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BREAST CANCER

inbrief

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Tomosynthesis: A Case Study

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D.T. is a 46-year-old woman who was enrolled in a digital breast tomosynthesis (DBT) research project, which compared conventional digital mammography (2D) to DBT for women with a mammographic abnormality scheduled to undergo percutaneous biopsy.

D.T. had indeterminate calcifications in her left breast for which stereotactic breast biopsy was recommended. Upon review of her DBT study, an unsuspected area of architectural distortion in the contralateral right breast was discovered. Even in retrospect, this area was not apparent in the original 2D mammogram, nor was it visible when the patient was recalled for additional mammographic views and targeted ultrasound.

Ultimately an MRI was performed, which demonstrated an abnormal area of enhancement which correlated with the DBT finding. The MRI finding was subtle, because there was considerable background enhancement in the breast. Nevertheless after an MRI-directed biopsy was performed and an infiltrating ductal carcinoma was diagnosed, D.T. underwent a segmental mastectomy and an 8 mm infiltrating duct carcinoma was removed. This case illustrates some of the potential benefits of tomosynthesis.

Continued pg. 2

TOMOSYNTHESIS: A CASE STUDY (continued)



It is well-known that mammography is an imperfect tool. In part, this is because it creates a two-dimensional image in which overlapping tissue structures can obscure lesions. This limitation can be partially overcome by performing multiple mammographic views, including angled and spot-compression views. These techniques were devised to look at lesions from other angles and to try and remove overlapping tissues with increased compression. Mammography therefore has a limited sensitivity, which averages approximately 70%. The range, however, is quite large, with sensitivity inversely related to increasing breast density. DBT is a tool that can remove overlapping structures and, therefore, in theory, improve sensitivity and specificity over a two-dimensional mammogram.

DBT is essentially a digital version of an old radiologic tool called tomography that was used for many years in the predigital era. With this technique, the x-ray tube moves in an arc across the patient, while the film or detector plate remains stationary.

Years ago, before CT scanning, it was common practice to perform tomography. For example, when the kidneys were evaluated during intravenous urography, tomography was commonly performed to view the kidneys without overlying tissues. Digital tomosynthesis employs the same physics principles, except that it is produced by using digital technology. The DBT machine looks very much like a traditional mammography machine (Figure 1). The main difference in construction between a mammography machine and a tomosynthesis machine is that the tube moves through an arc, while the breast is compressed against the digital detector plate. The resultant reconstructed images are displayed as 1 mm-thick slices through the breast, with very high resolution (approximately 100 microns). Currently images are taken in the traditional cranio-caudal (CC) and mediolateral-oblique (MLO) views.

Following the tomosynthesis acquisition, a 2D image is performed in each projection (CC and MLO). Therefore, the radiation dose for a tomosynthesis study is twice that of a conventional mammogram. The dose, however, is still well below acceptable FDA allowance for the radiation dose of a 2D mammogram.

The advantage of a 3D study (DBT) versus a 2D mammogram is that overlapping tissue can be eliminated, making the edges of masses and architectural distortions more apparent. Not only does tomosynthesis have the potential to find additional cancers, particularly in the dense breast, but it increases the edge conspicuity of masses, which allows the radiologist to better distinguish benign from malignant lesions. It does this both by increasing the edge conspicuity of lesions and making architectural distortion of normal breast tissue more apparent. In the fibrocystic breast, DBT may reveal many similar cysts and fibroadenomas, which might not have been apparent with 2D imaging, thereby increasing the radiologist's confidence that a new lesion is simply another benign fibrocystic nodule.

