

Update on Breast Interventional Procedures and Outcomes

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Imaging Guided Biopsy

Modality

- Stereo
 - Calcifications
 - US occult masses
- US
 - Masses
 - Calcifications with sono-correlate
- MRI
 - MR only lesions

Method of biopsy

- FNA
- Core biopsy
 - US
- Vacuum-assisted
 - Stereo and MRI

Image-guided procedures – what's new

- Pre-op localization
 - Tomosynthesis
 - Seed localization
- Lesion type
 - More Architectural Distortion (AD)
- Tomo-guided stereos
- Management
 - what requires surgical excision?

US guided Intervention

- Majority of suspicious mammographic findings are seen with US
 - Masses
 - Some AD, calcs
- Most common diagnostic needle biopsy procedures performed
- Requires good quality equipment and careful targeted scanning
- Advantages:
 - Patient comfort
 - Real-time visualization of needle
 - Accessibility to all parts of breast and axilla
 - Shorter procedure time
 - Fewer cores
 - Greater patient throughput
 - Lower cost

Pre-biopsy work-up – Lesion Selection

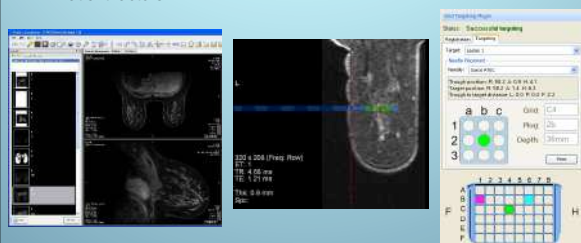
- Many lesions (most?) seen on tomosynthesis can be successfully identified with US
 - Localize area precisely with tomo
 - careful targeted scanning will identify most masses
 - use of BB technique may help establish correlation
- Some calcification lesions will also have an US correlate
 - permits easier, less invasive biopsy
- Many architectural distortions will represent malignancy
 - most will be identifiable by US
- Many RS/CSL have subtle sonographic findings:
 - Distortion or tissue
 - vague hypoechogenicity
 - associated small cysts

Lesion Selection

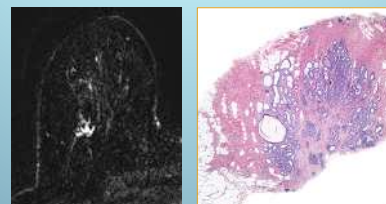
- US bx - Utilize biopsy markers and perform post US biopsy mammographic imaging necessary to confirm that marker correlates with original tomo finding

MR-guided Biopsy

- MRI-only lesions
- Second look mammo (DBT) and US should be performed first
- Higher costs
- Patient factors



- A recent study suggests that if no ultrasound correlate is seen, AD may be more likely to be a radial sclerosing lesion rather than carcinoma¹
- However some malignant pathology (e.g ILC) may be US occult



¹Partyka, L et al. *AJR* 2014; 203: 216-222

Tomosynthesis-guided biopsy

- Tomosynthesis-guided breast biopsy capability is important for a practice that uses tomosynthesis
 - Some lesions are seen only on tomosynthesis
 - Difficult or impossible to biopsy using two-dimensional (2D) stereotactic guidance
- Even after careful work-up with ultrasound and/or MRI, some lesions may still not be confidently identified
 - US findings may not correlate
 - MR findings may not preclude biopsy
- Avoids multiple additional troubleshooting exams (MRI)
- Avoid unnecessary or additional biopsies



Tomosynthesis-guided Wire or Seed Localization

- If tomo-stereotactic equipment is not available or patient preference
 - Requires only DBT mammo unit
- Thorough diagnostic work-up required - careful US
 - If sonographic or MR correlate, then needle biopsy generally preferable
- **Some** architectural distortion lesions may be appropriate for primary surgical excision depending on patient factors and institutional practice – e.g. presumed radial scar



