

BREASTSCREEN AUSTRALIA'S POSITION STATEMENT ON THE USE OF TOMOSYNTHESIS IN SCREENING AND ASSESSMENT

BreastScreen Australia is a population-based screening program for well women aged 50 to 74 years. BreastScreen Australia uses mammography to find breast cancer as early as possible while minimising potential harm to women. Early detection of breast cancer means women have the greatest number of treatment options available. Early treatment means women are less likely to die of breast cancer.

The Department of Health (Australia) commissioned a comprehensive review of the scientific literature on digital breast tomosynthesis to ensure that this position statement accurately reflects the current state of knowledge as at 1 January 2018 (for screening) and 30 June 2018 (for assessment).¹ As this is an active area of research, further amendments may be required as new evidence emerges. This statement acknowledges the extensive use of tomosynthesis in the assessment of screen-detected abnormalities within BreastScreen Australia programs.

KEY POINTS

Tomosynthesis is a type of mammogram. When used with two-view digital mammography, tomosynthesis increases test sensitivity but increases in test specificity are uncertain. It is not yet clear which imaging protocol is the safest and most effective at detecting breast cancer. Before recommending tomosynthesis as a screening test, further information that it is more effective, safer and saves more lives than two-view mammography alone is needed. Tomosynthesis improves the assessment of screen-detected abnormalities. BreastScreen Australia supports more research on tomosynthesis as a screening test.

Tomosynthesis is a type of mammogram

Tomosynthesis (also called 3D mammography or digital breast tomosynthesis), is used in the assessment and diagnosis of breast disease. Continuous low dose image slices are obtained through the breast and are usually reconstructed at 1 mm intervals to create a 3D image.

When used with two-view mammography, tomosynthesis increases test sensitivity but increases in specificity are uncertain

Data from prospective, fully paired studies embedded in population-based screening programs indicates that combining tomosynthesis and two-view mammography:

- increases the number of all cancers detected, and increases test sensitivity compared to two-view mammography alone, ^{2,3,4,5,6,7} and
- may increase the number of invasive cancers detected compared to mammography alone.^{2,5,8}

Emerging evidence from other studies also suggests that the positive predictive value (the number of cancers detected per number of women recalled from screening) is higher when using tomosynthesis and two-view digital mammography together.^{9,10,11,12,13,14,15} Inter-observer

agreement increases with the use of tomosynthesis and increased agreement can avoid unnecessary investigation of screen-detected abnormalities with a final benign outcome.^{16,17,18} The contribution of tomosynthesis to overdiagnosis needs further research.⁴

Using tomosynthesis and two-view mammography may reduce the number of women recalled for further tests but who do not have cancer (i.e., increased specificity, or the true negative rate, compared to two-view mammography alone).^{2,3,10,12,13,15} Other prospective, fully paired studies have found that tomosynthesis may increase false positive recall rates, but this increase might be explained by differences in reading or arbitration strategy, or reader experience.^{19,20,21}

It is not yet clear which imaging protocol is the safest and most effective

The radiation dose of a combined tomosynthesis and two-view mammogram screen is higher compared to two-view mammography alone.^{22,23} Radiation dose is an important safety consideration and images need to be of optimum quality while minimising radiation dose to women.

Prospective, fully paired studies embedded in population-based screening programs have investigated different combinations of tomosynthesis and mammography including combinations to lower per-view radiation dose.^{4,5,19,20,21} Emerging evidence suggests that combining tomosynthesis and synthesised mammography lowers per-view radiation dose, increases cancer detection and may reduce false positive recall rates compared to two-view mammography or combined tomosynthesis and two-view mammography.^{4,9,19,21,25,26,27,28} It is not yet known which imaging combinations (tomosynthesis in one or two views, alone or combined with one- or two-view mammography or with synthesised mammography) result in the greatest increases in sensitivity and specificity with the lowest radiation dose possible.

Before recommending tomosynthesis as a screening test, further information that it is more effective, safer and saves more lives than two-view mammography is needed

Two-view mammography is the only test proven to reduce the chances of dying from breast cancer because of early detection.

New tests for breast cancer screening must meet the Australian criteria for population screening.^{29,30} It is not certain if tomosynthesis cost-effectively reduces deaths through early detection of breast cancer. There is little evidence describing the impact of tomosynthesis on reducing interval cancers.^{13,25,31} No studies to date have reported that tomosynthesis reduces morbidity from breast cancer or decreases breast cancer deaths more than screening with two-view mammography. Evidence on mortality benefits via modelling or surrogates (studies using interim endpoints) for mortality may be of use to better understand the effect of tomosynthesis.

