

Clinical Benefits of Tomosynthesis Guided Breast Biopsy

Lars Grimm, MD, MHS

Assistant Professor, Duke University Medical Center, Durham NC

Summary

This white paper will cover the benefits of tomosynthesis guided biopsy in comparison to traditional two-dimensional mammographic guided biopsies. Specifically, this paper will apply to the Hologic Affirm® Prone Biopsy System and the Affirm® Breast Biopsy Guidance System for the Selenia® Dimensions® and 3Dimensions™ mammography Systems. This paper covers the need for, and the benefits of, tomo-guided biopsy. Hologic offers multiple solutions, such as both upright and prone positioning, and vertical and lateral needle access to the breast. The primary benefits outlined in this white paper are listed in Table 1.

Clinical Benefits	
Capability to biopsy tomosynthesis only abnormalities	'Clear' paddle to better localize abnormalities outside of the biopsy window
Lateral needle approach for thin breasts	Improvement in image quality vs previous generation biopsy imaging systems
Dose reduction	Speed
Avoidance of blood vessels	Clip migration

Table 1. Primary benefits of a biopsy with the Affirm biopsy system with tomosynthesis guidance.

Capability to biopsy tomosynthesis only abnormalities

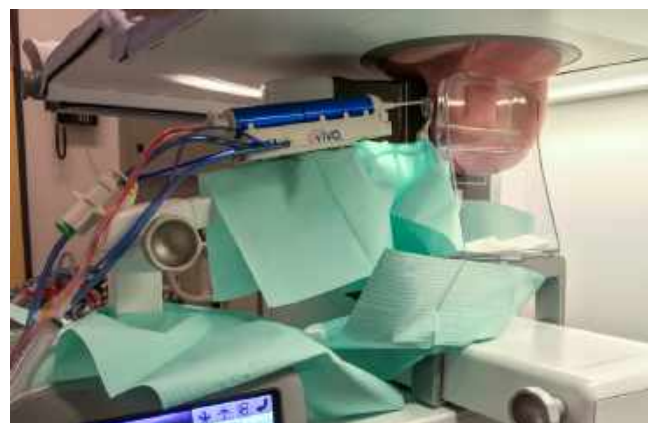
Compared to traditional 2D mammography screening, Hologic's digital breast tomosynthesis is associated with an increased cancer detection rate and a reduced recall rate^{1,2} While these excellent metrics are improving breast cancer screening overall and leading to rapid adoption nationwide, they create a dilemma as many of these additional cancers are only visible on tomosynthesis. This is particularly true for architectural distortion which is less likely to have an ultrasound correlate when seen only on tomosynthesis images³. Furthermore, approximately one third of architectural distortions will be tomosynthesis only³. Tomo guided biopsy is important because tomo detected cancers can be difficult to biopsy using ultrasound. Detecting an abnormality on

tomosynthesis without the ability to adequately sample it limits the value of tomosynthesis and so it is imperative that tomosynthesis only abnormalities can be biopsied.

Tomosynthesis guided biopsies are the only way to definitively sample lesions visible only on tomosynthesis. If tomosynthesis biopsy capabilities are not available, there are several less desirable options available. Patients can be referred to a site with tomosynthesis biopsy capabilities, which can result in delays in diagnosis or a loss in follow up. A tomosynthesis guided localization can be performed prior to surgical excision, but this increases healthcare costs and patient morbidity. If a site does not have tomo guided biopsy, they may lose the patient to another center that does. Finally, a biopsy can be attempted by relying on local 2D landmarks, but this approach may miss the abnormality in question, especially due to differences in the field of view and patient positioning between the diagnostic and biopsy images. An example of architectural distortion seen only on tomosynthesis is shown in Figure 1.

