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Supporting Information

Supplementary methods and results

**This appendix was part of the submitted manuscript and has been peer reviewed.
It is posted as supplied by the authors.**

Appendix to: Houssami N, Lockie D, Clemson M, et al. Pilot trial of digital breast tomosynthesis (3D mammography) for population-based screening in BreastScreen Victoria. *Med J Aust* 2019; doi: 10.5694/mja2.50320.

1. Breast tomosynthesis study information sheet for women attending breast screening at Maroondah BreastScreen

Research at Maroondah BreastScreen

We are doing research to evaluate the use of tomosynthesis (3D-mammography) in the BreastScreen Australia program. This sheet provides information about this research so you can decide if you want to be involved.

What is the research for?

BreastScreen Victoria services have been using standard 2D-mammography for the past 20 years. In 2D-mammography, two single X-rays are taken of each breast. This test has been proven highly effective in detecting breast cancer.

Tomosynthesis, also known as 3D-mammography, is a new technology that takes multiple x-rays from different angles. This allows a computer to create 3D images of the breast. Overseas research has shown that using 3D-mammography could increase breast cancer detection.

The reason for this research is to find out if 3D-mammography improves screening outcomes for Australian women and if it is feasible to use it for screening in the BreastScreen program.

Who are the researchers?

The research is a partnership between BreastScreen Victoria, Eastern Health and the University of Sydney. The research is funded by the National Breast Cancer Foundation and approved by the Eastern Health Human Research Ethics Committee.

What happens if I agree to participate?

Women agreeing to participate in this research will receive by chance either a 2D or 3D-mammogram. Your appointment will be the same as a standard 10-minute appointment and, in other respects, the mammogram procedure is the same for all women.

Who is taking part in this research?

Over 12 months we anticipate screening 8500 women at Maroondah BreastScreen and of the women screened, five thousand women will receive by chance screening tomosynthesis.

What are the risks?

Each time you have a mammogram, your breasts are exposed to a small amount of radiation. By participating in this research you are likely to receive a slightly increased dose of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv) each year. The additional effective dose you may receive from entering this trial is approximately 0.2mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too low to measure and any risk is believed to be extremely low.

What are the benefits?

Your participation will contribute to finding out if 3D-mammography is practical for use in screening for breast cancer in the Australian setting. Following this research more informed decisions can be made about the feasibility of using tomosynthesis for screening in a larger population based study.

Privacy

The information that we collect from this research will be kept confidential. More information: www.breastscreen.org.au/privacy

Research results

We will publish the results in medical and scientific journals.

It is your choice

It is your choice to be involved. If you choose not to be involved, you will still receive the standard 2D-mammogram. **If you do not wish to participate in this research, please tell the receptionist when you arrive for your appointment.**

2. Service preparation for the trial

Maroondah BreastScreen commenced using tomosynthesis for assessing positive screens in 2013. The implementation of tomosynthesis for screening in the pilot trial required significant changes to the Client Information System (CIS) and the Picture Archiving and Communication System (PACS). The CIS was upgraded to separately identify women who had standard mammography or tomosynthesis (3D), to allow electronic data entry for 3D images, to enable readers to read by modality (batching 3D reads), to record reading time, to flag lesions detected only in the 3D image, and to record client decisions to opt out of tomosynthesis. A new automatic 3D hanging protocol was developed for PACS.

Training in tomosynthesis screen reading was provided to radiologists, and focus groups for radiographers and receptionists explored the study design and managing women's questions and expectations. It was important that women were aware that 2D mammography is "standard care" and were given the opportunity to opt out of tomosynthesis screening. A script was provided to receptionists for explaining the study to women.

3. BreastScreen Victoria tomosynthesis trial: interim analysis of radiation dose measures

Prepared by John CP Heggie AM, Consultant Medical Physicist, BreastScreen Victoria, 6 June 2018

Two mammography units with different specifications were used in 2D mode at BreastScreen Maroondah; only one of these units was used for tomosynthesis acquisitions. The units acquire images and estimate breast thickness using different techniques, so data should be interpreted cautiously in light of these differences.

Descriptive analysis of the 2D mode is shown in Table 1. From the dosimetry perspective, the two machines use different internal models to estimate the mean glandular dose (MGD) associated with imaging. The Hologic unit possibly requires a slightly higher dose per view than the Siemens unit (mean ratio, over all breast thicknesses: 1.07; standard deviation, 0.55), but the difference is not statistically significant.

