STEREOTACTIC & TOMOSYNTHESIS GUIDED BREAST BIOPSY (CATEGORY A VERSION)

INTRODUCTION

Stereotactic breast biopsy procedures have been widely used for the definitive diagnosis of nonpalpable mammographically detected breast abnormalities for many years. Prior to stereotactic breast biopsy, the alternative was needle wire localization followed by open surgical biopsy for definitive diagnosis. The stereotactic breast biopsy system and procedure, with the addition of post biopsy clip placement, was described decades ago by Bolmgren and colleagues [1]. Since then, hundreds of studies have been conducted and scientific papers published in peer review journals regarding stereotactic breast biopsy. The stereotactic biopsy principle is that the exact location of a lesion within a breast can be identified through imaging and mathematical tools. The idea of stereotactic biopsy comes from the term stereology which means “a branch of science concerned with inferring the three-dimensional properties of objects or matter ordinarily observed two-dimensionally” [2]. Research has shown the procedure to be accurate, safe, and quick, with minimal pain and excellent cosmetic results. In general, needle core biopsy leaves minimal to no internal breast tissue scarring, which is often associated with open surgical biopsy. In comparison to open surgical biopsy, the procedure is less invasive, reducing complications and recovery time for the patient. When concordant benignity is diagnosed at biopsy, surgical biopsy is no longer necessary. When a malignancy is diagnosed after a stereotactic biopsy, the patient and referring physician can proceed to the surgical planning procedure of choice. In most cases, patients have their stereotactic core biopsy results within 24 to 48 hours, minimizing time to treatment planning. When definitive diagnosis is achieved through needle core biopsy, health care costs are reduced and patient anxiety is minimized [3, 4, 5, 6, 7]. Brenner et al. in 1997 reported cost savings of upwards of 50% when needle core biopsy provided a diagnosis verses open surgical biopsy. However, performing needle core biopsy for probably benign lesions (BI-RADS category 3) is more costly in comparison to mammographic surveillance of these lesions [8]. Lee and colleagues specifically looked at cost savings for stereotactic core needle biopsy in comparison to open surgical biopsy using Medicare reimbursement as a guide. The study reported that overall, in the year 1995, stereotactic core biopsy resulted in a $741 cost savings over open surgical biopsy [9]. Early in its implementation, stereotactic core biopsy proved itself an extremely valuable tool.

Digital Breast Tomosynthesis (DBT) use in clinical practice continues to grow. As of May 2020, there are more than 6,000 certified facilities with DBT units, and more than 8,800 accredited DBT units [10]. Currently, DBT is being utilized in a variety of clinical settings and has been shown to perform well in a variety of exam and patient indications [11]. Multiple studies have reported decreased recall rates and increased breast cancer detection rates [12-18].

With increased use of the technology, there has been a rise in clinical practice of scenarios in which a suspicious lesion is identified only on DBT imaging, which has created a management dilemma for the

radiologist. Therefore, access to biopsy equipment capable of localizing lesions with DBT is recommended but not mandatory. Tomosynthesis-guided core biopsy has been introduced to offer a solution to these situations, by providing the ability to biopsy these lesions the way there were identified. Studies have found that DBT VAB can offer better lesion localization by 3D nature of the technology of both low-contrast masses and distortions [19, 20]. Waldherr et al. evaluated the feasibility and performance of (upright) DBT – guided VAB compared to stereo (SVAB) and found that all TVAB biopsies were technically successful and obtained the targeted lesion (microcalcifications) in 100% of cases; SVAB did not obtain the targeted microcalcifications in 1/86 [21]. DBT VAB had superior performance in comparison with PS VAB in a clinical evaluation by Schrading et al.; DBT VAB had a 100% technical success rate, versus 93% for PS VAB [20]. Reidentifying and targeting lesions during PS VAB took longer than it did during DBT VAB (P, .0001), and time for tissue sampling was about the same for both methods (P = .067). These findings give the clinician the confidence needed to pursue the adoption of DBT guided biopsy.

STEREOTACTIC AND TOMOSYNTHESIS BIOPSY REQUIREMENTS

Currently, the American College of Radiology (ACR) Appropriateness Criteria specifies stereotactic biopsy indications, contraindications, staff requirements, procedure specifications, equipment quality control and specifications [23]. The requirements for tomosynthesis-guided biopsy are the same as for stereotactic biopsy. The next section will review these guidelines.

INDICATIONS FOR STEREOTACTIC CORE BIOPSY AND TOMOSYNTHESIS-GUIDED BIOPSY

If an abnormal finding is detected during a mammography or digital breast tomosynthesis (DBT) study, a complete diagnostic evaluation is conducted. This evaluation should include additional mammographic views and targeted ultrasound. Biopsy is recommended for lesions after diagnostic imaging is complete and the final BI-RADS assessment is a Category 3 (probably benign), 4 (suspicious for malignancy) or 5 (highly suggestive of malignancy). The biopsy method is chosen based on how the lesion is best demonstrated. For example, if a lesion is seen mammographically, and on DBT and ultrasound, the lesion will be biopsied using ultrasound guidance. If the lesion is only seen mammographically, stereotactic guidance is chosen. Now, with recent Food and Drug Administration (FDA) approval, if a lesion is demonstrated only with DBT imaging, a stereotactic DBT guided biopsy can be performed.

Indications have been outlined by the ACR. As mentioned previously, stereotactic-guided biopsy is suitable for most mammographically detected lesions. One category specifies nonpalpable lesions not seen by ultrasound imaging assessed as highly suggestive of malignancy (BI-RADS Category 5). Specifically included in this category are irregular shaped masses, spiculated masses, microlobulated masses, indeterminate or suspicious calcifications (pleomorphic, linear, and branching), and asymmetries with or without associated suspicious calcifications. Nonpalpable lesions not seen by ultrasound imaging that are assessed as suspicious abnormalities (BI-RADS Category 4) also are included. Additionally, nonpalpable lesions not seen by ultrasound imaging, assessed as probably benign (BI-RADS Category 3), can undergo stereotactic biopsy when clinically indicated or when follow-up would be difficult, an example of which would be an enlarging circumscribed mass. When multiple suspicious lesions are detected, in multicentric distribution, stereotactic biopsy can help to facilitate treatment planning. Lesions that are visualized in retrospect on mammography that correlate with suspicious areas of enhancement initially detected on contrast-enhanced breast MRI are indicated for stereotactic breast biopsy as well. Repeat stereotactic biopsy is an alternative to surgical biopsy when the initial biopsy results are non-diagnostic or discordant with imaging.

DBT-guided biopsy technique may be used instead of stereotactic guidance for lesions or calcifications that are identified on DM. Documentation of images for DBT biopsy should follow the ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedure.

CONTRAINDICATIONS FOR STEREOTACTIC BIOPSY

The ACR Practice guidelines outline several contraindications for stereotactic guided breast biopsy, which will also be applicable for tomosynthesis guided biopsy. Inability to visualize the lesion mammographically being the main contraindication. When a lesion is visualized comparably on both mammography and ultrasound, ultrasound guided biopsy is the preferred method for sampling. The patient's ability to lie prone on the stereotactic table should be evaluated prior to the procedure; if the patient has spinal fusion or arthritis, for example, then stereotactic biopsy may be contraindicated. Additionally, patient weight needs to be considered as stereotactic biopsy tables have a weight limit that can exclude a patient from the procedure. Patient habitus/small breast size and negative needle stroke margin will exclude a patient from safely undergoing this procedure. Pregnancy often excludes a patient from eligibility for a stereotactic biopsy as it is not optimal for the pregnant patient to lie prone.

It is advised to proceed with caution when performing a stereotactic guided biopsy on a patient who has allergies to tape or local anesthetic. Performing a complete assessment of these allergies is necessary to ensure the patient is a good candidate for the procedure. Facilities often have multiple options in order to avoid an allergic reaction. If the patient is on aspirin or anticoagulant, or has a history of bleeding diathesis, there are a few options. The patient can be asked to discontinue aspirin use, or other anticoagulation, if it is cleared with their health care provider, and return on a different day for the procedure. Applying an ice pack to the potential biopsy area before the procedure may be helpful to limit bleeding. When the procedure is complete, holding pressure along the biopsy track for a minimum of 5-10 minutes helps to minimize bleeding, and post-procedure bruising or hematoma. Utilizing a pressure bandage, pressure wrap, and ice treatment longer than average will be very helpful with these patients.

As mentioned previously, stereotactic biopsy tables have a weight limit, so when a patient's weight is approaching the table limit, it may be best to investigate other options. This is important, as aside from the weight limit of the table being a limitation, there are also issues when performing the biopsy procedure on the overweight or obese patient. These include difficulty in positioning, for example a protuberant abdomen may prevent the posterior aspect of the breast from being fully imaged.