Lateral needle approach for thin breasts

Although not an intrinsic feature of tomosynthesis guided biopsies, both Affirm systems allow for a lateral needle approach. The standard needle approach, with the needle approaching perpendicular to the imaging plane, may not



Lateral needle approach. Image courtesy of Dr. Margot Henebiens, Spaarne Gasthuis Hoofddorp, Netherlands

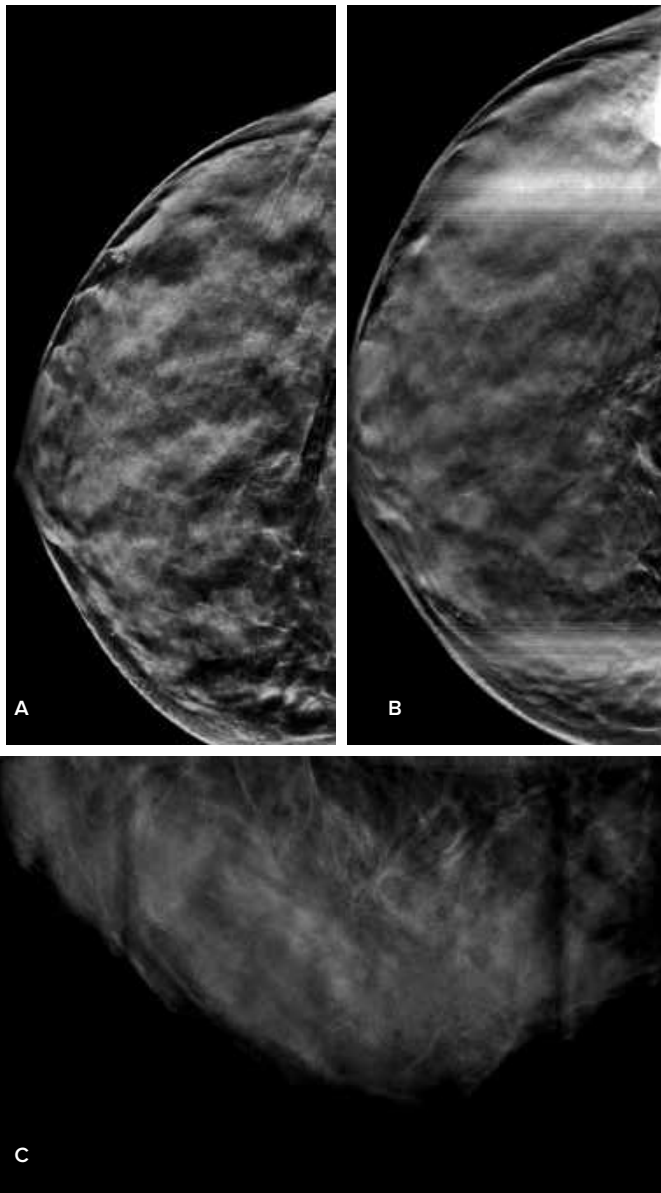


Figure 1. Architectural distortion not seen on the C-view image (A), well seen on the tomosynthesis slices (B), and seen even better with the added compression and smaller field of view during biopsy on the Affirm prone system. (C).

be possible for women with very thin breasts. If the breast thickness while in compression is less than the needle well length plus the dead space at the needle tip, then a standard needle approach is not possible. It is estimated that approximately 4% of the US patient population has compression <3.5 cm.* Traditionally, these women have been referred for surgical excision even if the risk of malignancy is very low. Using the lateral approach may save up to 4% of women the need for more invasive surgical excision. On the Affirm prone system, the biopsy approach can be easily switched from the standard to the

lateral needle approach with the touch of a button. There is no additional equipment that needs to be utilized for a lateral needle approach and the decision can be made after targeting. Figure 5 demonstrates images from a woman who was scheduled for surgical excision due to a breast that compresses to only 1.5 cm, but was able to be safely and successfully biopsied via a lateral needle approach.

The lateral needle approach is not limited to women with thin breasts and can be used in place of the standard needle approach in any case. One advantage of the lateral needle approach is that there is less risk of clip migration. With a standard needle approach, the deployed clip may migrate due to the ‘accordion’ effect as the breast is released from compression. With a lateral needle approach, the direction of compression is orthogonal to the needle pathway so there are no mechanical forces that may cause clip migration. Additionally, for abnormalities that are seen only in one view or seen best in one view, the shortest path may be orthogonal. For these cases, the lateral needle approach may be the safest option. The lateral approach is useful in (1) thin breasts, (2) reducing clip migration, and (3) keeping biopsy paths as short as possible. Of note, when using a lateral needle approach, it may be helpful to use a longer needle for the administration of local anesthetic as the operator must work behind the paddle and the breast is compressed in the plane of approach. A spinal needle works very well for this task. Care should be taken when orienting the directional vacuum sampling so as not to vacuum the subcutaneous tissues or skin. Of note, there is a built in 5 mm safety margin to the paddle and detector side to help prevent this from occurring

