# Pilot trial of digital breast tomosynthesis (3D mammography) for population-based screening in BreastScreen Victoria

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**The known:** Overseas studies have found that digital breast tomosynthesis (3D mammography) can increase breast cancer detection rates and reduce the frequency of unnecessary recalls for assessment.

**The new:** Our prospective pilot trial of population-based tomosynthesis screening in Maroondah BreastScreen found that more breast cancers were detected by tomosynthesis (9.8 [95% CI, 7.2–13] per 1000 screens) than by standard mammography (6.6 [95% CI, 4.6–9.2] per 1000 screens), but the recall rate was also higher (4.2% *v* 3.0%).

**The implications:** Tomosynthesis breast screening is feasible if infrastructure and service preparation are adequate. Our findings could inform larger evaluations of tomosynthesis and standard mammography for breast screening in BreastScreen.


## Abstract

**Objectives:** To estimate detection measures for tomosynthesis and standard mammography; to assess the feasibility of using tomosynthesis in population-based screening for breast cancer.

**Design, setting:** Prospective pilot trial comparing tomosynthesis (with synthesised 2D images) and standard mammography screening of women attending Maroondah BreastScreen, a BreastScreen Victoria service in the eastern suburbs of Melbourne.

**Participants:** Women at least 40 years of age who presented for routine breast screening between 18 August 2017 and 8 November 2018.

**Main outcome measures:** Cancer detection rate (CDR); proportion of screens that led to recall for further assessment.

**Results:** 5018 tomosynthesis and 5166 standard mammography screens were undertaken in 10 146 women; 508 women (5.0% of screens) opted not to undergo tomosynthesis screening. With tomosynthesis, 49 cancers (40 invasive, 9 in situ) were detected (CDR, 9.8 [95% CI, 7.2–13] per 1000 screens); with standard mammography, 34 cancers (30 invasive, 4 in situ) were detected (CDR, 6.6 [95% CI, 4.6–9.2] per 1000 screens). The estimated difference in CDR was 3.2 more detections (95% CI, −0.32 to 6.8) per 1000 screens with tomosynthesis; the difference was greater for repeat screens and for women aged 60 years or more. The recall rate was greater for tomosynthesis (4.2%; 95% CI, 3.6–4.8%) than standard mammography (3.0%; 95% CI, 2.6–3.5%; estimated difference, 1.2%; 95% CI, 0.46–1.9%). The median screen reading time for tomosynthesis was 67 seconds (interquartile range [IQR] 46–105 seconds); for standard mammography, 16 seconds (IQR, 10–29 seconds).

**Conclusions:** Breast cancer detection, recall for assessment, and screen reading time were each higher for tomosynthesis than for standard mammography. Our preliminary findings could form the basis of a large scale comparative evaluation of tomosynthesis and standard mammography for breast screening in Australia.

**Trial registration:** Australian New Zealand Clinical Trials Registry, ACTRN12617000947303.


Two-dimensional (2D) x-ray mammography is the only public health strategy officially endorsed for population breast screening with the aim of reducing breast cancer mortality.[1–3] Digital breast tomosynthesis, or three-dimensional (3D) mammography, has recently been introduced as an alternative screening modality. In tomosynthesis, a series of low dose x-ray images of the breast are obtained from a range of angles, from which millimetre-thick cross-sections are constructed for sequential viewing. This approach reduces a problem encountered with standard mammography: overlapping breast parenchyma can both obscure breast cancers and simulate the appearance of abnormalities, consequently increasing the likelihood of false negative and false positive findings.[4–6] Prospective non-randomised trials in European screening programs have found that employing tomosynthesis in addition to or instead of 2D-mammography increases the detection of breast cancers by 2.2 to 2.7 instances per 1000 screens.[5–7] Randomised trials comparing tomosynthesis and standard mammography screening are underway overseas,[8] but whether tomosynthesis screening has an incremental health benefit is not yet known.[1,6]

Tomosynthesis is used in some radiology services and breast centres in Australia, but it is not endorsed for screening by the national screening program, BreastScreen. We report the first population-based pilot trial of digital breast tomosynthesis screening in Australia. In this prospective trial, embedded in the BreastScreen Victoria program, we assessed detection measures and the feasibility of implementing tomosynthesis screening, and provide data from the local screening program to inform evaluation of this new mammography technique.

