

Clinical Experience Implementing the Hologic Affirm® Prone Biopsy System

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Introduction

Advances in breast screening technology, most notably tomosynthesis, are enabling us to visualize subtle lesions, not previously seen on 2D images. However, the improvements in imaging quality and specificity provided by tomosynthesis pose challenges to our protocols for the management of lesions identified with the technology.

Our center performs approximately 50,000 3D™ Mammography exams annually and on a daily basis we find small spiculated masses and distortions, including invasive carcinoma, DCIS, and some high risk pathological entities. Until recently, traditional prone stereotactic biopsy systems could not perform 3D™ imaging. As a result, our previous prone biopsy system presented two significant challenges. First, it didn't support the ability to target subtle calcifications and low-contrast lesions, which could only be seen on 3D mammography images. In a small number of cases, we even had difficulty targeting lesions visible with 2D mammography. And, secondly, our stereotactic table didn't provide the ability to easily biopsy thin breasts.

In this paper I will discuss our center's experience with the Affirm® prone biopsy system, which allows us to use the same high-quality 3D™ imaging for the mammogram and the biopsy. Over the past two years, our center has performed more than 1,200 tomosynthesis-guided biopsies utilizing this system. We found that the improvements in image quality enabled us to reduce the number of images required, shorten procedure times, and improve our diagnostic confidence.

3D Imaging Streamlines Targeting

Breast tomosynthesis has demonstrated its ability to reduce false-positive screening recalls and increase cancer detection rates for both invasive and ductal carcinoma in situ (DCIS). Consequently, one of the most important benefits of the Affirm Prone system is the ability to accurately and confidently target lesions that are only seen on tomosynthesis slices, typically areas of architectural distortion, microcalcifications, and small masses.

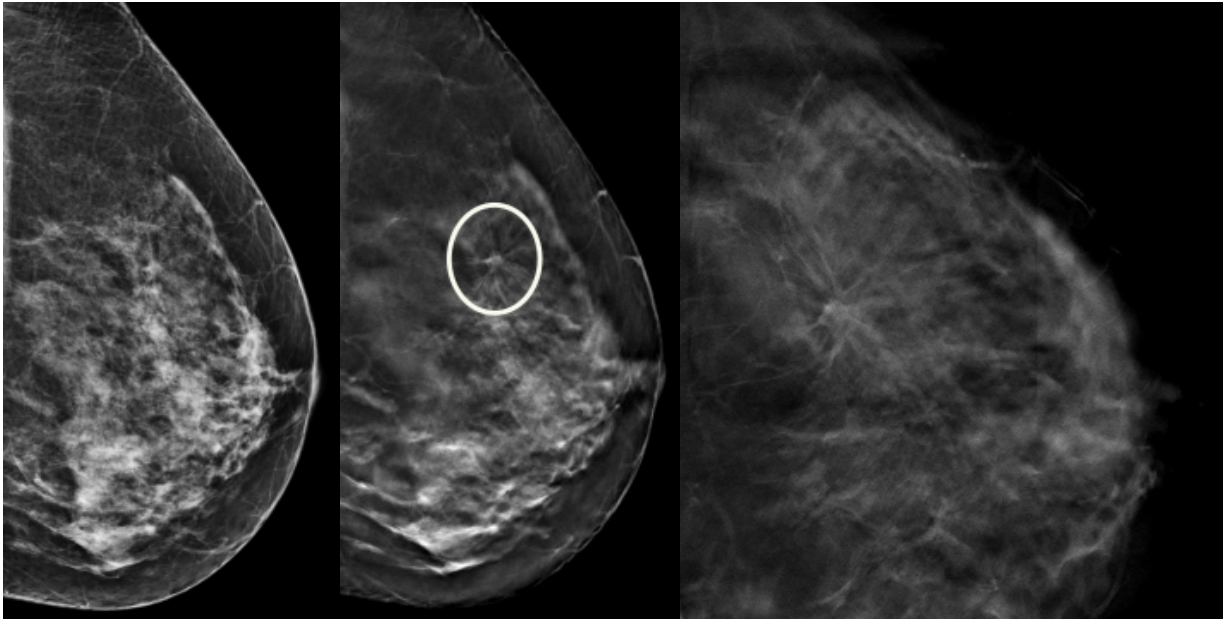
In our first year, we performed 502 biopsies with the Affirm Prone system. In the first 30 cases, we saw:

- 51% benign changes
- 53% high risk lesions
- 26% malignant lesions. Of these 42% were invasive carcinoma, 50% DCIS and 8% DCIS plus invasive carcinoma

When we look at the 3D™ images, we can see high-contrast and low-contrast lesions and the percent of malignancy, as well as high-risk and benign changes. Previously, when lesions visible on the 3D images were not easily visible or easily biopsied using our previous stereotactic system, we would employ an ultrasound-guided biopsy approach. However, in some cases, lesions clearly visible on the tomosynthesis slices were not visible even on ultrasound; and, we would need to send patients for more invasive open surgical biopsies.

