Stereotactic Breast Biopsy: Same Old Same Old

SBB Systems and Requirements
- Review of breast biopsy
- What’s out there?
- What’s new?
- How do we test them?

Breast Biopsy Review
- Breast biopsy can be done via
  - Fine Needle Aspiration (FNA)
  - Core Needle Biopsy
  - Vacuum-Assisted Biopsy (Mammotome)
  - Large Core Biopsy (ABBI)
  - Open Surgical Biopsy

Stereotactic Breast Biopsy
- 1979 – stereotactic breast biopsy using FNA was introduced in Sweden
- Limitations of FNA
  - High rate of insufficient samples (0-37%)
  - Cannot differentiate between noninvasive and invasive breast cancer
  - Requires experienced cytopathologist for interpretation, preferably onsite
  - Very limited tissue sample size

Stereotactic Breast Biopsy
- 1982 – Lindgren in Sweden introduced core needle biopsy using automated gun
- 1990 – Parker adapted automated needle-gun combination for stereotactic breast biopsy
- SBB has since become an important tool in early cancer diagnosis and reduction in mortality due to breast cancer

Goals of Image-guided Breast Biopsy
- Reduce the number of benign open surgical breast biopsies generated by mammographic screening
- Preoperatively characterize breast malignancy to allow adequate surgical therapy with as few open procedures as possible
Guidance for Breast Biopsy

- **Stereotactic guidance** is suitable for biopsy of masses, calcifications, architectural distortions.
- **Limitations**:
  - Widely dispersed calcifications or lesions too vaguely defined to generate useful coordinates.
  - Abnormalities high in axilla or very close to chest wall.
  - Rarely, lesions in very thin breasts.

Prone Systems

- **Advantages**:
  - Better access to the breast: space and angle of approach.
  - Patient motion is minimized.
  - Vasovagal reactions are minimized.
  - Procedure takes about half the time.

- **Limitations**:
  - Expense of dedicated prone tables.
  - Single use equipment.
  - Large space requirement.
  - Weight limitations.
  - Patients unable to lie prone.

Biopsy Devices

- **Equipment improvements**:
  - 14-g Tru-cut type needle paired with automated gun.
  - Vacuum-assisted devices.
  - Radiofrequency excisional device.

Biopsy Needles

14 Gauge spring-loaded biopsy gun.
**Biopsy Needles**

- 8g VA
- 10g VA
- 11g VA
- 14g Cutting

**Breast Biopsy Sample Weights**

<table>
<thead>
<tr>
<th>Device</th>
<th>Sample Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>14g Cutting Needle</td>
<td>18 mg</td>
</tr>
<tr>
<td>14g Mamrotome</td>
<td>37 mg</td>
</tr>
<tr>
<td>12g Suros ATEC</td>
<td>49 mg</td>
</tr>
<tr>
<td>11g Mamrotome</td>
<td>95 mg</td>
</tr>
<tr>
<td>9g Suros ATEC</td>
<td>118 mg</td>
</tr>
<tr>
<td>8g Mamrotome</td>
<td>300 mg</td>
</tr>
</tbody>
</table>

**Core Biopsy Sample Sizes**

- 14G Core Needle: 12-17mg
- 14G Mamrotome: 35-40mg
- 11G Mamrotome: 85-110mg
- 8G Mamrotome: 250-310mg

**INTACT™ Breast Lesion Excision System**

- Uses RF energy for cutting
- Obtains entire sample in one pass

**Larger Specimen Weight**

- 3.0 grams
- 2.1 grams
- 1.1 grams
- 0.6 grams

**Specimen Radiograph**
## Biopsy Method Comparison

<table>
<thead>
<tr>
<th>Method</th>
<th>Use</th>
<th>Pros</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fine needle</td>
<td>Cysts, masses</td>
<td>Fast, minimally invasive</td>
</tr>
<tr>
<td>Core</td>
<td>Solid mass, calcanea</td>
<td>Larger sample size, no scattering</td>
</tr>
<tr>
<td>Vacuum-assisted</td>
<td>Calcanea, solid masses, calcanea</td>
<td>Large sample size, minimal size</td>
</tr>
<tr>
<td>Large core</td>
<td>Non-palpable masses, calcanea</td>
<td>Hard to reach, better image, better lesion visibility</td>
</tr>
<tr>
<td>Open surgical</td>
<td>Hard to reach masses, calcanea</td>
<td>Most accurate</td>
</tr>
</tbody>
</table>