Procedure

- The procedure mirrors conventional 2D needle localization
- Pre-procedure planning is identical to the 2D procedures
 - preferred route—either shortest distance and/or best visualized projection
 - appropriate needle length
- For **seed localizations**, the needle containing the seed may be placed at the correct 3D position within the breast without the need for an orthogonal image to readjust the needle tip prior to deploying
- For **wire localizations**, the breast can be imaged in the orthogonal plane
- A final tomosynthesis acquisition or 2D is obtained to demonstrate the placement of the wire through the targeted lesion on tomosynthesis slices



Radioactive Seed Localizations

- Increasing adoption by many centers for pre-operative localization of non-palpable lesions
- Facilitates surgical scheduling
- localization procedures done prior to day of surgery
- Similar procedure to wire localization
- Requires nuc med regulator involvement
- Seeds can get lost or transected in surgery
- Data shows surgical outcomes appear similar to well-established wire loc results



Langhans et al. *Ann Surg*. 2017 Mar 2. doi: 10.1097. [Epub ahead of print]

Radioactive Seed Localizations

- Randomized trial – WL or RSL, multicenter trial
- Primary outcome – positive margins
 - 409 patients, 413 lesions
 - Resection margins were positive in 23 cases (11.8%) in the RSL group and 26 cases (13.3%) in the WGL group ($P = 0.65$)
- There were no significant differences in:
 - margin status ($P = 0.62$)
 - duration of the surgical procedure ($P = 0.12$)
 - weight of the surgical specimen ($P = 0.54$)
 - patients' pain perception ($P = 0.28$)
- RSL offers logistic advantage with similar surgical outcomes

Langhans et al. *Ann Surg*. 2017 Mar 2. doi: 10.1097. [Epub ahead of print]

Radioactive Seed Localizations

- 565 women with 660 breast lesions underwent RSL or WL
- Close positive margin, reexcision, and mastectomy rates remained similar in the WL group and RSL group
- There was no difference between the RSL group and the WL group in:
 - close positive margin status (20% each, $p = 0.81$)
 - reexcision rates (20% vs 16%)
 - mastectomy rates (6% each, $p = 0.96$)
- Increasing lesion size and the presence of calcifications were significant predictors of positive margins, whereas the use of more than one wire or seed was not

Dryden MJ et al. *AJR Am J Roentgenol*. 2016 May;206(5):1112-8.

Tomo-guided Stereotactic Biopsy

Add-on unit



Prone table



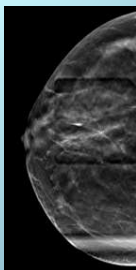
Advantages of Tomosynthesis-Guided Stereotactic Biopsy

- **Upright tomo-stereo**
- Improves patient access by addressing barriers to prone stereotactic biopsies
 - patient physical limitations
 - lesion position
- Quicker than 2D prone
 - DBT-guided stereo requires less than half the time to complete than 2D
 - Full field of view
 - Fewer targeting attempts
- Reduced radiation exposure
 - Fewer required images to complete
- Improved workflow/patient throughput
 - Unit can be used for routine imaging when not being used for stereo procedures



Advantages, continued...

- Tomosynthesis units use high spatial resolution digital receptors
 - better signal-to-noise and contrast-to-noise ratios than charge-coupled device (CCD) receptors (conventional prone stereo devices)
- Larger field of view provides better orientation when targeting
 - Full detector used
 - 2D prone stereotactic biopsy has a smaller (5X5cm) limited window on its compression paddle.
- Localization of subtle lesions or one-view only findings is easier
 - Targeting done off scout view – no need to identify lesion in paired stereo images



Tomo-guided biopsy Lesion Selection

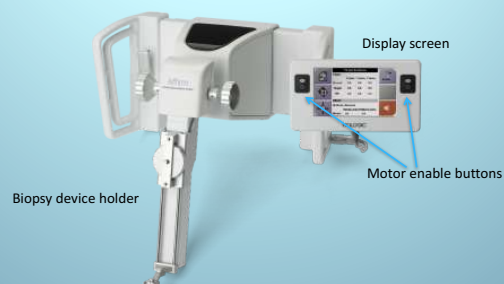
- Indications:
 - Targets visualized by **tomosynthesis alone**
 - Architectural distortion
 - Small masses
 - Calcifications
 - **Subtle lesions** better visualized with tomosynthesis compared with 2D mammography
 - Lesions seen only on **one mammographic view**