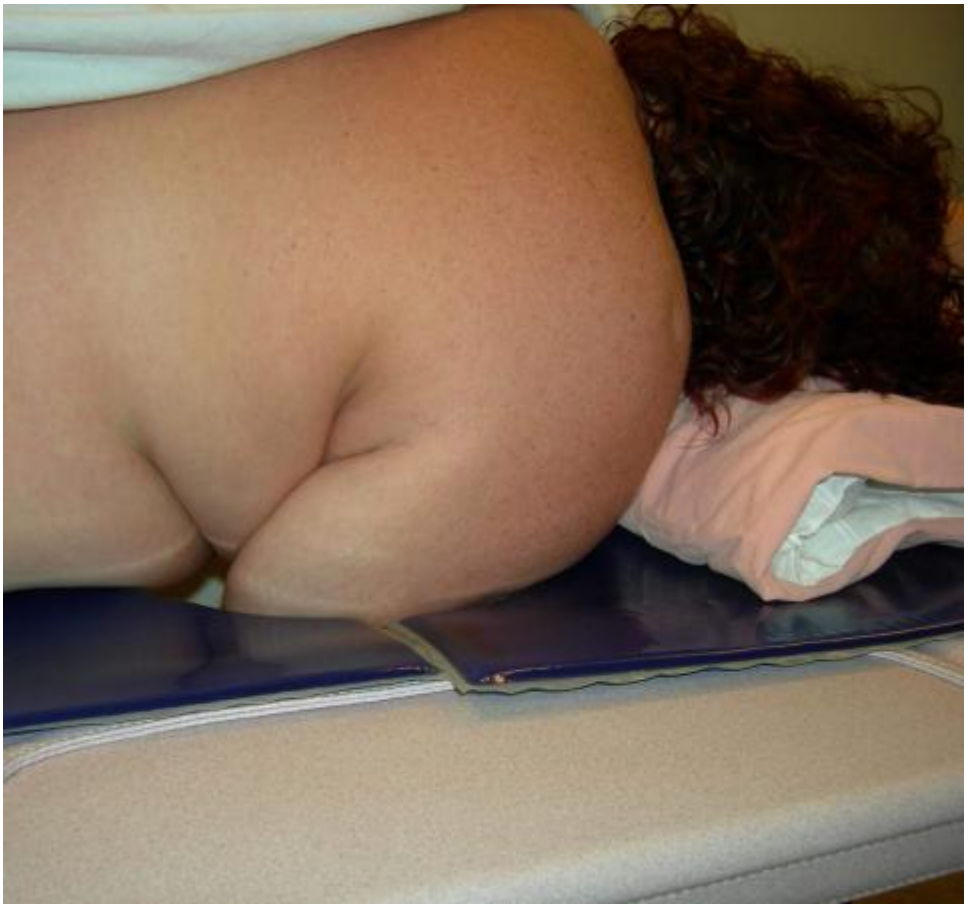


Figure 1a: Depicts the table opening is not large enough to allow the arm through for posterior breast access.

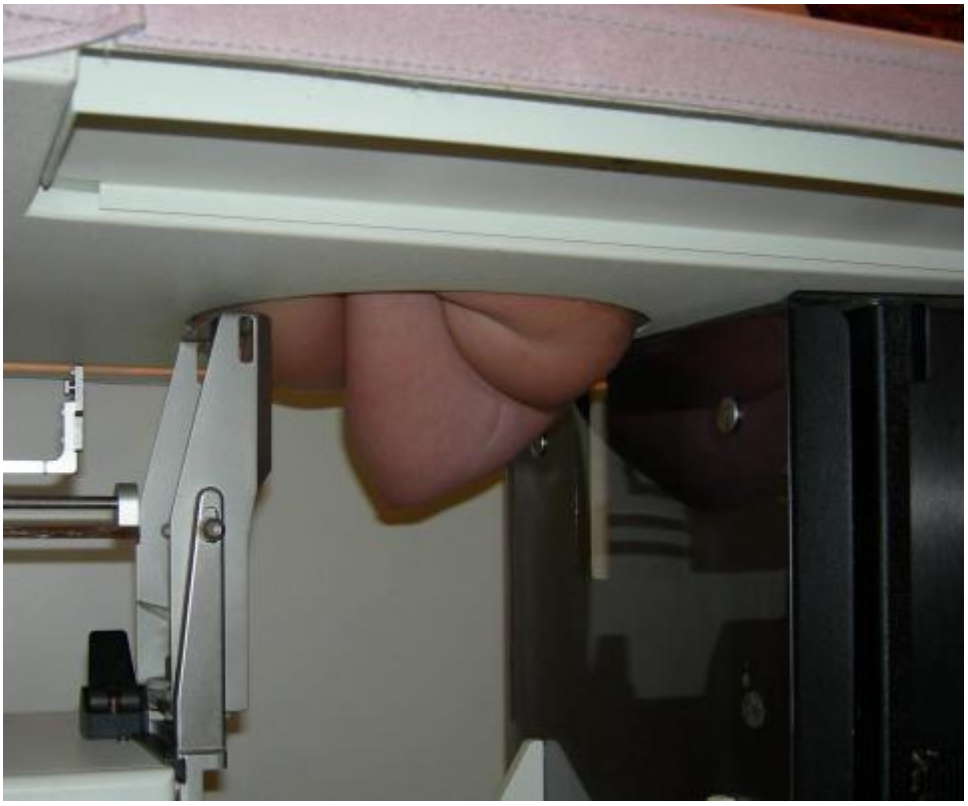


Figure 1b: Demonstrates tissue folds and abdominal protuberance that is often common with obese patients.

The large breast size may require multiple scout images before the target can be located [24]. Greater breast thickness can lead to geometric blur. Increasing kilovoltage or tube current to correct the issue

can lead to poor lesion conspicuity [25]. These contraindications and cautionary scenarios are important to consider when determining if stereotactic guided biopsy is the best method for the patient. When a patient has any of the limitations mentioned above, and the lesion is identified on ultrasound, ultrasound guided biopsy should be pursued. If ultrasound guided biopsy is not an option, open surgical biopsy may be the alternative of choice.

QUALIFICATIONS AND RESPONSIBILITIES

Radiologists performing stereotactic guided breast biopsy should meet the qualifications specified in the ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography [26]. The Physician must have 3 hours of Category 1 CME didactic instruction in stereotactic-guided breast intervention, as well as have performed at least 3 hands-on stereotactic breast biopsies under the supervision of a qualified radiologist (completion of this during residency/fellowship is acceptable). In independent settings, the radiologist should also have 15 hours of Category 1 CME in breast imaging and disease. Non-radiologist physicians must meet the criteria above and have an additional 4 hours of Category 1 CME in medical radiation physics and have evaluated 480 mammograms every 2 years in consultation with a physician who has the qualifications specified in the Mammography Quality Standards Act (MQSA). To maintain competence in stereotactic biopsy, the physician should perform at least 24 stereotactic guided biopsies over a 24-month period and show 3 hours of category 1 CME in stereotactic biopsy every 3 years. Additionally, the physician is responsible for determining adequacy of sampling. To do so, the physician, or an MQSA-qualified physician designee, is responsible for obtaining histopathologic results and determining concordance. Similarly, physicians performing DBT image-guided biopsies must be qualified to interpret DBT images and therefore must have successfully completed the required 8 hours of DBT training mandated by the FDA.

According to the ACR, the medical physicist will need to meet the qualifications specified in the ACR Practice Guidelines and have performed at least one hands-on stereotactic breast biopsy survey under the guidance of a qualified medical physicist. To maintain qualifications, the physicist will need to perform 2 stereotactic biopsy unit surveys every 2 years and show 3 CME hours in stereotactic breast biopsy physics every 3 years.

Initial qualifications for the Radiologic Technologist consist of 3 hours of Category A continuing education credits in stereotactic guided intervention as well as participation in at least 5 supervised hands-on procedures. To maintain qualifications, the Radiologic Technologist must have participated in 24 stereotactic biopsies every 2 years and show 3 hours of CME within 3 years for continued education.

REQUIREMENTS FOR PREPARATION OF THE PROCEDURE

A requisition for the procedure is made after adequate imaging evaluation of the breast is made, and medical necessity is determined. Relevant information to be included consists of signs and symptoms, and/or relevant history. Additional optional information includes reason for the examination or provisional diagnosis. Signed and dated informed consent listing the benefits, risks and limitations of the procedure must be obtained. A strict adherence to the “Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery TM” for a non-operating room setting is required. Many mammography facilities that offer stereotactic breast biopsy are in a private, outpatient office setting. Sites such as these should have a protocol in place to minimize/eliminate wrong site or wrong patient mishaps. Before the procedure, the technologist must ask the patient to state her date of birth, spell her last name and tell you what breast/area the doctor is concerned about. Some outpatient centers use wrist bands for their biopsy patients, including identifiers such as name, date of birth, and

breast biopsy information (laterality, clock position and lesion type).

