Radar imaging of breast lesions - a clinical evaluation and comparison

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Aims and objectives

Imaging of the breast exploits a number of different physical properties of breast tissue such as electron density or acoustic impedance. Dielectric property, which determines propagation and absorption of radio waves, similarly varies in different tissues of the breast and has been considered for imaging since 1991 (1), but it was the development of an ultra-wideband radar technique at sufficiently high frequency to permit visualisation of relatively small regions that made development of a practical dielectric imaging system possible (2-4). In the breast the fat content is of low dielectric constant, whereas protein and water exhibit much higher values. This is the situation in fluid filled cysts and in tumour areas where the cell content is high. Glandular tissue also has elevated dielectric values but except in the lactating breast these are still lower than that of most lesions (5-8). With Research Ethics approval, a series of prototype MARIA radar scanners were constructed within the Electrical Engineering department of the University of Bristol with funding from Micrima Ltd, and were used to scan a number of patients referred to a symptomatic breast care clinic. On the basis of the results of this study a clinically acceptable scanner was designed and constructed by Micrima Ltd, subjected to CE approval and used within the same clinic. This paper presents the clinical results from the MARIA M4 which is the last of the University prototypes, and from the MARIA M5 which is one of the first CE approved scanners constructed by Micrima.
Clinical: Patient Cohort: 86 patients attending a symptomatic breast care clinic were identified by clinicians as meeting the study selection inclusion criteria and were recruited at either Frenchay or Southmead Hospital, Bristol, UK and included in the observational, prospective MARIA M4 clinical evaluation study (approved by Central & South Bristol Research Ethics Committee (REC) 06/Q2006/30). A further 41 patients were recruited to the MARIA M5 study (approved by Yorkshire & The Humber and South Yorkshire REC 15/YH/0084, ClinicalTrials.gov NCT02493595).

Description of the procedure: Where possible patients had an ultrasound examination and a mammogram as well as cytology or histology (if appropriate and for patient benefit) as part of normal procedure. Patients were scanned before any surgical or biopsy intervention. Data collected were BIRADS score, age and menopausal status, and breast size. The subject was required to lie prone with the breast inserted into the ceramic cup lined with a small amount of "contact fluid" of dielectric constant 10. The scan consisted of checks for goodness of fit of the breast (lack of air gap) and then at least two scans of about 30 seconds each. With the M4, data was processed off-line, but with the M5 the scans could be processed with the patient present in about 120 seconds.

Data collection: Evaluation consisted of two stages: A judgement of lesion(s) type, size and location using all available clinical data by a researcher who had no knowledge of the MARIA image, and, an assessment of the MARIA image by an engineer who had no access to the clinical data or image. The two observations were then compared jointly by the two observers to decide on the available data of a good correspondence, failure to correspond, or a need to exclude. In this, the results from ultrasound with or without mammogram was the "gold standard".

Equipment: Micrima initiated commercial conversion of the University of Bristol imaging platform in late 2012. The design although based closely on the University of Bristol design is improved by the introduction of a new Vector Network Analyser (VNA) technology providing additional functionality for system calibration. Being much smaller than the earlier unit allows significant reduction in the system clinical footprint. The original university research (M4) microwave switch array and co-located antenna array assembly were redesigned for ease of manufacture and field service. A picture of the redesigned switch matrix and antenna array is shown below (Fig 1).
Fig. 1: Figure 1a. Antenna Array with ceramic coupling shell (applied part) removed to show the 60 antennas that comprise the MARIA receive-transmit system. 1b Section through array showing relationship between the antenna array, coupling fluid layer and ceramic coupling shell. A range of ceramic spacers are supplied which fit inside the coupling shell to maintain contact with the breast tissue for a range of breast sizes. 1c Antenna array and switch assembly

References: Micrima Ltd

The microwave components and supporting mechanical parts are incorporated into a fully integrated bed/system cabinet design (Fig 2 and 3).
The antenna array position is adjustable with the patient in position on the bed. It can be raised and lowered and is provided with lateral and cranial/caudal adjustment to allow the operator to optimally position the breast within the scanning cup without the patient having to move during normal clinical application.
The system cabinet can also be rotated out from under the bed to allow introduction of additional inserts designed to accommodate smaller breast cup sizes into the basic breast cup (Fig 4).
Fig. 4: Figure 4. Cabinet rotated out to allow cup insert change

References: Micrima Ltd

In normal clinical use a dielectrically stable coupling medium (Fig 5) is necessary to eliminate/place trapped air that may be present between the breast tissue and the surface of the scanning cup and to optimise coupling/minimise loss of the scanning signal into and out of the breast tissue.
Fig. 5: Figure 5. Coupling fluid and various size cup inserts

References: Micrima Ltd

The system employs a display and keyboard that can be positioned up to 3 meters away from the main cabinet to allow system control and overall privacy of the imaged result.