Limitations of tomo-guided biopsy

- Image interpretation
 - Images displayed on upright monitor
 - Different than prone table
 - Orientation of images relative to patient is different
 - Biopsy device is angled
 - positioned approximately 10 degrees off the perpendicular axis so that the device does not obscure the image
 - Requires some mental gymnastics!
- Vaso-vagal episodes
 - Patient is upright with biopsy device in full view
 - May lead to more syncopal episodes



Biopsy module components



Tissue sampling methods

- Biopsy devices:
 - Hologic Eviva – 9g
 - Mammotome Revolve – 11 or 8g
- Marker deployment
 - Eviva - end-deploy through sheath
 - Mammotome – through probe

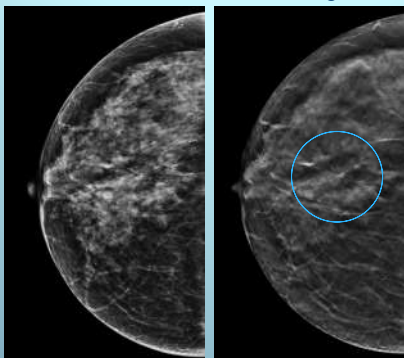


Procedure – Targeting Lesion

- Acquire preliminary tomosynthesis scout view (visualize full field of view)
 - In comparison with conventional stereotactic biopsies, a tomosynthesis scout is obtained in place of a 2D scout
- Adjust position of paddle window if necessary

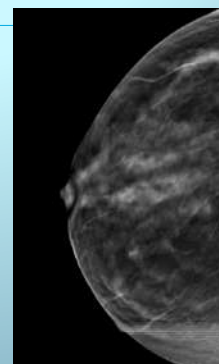


Screening mammogram – 51 yo Architectural Distortion right breast

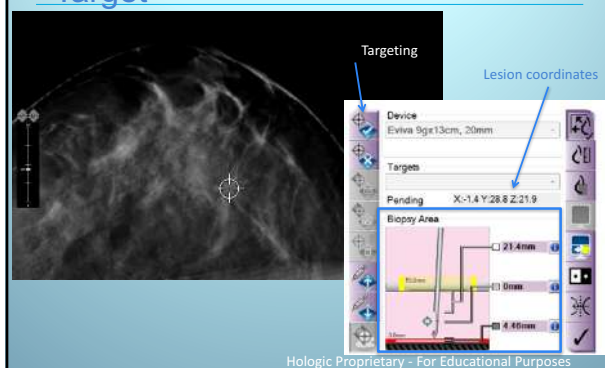


Tomo stereo - Scout

- Scroll through images using the scroll wheel to the tomo slice at which the target lesion is best visualized
 - This determines the depth (Z), and X and Y
- Scroll through entire stack of tomo images
 - Check for vessels in the path of the needle on the slices superficial (or deep) to the target
 - Be certain that the correct area is being sampled



