C-10755 Investigating the patient experience of using a novel microwave breast imaging device within the symptomatic breast

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Type:

Scientific Exhibit

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Breast, Experimental, Experimental investigations, Cancer, Prospective, Performed at one institution

Purpose

MARIA® is a novel breast imaging device that utilises the variation in microwave permittivity of breast tissue to create an image of the internal breast structure, as described and demonstrated here [1] and here [2].

Fig. 1: The MARIA® system, showing the microwave array underneath the bed

The design of MARIA® involves the participant lying in a prone position with her breast pendulous through a circular aperture in the bed. The antenna array is housed underneath this aperture and rises to meet the breast, ensuring a close fit with no compression via a hemispherical ceramic insert. Different size cup inserts are used with MARIA® in order to accommodate a wide variety of breast sizes.

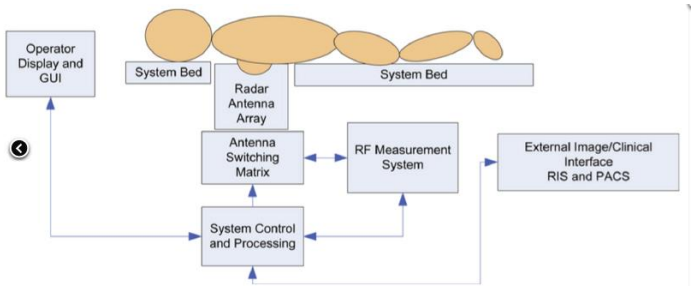


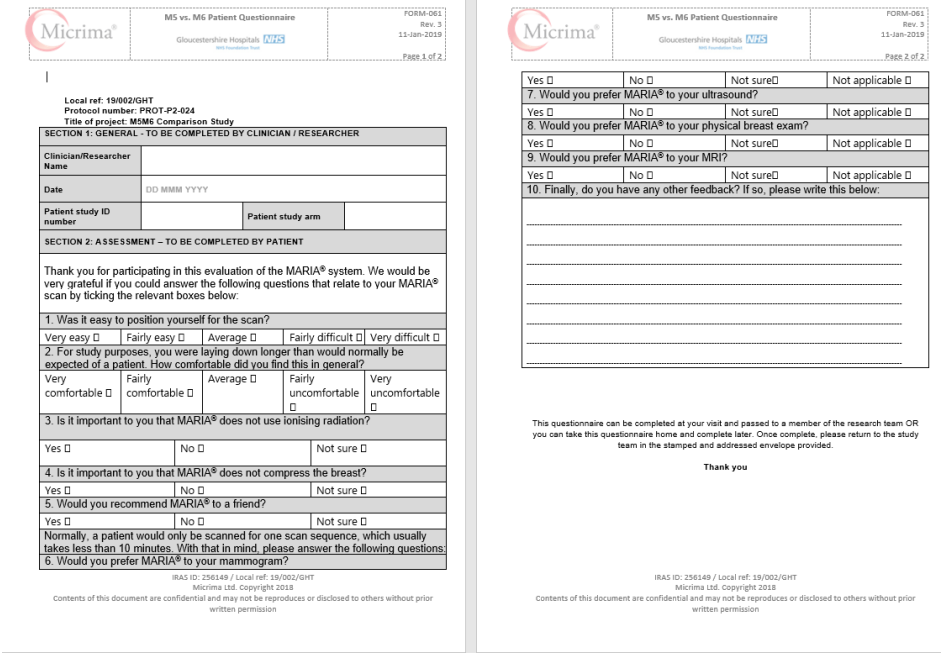
Fig. 2: A schematic diagram of the MARIA® scanning process

The purpose of this research was to collect information from participants regarding their experience with MARIA® so that the patient acceptability of the technique could be assessed.

Methods and Materials/ Background

Between date and date 20 consecutive participants who underwent a procedure using MARIA were invited to complete a feedback questionnaire at the end of their study visit. The questionnaire comprised

of 9 questions and a free text box for additional comments. They were able to either hand the questionnaire back to the operator once completed, or take away a stamped, addressed envelope to return the questionnaire via post later. All participants opted to return their questionnaire to the operator on the day.



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Local ref: 19/002/GHT
Protocol number: PROT-P2-024
Title of project: M5M6 Comparison Study

SECTION 1: GENERAL - TO BE COMPLETED BY CLINICIAN / RESEARCHER			
Clinician/Researcher Name			
Date	DD MMM YYYY		
Patient study ID number		Patient study arm	

SECTION 2: ASSESSMENT – TO BE COMPLETED BY PATIENT

Thank you for participating in this evaluation of the MARIA® system. We would be very grateful if you could answer the following questions that relate to your MARIA® scan by ticking the relevant boxes below:

1. Was it easy to position yourself for the scan?

Very easy ☐	Fairly easy ☐	Average ☐	Fairly difficult ☐	Very difficult ☐

2. For study purposes, you were laying down longer than would normally be expected of a patient. How comfortable did you find this in general?