Dose reduction

Radiation dose reduction is a very important topic and a major focus of outreach from the American College of Radiology via the Image Wisely campaign^{4,5}. Radiation doses in breast imaging overall are extremely low and are federally regulated via the Mammography Quality and Standards Act (MQSA). Mammograms during screening are required to have a radiation dose of less than 3 mGy per view, which is an equivalent radiation exposure to spending a few weeks on vacation in Denver. The total radiation dose for a typical 2D stereotactic breast biopsy is 10-15 mGy, which is still very low and the risks of radiation are far outweighed by the benefits of cancer detection. Nevertheless, the adoption

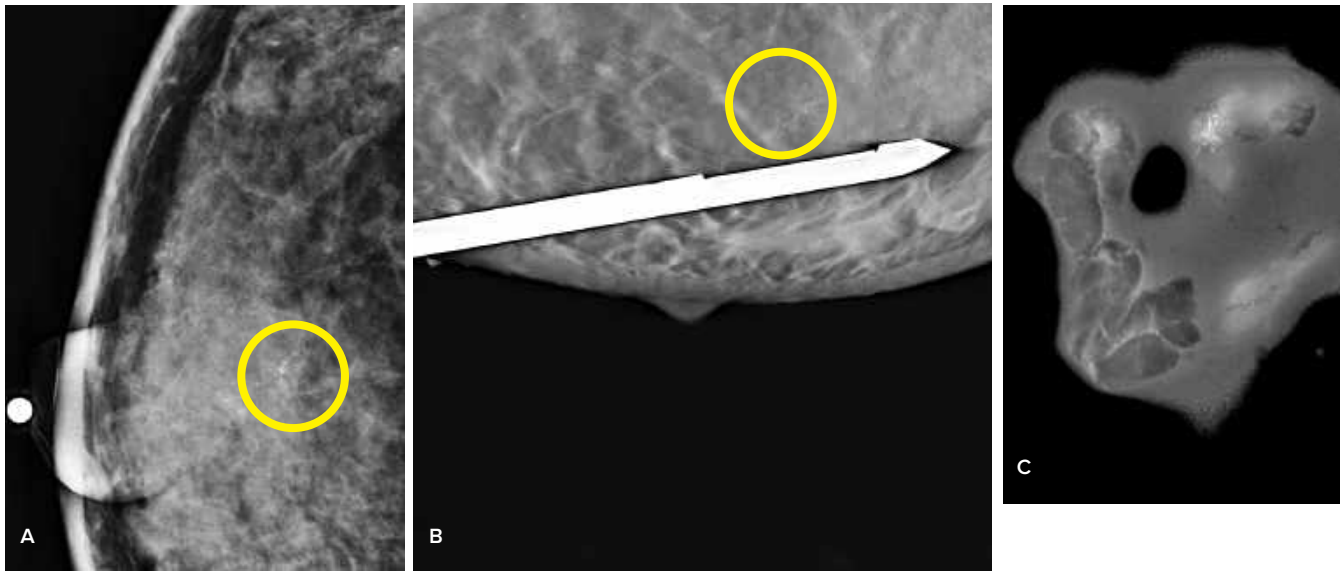


Figure 2. A woman with a group of amorphous calcifications (circle) in the subareolar breast was ineligible for a standard approach biopsy as her breast compressed to 1.6 cm (A). Using a lateral biopsy approach the needle can be seen correctly positioned adjacent to the calcifications (circled, B). The specimen radiograph confirmed accurate sampling of the calcifications which represented atypical ductal hyperplasia (C).

Dose comparison for different procedure types			
	2D Biopsy Procedure (mGy)	3D™ Biopsy Procedure (mGy)	Full 3D™ Biopsy Procedure (mGy)
Scout	1.6	1.8	1.8
Targeting	3.2	—	—
Pre-fire*	3.2	3.2	1.8
Post-fire*	3.2	3.2	1.8
Post-procedure	3.2	1.8	1.8
TOTAL	14.4	10	7.2
% Reduction (compared to 2D)	—	31%	50%

Table 2. Radiation dose (mGy) for 2D, hybrid, and tomosynthesis only guided stereotactic biopsies. Radiation dose estimates are based on a 4.2 cm, 50% fatty 50% glandular tissue, assuming 1.6 mGy per 2D image and 1.8 mGy per tomosynthesis image set.