BreastScreen Australia supports more research on tomosynthesis as a screening test

The role of tomosynthesis in breast cancer screening continues to be investigated in population-based clinical trials embedded in national screening programs. More information is needed on:

- the best way to use tomosynthesis as a screening test including refining understanding about which women may benefit the most from screening using tomosynthesis

- morbidity and mortality benefit of tomosynthesis compared to two-view mammography
- the impact of reader experience on education needs, image interpretation and reading time
- implementation considerations such as reading time and the storage and transmission of large tomosynthesis files
- analysis of the clinical benefits and harms and cost-effectiveness of implementing tomosynthesis, and
- acceptability to women and clinicians.

Results from clinical trials will continue to provide valuable information about the use of tomosynthesis for routine breast screening.

Tomosynthesis improves the assessment of screen-detected abnormalities

Tomosynthesis is used to assess women recalled from screening in BreastScreen Australia programs and in diagnostic radiology practice. There is evidence that tomosynthesis is beneficial in an assessment setting.^{32,33} Like additional mammographic views, tomosynthesis has excellent diagnostic accuracy.^{32,33} Tomosynthesis can reduce the number of additional mammographic views needed to assess a screen-detected abnormality.^{32,33} It reduces tissue overlap and makes it easier to see features like architectural distortion, focal asymmetry and masses.^{8,18,34,35,36,37,38,39} This can reduce inconclusive results, avoid additional diagnostic imaging studies and lower life-time exposure to radiation dose, especially for lesions with a benign final outcome.

Emerging evidence suggests that tomosynthesis-guided vacuum-assisted biopsy may be faster and more technically successful than mammography guided biopsy.^{40,41,42,43,44}

Summary

Two-view mammography remains the most effective screening test for asymptomatic women aged 50-74 years for reducing deaths from breast cancer in a population-based screening program. There is evidence that tomosynthesis increases cancer detection, but it is unclear whether increased detection contributes to decreased mortality from breast cancer.

The Standing Committee on Screening recommends that, until further information on the cost-effectiveness of tomosynthesis as a screening test is available, biennial bilateral two-view mammography continue as the BreastScreen Australia screening test. In the interim, results from clinical trials will continue to provide valuable information about the use of tomosynthesis for routine breast screening.

The Standing Committee on Screening will continue to evaluate emerging evidence on tomosynthesis as a screening test and provide up-to-date, evidence-based reliable information to Australian women.

Tomosynthesis is beneficial in assessing screen-detected abnormalities or breast cancer symptoms. BreastScreen Australia programs should consider implementing tomosynthesis in the assessment of screen-detected abnormalities.

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ANNEX B BREASTSCREEN AUSTRALIA'S POSITION STATEMENT ON THE USE OF TOMOSYNTHESIS IN SCREENING

Breast tomosynthesis (3D mammography) is a new digital mammography technology that is in the early stages of testing and clinical evaluation for its possible benefits in screening and assessment. Currently, BreastScreen Australia uses two-view digital mammography as the primary test to screen women for breast cancer.

Tomosynthesis uses a modified digital mammography unit to create 3D images¹. A number of low-dose images (usually 11-25) of a compressed breast are taken from different angles and then digitally reconstructed to create a 3D image². The radiation dose with tomosynthesis may be higher compared to two-view mammography, however the evidence remains unclear.^{3,4}

Preliminary study results suggest that tomosynthesis has the potential to decrease the number of women who are recalled for further tests (reduce recall rates) and possibly increase the detection of breast cancer (improve sensitivity). A number of small studies have shown favourable results when comparing tomosynthesis to digital mammography.^{5,6,7,8,9,10 11}

BreastScreen Australia is a population-based screening program for well women, and robust evidence is required before tomosynthesis could be used as a routine screening tool. This is because the relative harms and benefits to well women of radiation dose, and the cost, efficiency and effectiveness of using this technology are as yet unclear. The results of further clinical trials are needed before the technology could be recommended for population screening.

At this time, two-view mammography continues to be the most effective population primary screening test for breast cancer.¹² New technologies for breast cancer screening must meet the Australian criteria for population screening as outlined in the Population Based Screening Framework.^{13,14}

There is evidence that tomosynthesis can be of benefit in an assessment setting.^{15 16 17} There is less supporting evidence for the benefit of tomosynthesis as the screening test for population screening of well women. It is therefore important to wait for results from international and Australian clinical trials, before tomosynthesis is considered for routine screening use within BreastScreen Australia.^{4,18,19}

The Standing Committee on Screening recommends that, based on current evidence, the use of tomosynthesis as a screening technology in BreastScreen Australia be confined to clinical trial settings. **Two-view mammography remains the most effective screening test at this time.** Tomosynthesis can be of benefit in an assessment setting.

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