OVERVIEW OF THE PROCEDURE TECHNIQUE

Positioning is a key element of the procedure. Imaging is performed once the patient is positioned to confirm the lesion lies within an accessible area.

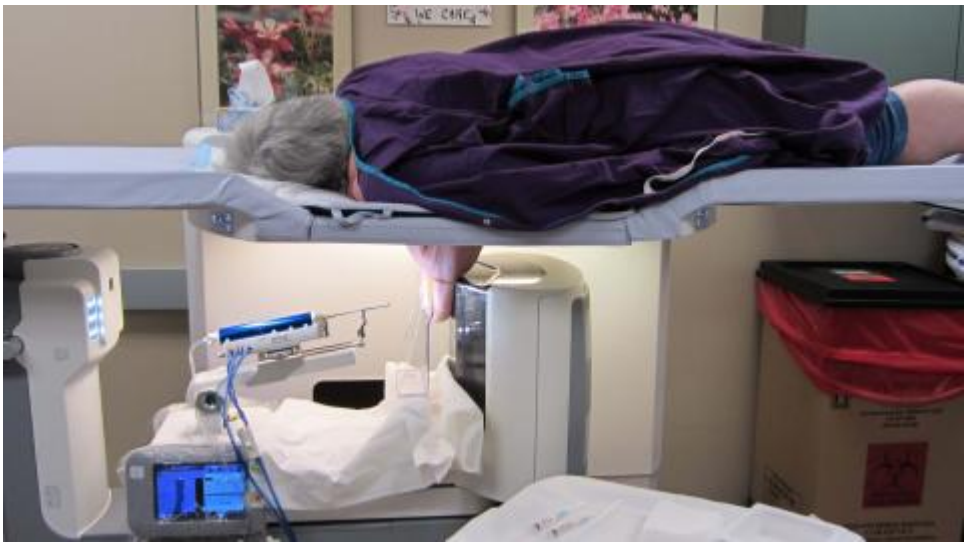


Figure 2: Imaging is performed once the patient is positioned to confirm the lesion lies within an accessible area

The best approach to obtain the shortest skin to lesion distance is determined after all imaging is reviewed. It is important to position the breast in such a way as to avoid blood vessels in the biopsy track, ultimately avoiding additional bruising and bleeding.

Once this is confirmed, scout and stereo imaging is performed. It is important to assure that the breast thickness is greater (minimum of 5mm) than the depth of the lesion to avoid having the biopsy needle penetrate the entire breast [27]. The computer-generated coordinates are transferred to the biopsy device. The skin entry site is cleaned utilizing Betadine or equivalent, along with the surrounding area, to minimize risk of infection and prepare the site for the procedure. Local anesthesia is administered using Lidocaine (2%), or Lidocaine/xylocaine (1 or 2%) with epinephrine for deep breast anesthesia. Documentation of needle positioning for sampling should be obtained and recorded in the patient record. Each facility may have a slightly different stereotactic biopsy protocol; follow your site's specific protocol. After the procedure, specimen radiography should be obtained if the biopsy is performed for microcalcifications to ensure adequate sampling. A tissue marker is often placed at the biopsy site. This is especially beneficial if the lesion is difficult to visualize after the biopsy, when confirmation is needed that the proper lesion was sampled, or if neoadjuvant chemotherapy is being considered. Further, when multiple lesions are sampled, marker placement of different shapes should be considered. At the completion of the procedure, adequate compression of the skin entry site/biopsy path is needed in order to achieve hemostasis. Post-biopsy mammography should be performed (Craniocaudal and Lateral projections) for tissue marker documentation. The location of the clip in relation to the biopsy site should be documented in the medical report. Further detail on the biopsy procedure will be provided later. Required image labeling and documentation consists of patient name (first and last), identifying number and/or date of birth, examination date, facility name and address, laterality, annotation of view (CC, MLO, Lateral) and technologist identification number, if applicable, or initials. Physician identification may also be included.

The medical report dictated by the physician should include the procedure performed, laterality,

description and location of the lesion, the performance of safety timeout, approach used, type and amount of anesthetic, skin incision (if made), needle gauge and type of device used, number of core specimens/samples obtained, specimen images performed and their results, tissue marker placement (if performed), complications and treatment (if any), and post procedure mammography documenting tissue marker placement and location in relation to the biopsied lesion.

Patient follow-up after the procedure should include documentation of any delayed complications and the treatment administered, and a determination of concordance of the pathology results with the imaging findings. When discordant, repeat biopsy should be considered, or surgical excision. Physician recommendations based on the pathology results, imaging findings, and concordance analysis should be provided. A record of the communication of the results with the patient and/or referring physician is required.

TRADITIONAL STEREOTACTIC BIOPSY EQUIPMENT AND PROCEDURES

Due to the advances made by ultrasound manufacturers, even small, subtle masses and architectural distortions are often now sampled under sonographic guidance. Typically, this is the preferred method as the questionable area is seen in “real time”, as well as that the patient is more comfortable lying supine on the examination table, and the examination is less expensive. Once the decision is made to perform a stereotactic guided biopsy, the radiologist must also select the needle to utilize for the procedure. The needle and biopsy device of choice for stereotactic core biopsy should be the vacuum assisted biopsy (VAB) device. The VAB system ensures that the radiologist obtains a larger volume of tissue which is ultimately helpful for the pathologist ; also, multiple samples can be obtained from a 360-degree rotation of the device without repeated removal and re-insertion of the needle into the breast [27]. VAB devices have also proven to be more accurate in comparison to open surgical outcomes, as well as more accurate at retrieving calcifications [27].

Present day stereotactic equipment consists of either an add-on stereotactic biopsy device for a mammography unit or a dedicated stereotactic prone biopsy table. Both biopsy methods use the same imaging principles. As stated previously, the stereotactic breast biopsy system is designed to accurately localize a suspected abnormality identified by mammography in 3 dimensions; horizontal, vertical and depth. This is achieved by obtaining an x-ray “scout image” which demonstrates the abnormality as close to center of the image as possible. Two x-ray images, “stereo pairs”, are acquired after moving the x-ray tube 15 degrees from each side of the scout. The lesion is then targeted on each of the stereo images and the coordinates of the lesion within the breast are obtained. These coordinates provide the target for the biopsy needle.

