Clinical results and user feedback from recent MARIA trial carried out in South West of England

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Association of Breast Clinicians Study Day
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MARIA™

Radio-wave array accommodating a range of breast sizes

Patient bed providing a comfortable patient experience with no breast compression

Scanning and data processing unit

PACS/VNA support

Operator and review display

Evolving Medical Imaging

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How does MARIA™ work

• The array contains 60 radio frequency antennae that surround the breast. They are configured to operate over a wide range of frequencies.

• Each antenna transmits and the other 59 record the signal back from the breast tissue which allows to build up a 3D map of tissue variation throughout the breast.

• The scanning process takes less than 5 minutes.
How does MARIATM work

• The data is then reconstructed before being presented to the clinician as a DICOM-compatible 3D volume. captures variations in the impedance, permittivity and conductance of tissue within the breast to differentiate between normal tissue and lesions, and also between types of lesions based on their individual electromagnetic response.

• This contrast mechanism performs particularly well in dense tissue and has been shown to detect tumours as small as 5mm.
## Dense Tissue Performance

<table>
<thead>
<tr>
<th></th>
<th>XRM</th>
<th>MARIA™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Sensitivity (Ss)</td>
<td>77%</td>
<td>77%</td>
</tr>
<tr>
<td>Cancers Ss</td>
<td>88%</td>
<td>72%</td>
</tr>
<tr>
<td>Dense tissue Ss</td>
<td>71%</td>
<td>84%</td>
</tr>
<tr>
<td>Cancers in dense tissue Ss</td>
<td>69%</td>
<td>85%</td>
</tr>
<tr>
<td>Cancer in very dense</td>
<td>&lt; 50% [1]</td>
<td>100%</td>
</tr>
</tbody>
</table>

- Over 400 women scanned in clinical studies
- 313 cases evaluated across two clinical trials

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Clinical exemplar – P028R
Clinical exemplar – P230L

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Patient Feedback

- Patient was happy with the feel of the coupling fluid; could be wiped off
- Patient found very comfortable and far more relaxing than a mammogram
- Lady was very comfortable. Found it far better than a mammogram and was very keen for research to continue.
- Positive experience compared to mammogram
- Patient with concave chest fitted very well
- Good fit, patient has had yearly mammograms for 15 years, now 47 years old, found this far more comfortable
- Patient said comfortable and not painful like the mammogram
- Better than mammogram. No pressure
Patient/ Operator Feedback

• The patient would fit into the smallest cup, the cup does not rise up to fit and hence poor reading. Patient had scoliosis
  – Maximum height of the array has been increased

• Difficult patient to scan. Used xsmall bowl. The next size up would have been too big.
  – XSmallShallow insert (197ml) added

• Patient found the circle on the bed uncomfortable below her breasts i.e., top rib cage.
  – Bed padding increased
Patient/ Operator Feedback

• Simplifying patient fitting:
In Development – Pulse Synchronised Data Capture

M6 Pulse Synchronisation
2 Lesion Patient

Lesion 1 Fibroadenoma

Lesion 2 Tumour

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Lesion classification - example from published data

Lesion classification – clinical data
MARIA™ - The Next 12 Months

• New clinical trials commencing at:
  – Royal Marsden, Chelsea (Steven Allen)
  – Cheltenham (Iain Lyburn)
  – Radboud, Nijmegen (Ritse Mann)
  – AKH, Vienna (Pascal Baltzer)

• Early sales in UK, Germany, Austria

• Several software upgrades including automatic lesion classification

• Development of a biopsy variant (InnovateUK funded)
Acknowledgements

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• Great Western Hospitals Breast Centre (PI: Dr Sarah Taylor)