*Many providers may choose to perform either pre-fire or post-fire images, but not both, thus reducing the radiation dose further.

of a tomosynthesis guided biopsy approach can notably reduce the procedure dose.

Assuming the biopsy of a woman with a typical 4.2 cm breast that is 50% fatty and 50% fibroglandular tissue, the typical dose from a 2D image is 1.6 mGy or 3.2 mGy for a stereo pair, while the typical dose of a

tomosynthesis image is 1.8 mGy. This results in a dose reduction of 1.4 mGy every time a 2D stereotactic pair is replaced by a tomosynthesis acquisition. Furthermore, since targeting can be done on the initial scout images for tomosynthesis, the 2D targeting sequences can be removed saving an additional 3.2 mGy. The total dose reduction will depend on the practice of the performing radiologist and the need for pre-fire plus post-fire images, both 2D stereo pairs or tomosynthesis sweeps, but dose reduction can be up to 50%. The total dose of different imaging strategies is shown in Table 2.

Avoidance of blood vessels

Bleeding is the most common complication following a breast biopsy, but the overall incidence of a post-biopsy hematoma is estimated to be less than 1%.^{6,7} However, for patients on anticoagulation therapy the incidence of bruising and hematoma is increased.^{8,9} It is therefore good practice to reduce the risk of bleeding as much as possible and this can be achieved by avoiding larger blood vessels during biopsy planning. On traditional 2D images, some blood vessels may be visible, but due to superimposition it is not possible to tell if the vessel is in front of or behind the biopsy target. With tomosynthesis, blood vessels are better visualized, and their exact location can be confidently identified.

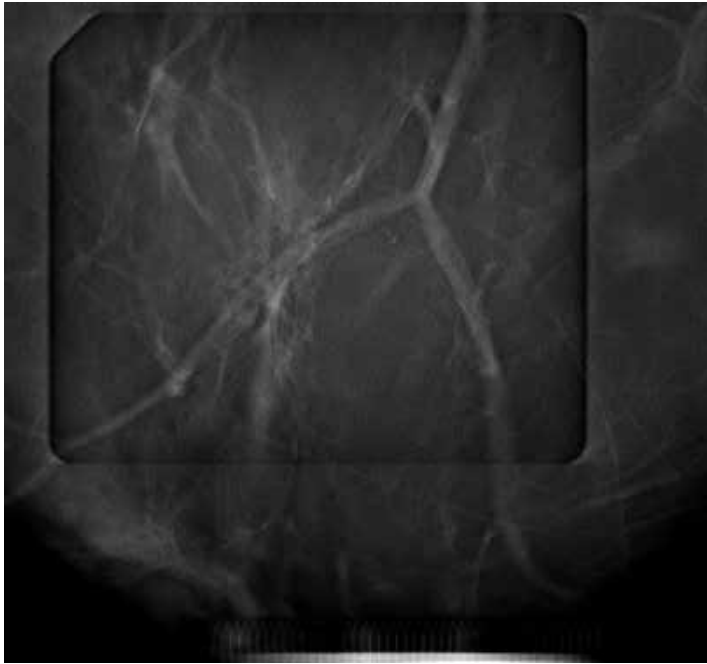


Figure 3. Tomosynthesis guided biopsy image demonstrating a blood vessel positioned directly over the architectural distortion biopsy target.

If a radiologist sees a blood vessel in the pathway of the biopsy needle during a tomosynthesis biopsy (Figure 2), there are several options available. Since most larger blood vessels are very superficially located, the technologist can reposition the patient by rolling the breast to remove the direct overlay of the blood vessel. Alternatively, the biopsy target can be adjusted in the X or Y direction so as to miss the blood vessel and samples can be obtained directionally to compensate. Finally, if the blood vessel is very closely apposed to the biopsy target site, then a different obliquity or angle of approach as well as switching to a lateral approach can be utilized to avoid the vessel¹⁰. By being able to more confidently identify and localize blood vessels, radiologists can take necessary steps to reduce bleeding complications.