Provision is made for a hospital network connection in order to connect the system to the local DICOM/PACS network.

Software and user applications:

The system employs a system application that operates within a Windows OS environment. The application provides for:

- Patient information entry, Local and RIS based input
- Query Worklist function
- Scanning information, Bra size, selected cup, Left/right
- Patient Study database search and recall capability
- Tissue to Cup fitting image, used to assess "fit" of breast into scanning cup
• Scanning function, operates the internal RF system to Transmit signals into and Receive return signals from the breast for image construction
• Image construction, Algorithms that analyse the scattering parameters and use the data to construct a 3D image of the breast
• Image presentation and manipulation, Multiple Slice and 3D ISO-Surface selectable and rotatable images in three "fields of view". "Fields of View" function allows interrogation of varying depths of tissue without signal loss or masking.
• DICOM file output to PACS server for remote viewing of the MARIA image file.
• Administrative ONLY access for System Checks and on-site Calibration.

![Image of a query worklist selection screen]

**Fig. 6**: Figure 6. Sample Query Worklist Selection screen

**References**: Micrima Ltd
**Fig. 7:** Figure 7. Initial "Fit" Assessment Screen

**References:** Micrima Ltd

<table>
<thead>
<tr>
<th>System</th>
<th>Scan</th>
<th>Review</th>
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<td>ROI</td>
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<td>40.97</td>
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<tr>
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<td>Search</td>
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<td>Plot Type</td>
<td>Images</td>
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<td>Cineplan Panel</td>
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<td>Cranioaxial Panel</td>
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<td>Free 3D Threshold value</td>
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</tbody>
</table>

**Fig. 8:** Figure 8. Image review, Slice Selection and ISO 3D

**References:** Micrima Ltd
Fig. 9: Figure 9. MIP Image review

References: Micrima Ltd

System Algorithms: Image construction from collected RF scattering data uses a DAS (delay and Sum) algorithm similar that used extensively in the earlier University of Bristol research system. This algorithm design is discussed in (9). The original algorithm code has however been optimised to improve processing speed allowing concurrent image generation in the clinic rather than off-line as in previous devices. This improved processing speed coupled with the significantly improved operator and Radiologist image interface has resulted in a product suitable for regular clinical use. In addition new image presentation software to include CC, ML and Physicians POV sliding slice imagery, ISO surface 3D with threshold and slice/3D MIP enhance the options available to the consulting Radiologist for image interpretation.

Clinical QA: The current system provides for simple operator initiated system verification prior to daily use. This self-test capability limits Medical Physics interaction with the device to a wider quality control sampling interval.

Regulatory Approvals: the system is fully CE-Marked having completed all of the necessary mechanical and electrical safety and EMC testing requirements for use in the European Union.
Fig. 1: Figure 1a. Antenna Array with ceramic coupling shell (applied part) removed to show the 60 antennas that comprise the MARIA receive-transmit system. 1b Section through array showing relationship between the antenna array, coupling fluid layer and ceramic coupling shell. A range of ceramic spacers are supplied which fit inside the coupling shell to maintain contact with the breast tissue for a range of breast sizes. 1c Antenna array and switch assembly

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Fig. 2: Figure 2. Complete System

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Fig. 3: Figure 3. Array Positioning controls

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Fig. 4: Figure 4. Cabinet rotated out to allow cup insert change

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Fig. 5: Figure 5. Coupling fluid and various size cup inserts

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**Fig. 9:** Figure 9. MIP Image review