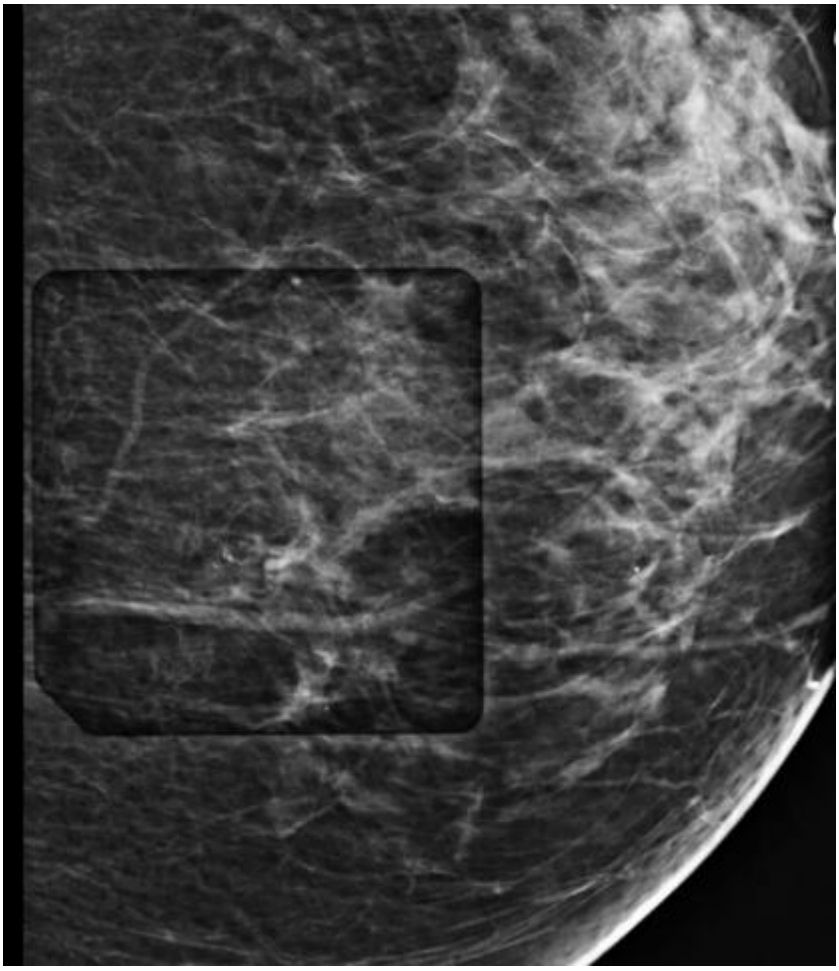
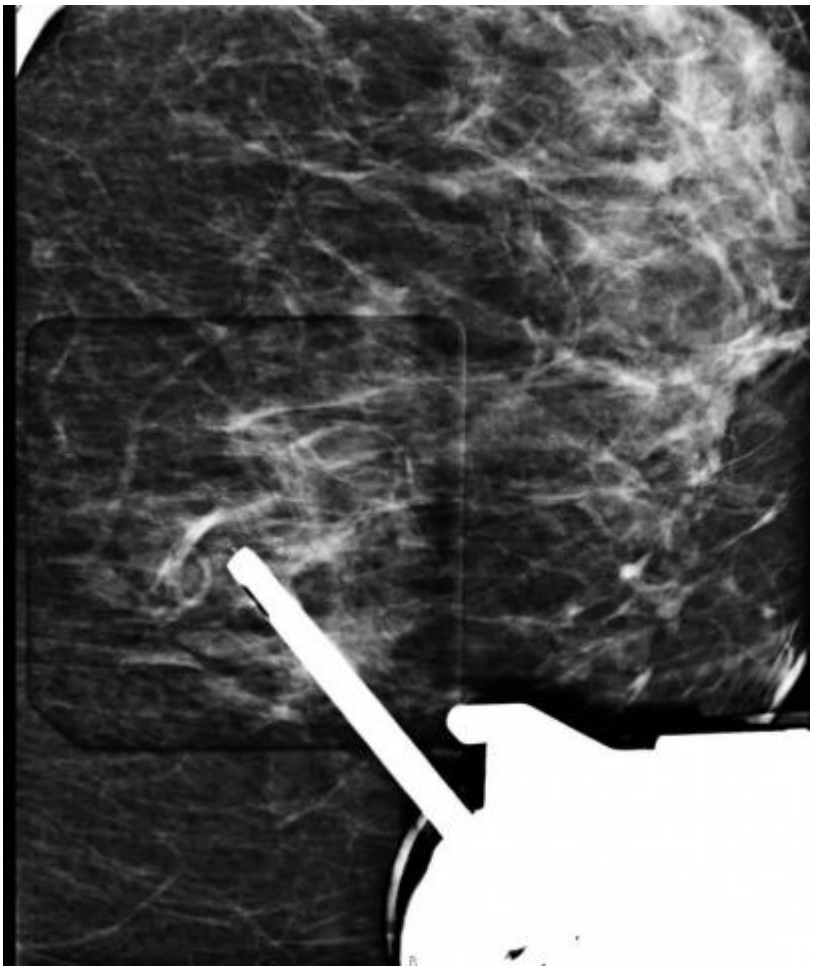


Figure 3: Scout image of calcifications



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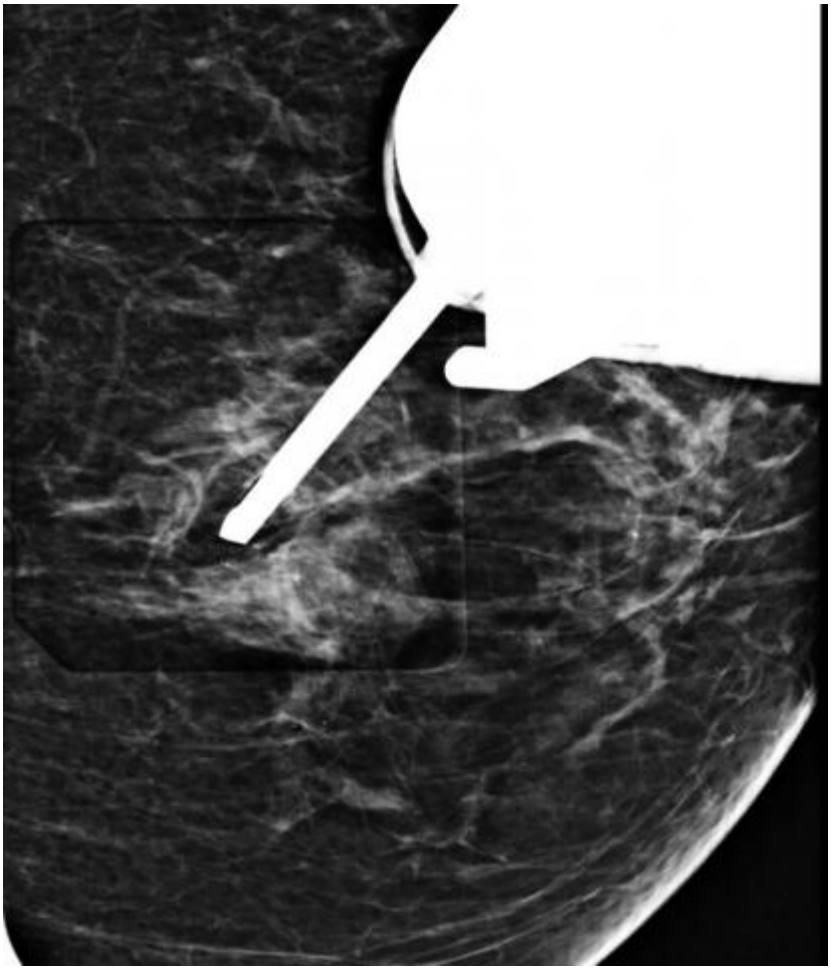

4b.

Figure 4a and 4b: Stereo pair images are obtained at 15 degrees from each side of the scout. The lesion is targeted on both of the stereo images and the horizontal, vertical and depth coordinates of the lesion are obtained. Stereotactic core biopsy results are infiltrating ductal carcinoma and ductal carcinoma in situ.

The Cartesian method (X (horizontal), Y (vertical), and Z (depth) axis) and the polar method (H (horizontal), V (vertical) and D (depth)) are the two coordinate systems used with current stereotactic biopsy devices [28].

UPRIGHT ATTACHMENT STEREOTACTIC BIOPSY UNITS FOR MAMMOGRAPHIC GUIDED BIOPSY AND TOMOSYNTHESIS-GUIDED BIOPSY

Upright biopsy attachment units are typically less expensive in comparison to the dedicated prone stereotactic unit.

Figure 5: Is an example of the upright stereotactic attachment that converts a digital mammography unit to an upright stereotactic biopsy unit.

The upright biopsy attachment may be an attractive investment when considering that the mammography unit is converted quickly and does not require the dedicated space needed for a prone stereotactic table.
For a busy mammography practice, converting the unit to a biopsy room will interrupt the screening or diagnostic schedule, but can be successfully accomplished with proper scheduling. Patient positioning for procedures utilizing the upright stereotactic unit is the same as for routine mammography imaging, except for some slight variations. What you can image and visualize on the mammography, you will be able to biopsy with the upright stereotactic accessory attachment, as the upright biopsy device can accommodate positioning in both upright and recumbent (medial or lateral) approaches.
Special reclining chairs are available for use with this type of procedure. Some upright add-on units, such as those compatible with the Siemens and General Electric full field digital mammography (FFDM) units, feature both the lateral and vertical needle approach, allowing easy access to inferior, medial, lateral and posterior lesions.

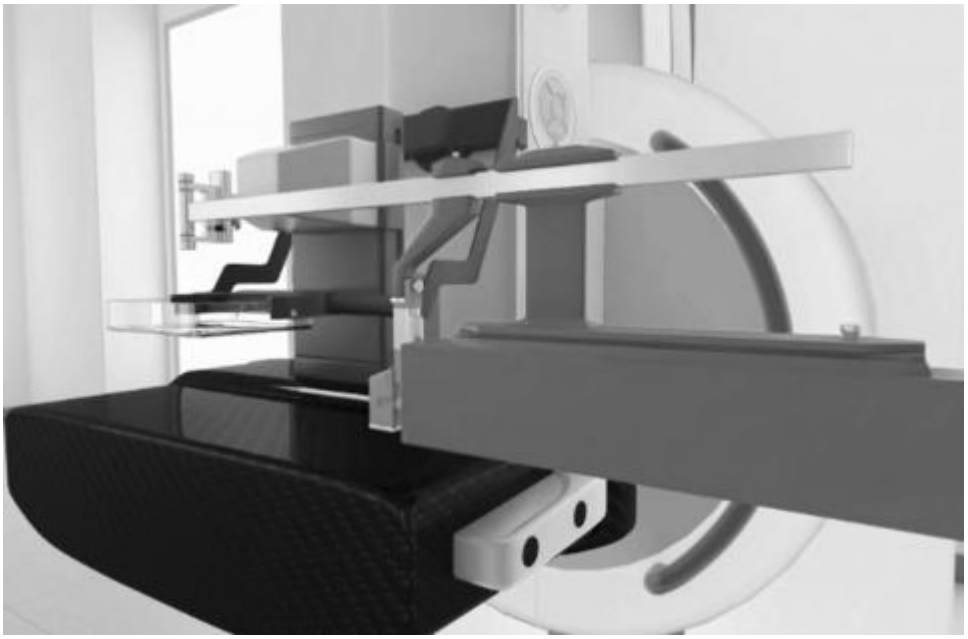

Figure 6: Lateral arm attachment to Siemens upright biopsy device, which allows more positioning options/biopsy approaches to the user (Image courtesy of Siemens).