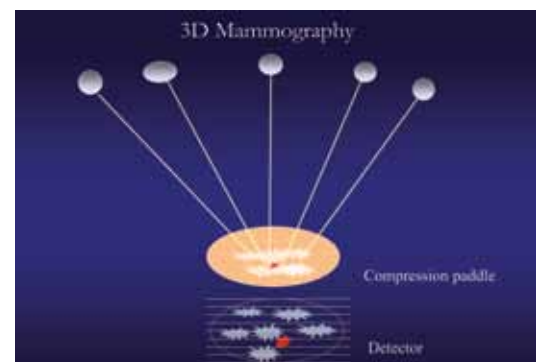
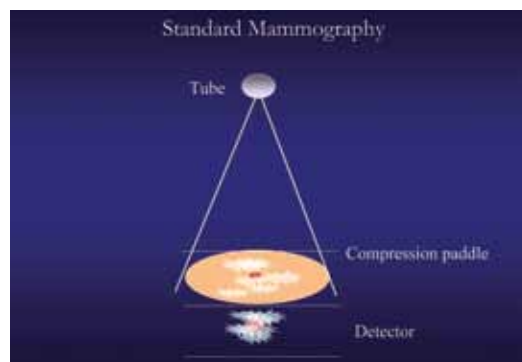
It appears that tomosynthesis may be equivalent to 2D mammography for evaluating microcalcifications, however, there is limited data regarding this to date. A recent article published in the *American Journal of Roentgenology* from our group at Magee-Womens Hospital of UPMC, showed slightly higher sensitivity for 2D mammography compared to DBT for calcification detection. With increased radiologist experience and improvements in the technology, it is likely that the two technologies will be similar in detection and characterization of microcalcifications. In its current state, therefore, DBT does not eliminate the need for magnification views used to evaluate microcalcifications.

The best-studied advantage of DBT to date has been to decrease call backs (recalls) from screening mammography. It is known nationally that recall rates are approximately 10%, but the range for individual radiologists is even greater. In other words, approximately one woman in 10 will be contacted following a screening mammogram to return to the breast center for additional mammographic views and possible ultrasound. The vast majority of these mammograms will prove to be normal or have benign findings. It has been shown in published reader studies, most notably by our group at Magee, that the recall rate can be reduced by approximately 30%. This has significant implications with regard to diminishing a patient's anxiety when called to return following an equivocal screening mammogram.



Two manufacturers' tomosynthesis machines depicted

The schematics shown to the right demonstrate how tomosynthesis removes overlapping structures. The moving of the x-ray tube changes the focal spot of the x-ray beam, which allows structures in adjacent slices (approximately 1 mm apart) to be viewed in isolation.



Conclusion

As with any new technology, there are some downsides. The machines and workstations to view the images are more expensive than traditional 2D machines. The actual performance of a DBT examination by the technologist takes about the same amount of time as a standard 2D exam, and, unfortunately, it still requires that the breast be placed in compression for the two views. Computer aided diagnosis (CAD) technology, which we routinely use with 2D digital mammography, has not been developed yet for DBT. It takes the radiologist longer to interpret the images, since there are many slices per view to examine. There is a learning curve and the radiologist viewing time does decrease, but it is unlikely to ever be as quick as a 2D mammogram. Another possible problem with tomosynthesis is that we may identify more benign lesions that could require biopsy for confirmation. Again, with experience, the radiologist should be able to more easily distinguish benign from malignant lesions.

At the present time there is no way to biopsy lesions found with tomosynthesis but not seen by 2D mammography, other than by second looks with ultrasound or MRI. There are evolving techniques that will soon allow relatively quick tomosynthesis-directed breast biopsy. It is anticipated that ultimately these techniques may replace current stereotactic techniques.

At Magee, we are incorporating 3D mammography into our practice in fall 2011. We have decided to begin using DBT as a diagnostic mammography tool, but not as a screening test. The radiologist will selectively use tomosynthesis to help evaluate equivocal findings found on a 2D mammogram, in lieu of additional 2D views such as compression-spot mammography or angled views. We feel that it is too early in our learning curve to begin screening, but we believe that in the near future, as we replace our 2D machines with DBT machines, screening will become a reality.

This should result in a significant decrease in recall rate. Our department believes that with refinements in the machines and increased experience with the new modality by breast imagers, that the future of DBT is bright and may someday replace 2D mammography as a stand-alone mammographic tool.

