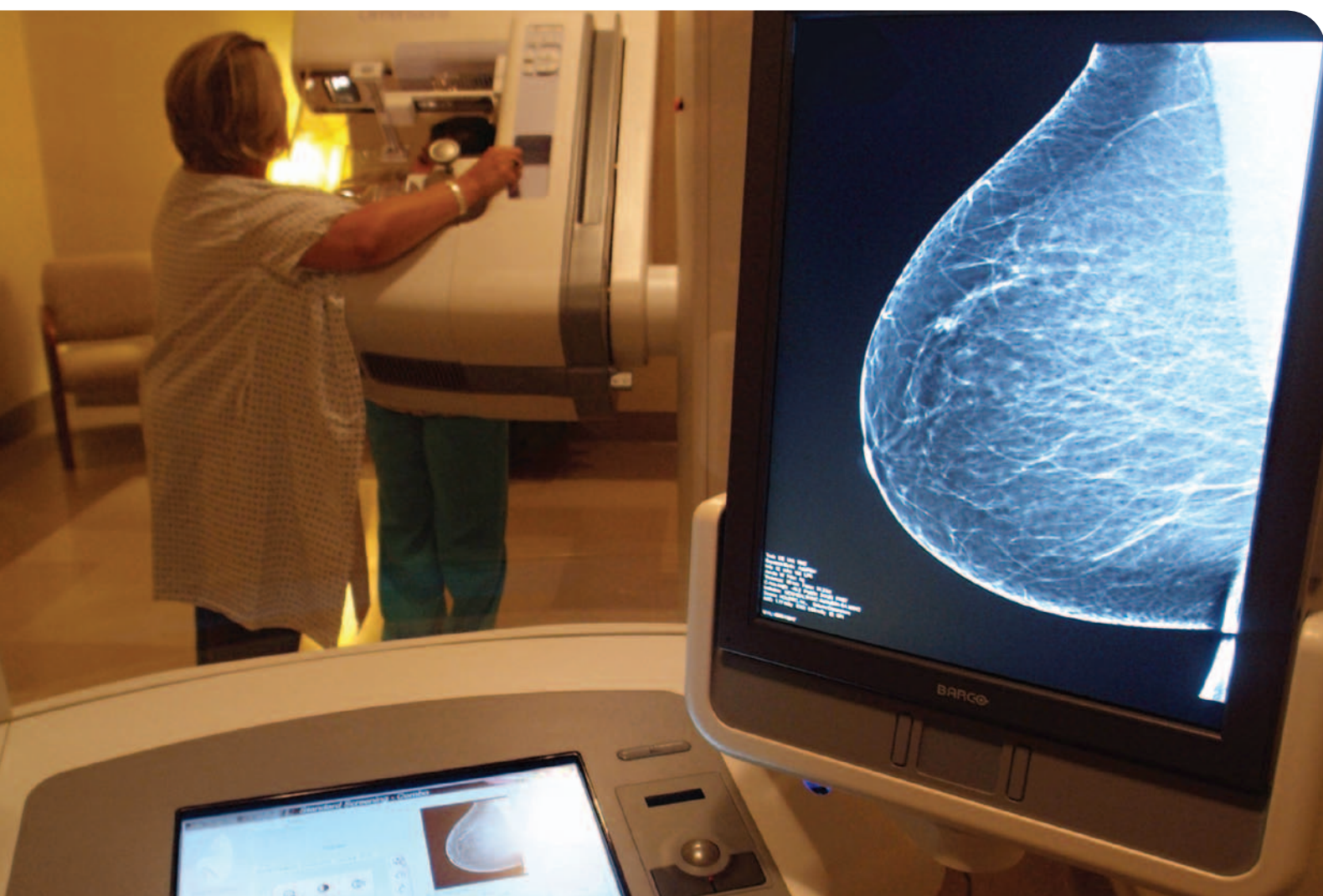


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Fall 2011
Volume 11

The Use of 3D Mammography
(Breast Tomosynthesis) in Clinical Practice

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From the Editor

The pathway from technical innovation to accepted clinical practice is long, arduous, and costly. Those who evaluate the potential of new technologies consider many factors—clinical need, technical performance, economic issues, and patient and societal perspectives.

This special collection of published stories summarizes the views of leading clinicians on the role of 3D breast tomosynthesis as a screening and diagnostic tool. Included in this issue are the stories of eight hospitals and imaging centers that share a passion for bringing the latest in breast cancer treatment, diagnosis, and less invasive treatment to women.

inside

02

Massachusetts General Hospital
Boston, Massachusetts

04

John C. Lincoln Health Network
Phoenix, Arizona

06

Breast Pathology Center
at Tejerina Foundation
Madrid, Spain

07

Cerrahpasa Medical Faculty
at Istanbul University
Istanbul, Turkey

08

Klinik Engered
Berne, Switzerland

09

Maroondah Hospital
Melbourne, Australia

10

Women's Center for Radiology
Orlando, Florida

12

Hôpital Lapeyronie
Montpellier, France

The views and opinions expressed in the stories in this publication are those of the contributing sites and do not necessarily reflect those of Hologic.

Cover photo: Georgia Health Sciences University in Augusta, Georgia uses its two tomosynthesis systems for all their screening and diagnostic mammograms.

A Pioneer in Women's Imaging

The Breast Imaging program at Massachusetts General Hospital is known for its cutting edge approach to comprehensive breast care—an approach that now also includes the latest innovation in breast imaging technology. In March 2011, physicians at MGH performed the first clinical 3D breast tomosynthesis exam in the United States. This marked the culmination of more than a decade of research under the leadership of Elizabeth Rafferty, M.D., Director of Breast Imaging at MGH.