Utilization of the lateral arm has a high success rate for thinly compressed breasts and for lesions located near the chest wall [28]. However, when the upright approach is used for biopsy, the chance of a vasovagal reaction

Figure 7: The patient sits upright in biopsy chair for the biopsy procedure with the upright system, which can increase the chance of a vasovagal reaction.

increases because the patient can see the process (biopsy equipment and needle) [29]. Turning the

patient's head away from the affected side and equipment will help minimize a vasovagal reaction. A 2011 study reported by Jung et al. showed how anxiety levels and vasovagal reactions were minimized when lateral decubitus positioning was used during stereotactic procedures [30]. Varying the position allows the procedure to be performed with the closest skin to lesion distance, minimizing the path of the biopsy needle in the breast. However, there is a disadvantage when positioning an inferior central lesion for biopsy with the upright unit. In this instance, the best approach is determined, whether the patient be in the lateral/medial position or medial/lateral position and the needle placement is inferior or superior. It is also feasible to perform all biopsies in the lateral or medial approach with the utilization of the lateral arm; however, most patients are most comfortable in the upright position. Once initial positioning is performed, lesion location and repeat investigation of dimensions and lesion distance from skin should be re-assessed to make certain that the position and location of the lesion is still obtainable. Ultimately, a combination of patient comfort and lesion accessibility will dictate the most optimal approach.

DEDICATED PRONE BIOPSY UNIT AND PROCEDURE

The prone stereotactic biopsy table is a stand-alone dedicated unit.

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Figure 8: Dedicated stereotactic prone biopsy table (manufactured by Hologic, Inc.)

This system is designed for stereotactic needle localization and biopsy of nonpalpable mammographically suspicious lesions. The patient is positioned prone on the table with the breast of interest suspended through the table opening allowing for imaging and access to the breast for the biopsy procedure. It is equipped with a digital x-ray unit, breast support and image receptor, compression plate/biopsy access and biopsy stage on a horizontal c-arm which is mounted underneath the patient positioning table. This c-arm can rotate over 180 degrees. The design of the Hologic stereotactic table is such that the opening for the breast is centrally located, allowing the patient's head to be positioned at either end of the table. This is an important feature to consider, as it allows access to all quadrants of the breast. Patient placement on the table along with the c-arm's ability to rotate over 180 degrees allows for 360-degree access to the breast. The table opening is generous (approximately 25 cm circumference) which allows room for both the ipsilateral arm and breast to simultaneously be placed through for localization and biopsy of very posterior lesions. The table height is controlled by a hydraulic lift which gives the physician and ancillary staff the ability to remain seated and work underneath the table for breast positioning, lesion localization, and the biopsy procedure.

Figure 9: The table height can be adjusted, which gives the physician and ancillary staff the ability to remain seated and work underneath the table for all aspects of the procedure.

Such a dedicated biopsy systems can be more costly than the upright add-on units, but there are many advantages. Having a dedicated stereotactic prone table does not interfere with patient scheduling of screening and diagnostic mammography room examinations. Same day stereotactic biopsy procedures can be performed for patients who attend facilities that provide same day results and workups of new findings, thus eliminating the need for multiple appointments and hastens the time to diagnosis. Vasovagal reaction is drastically reduced, if not eliminated completely, with the prone stereotactic approach [31] . The biopsy procedure is out of view of the patient, especially when the patient is positioned facing away from the work area. Motion is greatly minimized as patients are less likely to move during the procedure once the patient and the positioning technologist have addressed comfort issues. Posterior lesions, that one would anticipate being challenging, can be easy to access with the help of gravity, as the patient is in the prone position.

There are also disadvantages to prone stereotactic breast biopsy; the biopsy equipment is expensive, as mentioned previously. Additionally, there are several scenarios that contraindicate a patient from undergoing the procedure, including the table weight limit of 300 pounds, and the prone position the patient is required to be in for the procedure.

THE PROCEDURE

The stereotactic biopsy procedure is performed in the same manner, whether utilizing an upright or prone biopsy system, aside from the inherent differences of the equipment. Medical facilities offering stereotactic core biopsy will need a biopsy protocol in place and should designate experienced trained staff to assist with the procedure. Staffing is very important; a small proficient team of technologists (and nurses) will convey competence to the stressed and nervous patient. The technologist staff should be experienced in breast imaging with the knowledge of how lesions move in the breast. This allows the technologists the ability to problem solve. Excellent patient care skills are also a benefit.

After diagnostic imaging and biopsy is recommended, all options should be discussed with the patient (core biopsy verses open surgical biopsy). Once the patient agrees to the stereotactic core biopsy procedure, a detailed conversation with the patient explaining what will happen during the procedure, potential risks of the procedure (such as bleeding and pain) and when results will be available is

important. As mentioned previously, a procedural consent form should be signed by the patient before the core biopsy procedure and filed in the patient's chart. The biopsy requisition should be completed. Also, all applicable mammographic views of the lesion to be biopsied should be printed for the stereotactic technologist (if this is the facility's standard of care). Once the patient is in the room and the closest distance from the skin to the lesion is determined for patient positioning, a detailed explanation of the biopsy procedure should be conducted by the technologist. This is crucial, as the cooperation of the patient is ultimately the key to a successful, quick biopsy. After this discussion, positioning the patient will begin. Whether the patient is in the upright, decubitus, or prone position, the most important aspect of positioning preparation is getting the patient as comfortable as possible under the circumstances. This will help to avoid or eliminate the possibility of patient movement due to discomfort. A well-versed technologist will have tips and tricks for this, utilizing angle sponges, pillows, and blankets placed in strategic spots, such as pressure points, to provide neck support and or leg support [28]. Once the patient is tolerably comfortable, a scout image of the lesion is obtained with the fenestrated compression device.

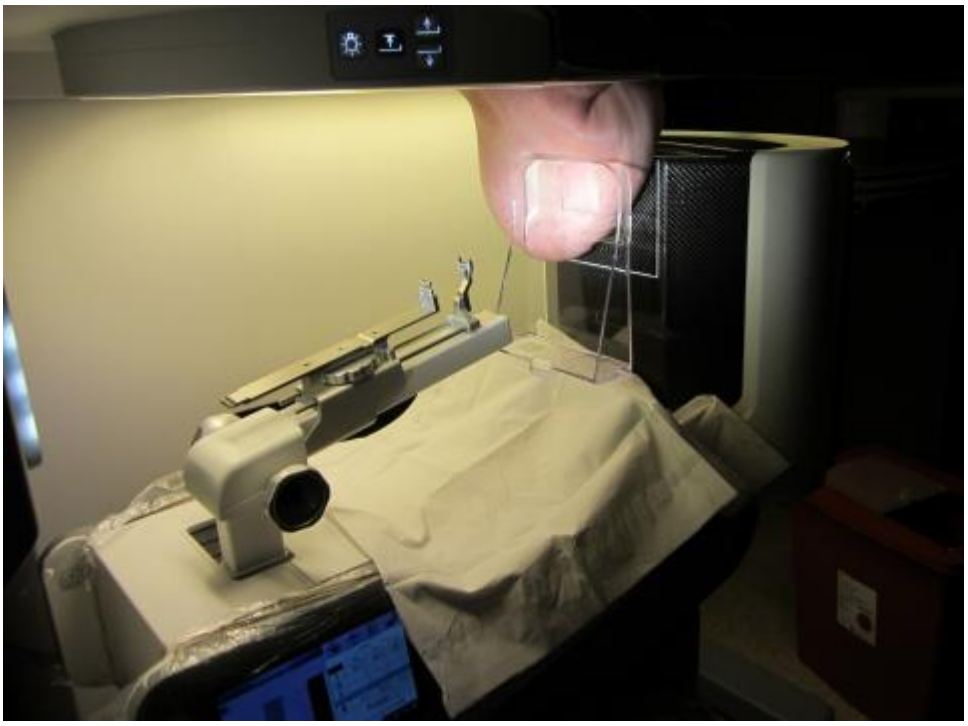


Figure 10: Patient is positioned and in compression using the fenestrated compression device.

