Radio-wave radar-based breast imaging system: an initial multi-site clinical evaluation

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Introduction

To determine the effectiveness, in an initial clinical study, of MARIA (Micrima Ltd, Bristol UK) – a non-ionising, non-compressing whole-breast scanning system utilising radiowaves – in symptomatic breast care clinics. Unlike x-ray mammography, radio-wave imaging does not suffer from impaired detection ability in dense breast tissue[1]. MARIA is a CE-marked radio-frequency (RF) medical imaging system comprising a patient bed, a Scanning and Data Processing (SDP) unit which is located under the bed and a touch-screen console featuring a software user interface that controls both acquisition and review. The SDP unit contains a hemispherical array of 60 RF antenna which encircle the breast and operate in both transmit and receive modes, resulting in a 3D dataset that records the dielectric properties of the breast. The breast lies pendant in the array through a hole in the bed and one of a set of conformal ceramic inserts that are placed into the array are provided to fit a range of breast sizes without the need for compression (see Figure 1 *inset*). A coupling fluid which has the consistency of hand moisturiser is applied between the breast and insert to maintain good RF contact. The scanning procedure comprises a fitting scan and then three scans of around 30 seconds. Data is reconstructed as a 3D volume for review.

Figure 1(main): Patient (model) positioned on MARIA bed for scanning at Southmead Hospital (inset) Coupling fluid consumable and spacing inserts to accommodate a range of breast sizes.

Method

Patients attending symptomatic clinics at three sites were identified by clinicians as having a palpable lump. Following informed consent, eligible patients underwent this prone imaging technique. The bilateral reconstructed 3D images were correlated with clinical information and other imaging studies including ultrasound and/ or mammography and, when relevant, core biopsy results to determine sensitivity scores. [Ethics approval (Yorkshire & The Humber and South Yorkshire REC 15/YH/0084, ClinicalTrials.gov NCT02493595)].

Analysis

For the 150 evaluated studies, a sensitivity of 79% was obtained for lesion detection (mean age 52.5 years, age-range 16-89). Sensitivity was 76% for cancers and 78% for cysts. Sensitivity scores were 78% in pre-/ peri-menopausal women (mean age 38, age range 16-60) and 76% in women with dense breasts (BI-RADS 'c' and 'd', mean age 50, age-range 19-81). Sensitivity was 90% for cancer in dense breasts.

Results

	Cases	Sensitivity Score (Ss)	Mean Age (Years)	Age Range	Cysts Ss	Cancer Ss	Other Ss
All	150	119 (79%)	52.5	16-89	42/54 (78%)	45/59 (76%)	29/36 (81%)
Pre-/Peri-	107	83 (78%)	38.0	16-60	36/48 (75%)	23/27 (85%)	26/32 (81%)
Post	41	36 (88%)	69.0	49-89	6/6 (100%)	27/33 (82%)	3/4 (75%)
Lucent	38	28 (74%)	64.5	40-89	3/5 (60%)	21/29 (72%)	4/4 (100%)
Dense	83	63 (76%)	50.0	19-81	33/41 (80%)	19/21 (90%)	15/19 (79%)
Unknown	29	25 (86%)	48.5	16-81	6/8 (75%)	10/10 (100%)	10/13 (77%)