A “Revolutionary” Technology

Dr. Rafferty was the principal investigator for the multi-institutional trials evaluating tomosynthesis. These trials concluded that radiologists reading digital mammography (2D) plus breast tomosynthesis (3D) as compared to 2D mammography alone demonstrated superior clinical performance in specificity, the confidence to rule out breast cancer without recalling the patient for further study, and improved sensitivity, the proportion of mammograms with cancer which were correctly diagnosed.¹

“We absolutely had the opportunity to find cancers earlier than we would have without tomosynthesis, as well as finding more extensive disease than was initially expected,” Dr. Rafferty says of her experience with the clinical trials.

“That’s one of the most exciting aspects of this revolutionary technology—the ability to get women the treatment they need.”

While mammography has played a significant role in women’s health, reducing the mortality rate from breast cancer by as much as 50 percent, it has a fundamental flaw. When breast structures are compressed into a standard 2D

mammogram, overlapping tissue can obscure abnormalities or make normal tissue appear suspicious. As a result, as many as 20 percent of breast cancers are missed on a mammogram, while approximately 10 percent of women are recalled for additional workup.

“Like flipping through the pages of a book, the radiologist is able to look at one page at a time instead of seeing the whole breast reduced to a single frame, as is the case with standard mammography,” says Dr. Rafferty.

By removing the confusion of superimposed tissue, tomosynthesis affects the two primary goals of mammography: finding cancers as soon as possible and reducing unnecessary callbacks. Radiologists have the ability to detect and diagnose small cancers, as well as rule out abnormalities that may have looked suspicious in a 2D mammogram, preventing the need to call women back for additional imaging or biopsies.

“Tomosynthesis is the most significant advancement in x-ray imaging of the breast in 35 years,” says Dr. Rafferty.

Integrating Tomosynthesis into Clinical Practice

Now that studies have shown the benefits of tomosynthesis, Dr. Rafferty says the challenge will be guiding radiologists on how to most effectively incorporate the technology into their practices. Issues like clinical application, patient selection and workflow will be particularly important to address.

One of the most common concerns about tomosynthesis is whether it is most effective in the screening or diagnostic environment. According to Dr. Rafferty, the answer is both. While radiologists may initially feel more comfortable incorporating it into the diagnostic environment, in order to take advantage of the benefits of tomosynthesis—improved detection and fewer recalls—it must be used for screening mammography, she says.

Patient selection for tomosynthesis is another issue that must be considered. While this will vary between practices depending on patient population, workflow and equipment availability, at the very least, physicians should initially offer tomosynthesis to women with dense breasts. Although studies make it clear



Elizabeth Rafferty, M.D. was the principal investigator for the Hologic multi-institutional trials evaluating tomosynthesis

that tomosynthesis can benefit every woman, its value in women who have dense breasts has been shown to be three times that in women who have non-dense breast tissue.

Radiologists may also consider broadening the application of tomosynthesis beyond dense-breasted patients. Fewer women will be recalled, which can have a positive impact on diagnostic volume and enable practices to use their equipment more efficiently.

"There is definitely a triage process when it comes to patient selection for tomosynthesis," says Dr. Rafferty. "The adoption of this technology requires strategic planning for any radiology group to determine how it is best utilized in their practice."

In today's world, the impact of a new modality on workflow is a major concern. The advent of digital mammography had a tremendous effect on workflow, and it provided radiologists with an important lesson. They realized that once they adapted to the tool and learned how it fit into the interpretive environment, they were able to streamline their workflow and decrease the length of interpretations.

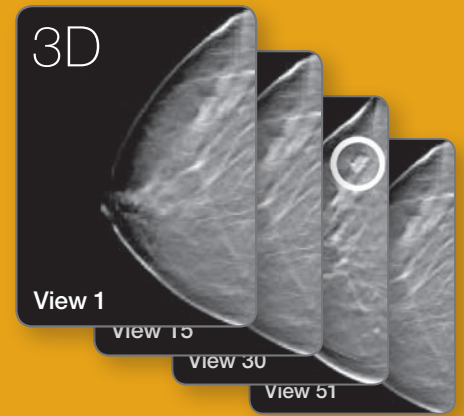
According to Dr. Rafferty, the same will happen with tomosynthesis—and adequate training will be the key to minimizing its impact on workflow.

"Tomosynthesis shows us so much more information, so radiologists need to be able to put that information in a practical framework—and training absolutely facilitates that process," Dr. Rafferty says. "A well-trained radiologist will be the key to keeping interpretive times down without diminishing quality."

Moving Toward a Future of Better Patient Care

The Selenia Dimensions system has a unique feature that can ease the transition from conventional mammography to tomosynthesis. The flexible platform utilizes multiple imaging modes, including 2D only, 3D only or 2D and 3D combined, in which a traditional digital mammogram and a tomosynthesis scan are acquired in the same compression.

The combination of 2D and 3D imaging, the mode used in clinical trials, provides several advantages. It facilitates easy comparison with prior images acquired with standard digital



"Right now our best weapon against breast cancer is early detection. If we can strengthen the position of mammography, it will make a huge difference in women's lives," Dr. Rafferty says.

"Any radiologist who reads mammograms will look at a tomosynthesis study and know this tool will enable us to do a better job. Tomosynthesis is going to make us better radiologists."

mammography, while getting radiologists accustomed to viewing 3D images. This allows them to develop the confidence needed to interpret tomosynthesis studies as the breast imaging world makes a gradual transition away from conventional 2D mammography.

Overall, Dr. Rafferty says radiologists must at least begin thinking about how to best implement tomosynthesis in their practices for the benefit of their patients. ■

¹ The Hologic Selenia Dimensions clinical studies presented to the FDA as part of Hologic's PMA (P080003) submission that compared Hologic's Selenia Dimensions 2D + 3D tomosynthesis to Hologic's 2D FFDM.