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Results

Of 86 MARIA M4 patients included in the study, a sensitivity score of 74% (64/86) correspondence with the 'gold standard' (mean age 51.4y, age range 24-87, diagnoses: cysts n=36 (57%), cancer n=20 (31%), other including FA (fibroadenoma) n=4 (6%), no pathology reported (NPR) n=4 (6%)) was obtained. There was 77% (66/86) sensitivity compared to mammogram (MMG) alone (mean age 52.3y, age range 24-87, diagnoses: cysts n=27 (41%), cancer n=29 (44%), other including FA n=5 (7.5%), NPR n=5 (7.5%)). Sensitivity was 86% (36/42) in MMG dense breasts (BIRAD c or d) (mean age 49.8y, age-range 24-72, diagnoses: cysts n=19 (53%), cancer n=9 (25%), other including FA n=4 (11%), ONR n=4 (11%)). Of 42 subjects with MMG dense breasts 69% (29/42) were pre-menopausal (mean age 45y, age range 24-54, cysts n=16 (56%), cancer n=7 (24%), other including FA n=3 (10%), NPR n=3 (10%)). MARIA M5 demonstrated 76% sensitivity (31/41) compared to the 'gold standard' (mean age 50.6y, age range 35-81, diagnoses: cysts n=12 (39%), cancer n= 15 (48%), others n=2 (6.5%), NPR n=2 (6.5%)) Table 1. An example of MARIA scan compared to mammogram and ultrasound scan is given (Fig 10).

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Sensitivity score (%)</th>
<th>Mean age (years)</th>
<th>Age range (years)</th>
<th>Cysts</th>
<th>Cancer</th>
<th>Others inc FA</th>
<th>PNR</th>
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<tr>
<td>MARIA M4 detection (vs gold standard)</td>
<td>64/86</td>
<td>74</td>
<td>51.4</td>
<td>24-87</td>
<td>36 (57%)</td>
<td>20 (31%)</td>
<td>4 (6%)</td>
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<tr>
<td>MARIA M4 MMG only</td>
<td>66/86</td>
<td>77</td>
<td>52.3</td>
<td>24-87</td>
<td>27 (41%)</td>
<td>29 (44%)</td>
<td>5 (7.5%)</td>
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<tr>
<td>MARIA M4 in MMG dense breasts (BIRAD c or d)</td>
<td>36/42</td>
<td>86</td>
<td>49.8</td>
<td>24-72</td>
<td>19 (53%)</td>
<td>9 (25%)</td>
<td>4 (11%)</td>
</tr>
<tr>
<td>MARIA M4</td>
<td>29/42</td>
<td>69</td>
<td>45</td>
<td>24-54</td>
<td>16 (56%)</td>
<td>7 (24%)</td>
<td>3 (10%)</td>
</tr>
</tbody>
</table>
Table 1. Patient demographics, sensitivity scores and diagnoses for MARIA M4 and M5. MMG, mammogram;

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<tbody>
<tr>
<td>MMG dense pre-menopausal</td>
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<tr>
<td><strong>MARIA M5</strong> detection (vs gold standard)</td>
<td>31/41</td>
<td>76</td>
<td>50.6</td>
<td>35-81</td>
<td>12 (39%)</td>
<td>15 (48%)</td>
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</tbody>
</table>

**Fig. 10**: Figure 10. Comparison of MARIA (a), MMG (b) and US scan (c). Carcinoma 17mm and fluid filled milk duct. Only tumour visible on mammogram. Both visible on MARIA and ultrasound scan.

**References**: Micrima Ltd
Images for this section:

Fig. 10: Figure 10. Comparison of MARIA (a), MMG (b) and US scan (c). Carcinoma 17mm and fluid filled milk duct. Only tumour visible on mammogram. Both visible on MARIA and ultrasound scan.

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Conclusion

Although the number of subjects analysed here are too small to permit extensive statistical comparisons, nevertheless, some trends can be demonstrated. A 'blind detection' rate of 74% in all 86 breasts scanned compares very well to the 78% score in digital mammography reported in the DMIST Study (10). Further improved results in dense breasts at 86% compares even more favourably to the DMIST dense breast group at 70%. We have no explanation for the apparently improved results in dense breasts. Subjects reported that the procedure was acceptable and easily managed by those able to lie prone, and still, for about 2 minutes and particularly appreciated the lack of breast compression.
Personal information

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References