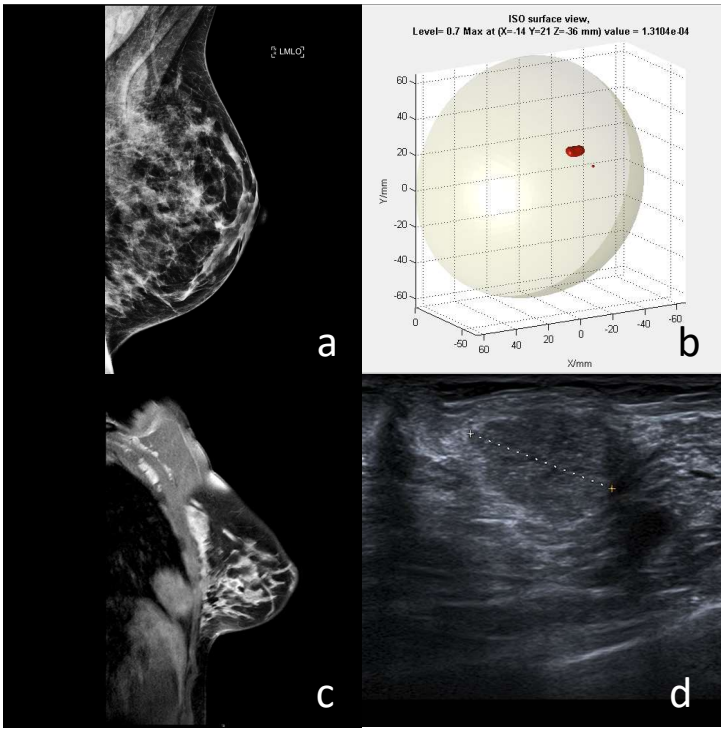

Figure 2: P035 Age 55, BIRAD 'd' Left (a) MMG showing no lesion (b) MARIA showing finding UOQ (c) Gadolinium-enhanced MRI showing 16mm irregular mass UOQ (d) US from image-guided biopsy which confirmed a Grade 2 mucinous carcinoma and DICS.

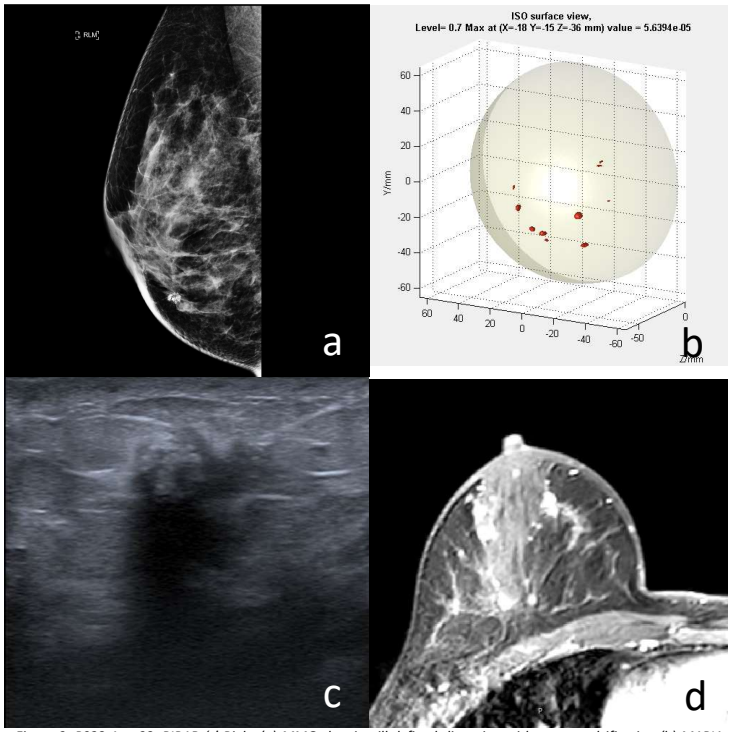

Figure 3, P028 Age 38, BIRAD 'c' Right (a) MMG showing ill-defined distortion with coarse calcification (b) MARIA showing multiple foci throughout lower half of breast (c) Initial US showing only an ill—defined region of concern (d) Gadolinium-enhanced MRI showing more than 10 lesions corresponding to grade 2 invasive ductal carcinoma with mixed pattern of growth accompanied by microcalcifications, high nuclear grade solid and micropapillary DCIS.

Discussion

The reported analysis is consistent with that reported for the pre-CE mark clinical evaluation study[2] which concluded a lesion detection sensitivity of 74% across 86 patients. The slight increase in detection performance may be attributable to the intrinsic population of each study, and also some improvements in signal to noise performance that have been realised since the original evaluation was carried out. The previous study found 12% additional findings compared to MMG alone and the multi-centre trial contains several examples of such cases, including those where the lesion was occult to MMG (see, for example, Figure 2) but visible to MARIA, as well as instances of patients contraindicated for MMG due to age (youngest patient was 16 at time of scan) and complex cases such as that shown in Figure 3 where the standard modalities used in the one-stop clinic were inconclusive.

Conclusions and Implications for Practise

Initial results indicate the potential that the MARIA system offers as a well-tolerated, non-ionising imaging modality. MARIA has been shown to be effective at detecting cancers in younger, pre-menopausal women with dense breasts. MARIA may contribute to overcoming some of the challenges posed by trying to optimise the balance between benefit and harm of screening in women of younger age. The results of this pilot study are very encouraging. We are continuing to evaluate this exciting novel imaging technique, noting that an update to the system offers a wider range of spacing inserts to fit an additional 10-15% of the patient population.

References

[1] Mammographic Density and the Risk and Detection of Breast Cancer. Boyd *et al*, NEJM 2007:356:227-36M

[2] Radar imaging of breast lesions – a clinical evaluation and comparison. Shere *et al*, ECR 2016, Vienna