Tomosynthesis procedure - Target



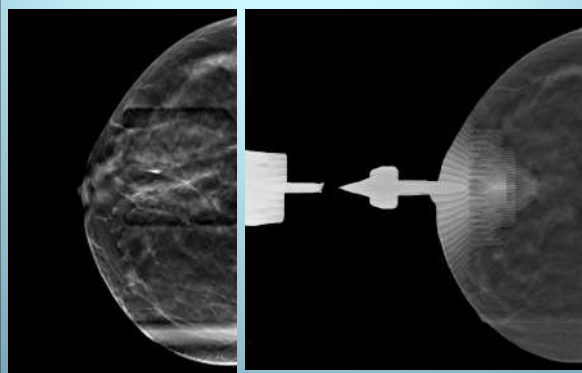
Steps in lesion targeting



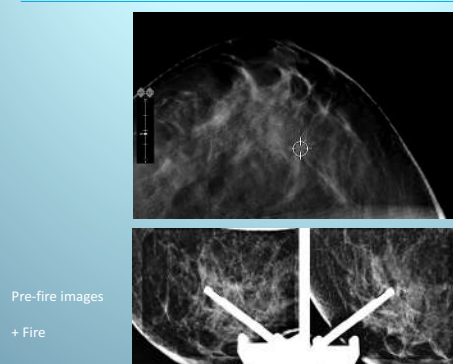
- The needle is advanced until the Z differential is zero
 - All three (X, Y, Z) are GREEN – Go!
- Obtain pre-fire stereo
 - Verify needle position
 - Note: although tomosynthesis images may be obtained when the needle is in place, the quality of the image is degraded due to artifact
 - 2D stereo pair is usually sufficient
- Alterations to the x and y positions may be made if necessary
 - On console or manually

Hologic
Eviva 5p13cm
20mm

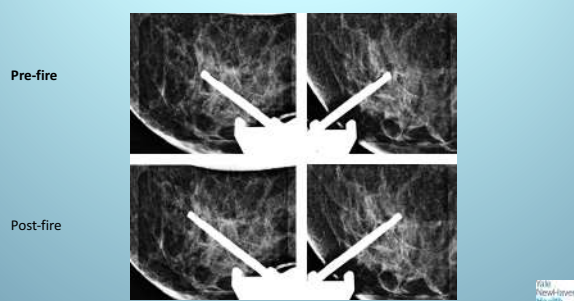
Tomo stereo - prefire



Tomosynthesis procedure – 2D Pre-Fire

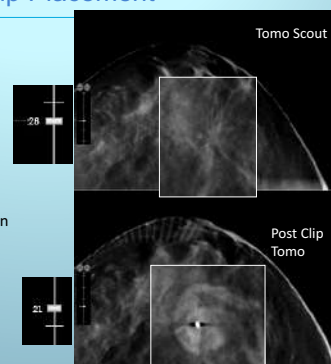


Tomosynthesis procedure – 2D Pre-Fire & Post-Fire (optional)

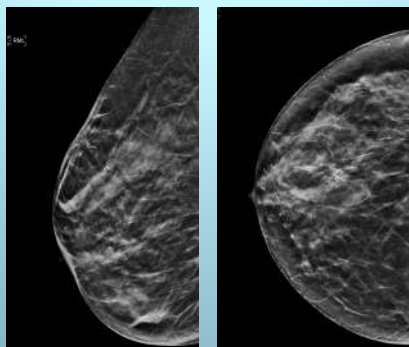


Tomosynthesis procedure - Post Biopsy & Clip Placement

- Display original tomo scout to view target
- Scroll up and down on post biopsy tomo
 - Check if lesion is gone
 - Compare depth hematoma/cavity ↔ lesion on target
- View Clip



Post procedure – full field 2 view mammogram



Trouble-shooting

- Adjustments to probe position can be more challenging
 - Image display
 - Angled approach
- Image on monitor has to be mentally morphed (rotated or inverted) to correspond to patient position
- Small adjustments can be made on monitor and transferred to automated stage
- Directional sampling is often adequate
- Use landmarks such as notch in paddle to determine clockface position to preferentially sample

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Tomo-stereo literature

- Studies have shown that DBT-guided stereo has a similar high success rate as prone stereotactic biopsy
- Requires less than half the time to complete
 - Ave. 9 minutes to complete

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- Sabatino et al. RSNA 2016
- Arianatnam et al. RSNA 2016

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Management after Core Biopsy Rad-Path Correlation