The Second Site in the U.S. to Adopt 3D Breast Tomosynthesis

John C. Lincoln Health Network, a Phoenix-based health system with two hospitals and many physician practices, is setting a new standard for breast care. In addition to being one of Arizona's first truly comprehensive breast centers, its Breast Health and Research Center is the first in the state—and only the second in the nation—to offer 3D breast tomosynthesis. Thanks to careful planning, John C. Lincoln was poised to immediately adopt the technology when it became available and began offering it to patients in April 2011.

Commitment to Patient Care

With its commitment to superior patient care, the Center viewed 3D tomosynthesis as essential for breast imaging.

“Tomosynthesis is absolutely amazing technology that enables us to clearly see some cancers that are not visible on conventional 2D mammography. We're able to detect even the tiniest cancers at the earliest stages,” says radiologist Linda Greer, M.D. “We're so excited to have this improved technology available to our patients.”

As Dr. Greer notes, “In just the month that we've had it, I've seen four or 5 cancers that I honestly would like to think I would have found on the original mammogram, but they were, without a doubt, present when we did the 3D imaging.” In addition, according to Dr. Greer, approximately five percent of patients who would have been called back for additional views have been spared the anxiety of unnecessary recalls.

For some patients, the benefit of tomosynthesis is simply peace of mind. A woman with extremely dense breasts had been considering a bilateral mastectomy due to years of uncertainty, but tomosynthesis helped radiologists determine—for the first time—that there

were absolutely no abnormalities. Another patient with dense breasts and a strong family history of breast cancer was found to have a large cyst that did not appear on any previous exams.

“The image was absolutely gorgeous. It definitely wasn't cancer, but it was interesting to see something we'd never been able to see before,” says Dr. Greer. The Center is using tomosynthesis for both screening and diagnostic mammography. The Center offers it primarily to women with dense breasts or fibrocystic tissue—or those who, due to overlapping tissues, had prior call-backs for additional views.

Easy Transition to Tomosynthesis

Gage predicts that ease of use is one key reason tomosynthesis will eventually become the gold standard of breast imaging. “If a superior technology is difficult to use and negatively impacts your workflow, it's not going to become the standard of care,” says Gage, who has overseen numerous technology installations at the breast center and noted that tomosynthesis was by far the easiest.

Optimizing workflow has always been a priority, and workflow considerations played heavily into the Center's original design.

An exam using tomosynthesis takes virtually no more additional time than a 2D mammogram, enabling the staff to continue scheduling screening mammograms every 10 minutes. However, with only one of its three digital mammography machines configured for tomosynthesis—and about half of the day's patients requiring 3D imaging—a slight workflow adjustment was required to accommodate the increased demand.

Two technologists are now assigned to the room with the Selenia® Dimensions® system. While the first technologist is performing an exam, the second is consulting with another patient in a different room. When the second technologist takes her patient in for the exam, the first begins a consultation with a new patient. “All it took was a small adjustment, and we were back on track,” says Gage, who estimates that they perform an average of 25 to 30 tomosynthesis exams per day.

A smooth workflow is especially important for future success because tomosynthesis is attracting more patients to the breast center. Gage says they are seeing a significant increase in new patients based on the number of exams being sent from outside facilities. The number has jumped to approximately

35-40 per day since the center started offering tomosynthesis, and women are coming from as far as Utah to receive a 3D exam.

“Many women are coming from other centers because they are called back for additional views year after year, and they want tomosynthesis to get rid of that uncertainty,” says Gage.

MammoPad Cushion Improves Patient Satisfaction

In addition to the latest imaging technology, women at the center also benefit from the Hologic MammoPad® breast cushion. The soft, foam cushion is placed on the mammography detector to create a warmer, softer exam, improving both patient comfort and clinical results.^{1, 2, 3}

Though Gage is now a big proponent of the MammoPad breast cushion, she was initially opposed to the expenditure. She wasn't sure it was worth the money, but quickly saw how much women appreciated the feeling of warmth, rather than the cold chill of a hard detector. “MammoPad really does provide unbelievable comfort, like putting your breast on a mattress,” says Gage. “We've seen firsthand how patient comfort improves compliance and keeps women coming back for their mammograms year after year.”

Technologists also noticed clinical benefits. The traction of MammoPad's foam surface holds the breast in place, enabling them to get more tissue and muscle in the image. Acquiring posterior muscle on a CC view was never a requirement, Gage says, but now it's become standard with the MammoPad breast cushion.

makes the Center a truly comprehensive breast center. Mammography is rarely the beginning—or the end—of its involvement with a patient's breast health.

“Technology is important, but you also need to help patients take control of their health,” Gage says. “We're very big on walking the patient through the entire journey of breast cancer.”

“For the last 80 years, this organization has been committed to providing the highest quality of care,” says Gage. “Tomosynthesis is simply the latest tool in our array of resources that ensure we fulfill this mission.”

“I didn't expect to see these kinds of clinical results. My technologists have good positioning skills to begin with,” she says. “But there's a difference between good positioning and excellent positioning.”

Truly Comprehensive Care

Customer service is equally as important as offering the latest technology. In particular, the Center places a special emphasis on education—particularly when it comes to new technology like tomosynthesis. In fact, it is the emphasis on education that

A Patient Care Coordinator assists women at every step, including scheduling appointments and communicating with referring physicians. ■

¹ Markle study. Comfort and compression. SBI 2001, The Breast Journal, 2004.

² St. John Hospital Study. Improvement in positioning and increased tissue (+0.26 cm). Effect of relaxation and physical characteristics of pad. NCBC 2005.

³ Coryell Study. 221 patients, 31 facilities, digital and analog. Increased tissue (+0.6 cm). Grip-like surface and reduced discomfort. NCBC 2006.



John C. Lincoln Breast Health and Research Center viewed tomosynthesis as an essential tool for breast imaging. Pictured left to right: Michael Alpern, M.D.; Sherry Gage; and Linda Greer, M.D.