Some of the newer stereotactic add-on upright devices have automatic features. For example, if the lesion is in the center of the scout image, the stereo pair images can be taken with a simple button selection and without the technologist moving from the exposure control area. The lesion is targeted, and coordinates are transferred for biopsy needle placement. The breast is prepped for biopsy and cleaned with betadine. A local anesthetic is administered, followed by a skin nick, and the biopsy needle is then dialed into the pre-fire position. A pre-fire stereo pair of images are obtained to confirm accurate needle placement. If placement is correct, the needle is fired to the targeted position.
A post-fire stereo pair of images are obtained to confirm if the position of the fired needle is accurate and, if so, the biopsy procedure is then conducted. Most sites will have a protocol for sampling. For example, if a vacuum-assisted biopsy device is used, the protocol might state that specimens will be collected from the clock positions of 12, 2, 4, 6, 8, and 10, for a total of 6 specimens. After biopsy, a

post-biopsy stereo pair of images are obtained, and a specimen radiograph of the core sample is obtained (if applicable). Once evidence of an accurate biopsy has been established, the tissue marker will be placed at the biopsy site and post-tissue marker stereo images will be obtained to ensure accurate placement. If the stereotactic core biopsy is considered successful and complete, the patient is then released from compression, and wound pressure is held along the biopsy path until hemostasis is achieved (approximately 5 minutes). Post-biopsy mammographic views are obtained for biopsy documentation and clip placement in relationship to the nipple.

TOMOSYNTHESIS GUIDED BIOPSY PROCEDURE

With the increasing use of Digital Breast Tomosynthesis (DBT) in breast imaging practices, a growing number of lesions are being identified by DBT only. DBT guided biopsy, both upright and prone, have become proven methods for accurate tissue sampling of these DBT-only lesions [19-22]. The DBT-guided procedure is very similar to a stereotactic biopsy. The approach is planned as would be done traditionally, based on the location of the lesion. The procedure that follows is based on performing a DBT guided biopsy utilizing the prone table

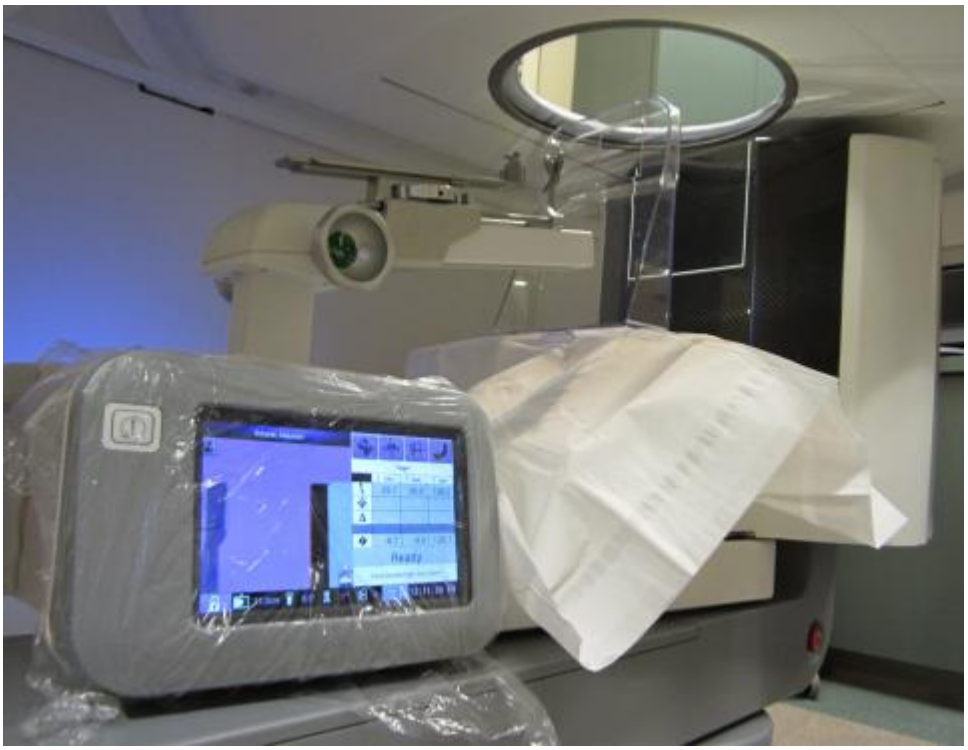
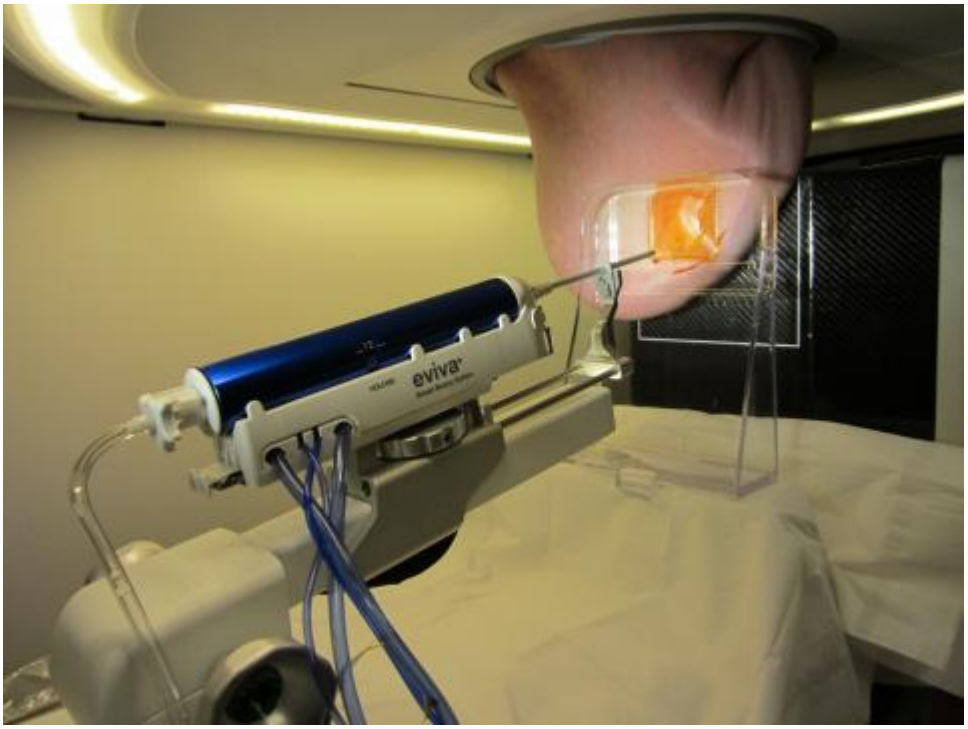


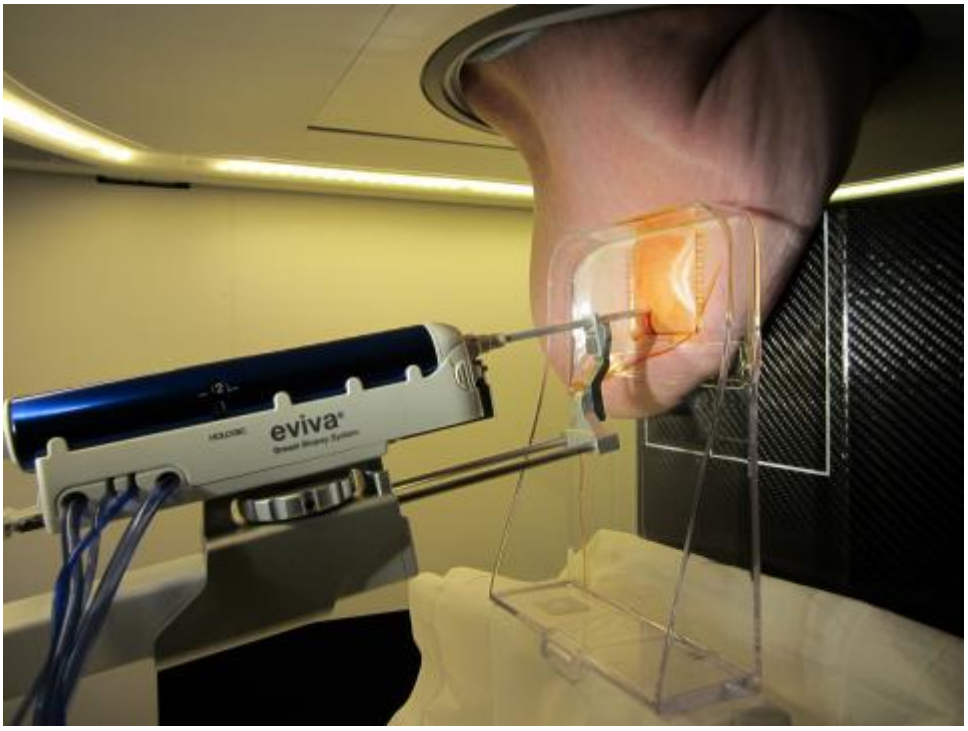
Figure 11: Prone table set up with screen to target the lesion and guide the biopsy procedure.