Very comfortable ☐	Fairly comfortable ☐	Average ☐	Fairly uncomfortable ☐	Very uncomfortable ☐

3. Is it important to you that MARIA® does not use ionising radiation?

Yes ☐	No ☐	Not sure ☐

4. Is it important to you that MARIA® does not compress the breast?

Yes ☐	No ☐	Not sure ☐

5. Would you recommend MARIA® to a friend?

Yes ☐	No ☐	Not sure ☐

Normally, a patient would only be scanned for one scan sequence, which usually takes less than 10 minutes. With that in mind, please answer the following questions:

6. Would you prefer MARIA® to your mammogram?

Yes ☐	No ☐	Not sure☐	Not applicable ☐

7. Would you prefer MARIA® to your ultrasound?

Yes ☐	No ☐	Not sure☐	Not applicable ☐

8. Would you prefer MARIA® to your physical breast exam?

Yes ☐	No ☐	Not sure☐	Not applicable ☐

9. Would you prefer MARIA® to your MRI?

Yes ☐	No ☐	Not sure☐	Not applicable ☐

10. Finally, do you have any other feedback? If so, please write this below:

.....
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.....
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This questionnaire can be completed at your visit and passed to a member of the research team OR you can take this questionnaire home and complete later. Once complete, please return to the study team in the stamped and addressed envelope provided.

Thank you

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Fig. 3: The participant questionnaire used during the research.

The study was approved by Yorkshire & The Humber Research Ethics Committee on 16 January 2019.

Results/Findings and procedure details

The response rate for the questionnaire was 95% (19/20 participants). After review of the returned questionnaires, most participants reported a comfortable scanning experience (n=16/19) and found it generally easy to position themselves for the scan (n=18/19). Participants also welcomed the fact that MARIA® does not use ionising radiation, with 18 of the 19 responders stating that this was important to them. Another key positive attribute of the MARIA® system is the lack of breast compression, which 12 out of 19 responders stated was important. When asked if they would recommend MARIA® to a friend, 17/19 said they would, with the other 2 stating they were not sure.

Question	Response (n)				
Was it easy to position yourself for the scan?	Very easy (8)	Fairly easy (10)	Average (1)	Fairly difficult (0)	Very difficult (0)
How comfortable did you find this in general?	Very comfortable (3)	Fairly comfortable (13)	Average (2)	Fairly uncomfortable (1)	Very uncomfortable (0)
Is it important to you that MARIA® does not use ionising radiation?	Yes (18)	No (0)	Not sure (1)		
Is it important to you that MARIA® does not compress the breast?	Yes (12)	No (3)	Not sure (4)		
Would you recommend MARIA® to a friend?	Yes (17)	No (0)	Not sure (2)		
Would you prefer MARIA® to your mammogram?	Yes (9)	No (1)	Not sure (2)	NA (7)	
Would you prefer MARIA® to your US?	Yes (5)	No (2)	Not sure (9)	NA (3)	
Would you prefer MARIA® to your physical breast examination?	Yes (4)	No (7)	Not sure (7)	NA (1)	
Would you prefer MARIA® to your MRI?	Yes (3)	N (0)	Not sure (7)	NA (8)	Not known (1)

Fig. 4: The results from the research

A few questions were then asked about preferences when compared to other procedures. Nine of the nineteen participants stated that they did prefer MARIA® to their mammogram. However, X participants had not had a mammogram so were unable to select their preference. These responders answered with “not applicable”. A similar outcome was found for comparisons to ultrasound, MRI, and the physical breast examination, with some participants also stating that they would have whichever procedure was the best for them even if that involved some degree of discomfort.

The free text box of the questionnaire enabled participants to feedback in their own words. Within this feedback were several examples whereby participants made suggestions on improvements to the bed design concerning the position of their head and neck, and the contralateral breast.

Conclusions

Participant questionnaires are an important source of unbiased feedback on the MARIA® device and the scanning procedure that have not been well utilised to date. Many of the areas highlighted, both positive and negative, are known to the company and participant opinion is vital for future iterations of the device.

This was a small study where the primary focus was the clinical research and the collection of the participant feedback. Due to the small sample, trend analysis is challenging, but it is possible to see clear areas where participants are expressing similar opinions. The low average age of the participants (y=42.5) means that potential feedback on positioning and comfort might be more favourable due to younger age.

Moving forward, all eligible participants will be invited to complete a questionnaire of their experience after their scan.

Personal information and conflict of interest

R. Sidebottom; Cheltenham/UK - Consultant at Micrima - Research/Grant Support at Micrima I. Lyburn; Cheltenham/UK - Consultant at Micrima E. J. Cornford; Cheltenham/UK - nothing to disclose C. Gillett; Bristol/UK - Employee at Micrima J. Graham; Bristol/UK - Employee at Micrima

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[2] M. Shere, I. Lyburn, R. Sidebottom, H. Massey, C. Gillett, L. Jones, MARIA M5: A mulitcentre clinical study to evaluate the ability of the Micrima radio-wave radar breast imaging system (MARIA) to detect lesions in the symptomatic breast, EJR 116 (2019) 61-67, https://doi.org/10.1016/j.ejrad.2019.04.017

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