

# Digital Breast Tomosynthesis

Overview of the evidence and issues for its use in screening for breast cancer

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## Executive Summary

Conventional mammography is the most effective screening tool for breast cancer at this time.<sup>1</sup> Any new technology needs to demonstrate a benefit at least equivalent to mammography in the screening context. New technologies for breast cancer screening must meet the Australian criteria for the assessment of population screening as outlined in the Population Based Screening Framework.<sup>2,3</sup> In particular, any new test needs to be highly sensitive and specific, validated, safe, have a high positive and negative predictive value and be acceptable to the target population. It must also be cost-effective.

Digital breast tomosynthesis (DBT) is a technology for breast imaging that is in the early stages of testing and clinical use.<sup>4</sup> It is a promising technology which may be able to improve diagnostic accuracy in the early detection of breast cancer. A number of small reader performance studies have shown favourable results when comparing DBT to digital mammography (DM).<sup>5,6,7,8,9,10</sup> In general, the results suggest that DBT has potential to decrease recall rates and possibly increase sensitivity but further evidence is required before the consideration of any widespread implementation of DBT in routine screening practice.

In January 2013, interim results were released from the first large scale population based screening trial (the Oslo Screening Trial) comparing the use of DBT in conjunction with DM, to DM alone.<sup>11</sup> The trial demonstrated an increase in the detection of cancers and a decrease in recall rates using DBT in conjunction with DM.

While the results from the Oslo Screening Trial are promising, they do not provide adequate information to define the role of DBT in clinical practice.<sup>12</sup> Questions remain on issues such as radiation dose, cost, efficiency, and benefit that need to be addressed before consideration of any widespread implementation of DBT in screening. It is not clear at this stage whether the future role of DBT will be in screening, or assessment, or in both settings.<sup>13</sup>

Whilst there is some evidence that DBT is at least as sensitive and specific as DM, it is not clear whether the use of DBT in large populations outside of a research setting would deliver the same results or whether the additional cost is justified. The issue of radiation dose also needs to be considered in terms of safety for women being screened.

The completion of the Oslo Screening Trial in 2015 will provide additional information that may further inform the assessment of this new technology.<sup>14</sup> The results from another large scale Scandinavian screening trial, the Malmo Breast Tomosynthesis Screening Trial, are expected to be available in 2014.

## **Background**

At the November 2012 meeting of the Standing Committee on Screening (SCoS) it was agreed that as part of monitoring emerging evidence and new technologies relevant to cancer screening, the SCoS secretariat would prepare a paper on the use of tomosynthesis for breast cancer screening (not assessment).

This paper has been developed to provide an overview of breast cancer screening in Australia, digital breast tomosynthesis (DBT), key international research on the use of DBT in screening and the issues related DBT which require further investigation and consideration.

## **Breast Cancer Screening in Australia**

Breast cancer is a major health issue for women: it is the second most common cause of cancer-related death in Australian women.<sup>15</sup> In Australia, 2,680 women died from breast cancer in 2007. The lifetime risk of women developing breast cancer before the age of 75 years is one in 11. Well organised mammographic screening can substantially reduce deaths from breast cancer.

BreastScreen Australia aims to reduce morbidity and mortality from breast cancer. The program, introduced in 1991, actively invites women in the target age group of 50-69 years of age to undergo free biennial screening mammograms. Women 40 years of age and over are also eligible to attend this free service. At present, BreastScreen Australia operates in over 500 locations nationwide, via fixed, relocatable and mobile screening units. It is recognised as one of the most comprehensive population-based screening programs in the world.

Since the introduction of BreastScreen Australia in 1991, there has been a reduction in breast cancer mortality in women 50-69 years of age of approximately 36.5%.<sup>16</sup> This is attributable to early detection through screening and advances in the management and treatment of breast cancer.

In 2009 and 2010, 55% of women aged 50-69 years participated in BreastScreen Australia, with more than 1.7 million women participating in the program overall.<sup>17</sup> Participation by women in the target age range of 50-69 years has remained steady at 55% to 57% between 1997-1998 and 2009-2010, with an overall increase in the actual number of women participating over this time.

## **Breast Cancer Screening Technology**

### **Mammography**

The standard procedure for use in breast cancer screening is mammography. In Australia, digital mammography (DM) was approved for public funding in 2008 and all BreastScreen Australia services will use DM (not analogue) by June 2013.

