Combined Contrast Enhanced Digital Mammography (CEDM) and Digital Breast Tomosynthesis (DBT) for Improved Diagnosis of Breast Cancer

Stony Brook University Medical Center

For an appointment or more information about Stony Brook’s contrast enhanced breast imaging research study, please call the study coordinators Carla DeVincenent or Jayne Schneider 631-638-2136 or 2137

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Background and Purpose
Breast cancer is the second leading cause of cancer death for women in the United States, and early detection through screening saves many (but not all) of these women. Mammography, in which x-ray images of the compressed breasts are obtained, is the standard breast screening tool and has been shown to reduce death from Breast Cancer by 20-50%. However, it has limitations since we see all of the shadows of the breast structures piled on top of each other. This superposition of normal breast structures creates a type of “anatomical noise”, which blocks our ability to see some small cancers. As a result, up to 20% of small breast cancers are missed.

The purpose of this study is to obtain images from the Siemens Mammatom Inspiration System with Digital Breast Tomosynthesis (DBT) capability. This experimental Siemens Mammatom Inspiration system has been modified from the standard unit approved by the United States Food and Drug Administration (FDA) for full-field digital mammography (FFDM), but not yet for DBT. The modification allows the energy of the x-rays to increase from the standard 35 keV to 49 keV, which allows imaging of blood vessels inside the breast after IV injection of contrast agent. Blood vessels form around tumors, therefore imaging them with contrast enhancement is a great tool for breast cancer diagnosis. In this study, we will collect two sets of contrast enhanced images of the breast in 2D, which is similar to mammograms. The total radiation dose of these two sets of mammograms will be equivalent to one screening mammogram, and will be used to form contrast enhanced digital mammography (CEDM) images of your breast at two different time points after contrast injection. We will also perform a 3D DBT scan of your breast. The DBT system produces a 3D image of the breast by taking several low-dose x-rays from different angles of the breast, with the total dose equivalent to a screening mammogram. The DBT image slices will reduce the obscuring effect of overlying breast tissue, and may allow radiologists to better detect breast cancer. The 2D CEDM images and 3D DBT images will be read by a participating radiologist to determine whether there is blood vessel formation around a breast lesion.

Procedure
You will undergo your scheduled routine contrast enhanced breast MRI for your diagnosed breast cancer. If you chose to participate in this research study, additionally you will undergo a combined CEDM and DBT imaging procedure on the experimental DBT system. Your total radiation exposure will be equivalent to a 2-view screening mammography, which is still a low dose. Your participation in the study, including informed consent, contrast injection and imaging procedure, will take approximately ½ hour to 1 hour.

Frequently Asked Questions

Q: How long will this study last?
A: Your participation in this study would last approximately ½ hour to 1 hour. If you agree to participate in this research, this would be done after your regularly scheduled breast MRI study.

Q: What is the difference between mammography, CEDM and DBT?
A: In mammography, one x-ray of a compressed breast is produced. In CEDM, two x-ray images of a compressed breast are taken with a combined radiation dose equal to a screening mammogram. One image is at low energy and the other image is at high energy. A subtraction of the two images produces one image with minimal “anatomical noise” and highlighted blood vessels. In DBT, several low-dose x-rays are made from different angles, which will be used to reconstruct image slices and allow the doctors to “see through” the breast tissue. The total radiation dose you receive from DBT is the same as from screening mammography.

Q: What are the risks and benefits of this study?
A: You will get additional radiation from being in this study. Your total radiation exposure would be equivalent to a 2-view screening mammography. The risk from this amount of radiation is too small to be measured directly, and considered low compared with other every day risks. You will also receive an IV contrast injection. There is a small risk of adverse reaction to contrast agent. About 5-8% of patients experience side effects, with the majority being nausea, dizziness, etc. Although rare, 1/10,000 patients experience severe side effects with the risk of death being extremely rare. You may benefit directly from this study, because the doctor will review images from both scans. In addition, the findings of the study may help guide the future use of CEDM and DBT for improved breast cancer detection.

Q: Who is eligible for participation in the study?
A: The following groups of female patients at the Carol Baldwin Breast Care Center of Stony Brook University Medical Center are eligible to participate: women 30 years or older scheduled for a breast MRI to follow up on a breast cancer diagnosis, who have no known history of compromised kidney function or adverse reaction to contrast agents.

Q: Will I be informed of the study result?
A: You will be informed of the study result if you make a request to the Principal Investigator Dr. Fisher.

Q: Will I get paid for this study?
A: Yes, you would be paid $100.