## Methods

The main aims of our prospective trial were to estimate screening detection measures (cancer detection and recall rates) for standard and tomosynthesis screening, and to determine the feasibility of tomosynthesis breast screening in Australia by investigating its implementation in a population-based screening service and examining selected secondary outcomes.

### Trial design and setting

The prospective trial, embedded in Maroondah BreastScreen (Eastern Health, Melbourne), commenced in August 2017. It was prospectively registered with the Australian New Zealand Clinical Trials Registry on 3 July 2017 (ACTRN12617000947303).

Maroondah BreastScreen provides routine biennial screening as part of the BreastScreen Victoria program. Maroondah BreastScreen has two screening rooms, one equipped with a tomosynthesis-capable mammography unit, the other with a

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• doi: 10.5694/mja2.50320 • See Editorial (Brennan).

standard mammography unit; whether a woman received tomosynthesis or standard screening in this trial was determined by which room was available when she was called in for screening (unless she had opted not to be considered for tomosynthesis screening). The women who underwent standard mammography comprised a natural control group for the trial, allowing comparison of our findings with those of conventional screening (Box 1).

### Eligible population and trial information

BreastScreen targets women aged 50–74 years, but also allows women aged 40–49 years and older women to be screened. All women who presented to Maroondah BreastScreen for breast screening were invited to participate in the study. A trial-specific information sheet (Supporting Information) was provided in the pre-attendance information package for women who had booked a screening appointment and to women who presented for screening. BreastScreen services provide written information about screening and require written consent from participants, and trial-specific information and consent forms were integrated into the BreastScreen information processes. Women were informed that they could be screened by tomosynthesis or standard mammography; women who opted not to undergo tomosynthesis were automatically assigned to standard mammography. Women unable to provide consent for routine mammography screening were deemed ineligible for the study.

### Screening technique and screen reading

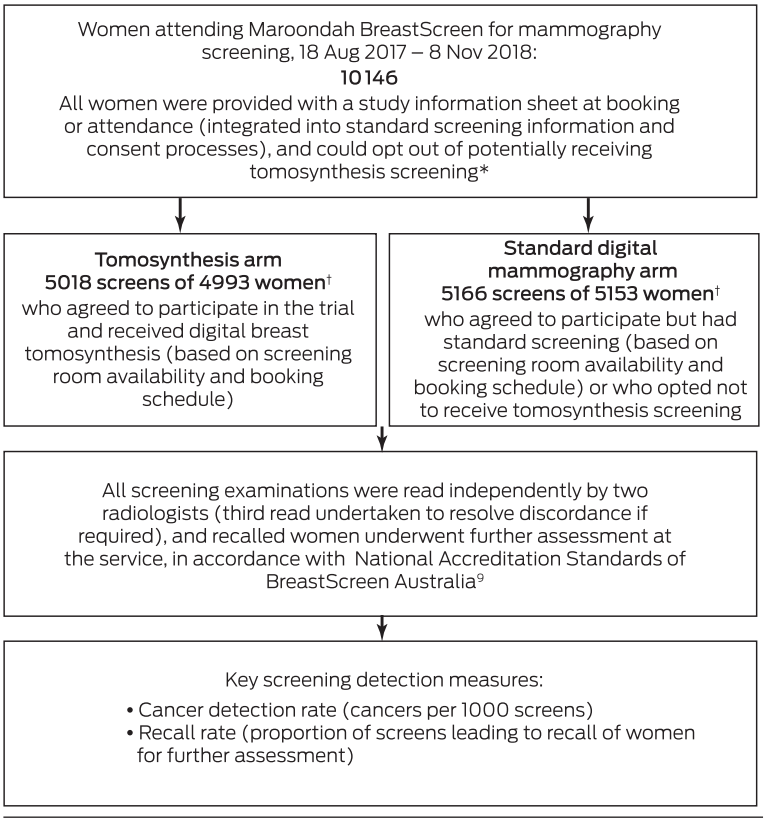
For tomosynthesis screening (3D mammography), two-dimensional images were also synthesised from the x-ray images of the breast (Selenia Dimensions 8000, with C-View 2D software, Hologic). Screen-readers viewed both the 3D and 2D images. Tomosynthesis has been available at Maroondah BreastScreen since 2013 for assessing screening-detected abnormalities. Routine mammography was performed with one of two units (Selenia Dimensions 8000, Hologic; Mammomat Inspiration, Siemens). In both techniques, mediolateral oblique and cranio-caudal views of each breast were obtained. Screen reading time — the time between a radiologist opening a woman's images for reading and their recording the screening outcome (clear or recall) — was measured automatically.

