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.
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 deoxygenated 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>CDU</th>
<th>Imagio®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>4a &amp; 4b</td>
<td>100%</td>
<td>0%</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

![Graph showing Upgrades of CDU BI-RADS category 4b with OA]

- # = 29
- # = 15
- # = 12
- # = 1
- # = 0

**net upgrades = 51.7%**
Results – Downgrades of Benign Masses

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

net downgrades = 34.1%
Results – Upgrades of Malignant Masses
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><strong>All 78 Masses</strong></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><strong>Learning Curve</strong></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.
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