, however DBT guided biopsy with an upright system is also an available option.

After positioning the patient on the prone table, a tomosynthesis scout image is acquired. On the screen, the technologist can scroll through the images to identify the appropriate tomosynthesis slice of the lesion to be biopsied. Once this is done, X, Y and Z coordinates automatically appear, creating the target, and allowing the procedure to progress. In a situation with multiple lesions, you can repeat this process for multiple targets (up to 12) using the Multi-pass button. Once the biopsy needle is in place, the tomosynthesis pre-fire image is acquired. It is important for the technologist to scroll through the slices to verify that the needle is placed accurately, targeting the lesion of interest. Sampling of the lesion then occurs as is done traditionally



12a.



12b.

Figure 12a and 12b: Sampling of a lesion on the prone stereotactic biopsy table.

, as well as for the clip placement, and specimen imaging (if applicable). A post-fire tomosynthesis image is then obtained; again, the user can scroll through the projection images to identify the lesion and ensure accurate sampling.

It has been observed that the DBT guided biopsy procedure takes less time when compared with traditional stereotactic guided biopsy. A main contributing factor to the decreased procedure time is that fewer exposures are needed to complete the procedure. Several studies have reported decreased procedure times to perform DBT-guided biopsy compared with stereotactic biopsy [19-22].

POST-STEREOTACTIC BIOPSY CARE

Post-procedure care is the same, whether the procedure is performed with stereotactic guidance or

tomosynthesis guidance. The patient's wound is dressed in a pressure bandage and ice is applied. Detailed post-biopsy instructions are reviewed with the patient before she leaves the center. The patient is instructed to the leave the pressure wrap and dressing on for several hours, to take Tylenol for pain, to avoid aspirin and strenuous activity for 24 to 48 hours, and to observe the area for infection. The technologist will also provide instruction on what to do in case of an emergency. Bruising and hematoma can occur, in which case warm compresses are recommended to improve blood flow and healing. Also, at our facility, the patient is given the doctor's cell phone number in case of an emergency.

COMPLICATIONS OF STEREOTACTIC AND TOMOSYNTHESIS GUIDED CORE BIOPSY

Bleeding and hematoma formation are the most common complications from stereotactic core biopsy. Infection can occur, though it is uncommon. Somerville and colleagues evaluated anticoagulation and bleeding risks after core needle biopsy and reported that it is safe to perform needle core biopsy on patients taking anticoagulant therapy [32]. The group compared a control group of women not on anticoagulation therapy to a group of receiving anticoagulant therapy. The group receiving anticoagulation therapy was found to experience more bruising (34%) than the control group (26.5%), but experienced similar hematoma formation rates (6% versus 4.2%, respectively). Additionally, if an upright system is utilized for the procedure, additional challenges exist. As mentioned previously, there is increased risk of the patient experiencing a vasovagal reaction. Use of an upright system can lead to operational challenges, as it requires use of a mammography unit, thus reducing availability of the unit for screening or diagnostic imaging.

CORE BIOPSY PATHOLOGY RESULTS

Upon completion of a breast core biopsy, pathology results are typically provided within 24 to 48 hours after the biopsy procedure at our facility, but this timeframe depends on the breast imaging facility, pathology laboratory and whether the biopsy occurred on a Friday or around a holiday. Core pathology results are reviewed for concordance to imaging by the radiologist and then conveyed over the phone to the patient by the radiologist who performed the biopsy procedure. A letter by postal mail is also sent to the patient and her referring physician per MQSA requirement. If the biopsy results reveal a malignancy, the attending radiologist will also call the patient's referring physician.

Open surgical excision is recommended when core biopsy reveals a malignancy. Surgical consultation can also be recommended when core biopsy results are atypical, though this has been controversial (this will be discussed this later). Atypical results may include atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), radial scar, lobular carcinoma in situ (LCIS) and papillary neoplasm. When results are discordant with imaging (for example, expected to be malignant and return as benign) a repeat biopsy can be recommended. The radiologist must review the pathology results in conjunction with imaging for concordance and make certain the procedure clip is in the correct area. If concordant benign results are achieved the patient will be asked to return for 6-month post-biopsy follow-up for lesion stability.

TRACKING CORE BIOPSY OUTCOMES- THE MEDICAL AUDIT

Tracking and monitoring outcomes, such as the core pathology outcome in relationship to imaging, is important for patient care and treatment, but is also required by law. A facility must have a system in place to track yearly positive mammographic findings and correlative pathology results. The system must include procedures to track the mammography examination, biopsy recommendation, pathology result, report to referring physician, and breast cancer diagnosis by a means other than mammography. The law does not mandate the way that a center tracks and monitors these outcomes, it just requires that these

elements are tracked. In the screening setting, it is recommended to separate DBT from DM to distinguish between the two modalities with respect to performance. If a facility does not perform DBT-guided intervention and refers tomosynthesis-only findings for biopsy to another accredited facility, it should have access to correlative pathology results from the procedure facility. The site is also required to appoint an “audit interpreting physician” to review the outcomes. The procedures to track outcomes must be readily available for explanation during a medical audit inspection.

A quality control program should be maintained for stereotactic-guided and tomosynthesis-guided biopsy. As mentioned previously, imaging pathologic correlation should be performed. Per the ACR guidelines, records should be maintained for the facility, practice and individual physicians including total number of procedures, total number of cancers found, total number of benign lesions, and total number of stereotactic biopsies needing repeat biopsy, categorized by reason and type of biopsy. Reasons for repeat biopsy including insufficient sample, discordance, and high-risk pathology.

Malignancies are important to track, but it is also very important to track atypical core biopsy diagnoses. Underestimation can often occur with these lesions; many published studies have shown that an atypical core biopsy is often upgraded to carcinoma at open surgical biopsy. Such studies, in addition to evaluating the rate of underestimation, or upgrade, have also evaluated factors that can contribute to the underestimation, such as needle gauge. Liberman et al. reported that 11 of 21 cases initially diagnosed as ADH after stereotactic needle core biopsy were carcinoma at open surgical biopsy (8 ductal carcinoma in situ and 3 invasive ductal carcinoma) [33]. This early study was important as it demonstrated the need for accurate diagnosis and follow-up recommendations regarding stereotactic core biopsy technique. In 1997, Jackman et al. reported on the comparison of 14-gauge (g) vacuum assisted biopsy and 14-g automated large core biopsy with subsequent open surgical biopsy [34]. Fourteen-gauge vacuum assisted biopsy was found to be 2.7 times more reliable in obtaining an accurate diagnosis than the 14-g automated core biopsy. The greatest improvement was demonstrated when 10 or more specimens per lesion were retrieved. Destounis and colleagues reported very little difference between 9-g and 12-g vacuum assisted needle core biopsies when looking specifically at underestimation rates in comparison to open surgical outcomes [35]. The authors reported an 8.24% underestimation for 9-g and 8% for 12-g, demonstrating the improvements made in reducing underestimation rates when incorporating a vacuum assisted device for biopsy. Studies have shown that there is consensus that vacuum assisted breast biopsy devices yield larger specimens with lower underestimation rates in comparison to automated large core biopsy [36]. These findings have contributed to the advances in the technology, and thus the way stereotactic guided biopsy is performed today. Ultimately underestimation will still occur, whether due to sampling error or disease etiology, and because of this open surgical biopsy often is the recommendation for atypical lesions. It is important to note that the recommendation for open surgical biopsy after a diagnosis of ALH, LCIS, or papillary needle core biopsy is controversial. While studies have demonstrated that underestimation does often occur with these lesions, many believe that follow-up is the appropriate management. Several research studies have been published to aide in decision making when these scenarios arise with patients. As recently as 2013, Atkins et al. described that with careful radiologic-pathologic correlation, when concordance is determined, women with a diagnosis of ALH or LCIS diagnosed at core biopsy can be safely observed [37]. An observation published in 2011 by Destounis et al. reported that 33% of diagnosed LCIS cases at core biopsy revealed cancer at open surgical biopsy, leading the authors to recommend open surgical biopsy for all women diagnosed with LCIS at needle core biopsy [38]. A review of 368 papillary lesions published in 2012 found a 20%

underestimation rate for those that preceded to open surgical biopsy, with a 6% underestimation rate for carcinoma [39]. The authors demonstrated that the underestimation rate was highest for atypical papillary lesions found at needle core biopsy and that benign papillary lesions had the highest accuracy rate. The study authors recommend open surgical excision of atypical papillary lesions found at needle core biopsy and close imaging surveillance for needle core biopsy diagnosed benign papillary lesions. As with many other topics in breast imaging, the rate of underestimation of atypical breast lesions is controversial, and the radiologist needs to take all factors into account; radiologic pathologic correlation on a per case basis need be performed, and in addition stay mindful of the literature published to ultimately make a decision that is best for the patient.