‘Clear’ paddle to better localize abnormalities outside of the field of view

Some stereotactic biopsy models utilize a metal paddle, which limits visualization of the breast only to the biopsy window. By incorporating a ‘clear’ paddle, the Affirm® system increases the field of view beyond just the biopsy window for a total viewing area of 14.3 x 11.7 cm. During targeting, if the lesion is not within the biopsy window it may

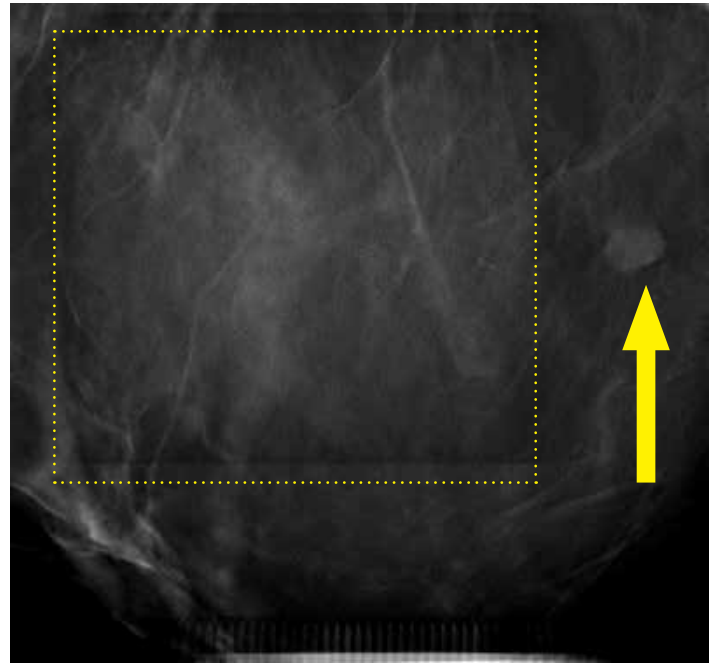


Figure 4. Stereotactic biopsy image demonstrating a mass positioned inferiorly to the biopsy window (yellow rectangle), but still visible because of the clear paddle.

be identified nearby and thus the technologists can easily adjust the patient’s position accordingly (Figure 3). This can help to shorten the procedure time, which decreased from 15 minutes with 2D to 4 minutes with tomosynthesis according to one study¹¹. Furthermore, by increasing the field of view additional regional landmarks are visible, which can increase the radiologist’s confidence that the correct target is being sampled.

Improvement in image quality

Although not unique to a tomosynthesis guided biopsy, the Affirm biopsy system offers excellent image quality. The detector technology on the biopsy system is the same as the diagnostic mammography unit. One of the major problems with older stereotactic biopsy units is that subtle abnormalities, especially calcifications and architectural distortion, could be identified on diagnostic mammograms but could not be convincingly identified during the procedure. This forced the radiologist to either make an educated best estimate of the biopsy target or cancel the biopsy and proceed with a localization for surgical excision. This is no longer a problem with the new detector technology in the Affirm biopsy system and if the lesion can be seen on the diagnostic mammography it should be able to be identified using the same

technology on the biopsy system. Figure 1 demonstrates an example of a case in which the architectural distortion is better visualized on the biopsy images than on even the diagnostic images, in part due to the better compression and smaller field of view.

System Development History

Total procedure length is an important consideration for patients and tomosynthesis guided biopsies have been shown to be significantly faster than traditional 2D biopsies¹¹. Compared to older 2D biopsy models which required a technologist to make manual adjustments between each stereo pair image acquisition, the Affirm system requires pressing only a single button for image acquisition in either 2D or tomosynthesis modes. As a result, images can be acquired faster with an approximately 5 second duration for a tomosynthesis sweep. Additionally, since targeting for a tomosynthesis guided biopsy can be performed on the scout image, the stereo pair targeting step can be skipped. These steps allow for a shorter total procedure time to improve patient comfort and increase patient throughput.