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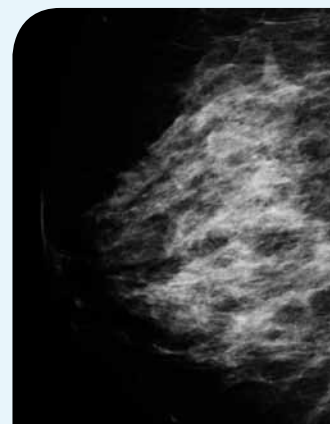
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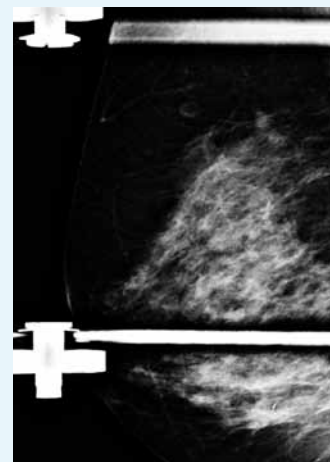
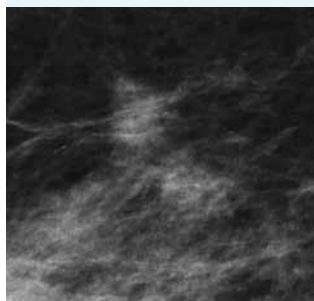
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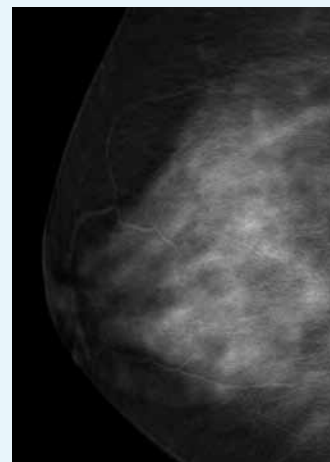
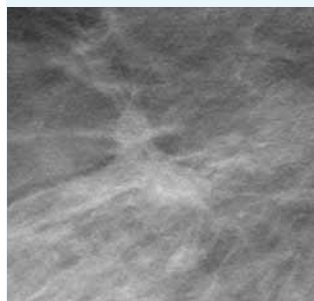
2D mammogram
interpreted as normal



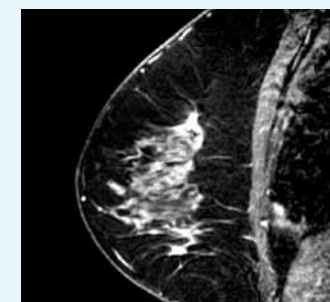
Compression spot performed
looking for the abnormality
demonstrated by 3D



Tomosynthesis shows
mass in upper Rt breast on
this MLO view



MRI demonstrates enhancing
mass lesion which was biopsied
with MRI guidance



UPCI and MWRI Launch the Women's Cancer Research Center

The WCRC is directed by Adrian V. Lee, PhD, and co-directed by Bob Edwards, MD. The WCRC Educational program is directed by Steffi Oesterreich, PhD.

Adrian Lee, PhD
Director, Women's Cancer Research Center
UPCI and MWRI

The Women's Cancer Research Center (WCRC) was established in fall 2010 as a collaboration between the University of Pittsburgh Cancer Institute (UPCI) and the Magee-Womens Research Institute (MWRI). As the only NCI-designated comprehensive cancer center in western Pennsylvania, UPCI is a recognized leader in providing innovative cancer prevention, detection, diagnosis, and treatment; biomedical research; compassionate patient care and support; and community-based outreach services. MWRI was established in 1992 as an independent research institute and the research arm of the Department of Obstetrics, Gynecology & Reproductive Sciences of the University of Pittsburgh. Together, UPCI and MWRI have combined efforts to create a center that rapidly drives research in women's cancer and improves patient care.

The mission of the WCRC is to reduce the incidence and death from women's cancer through the development and fostering of vibrant, basic, translational, and clinical research aimed at translating novel discoveries into improved patient care. To achieve the mission, the main goals of the WCRC are to perform cutting-edge research into the prevention, diagnosis, and treatment of women's cancers. Another major focus will be to translate the rapidly increasing information on the genetic and epigenetic defects that underlie the initiation and progression of women's cancers to knowledge that can be applied to improve patient care. This new molecular knowledge can be used in many areas, including diagnostic tests and novel targeted therapeutics.