Both analogue mammography and DM have been proven to reduce mortality from breast cancer.<sup>18</sup> Sensitivity levels for both analogue mammography and DM have been reported at 36% -70% depending on breast tissue density (sensitivity is lower in dense breast tissue).<sup>19</sup> This means that at least 30% of cancers are missed. Dense breasts have a high proportion of glandular tissue in relation to fat and are associated with younger age and the use of hormone replacement therapy.<sup>20</sup>

In conventional DM the structures and tissues of the three dimensional (3D) breast are projected onto a two dimensional (2D) image plane, resulting in the loss of 'depth vision'. Normal breast tissue may hide malignancies, causing a false-negative result.<sup>21</sup> Or in some cases the normal tissue may mimic a tumour, resulting in a false-positive result. The tomographic technique reduces the effect of superimposed tissue, which lessens this problem.<sup>22</sup>

### **Digital Breast Tomosynthesis**

Digital breast tomosynthesis (DBT) uses a modified DM unit which can produce 3D images.<sup>23</sup> DBT uses conventional x-rays and a digital detector to create cross-sectional images or 'slices' of a volume of tissue.<sup>24</sup> The slices are typically thin which largely eliminates the issue of overlapping tissue. A number of low dose images (usually 11-25) of the compressed breast are taken from different angles. These images are then reconstructed to a 3D volume using mathematical algorithms. There are several different algorithms that can be used and there is no general conclusion at this stage on which is best.<sup>25</sup>

For the patient, the experience of DBT is very similar to DM, with a small increase in examination time.<sup>26</sup> The expected benefits of DBT are improved detection of lesions (increased sensitivity)<sup>27</sup> and a decrease in recall rates.<sup>28</sup>

Scans of the evidence on the use of DBT as a breast cancer screening tool in were conducted for HealthPACT in 2008 and 2009.<sup>29</sup> HealthPACT is a sub-committee of the Australian Health Ministers Advisory Council that was established to provide advice on emerging technologies to inform financing decisions and to assist in the managed introduction of new technologies.

The 2009 HealthPACT review concluded that most studies reported that DBT and DM were similar in diagnostic capability. The review cited evidence that DBT can reduce radiation dose, and concluded that there may be some patient safety advantages to using DBT. However, the reported reductions in radiation dose were only found when using DBT for positioning patients for irradiation for cancer and for determining breast density, rather than for screening purposes. More recent evidence suggests that the radiation dose associated with DBT is actually slightly higher than DM.<sup>30</sup>

The HealthPACT review stated that although DBT may be used as an adjunct to DM, it is unlikely that there will be a significant uptake of this technology due to the recent implementation of DM in Australia. The review concluded that it is likely that tomosynthesis

may be the next generation of technology used for breast screening but this will only occur once DM equipment reaches a stage of natural attrition.

Since the 2009 HealthPACT review, the FDA has approved a tomosynthesis unit (Hologic's *Selenia Dimensions* system) for the screening and diagnosis of breast cancer.<sup>31</sup> The Hologic unit was approved in February 2011 to acquire 2D and 3D mammograms. The letter of approval stated that 'the screening examination will consist of a 2D image set or a 2D and 3D image set. The Selenia Dimensions system may also be used for additional diagnostic workup of the breast.'<sup>32</sup>

A number of BreastScreen Australia services have *Selenia Dimensions* units with tomosynthesis capability, including BreastScreen Victoria's Maroondah Screening and Assessment Service. The Maroondah service and the University of Melbourne are currently assessing the feasibility of the routine use of DBT as a first imaging modality in BreastScreen assessment services.<sup>33</sup> The primary objective is to identify whether DBT as a first imaging step in the assessment phase reduces follow-up biopsies among women with a benign final diagnosis, compared to the current standard protocol. The secondary objectives are to:

- Compare the radiation dose and staff time required when using DBT compared to standard protocols;
- Assess BreastScreen clients' experience of DBT imaging in terms of discomfort due to longer compression time compared to their screening mammogram;
- Assess whether outcomes differ according to mammographic breast density;
- Report on cancer diagnosis rates when using DBT compared to current standard protocols; and
- Report on the positive predictive value and negative predictive value of assessment findings after interval cancers are linked for whole study group.

It is anticipated that results of this work will be available by mid-2013.

## **Digital Breast Tomosynthesis Studies**

Since the HealthPACT review in 2009, there have been a number of further studies to assess the accuracy of breast cancer detection using DBT compared with DM. Studies either considered DBT as an adjunct to DM or DBT as a stand-alone procedure as an alternative to DM.<sup>34</sup> The majority have been small retrospective, reader performance assessments using cancer-enriched populations.<sup>35,36</sup> However, there are also two large prospective screening trials examining the use of DBT underway in Scandinavia (see page 6 for details).

### **Retrospective, reader performance studies**

An overview of some of the recent studies assessing DBT as a screening tool is provided in Table 1. In general, the results suggest that DBT has the potential to decrease recall rates in screening programs and possibly increase cancer detection rates (improved sensitivity) but

further evidence is still required. It should be noted that due to the many different machines and protocols, it is difficult to compare the results.

