BreastScreen Victoria tomosynthesis screening trial, Maroondah pilot: Preliminary Outcomes

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BreastScreen Victoria pilot trial of the feasibility and outcomes of tomosynthesis (3D-mammography) screening at Eastern Health [Trial ACTRN12617000947303]

Funded through a *National Breast Cancer Foundation* (Australia) Pilot Study Grant

Team of Investigators

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- Ms Vicki Pridmore, BreastScreen Victoria
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- Ms Sue Viney, Consumer Representative
- Dr Michael Luke Marinovich, University of Sydney
- Ms Genevieve Webb, BreastScreen Victoria
- Mr Matthew Scanlon, BreastScreen Victoria

DECLARATIONS and CONFLICTS

None to declare

OBJECTIVE

To examine the feasibility and screen-detection outcomes of routine tomosynthesis screening in women presenting to Maroondah BreastScreen, Eastern Health.

STUDY DESIGN

A prospective single arm screening trial embedded in a population-based mammographic screening service

PLANNED SAMPLE SIZE

5,000 women will undergo 3D-mammography

PLANNED SAMPLE SIZE

5,000 women will

enable feasibility of implementing 3D into Screening

allow a robust estimation of screen cancer detection rates (given that breast cancer is not a frequent outcome)

SELECTION CRITERIA

Women over the age of 40 eligible for routine mammographic breast screen within the BSV program

EXCLUSION CRITERIA

- Women deemed unable to provide informed consent

- All women with disabilities who are unable to provide consent for 3D will have standard 2D-mammography.

- Implants where a ‘pushback’ cannot be obtained due to technical reasons will have standard 2D-mammography

STUDY PROCEDURE

Bilateral 2 views (MLO and CC) 3D acquisition using HOLOGIC Selenia Dimensions

Acquisition time 3.7 seconds

reconstructed synthetic 2D images using HOLOGIC “C View” software

STUDY PROCEDURE

Reading

Standard double independent reading

Disagreement resolved by third Senior independent Reader

Assessment

3D screening images reviewed at Clinic

?require extra views ie 3D coned views, Mag views for Cal

Ultrasound /Surgical review / Biopsy

ANALYSIS PLAN

Primary analyses

- Cancer detection:
- number of detected cancers
- cancer detection rate per 1,000 screens (95% CI)
- Recall data:
- number recalled
- recall rate (%)
- false-positive recall % (95% CI)

ANALYSIS PLAN

- **<u>Secondary outcome measures</u>**
- Participation rates
- Screen-reading time for 3D compared to 2D
- Descriptive data on the characteristics of breast cancers (size, histology, grade, node status, and biomarkers)
- Data on assessment procedures and outcomes
- Quantitative measures of average radiation metrics: estimation of the breast mean glandular dose (mGy)

PRELIMINARY RESULTS

- Client Information
- Radiologist reading time
- Radiation dose estimates
- **Cancer detection metrics in Final Report**

PRELIMINARY RESULTS

- Client results based on 2026 3D episodes
- concurrent 2036 2D episodes for context
- Screening round
- Demographics
- Reading outcomes (Clear / Tech repeat / Recall)
- 3rd Read rates

Participation: 18 Aug 2017 to 20 Feb 2018

Received 3D	2026
Received 2D	2036
TOTAL	4062

Demographic data on the 2026 3D participants

age at screen date

57 (median)	52-64 (IQR)	40-82 (range)

family history

Yes	581	28.7%
No	1312	64.8%
NR	133	6.5%

previous history of Breast Cancer

Yes	12	0.6%
No	2014	99.4%

Demographic data on the 2026 3D participants

- **Screening round**

Round	2D		3D	
	N	%	N	%
1st Round	152	7.5	400	**19.7**
> 1st R	1884	92.5	1626	80.3
TOTAL	2036		2026	

- *Test of association between screening round and receipt of 2D or 3D: P<0.001*

Demographic data on the 2026 3D participants

- **Reading Outcomes**

Outcome	2D		3D		change
	N	%	N	%	
All Clear	1955	96.02	1918	94.67	
Tech	18	0.88	4	**0.20**	**- 65%**
Recall	63	3.09	104	**5.13**	**+ 66%**
TOTAL	2036		2026		

- *Test of association between screen-recommendation and receipt of 2D or 3D: P<0.001*