Improving Confidence in Diagnoses with 3D Breast Tomosynthesis

The Breast Pathology Center at the Tejerina Foundation in Madrid, Spain, has been leading the way in women's breast health for over 40 years. It is the only facility in Madrid dedicated exclusively to women's breast health, offering diagnostic services, medical and surgical treatment, and follow-up services.

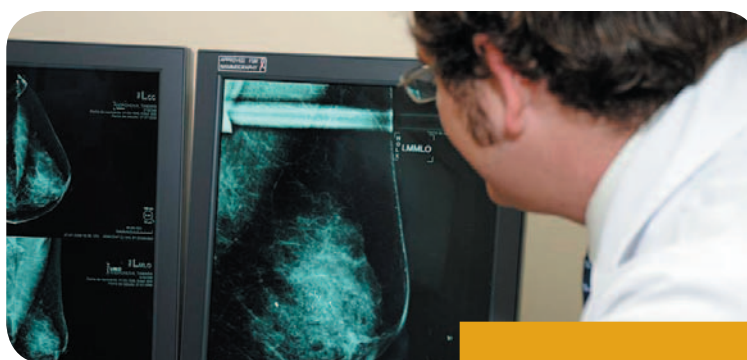
In 2000, the Center began using digital mammography before any other facility in Spain. Ten years later, it installed the Hologic Selenia® Dimensions® 3D breast tomosynthesis system, becoming one of the country's pioneers in the use of 3D imaging technology to improve early breast cancer detection.

"Tomosynthesis is very useful in characterizing nodules and mammographic distortions. It is also useful in patients with suspicious lesions, symptomatic patients, patients with family history and high-risk patients," declares Alejandro Tejerina, M.D., Breast Radiology Coordinator.

A team of 11 radiologists and 14 radiology technicians perform approximately 50,000 breast mammograms annually, often coupled with additional diagnostic tests such as ultrasound, magnetic resonance imaging (MRI) and cytohistological puncture. In just over a year, the center has performed approximately 3,000 mammograms using tomosynthesis, primarily for high-risk patients and for diagnostic exams.

A New Tool for the Early Detection of Cancer

In addition to the Hologic tomosynthesis system, the Center has seven Hologic Selenia digital mammography units, as well as breast MRI and breast ultrasound systems. "Each imaging test has its own



Dr. Tejerina says that with tomosynthesis they have been able to confirm that suspicious lesions have benign features and avoid unnecessary biopsies.

indication, and, when used properly and in concert with other modalities, the multiple systems considerably improve the accuracy of diagnoses," explains Dr. Tejerina.

As a 3D imaging technology, tomosynthesis provides a clearer view of areas within the breast that might otherwise be obscured by dense or overlapping tissue on a conventional 2D mammogram.

Improving Confidence in the Diagnosis

"Tomosynthesis provides very important diagnostic information, as well as different information from what we can acquire with 2D mammography," explains Dr. Tejerina. "We have been able to diagnose cancers with this new technique, and it has given us much more confidence when confirming or ruling out malignant processes. Using tomosynthesis, we have

"We added tomosynthesis because we want to be on the leading edge of technology."

also been able to confirm that suspicious lesions have benign features, avoiding unnecessary biopsies."

Radiologists at the Breast Pathology Center always perform both 2D and 3D exams with the Dimensions system. "We either perform a 2D and then 3D exam at two different times, or we combine 2D and 3D at the same time in a combo-mode study."

Dr. Tejerina adds that tomosynthesis provides capabilities not available with other modalities. "Using tomosynthesis, we can carry out millimetric breast incisions and detect small diameter lesions, enabling the interventional radiologist to reach the lesions from the back," states Dr. Tejerina. ■

On a Mission to Detect Cancer Early

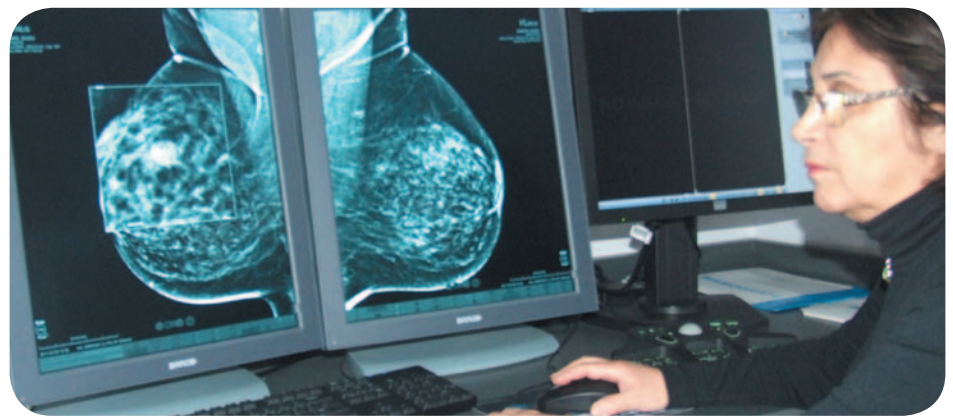
Breast imaging has long been a major focus of the radiology department at Cerrahpasa Medical Faculty, a top teaching hospital in Istanbul, Turkey, and one of 17 medical departments of Istanbul University. Three full-time radiologists and four full-time technicians, all dedicated breast imagers, perform 8,000 mammograms annually. Last year, as part of the University's commitment to provide leading-edge medical technology, Cerrahpasa Medical Faculty built a dedicated Breast Radiology Unit, investing in the latest technologies to detect and diagnose breast cancer at its earliest stages.

Breast cancer is the most common type of cancer for women in Turkey. It is estimated that 20,000 new cases of breast cancer are diagnosed each year. For Professor Altug and her staff at the Medical Faculty, early detection is the key. "Our mission is to detect breast cancer at the earliest stage, using innovations in technology, to provide better treatment for patients and to reduce mortality," states Professor Altug.