## Accreditation and MQSA

- ACR and Society of Breast Imaging
  - SBB should be included in MQSA

- NMQAAC
  - 9 of 14 members voted in favor of advising FDA to include SBB under MQSA (November 2007)
  - For: cited variable quality, lack of voluntary participation, dose
  - Against: cited access, documented need, intent of MQSA

## Accreditation Status

- 84.5% PASS on first attempt
- Of those failing:
  - Clinical + phantom: 9%
  - Clinical only: 36%
  - Phantom only: 50%
  - Dose only: 5%

## Equipment

- SBB includes:
  - Dedicated prone tables
  - Add-ons to screening units
- Same accreditation requirements
- Testing differs

## What's Out There?

- But what of Fischer?
  - Sold to Hologic in September 2005
  - Monopoly!
  - Sold to Siemens in January 2007
- Carestream took over service of installed base in September 2005
  - Still responsible for service of installed base
  - Current vendors of prone tables:
    - Siemens
    - Hologic
  - Everybody has an add-on

## Prone SBB and FFDM

- Seeing calcifications at FFDM that are not visible at prone SBB
- Technology of prone tables (CCD) has not changed and is not likely to:
  - 50 μm pixel, 10 lp/mm Nyquist (Siemens)
- Newer Hologic tables have some improved image processing
- Siemens working on image processing to make it “consistent” with FFDM
- Increasing dose helps to overcome some deficiencies
Fisher / Siemens Table

- Siemens is doing R&D for prone table
- Carestream is NOT doing R&D for installed Fisher tables
- New image processing will NOT be applicable to currently installed Fisher tables
- Parts are becoming difficult to find

Stereo Add-Ons

- Same IR for SBB as diagnostic
- Same image quality

Technologist QC

Technologist Testing

- Detector calibration (daily, per mfg)
- Localization accuracy, zero alignment (daily)
- Phantom images (weekly)
- Hardcopy output quality (monthly)
- Visual checklist (monthly)
- Compression test (semi-annually)
- Repeat analysis (semi-annually)

Detector Calibration

- Not in ACR QC Manual
- Manufacturer-specific
- Fisher system
  - Dark current
  - 8 flat field images (4 cm acrylic)
- Fixed technique
- Correction map applied
- Service function for Lorad

Localization Accuracy

- Must know that needle is going to the correct location
- Can use either ACR or manufacturer version
- Limits of 1 mm inaccuracy in each direction, or manufacturer if tighter
Localization Accuracy

Phantom Image
- May use standard Accreditation Phantom or the Mini-Phantom
- Similar targets, but not exactly the same

Phantom Details

Phantom Imaging
- If standard phantom, may use the minimum number of images required to visualize all objects
- Prone tables: 4
- Upright add-one 2

Hardcopy Output
Window width / level must be FIXED

Visual Checklist

Compression Test
- Similar to Mammography
- Power: 25-40 lbs
- Manual: at least 25 lbs
- Hologic may not meet this
- ~15 lbs power
- ~30 pounds manual
- This is acceptable

Repeat Analysis
- Semi-Annual rather than Quarterly
- Higher rate than mammography due to patient positioning
- Should be less than 20%

Screen-Film Tests
- Darkroom cleanliness (daily)
- Processor QC (daily)
- Screen cleanliness (weekly)
- Viewbox/viewing conditions (weekly)
- Fixer retention analysis (quarterly)
- Screen-film contact (semiannually)
- Darkroom fog analysis (semiannually)
Physicist Testing