**Table 1: Overview of studies assessing DBT as a screening tool**

Author (1 <sup>st</sup> )	Year	Methodology	Results
Gur <sup>37</sup>	2009	Retrospective study - 125 DBT and DM examinations (35 with biopsy confirmed cancer) were reviewed by eight experienced radiologists.	No evidence that DBT alone, or with DM, results in improved <i>sensitivity</i> . Combination of DBT and DM can reduce <i>recall rates</i> by up to 30% compared to DM alone.
Teerstra <sup>38</sup>	2010	DM and DBT investigations of 513 women with an abnormal screening mammogram or with clinical symptoms were prospectively classified.	There were no significant differences in <i>sensitivity</i> or <i>specificity</i> .
Gennaro <sup>39</sup>	2010	200 women with a suspicious breast lesion discovered by DM and/or ultrasound. DBT images in one view and DM images were rated by six radiologists.	No significant difference in <i>sensitivity</i> or <i>specificity</i> of DBT compared to DM.
Svane <sup>40</sup>	2011	144 women with abnormal mammograms (76 malignant lesions). Two radiologists assessed a single DBT image and a two-view set of DM images.	<i>Sensitivity</i> was slightly higher for DM and <i>specificity</i> was higher for DBT but neither was statistically significant. Patients favoured DBT, rating the comfort as much higher than DM (the trial used lower compression force)
Wallis <sup>41</sup>	2012	Multicentre observer study of 130 cases (40 cancers, 24 benign lesions, and 66 normal images) comparing DM with two-view DBT and single-view DBT.	<i>Statistically significant improvement in detection</i> of masses and calcifications using two-view DBT compared to DM, but only for readers with the least experience. No difference when single-view DBT was compared with DM.
Svahn <sup>42</sup>	2012	185 women, both symptomatic and asymptomatic (i.e. enriched population) were followed up for 23 months. Five radiologists assessed one-view DBT and two-view DM.	DBT had a significantly higher <i>sensitivity</i> than DM. There was no difference in the <i>false positive fraction</i> .
Rafferty <sup>43</sup>	2012	1192 women participated in a multi-reader, multi-centre study to assess radiologist performance on diagnostic accuracy and recall rate using DBT combined with DM and DM alone.	Diagnostic accuracy for DBT+DM was superior to DM alone. The addition of DBT resulted in a significant decrease in <i>recall rates</i> for non-cancer cases and increased the <i>sensitivity</i> .

### **Problems with retrospective studies**

Although a number of the retrospective studies demonstrated that DBT results in better visualisation of lesions than DM, there is not strong evidence for DBT performing better than DM.<sup>44</sup> Most of the studies looked at lesions initially detected through DM to ensure that a large number of lesions would be present for statistical analysis.<sup>45</sup> This study design favours the conventional technology for sensitivity as each lesion was already detected by DM.

Furthermore, small numbers of women were involved in these studies.<sup>46</sup> It is likely that the difference in lesion visualisation between DBT and DM is small and only able to be detected in a few cases per thousand women. Larger studies involving thousands of women are required to give more information on the potential benefits of DBT and its use in screening. This was also the case when DM was first investigated and a study of nearly 50,000 women was needed to demonstrate the advantages of DM over analogue mammography.<sup>47</sup>

### **Large Population Based Screening Trials**

#### **Oslo Tomosynthesis Screening Trial**

The Oslo Tomosynthesis Screening Trial in Norway consists of four arms.<sup>48</sup> In January 2013, the results of an interim analysis of two arms were released – one arm using DM alone, and the other using DM plus DBT. The study group of 12,631 women was derived from 29,652 women aged 50-69 years of age invited to undergo routine, biennial screening as part of the Oslo Screening Program. Of the invitees, 17,960 attended the screening program and 12,631 women agreed to participate in the study.

The study found that the use of DM plus DBT, compared to DM alone resulted in:

- a significantly higher cancer detection rate (27% increase);
- a significantly higher invasive cancer detection rate (40% increase); and
- a 15% decrease in false positive readings.

Cancer detection increased across all breast tissue densities, from dense to fatty.

The other two arms of the trial are looking at the use of computer-aided detection (CAD) in screening and the use of synthesised images to reduce radiation dose. The trial is due for completion in 2015.

#### **Malmo Breast Tomosynthesis Screening Trial**

The Malmo Breast Tomosynthesis Screening Trial started in April 2010 with the goal of enrolling 15,000 women aged 40-74, randomly selected from the regular population based mammographic screening program in Malmö, Sweden. The women in the study will undergo both DM and DBT. The number of breast cancers detected by DBT will be compared with the number detected by DM. A follow-up period of 24 months after the intervention period will provide information on the actual numbers of breast cancers in the study population through record linkage with the Swedish Cancer Registry. Sensitivity and specificity for breast cancer detection will be assessed for DBT and BT respectively. The trial



is due for completion in 2014 and the results will provide valuable information to enable further evaluation of DBT as a screening tool.<sup>49</sup>

## **Issues with Digital Breast Tomosynthesis**

Although DBT has the potential to improve breast imaging, a number of issues need to be addressed prior to any widespread clinical implementation. These are outlined below.