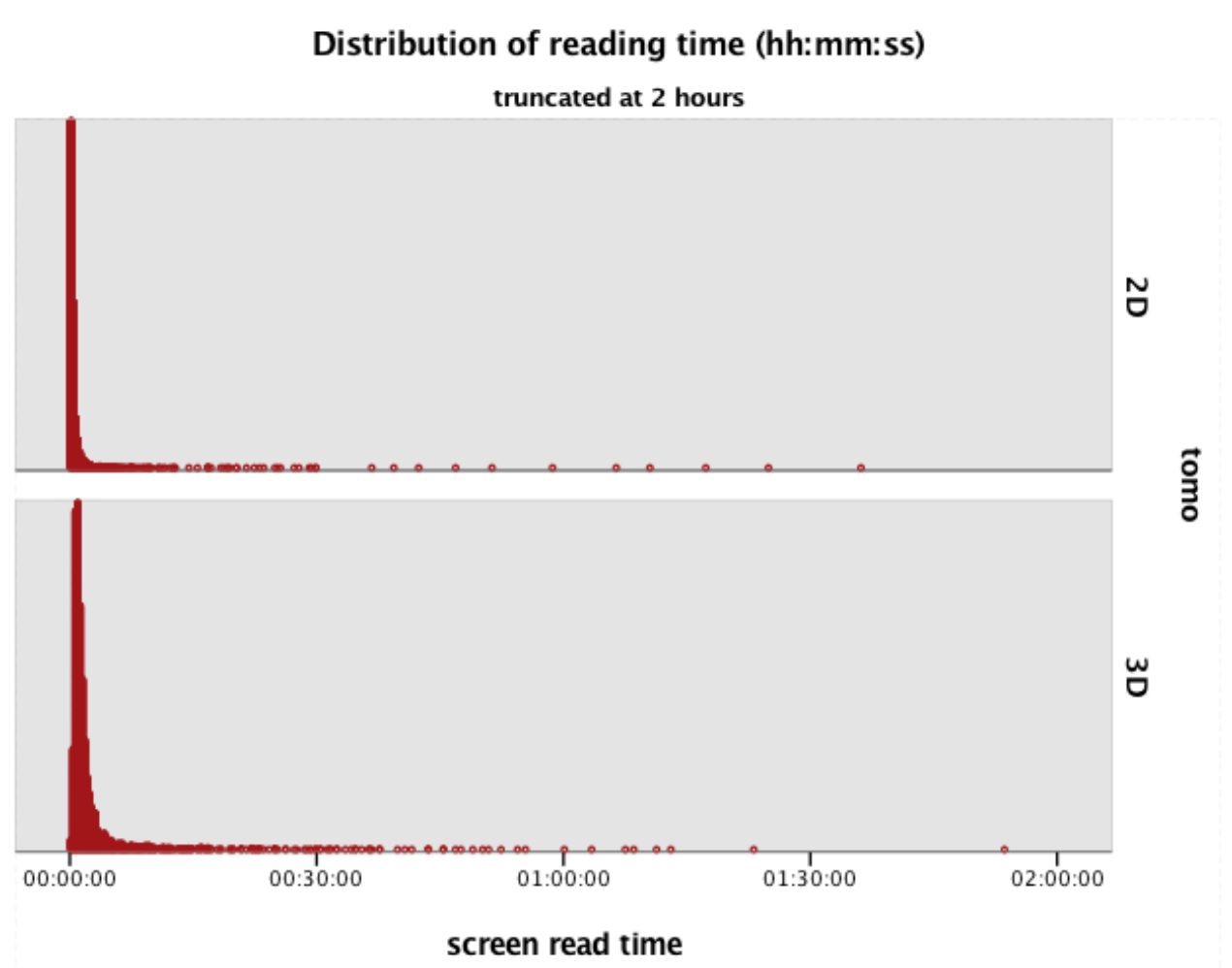
Demographic data on the 2026 3D participants

- **3rd Reading**

	2D		3D	
	N	%	N	%
2 reads	1913	93.96	1888	93.19
3rd read	123	6.04	138	6.81
TOTAL	2036		2026	

- *Test of association: P=0.32*

Radiologist Reading Times



Radiologist Reading Times

Read time (secs)	2D	3D	change
Number of reads	4072	4052	
Mean	**52.9**	**156.6**	**x3**
Standard Dev	327.6	450.5	
25th(Q1)	10	49	
Median	**16**	**70**	**x4**
75th(Q3)	29	116	

Radiation Dose Estimates

Dose *per client* (mGy)	**2D**	**3D**	
Number	2036	2026	
Total dose (4views) mean	**5.7**	**10.8**	**x1.9**
Total dose SD	2.0	3.9	
5th	3.5	5.3	
25th	4.4	8.0	
Median	**5.3**	**10.5**	**x2**
75th	6.4	13.1	
95th	9.5	17.2	

Radiation Dose Estimates

Dose/image (mGy)	2D	3D	
mean	1.3	2.5	x1.9
SD	0.4	0.8	

Average Breast Thickness

Thickness (mm)	2D	3D
Mean	**58.6**	**64.7**
Standard Dev	13.3	13.7
25th	50.5	56.0
Median	**59.3**	**65.8**
75th	67.8	74.5

Summary Interim Results

Interim results are not about effectiveness

inform us that:

- 3D screening is feasible in a local setting
- however 3D screening is resource intensive (increase reading time & recall)
- this will be examined at end of trial in the context of effect on CDR
- Dose data to be validated

Implications for the Future

- Local service data is essential
- results from international studies may not be generalizable to BreastScreen Australia
- By end of trial we will have sufficient data & information to make decisions on larger trials
- plan such trials using estimates from this pilot work

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