Toward this end, the radiology department worked with Hologic to install a Selenia® Dimensions® breast tomosynthesis system. "We are very pleased to have tomosynthesis technology because it is better for the detection of small tumors, less than 1 cm, and microcalcifications, obscured by dense breast parenchyma, enabling us to detect more DCIS," states Professor Altug.

Cerrahpasa Medical Faculty is using tomosynthesis to screen younger women between the ages of 40 and 50, women with dense breasts and high-risk women. The Breast Unit is also using tomosynthesis for diagnostic purposes. In the first three months of installation, the Breast Unit performed over 500 mammograms using the technology.

"Initially, we plan to implement projects to determine the women who will benefit most from tomosynthesis," explains



Professor Altug examines the tomosynthesis slices individually or in dynamic ciné mode on a diagnostic workstation.

Professor Altug. "It is our expectation that breast tomosynthesis will be better than 2D mammography to find multifocal and multicentric foci in women with dense breast parenchyma."

Says Professor Altug: "We perform all of the image guided interventional breast procedures including stereotactic, MRI-guided and ultrasound guided biopsies, and wire localizations.

"We chose Hologic's MultiCare® Platinum prone breast biopsy table and Hologic vacuum-assisted breast biopsy equipment because of the excellent image quality and the user friendliness of the systems. Hologic is helping us achieve our mission of detecting and diagnosing breast cancer at an early stage."

Using Technology, Detecting Earlier, Saving Lives

Since the diagnosis of breast cancer is basically dependent on a comprehensive imaging, its sensitivity, image quality, and user friendliness are critical. "In our clinical practice, detecting small lesions and obtaining biopsies of them are the main challenges," says Associate Professor Mehmet Halit Yilmaz, the Director of Breast Imaging. "The earlier we detect the lesions, the more we save lives." ■

First with 2D, First with 3D, Swiss Clinic Excels with Newest Technology

In a country known for high standards of medical care, Klinik Engeried stands out for its pioneering use of technology to improve women's breast health. Located in Berne, Switzerland, the 86-bed Klinik Engeried is ranked among the leading private hospitals in central Switzerland for its center of excellence in women's health.

Thirteen years ago, Klinik Engeried installed one of the world's first digital mammography systems and broke ground by offering all women routine digital mammograms. "We have been performing digital mammograms since the technology was introduced in 1991," states Peter Cerny, M.D., the radiologist who brought digital mammography to the hospital. "I was sure digital technology was the future of breast imaging, and Hologic was a step ahead in digital technology."

In 2008, the Klinik Engeried led the way again, with the installation of Hologic's Selenia® Dimensions® three dimensional breast tomosynthesis system, becoming Switzerland's first hospital offering this ground breaking technology.

The hospital performs 8,000 mammograms annually using Hologic's 2D Selenia digital mammography system and has performed more than 4,000 tomosynthesis examinations over the past two years, using Hologic's 2D/3D Selenia Dimensions tomosynthesis system.

Clearer Views Add up to Better Diagnostics

According to Dr. Cerny, "Tomosynthesis provides the best opportunity to detect cancer in women with dense breast tissue or hormonal treatments, as well as younger

women and women with a family history of breast cancer."

Technologists at Klinik Engeried routinely take four standard views for each patient using the Selenia system's 2D technology. If the radiologist sees structural changes or if the findings are unclear, additional pictures are taken using its 3D capabilities. "If we need to see small or difficult-to-detect structural changes or if the breast is dense, we take additional images with tomosynthesis," explains Dr. Cerny.

Tomosynthesis lets the breast center tailor its diagnostic tool to the patient. Says Dr. Cerny, "Digital mammography with the option of doing tomosynthesis is another step forward in diagnostics. You see things better. You detect more and you sleep better because you feel diagnostically more secure."

A Different Diagnosis

Dr. Cerny reports that tomosynthesis often changes the categorization of BI-RADS. "The ability to evaluate structural changes and evaluate the size and margins of an abnormality also reduces categorizations of the BI-RADS 3 and 0, reducing the recall rate and we believe, leads to slightly higher cancer detection rates. You get additional picture information because tomosynthesis removes overlapping tissue."

"We feel tomosynthesis has helped find several cancers that 2D imaging alone would have missed. We had some cancers we identified as BI-RADS 1 or 2, which are normally benign, and we changed the diagnosis to low or very high probability of malignancy because we could see more with tomosynthesis," states Dr. Cerny. ■



Dr. Martin Sonnenschein, M.D., head of Women's Imaging Team of Klinik Engeried.

"I was sure digital technology was the future of breast imaging, and Hologic was a step ahead in digital technology."

Tomosynthesis Delivers “Incredible” Detail

Through its years of service, the staff of Breast Imaging Department at Maroondah Hospital has seen, firsthand, the importance of clear, detailed images—for early breast cancer detection and for eliminating unnecessary work-ups.

So when it came time to replace its aging mammography system, the breast imaging team chose the Hologic Selenia® Dimensions® 2D/3D tomosynthesis system. With the equipment installed, it became Melbourne’s first hospital—and only Australia’s second—to offer tomosynthesis technology. “We have the most advanced mammography and breast biopsy equipment in Australia, second to none,” states Andrew Lawrence, M.D., Director of Radiology at Maroondah Hospital, a community hospital located in the outskirts of Melbourne.

“Any information you can get without additional views benefits the patient. There’s no comparison with tomosynthesis images; the detail is incredible,” says Stephanie Paul, Supervisor of the Breast Imaging Department. And after seeing a presentation of the equipment prior to purchase, Paul adds, “Hologic demonstrated excellent phantom images with four out of five possible speck groups clearly visible, which really sold me.”

Reducing Spot Compression Views

“In the dense breast, tomosynthesis makes subtle architectural distortions much easier to perceive. Plus, it provides better characterization of mass lesions for fewer indeterminate lesions,” explains Dr. Lawrence.