All other aspects of screening, screen reading and assessment, and follow-up were based on the National Accreditation Standards of BreastScreen Australia.[9] Findings deemed suspicious at assessment were investigated by image-guided needle biopsy (including tomosynthesis-guided biopsy when required). The routine BreastScreen practice of double reading (two independent readings per screen), was followed; disagreements between readers were resolved by a third, independent read. Seven radiologists assessed screens from both arms of the trial; each had about 5 years' clinical experience in using tomosynthesis to assess mammography-detected findings and had received additional training in tomosynthesis screen reading before the trial commenced. Further information on the preparation of the service for the trial is included in the online Supporting Information.

### Outcomes

The primary outcomes were the number of detected cancers and the cancer detection rate (CDR), based on the results of excision histology (for women who underwent surgery), and the number and proportion of recalls, based on the complete screen assessments for women who were recalled, including details on work-up imaging and needle biopsy histology results when applicable. Secondary outcomes, evaluated for assessing the feasibility of tomosynthesis for routine breast screening, were acceptability to women (proxy measure: opting out of tomosynthesis) and screen reading time. Further secondary outcomes included the characteristics of detected cancers (size, histology, grade, node status, biomarkers). An interim analysis of radiation dose estimates was also undertaken (Supporting Information).

**1 Design for our pilot trial of digital breast tomosynthesis, population-based screening by Maroondah BreastScreen, Victoria**




* Reception staff checked whether each woman had received trial information and verified their consent; a laminated study information sheet was also displayed in the reception area where women wait to be called in for screening. The radiographer could provide additional information about the trial if requested. † Thirty-eight women who were screened annually had two screening episodes each during the trial. ◆

### Statistical analysis

The trial was designed to estimate detection measures for tomosynthesis screening and to determine its feasibility, with an implementation time of about 14 months. Based on aggregate data from BreastScreen Victoria (CDR, 7.25 per 1000 screens)[9] and the reported increase in CDR of at least two extra detections per 1000 screens in European trials of tomosynthesis breast screening,[5–7] we estimated a CDR of 9.0 detected cancers per 1000 screens with tomosynthesis; for a sample size of 5000 screens, we estimated that the standard error would be about 1.3 per 1000 screens, which we deemed adequately precise for estimating CDR in our pilot study.

The characteristics of the screened women in the two screening groups were compared in Fisher exact tests (proportions) or independent samples *t* tests (continuous data). CDRs and

proportions of recalls were computed for each screening modality, with exact (Clopper–Pearson) 95% confidence intervals (CIs); differences between groups were calculated, with Miettinen–Nurminen 95% CIs. Results were stratified by screening round (first [prevalent] screen or subsequent [incident] screen) and by age group.

Sensitivity analyses assessed whether excluding second screens for individual women during the study period or excluding women who reported symptoms at the time of screening (lump or "lumpy", nipple change or discharge, pain or tenderness, non-specific symptoms) influenced the estimated CDRs or recall proportions or between-group differences in these estimates. Screen reading time and cancer characteristics were summarised as descriptive statistics. Analyses were conducted in SAS 9.4 (SAS Institute).

### Ethics approval

The trial was granted ethics approval by the Eastern Health Human Research Ethics Committee (reference, LR36/2017).

## Results

From 18 August 2017 to 8 November 2018, 10 146 women presented to Maroondah BreastScreen for 10 184 screening examinations (38 women undergoing annual screening each had two screens during the trial): 5018 tomosynthesis and 5166 mammography screens. A total of 508 women (5.0% of screens) opted not to undergo tomosynthesis screening (Box 2).