Selenium Detector Offers Wider Field of View

The Affirm Prone system incorporates the same selenium detector technology as the Hologic Selenia® Dimensions® and 3Dimensions™ systems. The detector's larger field of view, 14.3 cm x 11.7 cm, is more than 6.5 times larger than



2D Mammography

3D Mammography™

Affirm Prone system 3D™ image

Image 1. Biopsy with the Affirm Prone system of a small spiculated mass only seen on 3D™ images

the 5 cm x 5 cm field of view available with the previous generation of prone biopsy systems. This typically enables us to see the entire breast in our scout view, not just the surface of the biopsy window.

Additionally, this system uses translucent paddles with a wider window, which broadens our view of the targeted tissue and increases the probability of detecting the lesion on the first scout. For most cases, we only need to take one or two scout images. In comparison, we regularly took three or four scout images, and as many as five or six with our previous stereotactic system.

The 3D™ biopsy procedure is also much faster. We scroll through the tomosynthesis slices and target the slice where we see lesion, transmit the coordinates, and place the needle. The target only needs to be seen on the scout image; we no longer have to worry about selecting the same calcification on a set of stereo pairs.

It is important to note that this system provides the option of performing both stereotactic 2D and tomo-guided biopsies, depending on the individual case. There are two ways to utilize the 3D™ biopsy system. One option is to localize the target on tomosynthesis, then obtain traditional

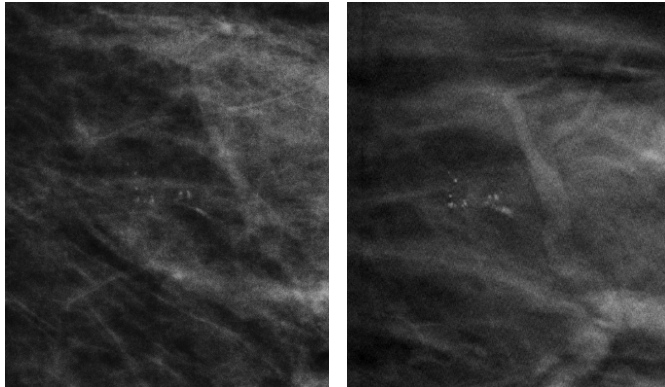
2D stereo pairs, pre-and post-fire. Alternatively, 3D™ biopsy images can be obtained at each step, depending on the finding and your level of comfort or preference. Whichever option you choose, the gantry automatically moves to the correct position, which reduces potential technical error and procedure time and improves overall workflow and productivity.

When we reach a lesion, we can do a pre-fire and post-fire, and after that the tomosynthesis post biopsy. We then compare that tomosynthesis slice in the scout with a slice from the tomosynthesis post biopsy, allowing us to see that the calcifications have been removed and are in the extracted tissue. Subsequently, we place the biopsy site marker and do a clip review to detect if the marker is on the same slice. We can detect any early migration of the clip.

Increased Confidence Improves the Management of Lesions

The improved imaging of this biopsy system is also changing how we manage the subtle lesions we see on 3D Mammography™ exams. With our older generations of prone biopsy systems, when we saw a very small group

of calcifications on the 3D™ mammogram, we would be concerned we would not see the same lesions during the biopsy. So, in some cases, such as BI-RADS-3, rather than biopsy the lesion, we would schedule a six-month follow-



2D Mammography

Affirm Prone 3D™

Image 2. Biopsy of a subtle group of microcalcifications seen on 2D mammography. Note the resolution of the 3D™ Affirm Prone image and the information on a blood vessel nearby in this case.

up. Now, with the new system we're more confident about performing the biopsy.

More Efficient Workflows

We have found that we have a higher probability of detecting a lesion on the first scout, which enables us to reduce the time of our procedures by as much as 40%. Today, our biopsy procedures on the Affirm Prone system average 18-21 minutes; prior to the addition of the 3D™ imaging, our biopsy procedures took between 30-35 minutes, because often times we needed to do more scouts to get the lesion in the window.

As a result of the shorter procedure time, we can biopsy multiple lesions in one breast in a single procedure. Previously, using our stereotactic system, we performed the biopsy in two or three procedures because the biopsy was too long for the patient to tolerate.

This workflow productivity gain makes for a more efficient use of assets, allowing us to increase the number of biopsies we are able to perform. For every two biopsies we were able to schedule on our previous stereotactic

table, we can now schedule 3-5 biopsies in the same amount of time.

We found the new system easily integrated into our workflow. Our center prefers the prone table because it provides flexibility in scheduling patients for biopsy without interrupting our mammography workflow, like our upright did.