### **Cost Effectiveness**

According to Tingberg<sup>50</sup>, there has not been an evaluation of the cost effectiveness of DBT compared with DM for breast cancer screening. However, DBT is widely reported as being more expensive. Some of the costs of implementing DBT are the price of the system itself, the cost of digital storage capacity to accommodate the large file size of DBT images and the cost of increased radiologist time due to the increased reading time for DBT images.<sup>51</sup>

The final results of the large Scandinavian trials are needed before the benefits and harms can be properly assessed to determine if a cost-benefit analysis is needed.<sup>52</sup>

### **Workforce and Facility Capacity**

The Australian Population Based Screening Framework states that the infrastructure and systems necessary to implement a program to achieve similar outcomes to those achieved in a research setting should exist or be able to be developed in a reasonable timeframe. This includes workforce and facility capacity to undertake the screening.<sup>53</sup> The Oslo Screening Trial was a single-institution study with a single group of radiologists.<sup>54</sup> If DBT was to be used in screening more broadly outside a research setting, by radiologists with varying practice patterns and expertise, the outcomes may well be different.<sup>55</sup>

If DBT were to be widely implemented large numbers of radiologists trained specifically for tomosynthesis would be needed. The Mammography Quality Standards Act in the United States requires eight hours of training specifically for tomosynthesis.<sup>56</sup>

### **Radiation Dose**

DBT increases the radiation dose slightly compared to DM.<sup>57</sup> According to Gur<sup>58</sup>, the issue of radiation dose is under investigation. It is possible that in the near future, DBT will be performed at a comparable dose to DM.<sup>59</sup> For example, the Oslo Screening Trial is currently investigating the use of synthesised images to reduce radiation dose.<sup>60</sup> Also, the radiation dose associated with DBT may well be offset by the potential for lower recall rates and fewer further imaging tests.

It is important to consider the potential radiation dose when DMT is used in conjunction with DM. In the Oslo Screening Trial, the radiation dose for the DBT combined with DM was 2.24 times that of mammography alone.<sup>61</sup> The study authors state that this is below limits set by the United States FDA and constitutes an acceptable risk. However, this risk needs to be weighed carefully against the potential benefits and for acceptability to people who undergo screening.

## **Patient Experience**

With current DBT systems, breast compression is similar to that used in conventional mammography.<sup>62</sup> However, studies have shown that there is potential to reduce the compression force on the breast when using DBT.<sup>63</sup> A study has demonstrated that DBT can be performed with half the compression force on the breast usually used for DM without compromising the quality of the image.<sup>64</sup>

## **Reading Time**

DBT reading time is significantly more time-consuming than the DM reading time. The Oslo Screening Trial results found that the reading time for DM combined with DBT was approximately double than for DM alone (91 vs. 45 seconds, respectively).<sup>65</sup> While some studies have concluded that the increased time is acceptable to radiologists, even in high volume screening<sup>66</sup>, the resource and program implications of this increased time need to be carefully considered.

Computer-aided detection (CAD) which can reduce interpretation times may play a more significant role with DBT than DB. However, according to Kilburn-Toppin<sup>67</sup> CAD is likely to remain a supplementary tool rather than a main reader for DBT, as it is with DM. One of the arms of the Oslo Screening Trial is investigating the use of CAD and is due for completion in 2015.

## **Biopsy**

To date, no widely available means exists to biopsy suspicious findings found only on DBT.<sup>68,69</sup> Developing an image-guided needle biopsy system was a key factor in the now widespread use of magnetic resonance imaging in breast imaging and will likely be an important component of implementing DBT.<sup>70</sup>

## **Imaging Protocols**

Prior to any consideration of widespread implementation of DBT for breast cancer screening, further research is required to determine the optimal imaging protocol.<sup>71</sup> For example, should DBT be used in combination with DM or replace DM? Potential imaging protocols could consist of 1) one DBT image of each breast, 2) two DBT images of each breast (views of two different positions) 3) a combination of one or more DM images with one or more DBT images. Developing an optimal imaging protocol must balance not only sensitivity and specificity but radiation dose, radiologist time to interpret the images, and memory storage costs.

## **Screening versus Diagnostic**

The results from further large-scale clinical trials are needed to determine whether DBT should be used for routine screening for breast cancer or as an adjunct for problem-solving to further evaluate lesions identified on DM.<sup>72</sup>

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