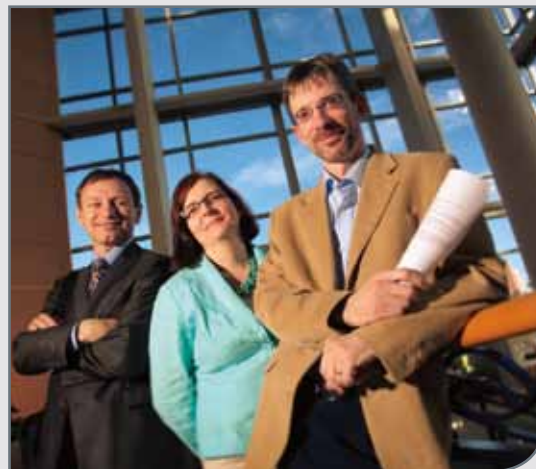
WCRC research is aimed at enhancing the personalization of prevention, diagnosis, and treatment of women's cancers. The research programs include many examples of this, such as studies of PARP inhibitors in BRCA mutant breast and ovarian cancer, germ-line single nucleotide polymorphisms,

which affect response and toxicity to hormone therapy, and molecular biomarkers of response to novel targeted therapies.

The WCRC has 168 members who are actively involved and share an interest in women's cancer research. Members have diverse backgrounds in women's cancer research, reflected in their multi departmental affiliations, which include pathology, medicine, pharmacology and chemical biology, surgery, ob-gyn and reproductive services, psychiatry, biomedical informatics, radiology, medical education, biostatistics, epidemiology, microbiology and molecular genetics, hematology/oncology, health science, cell biology and physiology, bioengineering, and pharmaceutical science.

The center will focus on enhancing collaborative interactions among its members through research meetings and a seminar series, discussion of scientific manuscripts (Journal Club), and a yearly scientific retreat.

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Radioactive Seed Program at Magee-Womens Hospital of UPMC

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When a nonpalpable breast lesion requires a surgical excision, the surgeon will require a preoperative wire localization using either ultrasound, mammographic, or MRI guidance. This procedure enables the surgeon to remove the targeted lesion.

However, the wire may create several problems for the surgeon. The entrance site of the wire is often not where the surgeon would prefer to make an incision. Therefore the surgeon must either compromise the incision site or mentally “triangulate” to the tip of the wire. Second, the surgeon can transect the thin wire during the operation. Finally the wire must be placed on the day of surgery. Accordingly, on the day of surgery, the patient must come to the Radiology department prior to the operating room to have the wire placed. Once the wire has been deployed, the patient is transported to the operating room.

Unfortunately, this process functionally links the scheduling and operations of two separate departments. This necessitates careful coordination for a smooth procedure to occur. It also requires that the patient arrive at the hospital several hours in advance of her appointment to have the localization performed. This is a significant inconvenience for the patient, particularly when an early morning operation is planned, which is frequently.

There is now an alternative to wire localization available at Magee-Womens Hospital of UPMC. Radioactive Seed Localization (RSL) is a new technique, which, in many instances, can replace standard wire localization. It involves the placement

of a tiny I125 seed (the same seeds used to treat prostate cancer) instead of a wire.

During surgery, the seed can be detected by the surgeon using a special probe designed to detect the radioactive signature of the seed. This probe is the same tool currently utilized to perform sentinel lymph node identification. The surgeon can choose an incision site strictly based on cosmetic concerns and the location of the tumor, and there is no wire to potentially transect. Because of the long half-life of the I-125 seed, it can be placed well in advance of the surgery. This means that on the day of the surgery, the patient can go directly to the operating room without a prior scheduled appointment in radiology.

At Magee the seed is typically placed the week prior to the surgery. If a sentinel lymph node dissection is being performed in conjunction with the tumor excision, the seed and sentinel lymph node injection may be performed simultaneously on the afternoon prior to the surgery.