With the increased use of digital breast tomosynthesis, facilities have reported that there has been an increase in detection of architectural distortion (AD) [40]. Bahl et al. reported that radial scar was the most common benign pathologic finding associated with AD at both 2D mammography and DBT but was significantly more common at DBT [41]. Pujara et al. found that the positive predictive value (PPV) of AD on DBT was high (35%), warranting biopsy of these lesions [42].

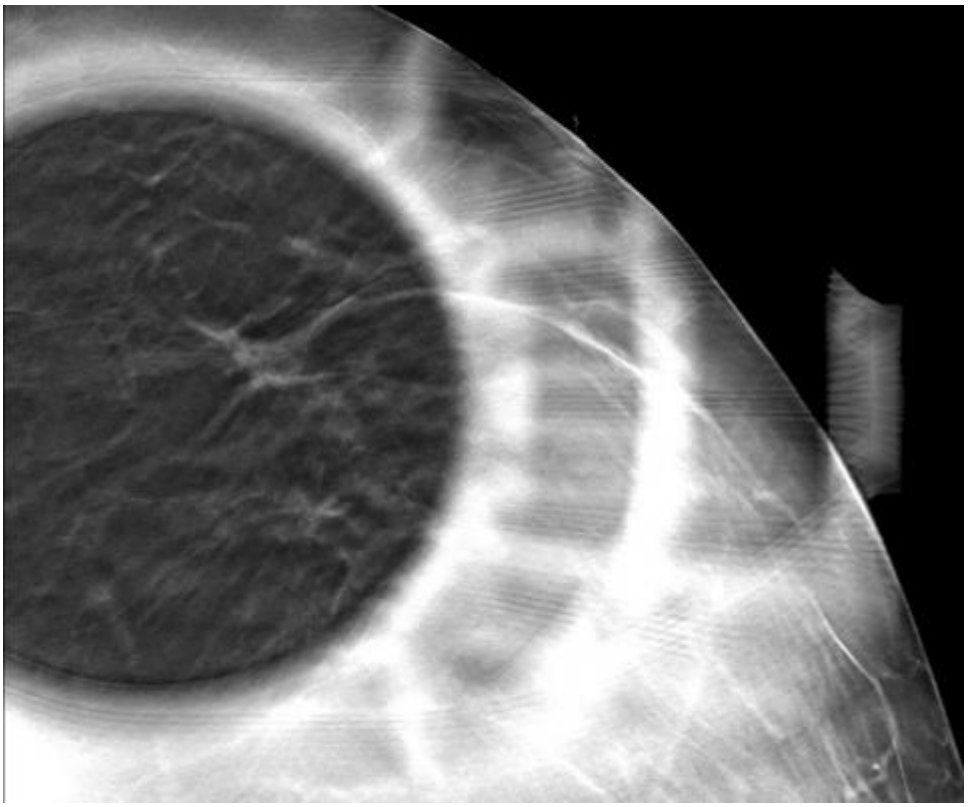


Figure 13a: Area of architectural distortion identified on tomosynthesis mammography after tomosynthesis guided biopsy on the prone stereotactic table.

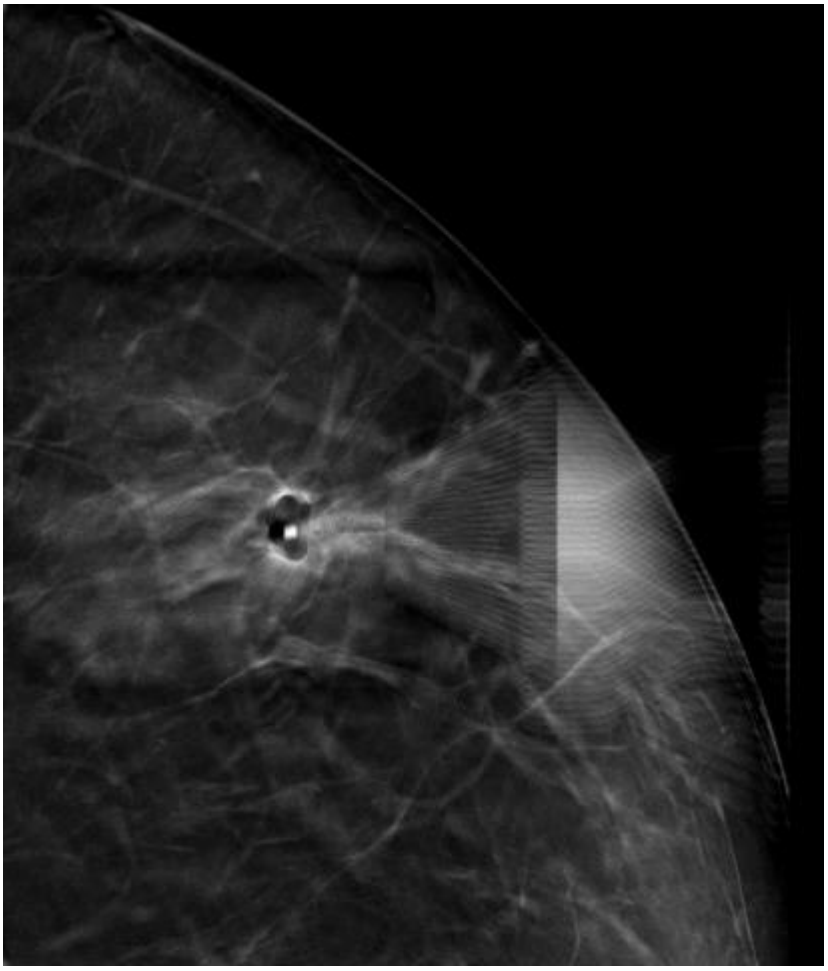


Figure 13b: Image of tissue marker placement, revealing malignant pathology.

Walcott-Sapp et al. [43] found that DBT-guided biopsy for AD detected malignancy in 19% of lesions. Of note, only 13% of DBT guided biopsied lesions were able to be seen on US, demonstrated the utility of DBT guided biopsy. While these studies demonstrate positive results, it has also been noted that there is an increased detection of noncancerous findings that present AD, specifically radial scars. The rate of radial scars identified in one review increased from 0.04% to .13% with DBT imaging, though the study did note that the rate of upgrade to malignancy was similar when comparing before and after DBT [44]. This is something that radiologists need to be aware of when utilizing DBT imaging.

CAVEATS OF STEREOTACTIC AND TOMOSYNTHESIS GUIDED CORE BIOPSY

Stereotactic core biopsy is an invaluable tool for breast imagers but is not without pitfalls. Stereotactic biopsy equipment is costly, whether the dedicated prone table or the upright biopsy attachment. There are positioning demands that are placed on the patient, and in some (although rare) cases, the patient will not be able to cooperate and continue with the procedure. There can be positioning challenges with a thinly compressed breast (under 3 cm); the breast may need to be boosted up with the use of a sling or tape in order to push the breast upwards towards the chest wall to increase thickness. Patients that have breast implants will require excellent positioning skills to eliminate the implant from the field of view/compression window in order to achieve adequate compression for lesion immobilization, as well as patient immobilization. Additionally, extreme lesion locations will require excellent positioning skills. These lesion locations include anterior, posterior, or superficial. Lesions located in these areas will often require additional review and repositioning to make the procedure successful. As mentioned previously, there are the procedural risks of pain and biopsy site bleeding and infection. Migration of the tissue marker can occur, if this is noticed, an additional tissue marker may need to be placed. When this occurs,

the patient's radiology report needs to clearly state which clip is within the region of interest. Pathologic underestimation due to small volume of tissue harvested or due to sampling errors can occur. For example, if the sample is unusually small or if sampling can no longer be performed due to the patient's inability to continue or excessive bleeding, then a surgical excision may be necessary.

With use of tomosynthesis guided biopsy, several situations may arise that allow for staff learning a specific tip or trick to assist others. For example, after targeting the lesion, and administering lidocaine, the field of view can become obscured, leading to biopsy staff questioning if the lesion of interest is still in view. It is important to trust your initial targeting, and do not attempt to re-target at this point. Additionally, when a scout image is obtained, and the area of interest is not seen in the biopsy window, but can be seen through the clear paddle, the depth can still be checked to determine if the approach chosen will be suitable, or if a different direction will be needed for accurate tissue sampling to occur.

CONCLUSION

The stereotactic core biopsy technology has become an integral part of breast imaging and diagnosis. Since its implementation, there have already been many progressions of the technology. As breast imaging technologies continue to change, the role of stereotactic guided biopsy will also change and adapt, as shown by the adaption to tomosynthesis biopsy. The tomosynthesis guided biopsy procedure is growing in use as more practices adopt tomosynthesis imaging in place of FFDM. The technique has been shown to be safe, effective and reliable for tissue sampling.

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