Women were recalled for further assessment following 210 tomosynthesis screens (4.2%; 95% CI, 3.6–4.8%) and 155 mammography screens (3.0%; 95% CI, 2.6–3.5%); the estimated difference in proportion was 1.2% (95% CI, 0.46–1.9%). Sensitivity analyses that excluded the second screens for the 38 women who were screened twice during the study period or women who reported symptoms at screening yielded similar results. The recall rates for women under 60 and for those aged 60 years or more were similar (Box 3).

### Breast cancer detection

A total of 49 breast cancers (40 invasive, nine ductal carcinoma in situ) were detected by tomosynthesis screening (CDR, 9.8 per 1000 screens; 95% CI, 7.2–13 per 1000 screens); 34 breast cancers (30 invasive, four in situ) were detected by standard mammography (CDR, 6.6 per 1000 screens; 95% CI, 4.6–9.2 per 1000 screens). The estimated difference in CDR was 3.2 more detected cancers per 1000 screens with tomosynthesis (95% CI, 0.32 fewer to 6.8 more per 1000 screens); the difference was more marked for incident than first round screens, and also greater for women aged 60 years or more than for younger women. Sensitivity analyses that excluded the second screens for the 38 women who were screened twice during the study period or women who reported symptoms at screening yielded similar results (Box 4, Box 5).

The mean tumour size of invasive cancers detected by tomosynthesis was 16.4 mm (standard deviation [SD], 12.9 mm), and 16.8 mm (SD, 12.3 mm) for those detected by mammography; for 24 of 40 cancers detected by tomosynthesis (60%) and 18 of 30 cancers detected by standard mammography (60%) the maximum diameter was no more than 15 mm ("small" cancers in the BreastScreen program) (Box 5).

Surgical treatment was recommended to all 83 women in whom breast cancers were detected. Surgical biopsy was also recommended for nine tomosynthesis-screened and two mammography-screened women, all of whom were found to have benign conditions.

**2 Characteristics of the 10 146 women who underwent tomosynthesis or standard mammography screening at Maroondah BreastScreen, 18 August 2017 – 8 November 2018**

| Characteristic | Tomosynthesis* | Standard mammography | *P* |
|---|---|---|---|
| Number of screens | 5018 | 5166† | |
| Age (years) | | | |
| Mean (SD) | 58.0 (8.4) | 62.3 (8.1) | < 0.001 |
| Range | 40–91 | 40–93 | — |
| Screening round | | | < 0.001 |
| First (prevalent) screen | 980 (19.5%) | 350 (6.8%) | |
| Subsequent (incident) screen | 4038 (80.5%) | 4816 (93.2%) | |
| Breast symptom reported‡ | 380 (7.6%) | 283 (5.5%) | < 0.001 |
| Family history of breast cancer | 1492 (29.7%) | 1499 (29.0%) | 0.43 |
| Personal history of breast cancer | 33 (0.7%) | 31 (0.6%) | 0.71 |

SD = standard deviation. * Digital breast tomosynthesis (3D) acquisition with synthesised 2D images. † Includes 508 women (mean age, 61.4 years; SD, 8.3 years) who opted not to undergo tomosynthesis screening, of whom 439 (86.4%) were having incident screens. ‡ Including lump or "lumpy", nipple change or discharge, pain or tenderness, and non-specific symptoms. ◆

### Screen reading time

The median screen reading time for tomosynthesis was 67 seconds (interquartile range [IQR] 46–105 seconds). The median screen reading time for standard mammography was 16 seconds (IQR, 10–29 seconds) (further details, including mean values, in the online Supporting Information).

## Discussion

For the first trial of digital breast tomosynthesis screening within the Australian population breast screening program, we recruited women attending Maroondah BreastScreen for routine screening. Our pilot provides comparative estimates of detection measures for tomosynthesis and standard mammography screening of participants from one population attending one breast cancer screening service. We found that it was feasible to implement tomosynthesis screening at BreastScreen Maroondah, with a low opt-out rate, and that tomosynthesis could increase the breast cancer detection rate. However, it also had disadvantages, such as longer screen reading times, that need to be considered when making decisions about larger trials of tomosynthesis screening or screening policy.