Table 1. Comparison of displayed mean glandular dose (MGD), with standard deviation (SD), for the two screening units in 2D mode

	2D Hologic unit			2D Siemens unit			
Thickness range	Number of images	MGD (mGy)	SD	Number of images	MGD (mGy)	SD	**Ratio**
< 36 mm	16	0.73	0.18	458	0.93	0.22	0.78
36–45 mm	26	0.83	0.12	964	1.01	0.22	0.82
46–55 mm	51	1.11	0.18	1922	1.15	0.26	0.96
56–65 mm	58	1.55	0.35	2456	1.30	0.30	1.19
66–75 mm	47	1.67	0.44	1765	1.50	0.35	1.11
> 75 mm	56	1.84	0.70	968	1.92	0.51	0.96
All	254	1.42	0.57	8533	1.32	0.004	1.07 (SD, 0.55)

Descriptive analysis of displayed dose for Hologic 3D and Siemens 2D mode is shown in Table 2. The data indicate that the breasts imaged in 3D mode were, on overage, substantially thicker than those imaged in 2D mode. A possible explanation would be that less compression was used in 3D mode, but this is not supported by an examination of the compression data (3D, mean 83 N [SD, 25 N]; 2D, 82 N [SD, 22 N]). It is more likely that the accuracy of the compressed breast thickness indicated on the images and included in the Digital Imaging and Communications in Medicine (DICOM) header may differ between the two units. Measurements during the final week of May 2018 using polymethyl methacrylate (PMMA) sheets, which may or may not replicate the situation when imaging breasts, suggest that the Hologic unit may overestimate thickness by as much as 3 mm, the Siemens unit by only 1 mm. This may partially explain the difference in thicknesses in the 2D and 3D data. The difference may seem minor, but it does have implications for any estimate of MGD for a particular image because the internal dose model assumes that the indicated breast thickness is the true thickness. Using the displayed MGD value as an indicator of relative dose may therefore be problematic when more than one machine is used. Nevertheless, the Hologic 3D MGD values are higher than those of Siemens 2D (mean ratio, 1.9).

Table 2. Comparison of displayed mean glandular dose (MGD), with standard deviation (SD), for Hologic 3D and Siemens 2D modes

	3D Hologic unit			2D Siemens unit			
Thickness range	Number of images	MGD (mGy)	SD	Number of images	MGD (mGy)	SD	**Ratio**
< 36 mm	247	1.12	0.02	458	0.93	0.22	1.21
36–45 mm	696	1.34	0.12	964	1.01	0.22	1.33
46–55 mm	1243	1.69	0.17	1922	1.15	0.26	1.47
56–65 mm	2117	2.21	0.17	2456	1.30	0.30	1.70
66–75 mm	2203	2.88	0.22	1765	1.50	0.35	1.91
> 75 mm	1986	3.67	0.39	968	1.92	0.51	1.92
All	8492	2.55	0.83	8533	1.32	0.42	1.92 (SD, 0.87)

4. Screen reading times for tomosynthesis and standard mammography*

Table 3. Mean and median screen reading times, complete and truncated, by time period. The analysis includes all data from double-reading (ie, excluding the third reads undertaken for a minority of screens)

	Tomosynthesis		Standard mammography	
Analysis	**Number of reads**	**Reading time (s)**	**Number of reads**	**Reading time (s)**
All screen readings	10 035†		10 332†	
Mean (SD)		130 (382)		43 (264)
Median (IQR)		67 (46–105)		16 (10–29)
Data truncated at 300 second‡	10 035		10 332	
Mean (SD)		92 (71)		30 (46)
Median (IQR)		67 (46–105)		16 (10–29)
All screen readings, by time period, mean (SD)				
18 August 2017 – 31 December 2017	2950	156 (470)	3066	56 (363)
1 January 2018 – 31 May 2018	3470	143 (416)	3050	40 (254)
1 June 2018 – 9 November 2018	3615	98 (242)	4216	35 (167)
Data truncated at 300 seconds, by time period, mean (SD)‡				
18 August 2017 – 31 December 2017	2950	99 (74)	3066	30 (50)
1 January 2018 – 31 May 2018	3470	94 (73)	3050	31 (48)
1 June 2018 – 9 November 2018	3615	84 (65)	4216	29 (42)

IQR = interquartile range; SD = standard deviation.

* Screen-reading time distribution was skewed (very dispersed from average observation); as a result, the mean and median values differed substantially. Statistical testing of significance of differences in reading time was not performed given the large difference in reading times, tomosynthesis consistently taking 3–4 times as long as mammography

† Counts are twice the numbers of screens because analysis based on data from double reading.

‡ Values exceeding 300 seconds were deemed implausible; they are probably attributable to the reader not closing read or interrupted reading.