“Tomosynthesis lets us look through the breast in layers,” adds Paul. “For many patients, scarring distorts the tissue, making the mammogram more difficult to read.



Stephanie Paul, Supervisor of the Breast Imaging Department, believes tomosynthesis gives Maroondah Hospital an advantage.

With 2D, we might see areas of overlap, which can mimic areas of uncertainty. With 3D, you can look right through the area and see if it’s glandular tissue or overlapping tissue, eliminating unnecessary work-ups.”

Since the department implemented tomosynthesis, the hospital’s radiologists have requested far fewer spot compression views. If uncertain about an area, the radiologist scrolls through the tomosynthesis reconstructions and gets the information needed without additional views.

Improving Patient Comfort and Streamlining Workflow

Paul reports that Hologic’s FAST Paddle™ system and automated shifting paddle technology have also improved the patient

experience and streamlined workflow. The FAST Paddle conforms to the breast’s natural contour, providing more uniform compression across the entire breast to enhance patient comfort. And the ability of the paddles to move automatically to the next view in the technologist’s pre-configured workflow minimizes exam time.

In addition, says Paul, “The efficiencies of the Selenia Dimensions system make it so much faster than our old CR system, we’ll be able to serve a greater number of patients.”

“Hologic’s SecurView® diagnostic workstation was another selling point,” he adds. “The images appear on the monitor in seconds, and we can see detail immediately.” The SecurView workstation also enables radiologists to simultaneously display patients’ prior mammography, MRI or ultrasound images, side-by-side with the tomosynthesis images.

“We’ve been able to visualize calcifications magnificently on tomosynthesis reconstructions, because we can scroll through to the actual calcification planes and get maximum information on shape, size and the way they cluster. Tomosynthesis gives us an advantage over the competition,” continues Paul.

Dr. Lawrence concurs: “Patients want the best technology. Referring surgeons want the best images. Without tomosynthesis, you are not getting the full story. Access to tomosynthesis is essential if you wish to provide the highest possible quality in diagnostic mammography.” ■

Tomosynthesis Technology: A Key Differentiator for Dedicated Women's Imagers

The sign outside the Women's Center for Radiology in Orlando, Florida, announces the arrival of 3D mammography. Susan Curry, M.D., Founder and Medical Director, wants to get the message out to women in Central Florida about 3D mammography and the difference it can make in the early detection of breast cancer.

In April of this year, the Women's Center became the first imaging facility in Orlando and one of only a handful of centers in the country to offer 3D mammograms. "Saving lives involves remaining cutting edge," explains Dr. Curry. "We installed Hologic's Selenia® Dimensions® digital tomosynthesis system because we believe it will help us to find cancer early, so we can make a significant difference in our patients' lives. We felt the technology was so superior, we purchased a second Dimensions system in July."

Leading the way with innovative and effective imaging technology isn't new for the Women's Center. When Dr. Curry founded the Women's Center for Radiology 30 years ago, its mission was to improve the survival rates for women with breast cancer. The Center brought together dedicated women's imagers with the most advanced imaging technology available and set the standard for care in breast imaging.

"We were years ahead of other facilities implementing digital mammography," explains Dr. Curry. "Digital technology is a better way to read mammograms. We can see more and find cancers in an earlier state."

Three radiologists and seven technicians focus solely on breast

mammography, performing more than 35,000 mammograms annually. Additional staff provides breast MRI and ultrasound, DEXA scans, ductograms, and biopsies, including stereotactic breast biopsies using Hologic's ATEC® breast biopsy and excision system and the MultiCare® Platinum stereotactic breast biopsy guidance system.

make a real difference in the Center's ability to diagnosis patients with dense breasts or other high-risk factors. "With a two-dimensional mammogram, dense tissue can obscure breast cancer," explains Dr. Curry. "If you can't find the architectural distortions, which may be the only finding you have with an invasive tumor, then you can miss the tumor."

Dr. Curry believes tomosynthesis is enabling her staff to find smaller cancers at earlier stages. "The goal is to find cancer early, when it can be cured," states Dr. Curry. "We're trying to find really small cancers to improve the outcome. With tomosynthesis, we found a 7 millimeter cancer and, as a result, that patient may not need chemotherapy."

Several times a month, the Women's Center's mobile imaging van, outfitted with a Selenia 2D digital mammography system and Hologic's Sahara® clinical bone sonometer, travels to local businesses, including Disney World and Universal Studios, to bring life saving imaging services to women who can't travel to the Center.

Making a Difference for Dense Breasts and High Risk Women

Dr. Curry reports that tomosynthesis will

One analogy I like is mammography is like a book," explains Dr. Curry. "With two-dimensional digital mammography, you can see the front and back cover, and you learn a little bit about what is in the book, but everything in-between is obscured, as in a dense breast. With tomosynthesis you can see what's inside, page by page. It's not just a better image. It's a more complete image."

Dr. Curry continues, "The 3D tomosynthesis images are incredible and

give us confidence in our diagnosis. We feel really confident we haven't missed anything that will cause a problem next year or that the patient will discover later. I think there's less stress when you read tomosynthesis mammograms."

Improving the Outcomes

With only two tomosynthesis systems and approximately 150 patients a day, the Women's Center uses a breast cancer risk assessment tool known as the "Gail model" to estimate a woman's risk of developing invasive breast cancer over specific periods.

If a woman has an elevated Gail Model or high risk factors, she has a tomosynthesis mammogram. Plus, Dr. Curry reports, "Women come to our center because we have the most advanced technology available, and if they ask for the 3D exam, they get it."

We're here to take care of the patient, which is why our technicians like the Selenia Dimensions system," states Dr. Curry. "It's easy to position the patient, and the Hologic FAST Paddle™ tilting paddle system makes the compression more comfortable for the patient. But, the greatest reason our technicians like tomosynthesis is because they do not have to take additional views. Recalls are difficult for the patient and time-consuming for the technician."