Our pilot trial was not designed to allow statistical comparisons of CDRs for tomosynthesis and standard mammography; our aim was to provide robust preliminary CDR estimates for tomosynthesis screening for informing decisions about larger evaluations. Nonetheless, the higher estimated CDR for tomosynthesis (an extra 3.2 [95% CI, –0.32 to 6.8] detections per 1000 screens) suggests that the newer technique detects more breast cancers.

**3 Screening recall: number of screened women who were recalled for further assessment, by screening modality**

| Analysis | Tomosynthesis | | | Standard mammography | | | Difference in proportion (95% CI) |
|---|---|---|---|---|---|---|---|
| | Screens | Recalls | Proportion (95% CI) | Screens | Recalls | Proportion (95% CI) | |
| All screens* | 5018 | 210 | 4.2% (3.6–4.8%) | 5166 | 155 | 3.0% (2.6–3.5%) | 1.2% (0.46–1.9%) |
| By screening round | | | | | | | |
| First (prevalent) screen | 980 | 74 | 7.6% (6.0–9.4%) | 350 | 26 | 7.4% (4.9–10.7%) | 0.12% (–3.4% to 3.1%) |
| Incident screen | 4038 | 136 | 3.4% (2.8–4.0%) | 4816 | 129 | 2.7% (2.2–3.2%) | 0.69% (–0.02% to 1.4%) |
| By age group | | | | | | | |
| < 60 years | 3012 | 128 | 4.2% (3.6–5.0%) | 1988 | 63 | 3.2% (2.4–4.0%) | 1.1% (–0.01% to 2.1%) |
| ≥ 60 years | 2006 | 82 | 4.1% (3.3–5.0%) | 3178 | 92 | 2.9% (2.3–3.5%) | 1.2% (0.18–2.3%) |
| Sensitivity analyses | | | | | | | |
| Second screens excluded† | 4993 | 209 | 4.2% (3.6–4.8%) | 5153 | 153 | 3.0% (2.5–3.5%) | 1.2% (0.50–2.0%) |
| Screens of women who reported symptoms excluded | 4638 | 193 | 4.16% (3.6–4.8%) | 4883 | 144 | 3.0% (2.5–3.5%) | 1.2% (0.47–2.0%) |

CI = confidence interval. * Does not include re-screening for technical reasons (mammography group, two; tomosynthesis group, none). † Excluded second screens for 38 women undertaken during the trial period. The results of a further sensitivity analysis that excluded both screens for these women yielded similar results (data not shown). ◆

The lower mean age and higher proportion of first screens in the tomosynthesis arm than in the control arm of the trial would be expected to have opposing effects on CDR (lower rates for younger women, higher rates for first screens). Stratified analyses indicated, however, that estimated CDRs were similar for first and incident screens in the tomosynthesis group. The between-group difference in CDR was greater for incident (subsequent) than first (prevalent) screens, and it is notable that 71 of 83 breast cancers identified in the two groups during the trial were identified by incident screens. We also found that the between-group difference in CDR for women aged 60 years or more (7.0 [95% CI, 1.1–14] more detections per 1000 screens with tomosynthesis) was similar to the finding of a European tomosynthesis trial (4.0 more detections per 1000 screens of women aged 60 years or more).[5] Our stratified results indicate that it is unlikely that differences between the two study arms in mean age or the proportion of first screens affected our findings. Further, excluding data for women who reported breast-related symptoms did not substantially alter our estimates of CDR or differences in CDR.

**4 Breast cancer detection: number of detected cancers and cancer detection rate (CDR, per 1000 screens), by screening modality**