- Stereotactic Breast Biopsy Unit Assembly Evaluation
- Collimation Assessment
- Focal Spot Performance and System Limiting Resolution
- kVp Accuracy and Reproducibility
- Beam Quality (HVL) Assessment

Physicist Testing – Part Duex

- AEC System or Manual Exposure Performance Assessment
- Receptor Speed Uniformity
- Breast Entrance Exposure, Average Glandular Dose and Exposure Reproducibility

Unit Assembly Evaluation

- Essentially the same as Mammography
- CHECK FOR TECHNIQUE CHART
  - Is it reasonable?

Collimation Assessment

- X-ray field should extend beyond the image receptor on all four sides
- ...but not by more than 5 mm
- X-ray field must be generally centered to image receptor (non-uniformity problems)

Collimation Assessment

- No film?
  - CR works well
  - Radiographic film (ISP Gafchromic XR-M, e.g.) can also be used (30 kVp, 300 mAs)
Focal Spot and Resolution

- QC Manual currently calls for both focal spot performance and system resolution
- FS performance requires film (CR introduces too much blur)
- Not an official FAQ yet, but Physics Subcommittee is considering specifying only system resolution test
- If you can’t do it, you can’t do it…

System Spatial Resolution

- Measure in both 512 and 1024 modes, if available
- Measure in both directions

kVp, Exposure and HVL

- LEAD OVER THE DETECTOR!
- Same as for Mammography

AEC Performance

- Unlikely to use SBB for 2 cm or less
- Measure signal/OD for 4, 6, 8 cm BR12
- 2, 4, 6 cm acrylic (~1.2x density of water)
- Per technique chart
- Standards
  - Signal ±20% of 4 cm signal
  - AEC and manual
  - Sensitometric ID 1/3 of the mean
  - Exposure time < 2 seconds (non-ACR)
- Lorad: 4000 (512 matrix), 6000 (1024 matrix)
- Fischer: 1800 – 2000 (standard)

Digital Receptor Uniformity

- SNR in the corners within 15% of SNR at the center
- No specific guidance for position in the corners
- If no SNR, use signal
- Lorad may have difficulties meeting this
  - Flat field calibration WITH compression plate in place
  - Ensure x-ray field carefully centered to image receptor
  - OK to measure at (100,100), (100, 400), (400, 400) and (400, 100)
- If no ROI capability
  - Pincushioning, dropped pixels, visible non-uniformity
  - Good to look for, anyway!

Lorad Uniformity

- Uniformity, no collimator
- Uniformity, collimator
- Uniformity, flat-fielded with collimator
ROI Measurements on Fischer

- It is possible to get ROI statistics on a Fischer unit:
  - Utilities
  - Analysis
  - Get images
  - Acquire corrected
  - Done
  - Image analysis
  - ROI
  - Statistic
  - Redraw ROI
  - Statistic

Dosimetry

- Similar to mammography
  - Small FOV, measure using fixed technique matching phantom
  - Matrix and signal dependent
  - Watch technique chart and clinical use
  - < 3 mGy for 4.2 cm, 50/50 breast

Image Quality Evaluation

- Either ACR Accreditation or Mini Phantom
- Use clinical techniques
  - kVp
  - Matrix
  - AEC, manual
- View on clinical monitor / viewbox
- Screen-film: 4 - 3 - 3 (MAP), 2 - 2 - 2 (Mini)
- Digital: 5 - 4 - 3.5 (MAP), 3 - 3 - 2.5 (Mini)

Artifact Evaluation

- Similar to artifacts seen in digital and film-screen upright units
- Uniformity may be the biggest culprit
- Any change after flat field calibration

Dust that moved after flat fielding.

Detector readout.
Localization Accuracy

- Have Technologist do this
- Gel phantom

Localization Test

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