Dr. Curry would like all Orlando women to know that tomosynthesis can help distinguish harmless abnormalities from real tumors—that means fewer callbacks and less anxiety. "If women know more about tomosynthesis, more women will request the three-dimensional exam."

"Almost everyone has been touched by breast cancer in some way," states Dr. Curry. "I personally have friends with breast cancer. So, it is important to think about that and find breast cancer early when you can make a difference in someone's life. Today, with smaller cancers found earlier, women may not need chemotherapy or radiation treatment, which is a much better outcome for the patient." ■



Dr. Curry, Women's Center for Radiology in Orlando, Florida

Dr. Curry Comments on Hologic Biopsy Devices

The Women's Center's commitment to using state-of-the-art technology to improve the outcome for patients extends to its biopsy equipment.

"We switched to Hologic biopsy devices about 5 years ago," states Dr. Curry, "They are easy-to-use, minimally invasive, and enable us to collect good tissue samples, which improves the accuracy of our diagnoses. The Hologic devices have made biopsy a virtually painless procedure for our patients."

"Hologic's biopsy devices provide a constant flow of pain medication during the procedure," explains Dr. Curry. "We don't have to stop the procedure to inject anesthetic. It is much more compassionate and efficient. Our patients tolerate the procedure very well."

Dr. Curry and her staff perform ultrasound-guided biopsies using the Hologic ATEC® breast biopsy and excision system and the Celero® breast biopsy device. The ATEC is a fully enclosed system with a dedicated collection chamber. It acquires large core samples with a single needle insertion, automatically collecting samples throughout the procedure. The Celero is a hand-held biopsy device which maneuvers easily, enabling the radiologists to sample hard-to-reach lesions.

"Most of our biopsies are performed with ultrasound, but if we see micro calcifications on the mammography images, we perform stereotactic biopsies," explains Dr. Curry. For stereotactic breast biopsies, the Women's Center uses Hologic's MultiCare® Platinum prone stereotactic breast biopsy guidance system with the Eviva® vacuum-assisted breast biopsy device.

"We've tried other biopsy devices," concludes Dr. Curry, "But we like Hologic products. Overall, they're less invasive and provide good tissue samples, which enable us to make accurate diagnosis. Plus, Hologic listens to our comments and is continuously improving their products."

Tomosynthesis Makes Mammography a Stronger Diagnostic Tool

For the radiology department at Hôpital Lapeyronie, in Montpellier, France, tomosynthesis provides a new tool in the fight against breast cancer, enabling them to identify more lesions. One of the largest teaching hospitals in France, Hôpital Lapeyronie has over 10 years of experience providing mammography and breast cancer diagnostic services to the women in the south of France.

Professor Patrice Taourel, University Professor and Head of the Radiology Department at the university hospital reports that tomosynthesis extends their capabilities. “Tomosynthesis has made us stronger and better. With the tomosynthesis images, we can see more lesions. We didn’t replace mammography with tomosynthesis,” continues Professor Taourel. “We acquire two-dimensional breast images along with three-dimensional tomosynthesis images in the same compression, in the combo mode. We can make progress in mammography, thanks to tomosynthesis.”

Seeing Beyond Overlapping Tissue and Detecting Additional Cancers

In 2009, the hospital added digital tomosynthesis, installing Hologic’s Selenia® Dimensions® 3D digital mammography tomosynthesis system, and has performed approximately 4,000 tomosynthesis exams since then. The hospital routinely uses the Dimensions 3D system in combo-mode, acquiring traditional 2D images along with 3D tomosynthesis images in the same exam—in the same compression.

According to Professor Taourel, tomosynthesis provides two benefits. “In my opinion, the real diagnostic benefits of tomosynthesis are specificity

and sensitivity. It means earlier cancer detection, better disease staging, and most importantly, tomosynthesis avoids patient anxiety caused by recalls.”

Professor Taourel explains. “Mammography systems using conventional 2D imaging have limitations caused by overlapping tissue in the breast that may hide lesions, or cause benign areas to appear suspicious requiring radiologists to recall healthy patients unnecessarily for additional examinations.”