In addition to the convenience for the patient, surgeon, and radiologist, there is another even more important potential benefit of this new technique. When segmental mastectomy is performed for breast cancer, there is an accepted rate of a positive margin. This often necessitates a second surgery, either a re-excision or mastectomy, to “clear the margins.” The national average for margin positivity is approximately 30%. It has been reported that RSL significantly reduces this rate by as much as 35%.

Magee is currently the only hospital in western Pennsylvania to offer this alternative to wire localization.

For more information
about the procedure,
please contact
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sumkjh@mail.magee.edu.

Trial Evaluates PARP Inhibitor as a Single Agent for Treating Breast and Ovarian Cancers

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The Magee-Womens Breast Cancer Program is conducting a monotherapy study of poly ADP ribose polymerase (PARP) inhibitor, ABT-888. This trial will, for the first time, examine ABT-888 as a single agent for patients with cancers related to the genetic mutation or dysfunction in the BRCA 1 or BRCA 2 genes, which predispose women to breast and ovarian cancers.

Cancer cells have been shown to have increased levels of PARP, which physician-researchers believe causes resistance to chemotherapies and other cancer treatments. Research has shown that tumor cells in patients with BRCA mutations are particularly reliant on the mechanism of DNA repair that is inhibited by the PARP.

The PARP protein is important for repairing single-strand DNA breaks. If single-strand breaks are not repaired, they get converted to double-strand DNA breaks. People with the BRCA-mutated gene have tumors with a defect in repairing double-strand breaks, which, if not repaired, are lethal to the tumor cells.

In previous trials in which ABT-888 was used as a combination treatment, it appeared to inhibit PARP, making cancer cells more sensitive to the chemotherapy. A goal of the trial is to demonstrate that patients with BRCA mutations or certain other breast or ovarian cancers may respond to ABT-888 as a single agent, so that treatment with cytotoxic chemotherapies, and the toxicities that may result from their use, may be avoided

For more information about the trial, please contact Dr. Puhalla at puhallas@mail.magee.edu.

CASE STUDY: RADIOACTIVE SEED LOCALIZED SEGMENTAL MASTECTOMY

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The patient is a 70-year-old female who underwent her annual screening mammogram, during which a nodular density was found in the outer half of the right breast. The patient subsequently underwent a diagnostic mammogram with spot compression views, which showed a density in the upper outer quadrant of the right breast. Ultrasound revealed a 1.25 cm solid nodule at the eleven o'clock position. An ultrasound guided biopsy was performed revealing infiltrating ductal cancer, which was hormone receptor positive and HER 2 negative.

Physical examination revealed a fullness in the lateral aspect of the right breast, but no discrete masses. The left breast exam revealed no masses. The axillae and supraclavicular fossae were negative bilaterally. MRI of both breasts revealed only the index lesion in the right breast.

Options for management of breast cancer were discussed with the patient and she chose breast conservation therapy. We felt she was an excellent candidate for radioactive seed localization (RSL) of the breast lesion and right sentinel node biopsy (SNB).

The patient had a RSL segmental mastectomy and SNB on July 28, 2011 (Figures 1 & 2). Pathology revealed a 1.5 cm infiltrating ductal cancer with negative margins. Three sentinel nodes were negative. The patient tolerated the procedure well.

Because of the increased utilization of screening mammography, breast cancer may be diagnosed at an earlier stage. Many patients presenting for treatment with this diagnosis have lesions which are not palpable, but are found only radiographically. Mammograms may reveal pleomorphic calcifications or small spiculated lesions within the breast.

Many surgeons rely on their radiology colleagues to localize the cancerous lesions for excision. Traditionally, the technique for localization of the cancer has been the placement of a thin wire into the breast at the site of the cancer. The patient is then taken to the operating room and the incision is made close to the site of the cancer with the goal being to remove the cancer with a negative margin. A secondary goal is to preserve the contour and cosmetic appearance of the breast. If these two goals cannot be achieved, the patient will require a mastectomy.

Though wire localization is the present standard of care, there are several drawbacks associated with it:

- 1 Often, the wire is placed by the radiologist in the radiology department and the patient is then transported to the OR with the wire taped to the breast. There exists the possibility of dislodging the wire during the transfer of the patient between departments.