| Analysis | Tomosynthesis | | | Standard mammography | | | CDR difference, per 1000 screens (95% CI) |
|---|---|---|---|---|---|---|---|
| | Screens | Detections | Estimated CDR, (95% CI) | Screens | Detections | Estimated CDR (95% CI) | |
| All detected breast cancers | 5018 | 49 | 9.8 (7.2–13) | 5166 | 34 | 6.6 (4.6–9.2) | 3.2 (–0.32 to 6.8) |
| By screening round | | | | | | | |
| First (prevalent) screen | 980 | 9 | 9 (4–17) | 350 | 3 | 9 (2–24) | 0.6 (–16 to 11) |
| Subsequent (incident) screen | 4038 | 40 | 9.9 (7.1–14) | 4816 | 31 | 6.4 (4.4–9.1) | 3.5 (–0.26 to 7.5) |
| By age group | | | | | | | |
| < 60 years | 3012 | 18 | 6.0 (3.6–9.4) | 1988 | 7 | 4 (1–7) | 2 (–2 to 6) |
| ≥ 60 years | 2006 | 31 | 15 (10–22) | 3178 | 27 | 8.5 (5.6–12) | 7.0 (1.1–14) |
| Sensitivity analyses | | | | | | | |
| Second screens excluded* | 4993 | 49 | 9.8 (7.3–13) | 5153 | 33 | 6.4 (4.4–9.0) | 3.4 (–0.08 to 7.1) |
| Screens of women who reported symptoms excluded | 4638 | 45 | 9.7 (7.1–13) | 4883 | 32 | 6.6 (4.5–9.2) | 3.2 (–0.46 to 6.9) |

* Excluded second screens for 38 women undertaken during the trial period. The results of a further sensitivity analysis that excluded both screens for these women yielded similar results (data not shown). ◆

**5 Characteristics of cancers detected by screening during the trial period, by screening modality**

| Tumour | Tomosynthesis | Standard mammography |
|---|---|---|
| Number of detected cancers | 49 | 34 |
| **Histology type** | | |
| Invasive breast cancer type | 40 | 30 |
| Invasive ductal carcinoma | 30 (75%) | 21 (70%) |
| Invasive lobular cancer | 5* (13%) | 7 (23%) |
| Invasive special or other types† | 5 (13%) | 2 (7%) |
| Ductal carcinoma in situ | 9 | 4 |
| Low grade | 1 (11%) | 0 |
| Intermediate grade | 6 (67%) | 0 |
| High grade | 2 (22%) | 4 (100%) |
| **Characteristics of invasive cancer** | | |
| Invasive cancer grade | | |
| Grade 1 (well differentiated) | 18 (45%) | 6 (20%) |
| Grade 2 (moderately differentiated) | 19 (48%) | 16 (53%) |
| Grade 3 (poorly differentiated) | 3 (8%) | 8 (27%) |
| Invasive cancer size (mm)‡ | | |
| ≤ 5 | 6 (15%) | 4 (13%) |
| 5.1–10 | 5 (13%) | 8 (27%) |
| 10.1–15 | 13 (33%) | 6 (20%) |
| 15.1–20 | 8 (20%) | 5 (17%) |
| > 20 mm | 8 (20%) | 7 (23%) |
| Axillary node status | | |
| No metastases | 34 (85%) | 24 (80%) |
| Metastases | 6 (15%) | 6 (20%) |
| Oestrogen/progesterone receptors§ | | |
| Positive for either | 36 (97%) | 27 (93%) |
| Negative for both | 1 (3%) | 2 (7%) |
| HER2 receptor status§ | | |
| HER2-positive | 5 (14%) | 0 |
| HER2-negative | 32 (87%) | 28 (100%) |

* Includes two mixed invasive ductal/lobular cancers. † Includes tubular, cribriform, and mucinous types. ‡ Tumours no more than 15 mm in size are classified as "small" cancers in the BreastScreen program. § Numbers do not sum to corresponding totals because of missing data. ◆

A greater number of invasive breast cancers were detected by tomosynthesis than by standard mammography (and the proportion of grade 1 cancers was higher); tomosynthesis also detected more ductal carcinomas in situ (including low and intermediate grade carcinomas). However, the numbers of detected breast cancers were too small for meaningful statistical comparisons. While initial studies suggested that the increased detection rate of tomosynthesis mostly involved invasive breast cancer,[6,7,10,11] our results are similar to the preliminary findings of a more recent randomised controlled trial which found that tomosynthesis increased the detection of both invasive and in situ malignancies.[8] More frequent cancer detection by tomosynthesis screening than in standard 2D mammography could indicate that it is more sensitive than standard mammography, but if it reflects increased detection of indolent malignancy it may not be associated with improved health outcomes. The International Agency for Research on Cancer has deemed the evidence that tomosynthesis reduces interval cancer rates inadequate; further, the available evidence is insufficient to determine whether the reduction in breast cancer mortality achieved by screening is greater for tomosynthesis screening than standard mammography.[1] Our pilot trial cannot fill these evidence gaps, which will require substantially larger studies with longer term end points.