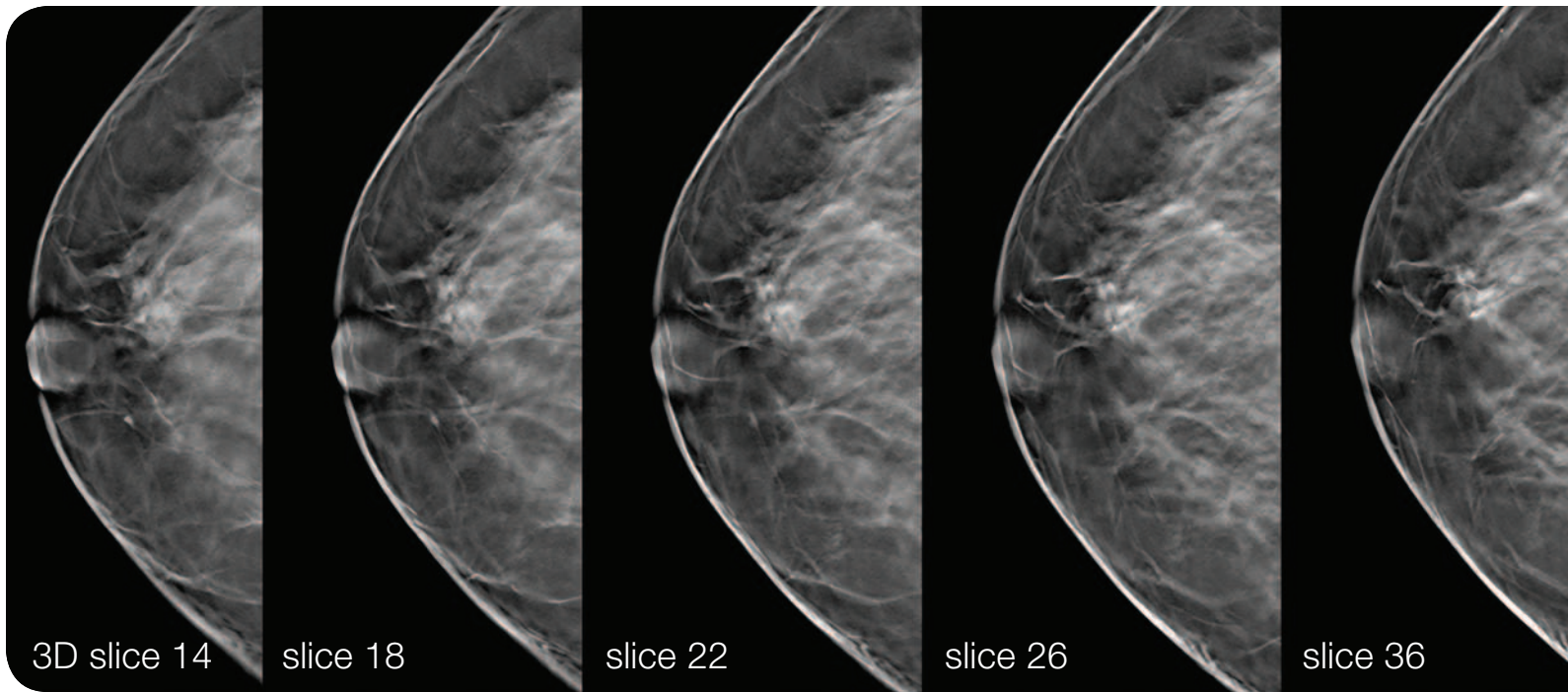
The second benefit of tomosynthesis, according to Professor Taourel, is a reduction in the number of false positives with BI-RADS 3, which leads to unnecessary biopsies. “Tomosynthesis has reduced the number of false positives significantly. It has also aided in the detection of additional cancers. It’s true that this doesn’t happen every day, not even every week, but every team using tomosynthesis, and ours in particular, finds additional cancers that would not have been seen in mammography. This is because two-dimensional mammography did not detect a trace of the cancer or it wasn’t pertinent enough; and, even if there were some signs of the cancer, they were too subtle, so they were missed,” states Professor Taourel. “So, there are cancers we detected with tomosynthesis

simply because we could see better; we could see contralateral cancers and multi-centric ones.”

The Hôpital Lapeyronie has all the imaging and interventional technology necessary for comprehensive diagnostic testing, performing approximately 6,500 mammograms, 150 stereotactic biopsies, and 50 MRI-guided breast biopsies each year. In addition to Hologic’s digital mammography and tomosynthesis systems, the hospital has dedicated ultrasound for breast imaging, breast MRI, and Hologic’s MultiCare® Platinum prone breast biopsy table, with ATEC® stereotactic biopsy device.

The Diagnostic Benefits of Tomosynthesis

When it first implemented tomosynthesis, the radiology department at Hôpital Lapeyronie believed the technology would be most effective in dense breasts, but has found tomosynthesis most effective at identifying certain types of lesions. “To perform a diagnosis, there must be some connection between the tumor and something that is less dense than the tumor, which is fat. So the best use of tomosynthesis is for what I call “disharmonious breasts”—breasts where the longitudinal features are not well



organized,” explains Professor Taourel.

“For masses, tomosynthesis shows the border of the mass, the presence of a thin and regular rim of fat which is a benign finding, any adjacent architectural distortion, and the location within the mass of eventual accompanying microcalcifications. For microcalcifications, although mammography analyzes the morphology and the outline of each microcalcification (morphologic descriptor) better, tomosynthesis has the advantage of better evaluation of the organization of a cluster of microcalcifications (distribution descriptor),” continues Professor Taourel.

“In asymmetric density which is classically the finding with the lowest cancer yield at screening examinations, tomosynthesis may better analyze the border and the outline of the density asymmetry and show spiculated outlines suggestive of a malignant breast lesion. The identification of architectural distortion or of a spiculated mass when the dense center is subtle is one of the main advantages of breast tomosynthesis.”

“In mammography we see pseudo distortions everywhere,” states Professor Taourel. “In tomosynthesis we are really able to say, ‘No. This is just a tissue overlap.’ Or sometimes we will be able to see something amidst the fat tissue

that was not seen otherwise, because in tomosynthesis we can clearly see distortions. Even if the tumor is not dense, it distorts, it pulls the sides, and that’s how we can recognize it.”

“Additionally, the characterization of benign structures is improved. For example vessels, especially those that are tortuous and are more easily traced, or lymph nodes with better visualization of fat within the node images or skin lesions, because the location on the skin is automatically verified from the position of the reconstructed section. So, if there is a mass with a stellar outline, or some architectural distortion, or the density is asymmetrical, if it has irregular contours, we will see the edges of the lesion much more clearly with tomosynthesis. The different densities are not that clear in tomosynthesis, but the edges, everything that is pulling, the distortions—all that is perfectly visible in tomosynthesis.”

“So my opinion is we should not reserve tomosynthesis only for dense breasts, or for low-density breasts; the diagnostic benefit of tomosynthesis will be more related to the type of lesion than to the density of the breast.”

“Our initial experience with tomosynthesis shows great promise in improving the limitations of

mammography—reducing the recall rate and improving the detection of cancers not seen in mammography and is consistent with published studies from other groups. It has value in both screening and diagnostic applications,” concludes Professor Taourel. ■



“Tomosynthesis has made us stronger and better.”

Professor Taourel, Head of the Radiology Department at the Hôpital Lapeyronie

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