Benign	High Risk	Malignant
<ul style="list-style-type: none"> Fibrocystic changes Fibroadenomas Sclerosing adenosis Fat necrosis PASH Flat epithelial neoplasia 	<ul style="list-style-type: none"> Atypical Ductal Hyperplasia (ADH) Lobular Intraepithelial Hyperplasia (ALH, LCIS) Papillary lesions Radial Scar/Complex Sclerosing Lesion 	<ul style="list-style-type: none"> DCIS Invasive carcinoma <ul style="list-style-type: none"> Ductal Lobular

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Diagnosis and Management of Benign, Atypical, and Indeterminate Breast Lesions Detected on Core Needle Biopsy

Neal et al. Mayo Clin Proc. 2014;89(4):536-547

- All core needle biopsy (CNB) pathology results must be correlated with the prebiopsy breast imaging to ascertain concordance.
- Atypical ductal hyperplasia detected by CNB warrants surgical consultation for excisional biopsy.
- Surgical consultation should be obtained for patients with lobular neoplasia detected by CNB.
- Excision of phyllodes tumors or cellular fibroepithelial lesions detected by CNB is advised.
- Atypical hyperplasia and lobular carcinoma in situ warrant discussion of risk-reducing strategies with patients as part of their overall management.

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Management after Core Biopsy Concordance vs Discordance

- Does pathology reflect suspected imaging outcome?
- For highly suspicious lesions, e.g. BIRADS 5, a benign finding is not generally considered concordant
- Sampling –
 - how accurate was targeting
 - % sampling in relation to the whole lesion (calcs, mass, or non-mass area)
- Imaging guidance method
 - MRI biopsies show higher underestimation rate

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High-Risk Lesions at MRI-Guided Breast Biopsy: Frequency and Rate of Underestimation

Ann R. Lammert¹
Hanan Khalil²
Matthew Tardiff¹
Linda Chougar²

- 446 MRI-guided breast biopsies, January 2006 through December 2010
- 96 (21.5%) were high-risk lesions
 - 42 of 96 lesions (44%) were masses
 - 54 (56%) showed nonmass enhancement
- Pathology
 - 20 of 96 lesions (20.8%) were ADH
 - 9% were lobular neoplasia
 - 28% were papillary lesions
 - 21% were radial scar
 - 21% were other atypias
- Sixteen of 69 (23%) lesions were upgraded to malignancy
 - 69% upgraded to DCIS
 - 31% upgraded to invasive carcinoma
- Underestimation rate
 - 32% (6/19) for ADH
 - 6% (1/17) for papillary lesions
 - 23% (3/13) for radial scar
 - 29% (2/7) for lobular neoplasia
 - 31% (4/13) for other atypias ($p = 0.43$)
- No patient or lesion characteristics correlated with underestimation rate.

AJR September 2014; 203:682-686

Management after Core Biopsy What requires excision?

- Fibroepithelial lesions suggestive of phyllodes tumor
- Atypical Ductal hyperplasia
- Pleomorphic LCIS
- High risk lesions with associated atypia (Papillary, LIN, FEA, RS)

Management after Core Biopsy What may NOT require excision?

- High Risk lesions without atypia
- FEA
- Papillary lesions
- Classic LIN (ALH, LCIS)
- Radial Scar/Complex Sclerosing lesions

Flat Epithelial Atypia

- Columnar cell alteration
- Not true atypia
- Variation in pathological reporting
- Institution specific
- Khoury et al. 81 FEA lesions:
 - 2% upgrade pure FEA
 - with LN – no stat sig higher rate
 - conclusion: close surveillance
- Yale: excise only is FEA associated with true atypia or other high risk lesion

Benign papillary lesions

- Upstaging after CNB of a papilloma without atypia reported from 0 – 5.9%
- Variability reflects patient selection, associated imaging findings, study design
- Recent studies advocate observation for lesions with low-suspicion imaging features

Papillary Lesions of the Breast: Outcomes of 156 Patients Managed without Excisional Biopsy