- 2 **The surgeon may have a difficult time knowing exactly where to make the incision to excise the tumor. The ideal entry site for the radiologist may be at a significant distance from the tumor. The surgeon may have a difficult time finding the wire tip.**
- 3 **Multiple procedures need to be scheduled on the day of surgery. This may be problematic for the surgeon, radiologist, and OR, as well as contributing to the patient's anxiety.**
- 4 **Wire localization scheduled as the first case of the day will delay OR start time.**

To address these issues, several other techniques have been developed.

One alternative to wire localization involves the placement of a radioactive seed containing 3.7 to 10.7mBq of I-125 into the breast at the site of the cancer.¹ These are the same seeds used in the treatment of prostate cancer, which have a half life of 60 days.

The seed is placed into the breast using an 18 gauge needle under ultrasound or mammographic guidance. Placement is confirmed by mammography. Because the half- life of the I-125 is 60 days, the seed can be placed weeks prior to the operative procedure. Most protocols require seed placement within 3-5 days of surgery. No special instructions need to be given to the patient after the seed is placed.

Most patients will have SNB performed for the management of the breast cancer. The isotope used for this procedure is Tc-99. It has a much shorter half life but a stronger gamma emission. Equipment required for the RSL is the same used for the SNB, a standard handheld gamma probe. Various isotopes can be detected with this probe by simply pressing a button on the machine. Because of this, the RSL and SNB can be performed in combination as the two gamma sources are easily identifiable with the gamma probe. This allows for removal of both the tumor and the nodes during the same surgical procedure.

The gamma probe is used to scan the breast tissue until the site of the greatest radioactivity locates the seed. The incision is made directly over the site. The probe is used to guide the surgical excision. Scissors may not be used during the surgical procedure, because of the possibility of damage to the seed and leakage of the I-125.

Once the tissue has been removed, the probe is used to confirm that the seed is within the specimen. The tissue is transported to the radiology department and a specimen radiograph is performed documenting that the seed and the tumor have been removed. The specimen is then transported back to the OR for pick up by pathology. The pathologist then marks the specimen appropriately for margin status.

The gamma probe is used to retrieve the seed from the specimen. The seed is placed in a lead lined container and sent back to the Nuclear Medicine Department for documentation of the retrieval and appropriate disposal of the seed. Protocols are in place to track the seed throughout the process. Use of radioactive sources in the United States must comply with Nuclear Regulatory Commission (NRC) guidelines. All physicians

participating in RSL must undergo radiation safety training and be supervised for a certain number of procedures prior to proceeding with cases on their own. Radiation exposure to the patient, physicians, technicians, and staff is minimal and safe.

Benefits to using the RSL technique:

- 1 flexible patient scheduling
- 2 seed is positioned at the lesion with rare seed migration
- 3 no external wire visible to the patient, the seed is contained within the breast
- 4 more precise localization of the seed and tumor so incision is directly over the lesion to be excised
- 5 ability to proceed with surgery at the earliest OR start time

Drawbacks to the RSL technique:

- 1 seed cannot be repositioned once it has been placed and there may be migration of the seed with needle withdrawal
- 2 bracketing lesions may be difficult requiring wire localization of the area
- 3 contamination of the room if the seed is cut, lost, or dropped—requires closing the room and delay of the remainder of the OR day.

There have been several reports on the use of this technique and the results. Jakub et al reported that negative margins were more likely in the RSL group compared to the wire localized group. However, Lovrics et al found that positive margin rates are comparable between the RSL and wire localization. They documented shorter operating times for RSL and surgeon ranking RSL as easier than wire localization.² This technique can be successfully combined with SNB using Tc-99.

We recently began performing RSL for the management of breast cancer at Magee. To date, 25 procedures have been successfully performed. Patients have tolerated the procedure well and the perception among the surgeons is that the procedure is easy with a smaller amount of breast tissue being removed. We are collecting data in hopes of adding our results to the already published literature on margin status, amount of breast tissue removed, patient and surgeon satisfaction, and OR time utilized. We also plan to expand our program to include satellite facilities within the UPMC system.

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