Clip migration

Migration of clips after deployment can be a major problem for a stereotactic breast biopsy as it can impair the ability to subsequently localize the abnormality for surgical excision¹². By utilizing a tomosynthesis guided biopsy, the radiologist can be confident that the clip was appropriately deployed at the desired location. The targeting images can be compared side by side with the post-procedure images. The slice number with the biopsy marking clip should correlate with the slice number used for targeting, and if so, then the radiologist can feel confident that the clip was deployed in the correct location.

Conclusion

A tomosynthesis guided biopsy system offers many advantages over a traditional 2D stereotactic biopsy system. Most importantly, tomosynthesis only abnormalities can be successfully biopsied via a percutaneous approach and thus the improved cancer detection rate from screening with tomosynthesis can be fully utilized. Additional benefits are aimed at improving the experience for both patients and radiologists.

References

*Hologic analysis of 3,218 patient mammograms, CC and MLO views. Data on file.”

1. Friedewald SM, Rafferty EA, Rose SL, Durand MA, Plecha DM, Greenberg JS, et al. Breast cancer screening using tomosynthesis in combination with digital mammography. *JAMA*. 2014;311(24):2499-507.
2. McCarthy AM, Kontos D, Synnestvedt M, Tan KS, Heitjan DF, Schnall M, et al. Screening outcomes following implementation of digital breast tomosynthesis in a general-population screening program. *J Natl Cancer Inst*. 2014;106(11).
3. Alshafeiy TI, Nguyen JV, Rochman CM, Nicholson BT, Patrie JT, Harvey JA. Outcome of Architectural Distortion Detected Only at Breast Tomosynthesis versus 2D Mammography. *Radiology*. 2018;171159.
4. Brink JA, Amis ES, Jr. Image Wisely: a campaign to increase awareness about adult radiation protection. *Radiology*. 2010;257(3):601-2.
5. Piscatelli N, Hyman N, Osler T. Localizing colorectal cancer by colonoscopy. *Arch Surg*. 2005;140(10):932-5.
6. Parker SH, Burbank F, Jackman RJ, Aucreman CJ, Cardenosa G, Cink TM, et al. Percutaneous large-core breast biopsy: a multi-institutional study. *Radiology*. 1994;193(2):359-64.
7. Mahoney MC, Ingram AD. Breast emergencies: types, imaging features, and management. *AJR Am J Roentgenol*. 2014;202(4):W390-9.
8. Somerville P, Seifert PJ, Destounis SV, Murphy PF, Young W. Anticoagulation and bleeding risk after core needle biopsy. *AJR Am J Roentgenol*. 2008;191(4):1194-7.
9. Chetlen AL, Kasales C, Mack J, Schetter S, Zhu J. Hematoma formation during breast core needle biopsy in women taking antithrombotic therapy. *AJR Am J Roentgenol*. 2013;201(1):215-22.
10. Mesurolle B, Brun F, El Khoury M, Petrou A, Bagard C, Monghal C, et al. Identification and Avoidance of Vessels During Imaging Guided Biopsies: An Additional Role of Breast Tomosynthesis. *Can Assoc Radiol J*. 2017;68(4):468-70.
11. Schradling S, Distelmaier M, Dirrichs T, Detering S, Brolund L, Strobel K, et al. Digital breast tomosynthesis-guided vacuum-assisted breast biopsy: initial experiences and comparison with prone stereotactic vacuum-assisted biopsy. *Radiology*. 2015;274(3):654-62.
12. Kass R, Kumar G, Klimberg VS, Kass L, Henry-Tillman R, Johnson A, et al. Clip migration in stereotactic biopsy. *Am J Surg*. 2002;184(4):325-31.

United States

250 Campus Drive
Marlborough, MA 01752 USA
Tel: +1.508.263.2900
Sales: +1.781.999.7453
Fax: +1.781.280.0668
www.hologic.com

Views and opinions expressed herein by third parties are theirs alone and do not necessarily reflect those of Hologic.

WP-00129 Rev 002 (6/18) © 2018 Hologic, Inc. All rights reserved. Hologic, 3D, 3Dimensions, Affirm, Dimensions, Selenia and associated logos or trademarks are registered trademarks of Hologic, Inc. and/or subsidiaries in the United States and/or other countries. All other trademarks, registered trademarks, and product names are the property of their respective owners.