Paloma Wey, MD,* Zsuzsanna Varga, MD,[†] Matthias Rösle, MD,[‡] and Christoph J. Renger, MD*

- 174 patients with 180 papillomas diagnosed by
 - core needle biopsy (113 cases)
 - vacuum-assisted biopsy (67 cases)
- February 2002 and May 2011
- Mean follow-up of 3.5 years
- 13 further events (8%)
 - 2 cases of ductal carcinoma in situ (one after 4 and one after 6 years)
 - 1 case of atypical ductal hyperplasia
 - 1 radial scar
 - 8 cases of papilloma
 - 1 case of flat epithelial atypia
- No invasive carcinomas occurred
- Surveillance is reasonable option

The Breast Journal, Volume 20 Number 4, 2014 394-401

Benign Papillomas Diagnosed on Large-gauge Vacuum-Assisted Core Needle Biopsy which Span <1.5 cm Do Not Need Surgical Excision

Andrew D. Mosier, DO,* Joren Keylock, MD,* and Donald V. Smith, MD²

- 6.5-year period
- 86 breast lesions were diagnosed as a benign papilloma (BP), <1.5cm utilizing an 11- or 8-gauge vacuum-assisted core needle biopsy(VACNB) device
- ≥2 years of imaging surveillance, without surgical excision following initial detection
- none of the 86 BPs demonstrated imaging findings that necessitated repeat biopsy or surgical excision

The Breast Journal, Volume 19 Number 6, 2013 611–617

Lobular Intraepithelial Neoplasia – ALH, LCIS

- ALH, LCIS – incidental finding, risk factor
 - ALH 4-5X
 - LCIS 9-10X
- Predominantly premenopausal women
- CNB - Usually associated with calcifications
- Rare on US bx
 - Recent study*:22/8205 US bx LN as most significant lesion
 - 20 excised – 5 malignancies (25% upgrade rate)
- Early literature suggested significant association with malignancy for LN on CNB
- Recent literature suggests no increased association in concordant bx
- Differentiation of classic from pleomorphic LCIS
- Classic LCIS –
 - risk of invasive cancer over 10 years – 7%
 - Ductal or lobular and in either breast
 - Surveillance is reasonable
- Pleomorphic LCIS –
 - Review study** - associated with invasive disease (40%) or DCIS (16%)
 - Excision indicated

*Ferre et al. AJR March 2016; 208:669-675

**Wazir et al. Oncol letters 2016; 12:4863-4868

RS/CSL

- Recent increased incidence of RS/CSL due to
 - population based screening
 - supplemental screening (US and MRI)
 - DBT
- Incidental vs targeted lesion?
- Size?
- Sampling adequacy?
 - CNB vs VAB
 - Central core vs periphery?
 - More atypia reported in spicules
- Patient age
 - associated malignancy: older (61yo) > young (52)
- Several recent studies have shown No upgrades for RS without atypia

RS/CSL Management

- Most tomo-only findings are architectural distortions
 - If appropriately worked up, most will prove to be radial scars/complex sclerosing lesions
- Management of RS/CSL lesions is still evolving
- Recommend excision if:
 - atypia or other co-existing histologic 'high-risk' lesion is found
 - is a new tomo-finding (prior tomo did not reveal)
- Consider following (in appropriate patients) if:
 - no atypia
 - lesion is possibly stable (may have been present but occult on prior 2D imaging)
 - Multiple lesions (some women have multiple RS/CSL)
- 6 month follow-up? For how long?
- MRI?

Summary

- It is important for practices that use breast tomosynthesis in both the diagnostic and screening settings to have tomosynthesis-guided biopsies capabilities
- There will be lesions identified solely by tomosynthesis or better visualized with tomosynthesis that will require tomosynthesis guidance for biopsy
- There are many advantages to tomosynthesis-guided breast biopsies, such as speed, cost effectiveness, patient tolerance, and improvement in workflow
- Tomo-guided wire and seed localizations are also quick and easy to perform
- Management of tomo-only lesions is still evolving

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