360-degree Access Enables Biopsies of Thinly Compressed Breasts and Challenging Lesions

The unique structure of the C-arm has allowed us to biopsy women with very thin breasts, down to a thickness of 2.5 cm, and provides access to posterior lesions. The C-arm has an independently rotating biopsy arm that allows us to switch from a standard to lateral needle approach very quickly — it doesn't require additional attachments and we do not have to reposition the patient or acquire additional images. Additionally, when needed, we can work comfortably with the patient's arm positioned through the aperture and resting on the support to access some regions that were challenging on our old system. This makes the procedure much more comfortable for the patient.

| | | Affirm Prone (Tejerina Foundation) n=100 | Conventional PS (Schradig ¹) n=165 | % Difference |
|----------------|--------|--|--|--------------|
| Total Time | Mean | 21.32 ± 6.57 | 29.11 ± 0.1 | -27% |
| | Median | 20 (7-42) | 28 (12-65) | -29% |
| Targeting Time | Mean | 1.65 ± 2.11 | 15.0 ± 9.3 | -89% |
| | Median | 1 (1-14) | 12 (2-34) | -92% |
| Sampling Time | Mean | 4.61 ± 3.40 | 10.3 ± 4.5 | -55% |
| | Median | 4 (1-17) | 9 (5-31) | -56% |

Table 1. Time comparison of key procedure steps compared to previously published values. Mean values include +/- standard deviation. Median values have full range in parenthesis.

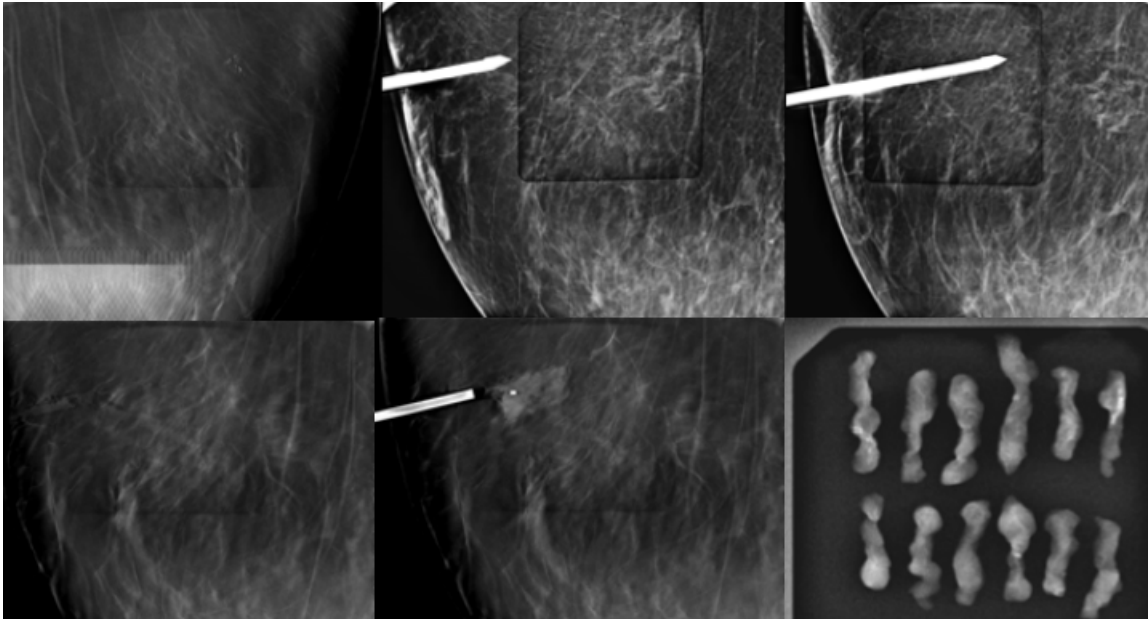


Image 3. Lateral needle access with the biopsy-arm in a thin breast biopsy

Conclusion

Because the advanced imaging available with 3D Mammography™ exams may visualize lesions not visible or easily biopsied with other imaging modalities, we feel it is critical to have a tomosynthesis-guided biopsy system for day-to-day diagnostic work. We find the Hologic Affirm Prone biopsy system facilitates complex biopsies, improves the efficiency of our workflows, and increases the diagnostic confidence of our physicians.

Alejandro Tejerina, MD is Director of Breast Imaging at the Breast Pathology Center of Madrid. The center is dedicated exclusively to women's breast health, offering diagnostic services, medical and surgical treatment, and follow-up services. The center's team of 11 radiologists and radiology technicians perform approximately 50,000 breast mammograms annually using the Hologic Selenia® Dimensions® 3D™ system. They perform approximately 600 biopsies a year.

References

1. Schrading S. et. Al. Digital breast tomosynthesis-guided vacuum-assisted breast biopsy: initial experiences and comparison with prone stereotactic vacuum-assisted biopsy. Radiology. 2015 Mar; 274(3):654-62.

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