MAESTRO Interim Results
from 75 of the 200 Subject MAESTRO Study

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Some of these images are taken with the Seno Imagio® breast imaging system and are not to be reproduced.

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To assess the diagnostic value in terms of sensitivity and specificity of additional Opto-Acoustics (OA) to conventional diagnostic ultrasound in masses classified as BI-RADS 4a and 4b.
Purpose Study

To evaluate BI-RADS 4a and 4b masses and reclassify BI-RADS category using OA feature scoring

• Downgrade benign masses (to BI-RADS 2 or 3)
• Upgrade malignant masses (to BI-RADS 4c or 5)
Materials and Methods

Used Seno Medical Instruments
Opto-acoustic imaging device, Imagio®

SENO IMAGIO® DEVICE
Seno Imagio® Device

Optical Absorption within Breast Tissues
• at two laser wavelengths
Materials and Methods

Opto-Acoustic (OA) and Ultrasound Images
Real-time hemoglobin map

Malignant
more
deoxyxgenated
hemoglobin

Benign
more oxygenated
or absent
hemoglobin
Materials and Methods

Invasive ductal carcinoma, grade 3
Materials and Methods

Multi Centre Study

• UMC Utrecht
• Radboud UMC
• Rijnstate Hospital
• ZGT Hospital
• Albert Schweitzer Hospital
Materials and Methods

- 78 masses with BI-RADS 4a or 4b
  - 44 benign
  - 34 malignant

- All underwent biopsy

- Prior to biopsy; Radiologists (unlike previous PIONEER study)
  - Scored 5 OA features
  - Assigned percentage change of malignancy (POM)
  - Assigned and OA BI-RADS category

- Central Pathology Review
  - Prof dr M. van de Vijver (AMC Amsterdam)
## Results: Sensitivity and Specificity

### MAESTRO: 78 Masses

#### Sensitivity and Specificity

<table>
<thead>
<tr>
<th>BI-RADS</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Sensitivity</th>
<th>Specificity w/o nomograms</th>
<th>Specificity with nomograms</th>
</tr>
</thead>
<tbody>
<tr>
<td>4a &amp; 4b</td>
<td>100%</td>
<td>0%</td>
<td>97.1%</td>
<td>43.2%</td>
<td>68.2%</td>
</tr>
</tbody>
</table>

The nomenclature “nomogram” may change in future documentation.
Results: Downgrades and Upgrades

MAESTRO: 78 Masses - Downgrades and Upgrades

<table>
<thead>
<tr>
<th>BI-RADS</th>
<th>Benign Mass Downgrades</th>
<th>Malignant Mass Upgrades</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
<td>Using Nomograms</td>
</tr>
<tr>
<td>4a &amp; 4b</td>
<td>43.2%</td>
<td>68.2%</td>
</tr>
<tr>
<td>4a</td>
<td>44.4%</td>
<td>75.0%</td>
</tr>
<tr>
<td>4b</td>
<td>37.5%</td>
<td>37.5%</td>
</tr>
</tbody>
</table>

The nomenclature “nomogram” may change in future documentation.
MAESTRO interim - benign masses - CDU BI-RADS 4a downgrades

net downgrades = 27.8%
MAESTRO interim - malignant masses - CDU BI-RADS 4b upgrades

net upgrades = 51.7%
Results – Downgrades of Benign Masses

MAESTRO interim - benign masses - Downgrades of CDU BI-RADS categories 4a,4b with OA

% of change

100.0% 90.0% 80.0% 70.0% 60.0% 50.0% 40.0% 30.0% 20.0% 10.0% 0.0%

BI-RADS 2
BI-RADS 3
BI-RADS 4a
BI-RADS 4b
BI-RADS 4c
BI-RADS 5

net downgrades = 34.1%

CDU (pre-OA)
post-OA
Results – Upgrades of Malignant Masses

MAESTRO interim - malignant masses - Upgrades of CDU BI-RADS category 4a,4b with OA

- BI-RADS 3: # = 1, 2.9%
- BI-RADS 4a: # = 4, 11.8%
- BI-RADS 4b: # = 13, 38.2%
- BI-RADS 4c: # = 29, 85.3%
- BI-RADS 5: # = 15, 44.1%

Net upgrades = 44.1%

UMC Utrecht
## Results: Learning Curve

**MAESTRO Learning Curve**  
Specificity Improved - False Positives Decreased

<table>
<thead>
<tr>
<th>BI-RADS</th>
<th>Benign</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>All 78 Masses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4a</td>
<td>20 FPs</td>
<td>1 FN</td>
</tr>
<tr>
<td>4b</td>
<td>5 FPs</td>
<td>0</td>
</tr>
<tr>
<td>Learning Curve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First 30</td>
<td>11 FPs (0.367)</td>
<td>0</td>
</tr>
<tr>
<td>Last 48</td>
<td>14 FPs (0.292)</td>
<td>1 FN</td>
</tr>
</tbody>
</table>

**20% absolute reduction in FP rate in last 48 cases**
PIONEER - Pilot Downgrades from BI-RADS 3 to BI-RADS 2 can potentially obviate follow-up in addition to preventing biopsy.

Net downgrades = 18.9%
Conclusions

- OA appears to better distinguish between benign and malignant masses than does US.
- OA has the potential to decrease benign biopsies by downgrading.
- OA has the potential to upgrade BI-RADS category in malignant masses.
- The completed PIONEER Pivotal Study (N=2,095) and the MAESTRO Study (n=200) may further confirm these results.
Thank you