We estimated recall rates of 4.2% (95% CI, 3.6–4.8%) for tomosynthesis and 3.0% (95% CI, 2.6–3.5%) for standard mammography screens, a 1.2% (95% CI, 0.46–1.9%) difference. The reported effects of tomosynthesis screening on recall rates have been heterogeneous, but in prospective studies it increased the recall rate by 0.5–1%[6,7] or had little effect,[8] findings consistent with ours. However, retrospective studies in the United States, where the mammography recall rate is generally higher than in Australia,[6,9] have found that tomosynthesis screening reduced the number of unnecessary recalls.[6] The recall rate associated with tomosynthesis screening may decline in Australia as screen readers become more experienced with the technique and have tomosynthesis screens from earlier screen rounds that can be compared with current screens.

As BreastScreen Australia does not routinely report mammographic breast density, we did not measure it in our trial, but it may be possible to derive this information from archived imaging data in order to report density-related screening outcomes, which would be useful given the recent discussion of breast density notification legislation.[12]

We found that that the screen reading time for tomosynthesis was about three times as long as for standard mammography, and was longer than reported by other authors.[13] Although automated measurement of reading time probably explains some implausible values being recorded (the results of interrupted reading, for instance) and the mean value for both screening techniques declined with time (Supporting Information, table 3), the mean reading time for tomosynthesis was consistently about three times as long as for standard mammography. Radiologists may have assessed tomosynthesis screens more meticulously because of the novelty of the technique and the context of a pilot trial.

The increased radiation exposure associated with tomosynthesis identified in our interim dosimetry report (Supporting Information, table 2) also needs careful consideration before adopting it for routine screening. The imaging data and information infrastructure (including image display and archiving) is another important aspect. Careful planning enabled modifications that supported implementation of tomosynthesis in this pilot trial, but substantial changes would be needed to facilitate its use in a high volume population screening program, and would be subject to a thorough health economics evaluation.

## Limitations

Our pilot study did not have sufficient power to allow assessment of the statistical significance of the differences in CDR between the two screening modalities, or for assessing differences in interval cancer rates. These endpoints would require larger studies with adequate follow-up of screened women to identify interval cancers. We inferred acceptability of tomosynthesis for women from the proxy measure of opting out of tomosynthesis;

acceptability would ideally be assessed more directly in screened women.

## Conclusion

Our pilot trial of tomosynthesis screening in a BreastScreen service found that breast cancer detection and recall rates were higher than for standard mammography. Tomosynthesis entailed longer screen reading times and exposure to higher radiation doses than standard mammography, and also required additional infrastructure. Higher detection rates for both invasive and in situ breast cancers indicate that tomosynthesis screening could have health benefits for women or lead to overdiagnosis of malignancies. Our trial provides findings that could be further examined in larger, multi-service comparisons of tomosynthesis with standard mammography for breast screening, including longer term endpoints (such as interval cancer rates) that were beyond the scope of our pilot study. The balance between the incremental benefit and harms of this new technology must be carefully assessed to ensure that BreastScreen provides the most effective form of screening to Australian women.

**Acknowledgements:** The study was funded by a National Breast Cancer Foundation (NBCF) Australia pilot study grant. Nehmat Houssami is funded by an NBCF Breast Cancer Research Leadership Fellowship. We thank Sue Viney and John Heggie for important contributions to our study. We thank the radiology, radiography, data and administrative staff at Maroondah BreastScreen, and also thank the information technology staff, the client communications and recruitment team, and the data management staff at BreastScreen Victoria for helping us implement the trial. We thank the women who attended Maroondah BreastScreen and participated in the study.

**Competing interests:** No relevant disclosures.

Received 26 April 2019, accepted 19 June 2019 ■



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## Supporting Information

Additional Supporting Information is included with the online version of this article.