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Digital Breast Tomosynthesis (DBT) Versus Automatic Breast Ultrasound (ABUS): A Review

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Simple Summary

Over the past 15 years, two imaging modalities have received regulatory approval and emerged as useful technologies for the early detection of breast cancer. These are: digital breast tomosynthesis (DBT), a type of 3D mammography; and automated breast ultrasound (ABUS) which produces 3D images of the whole breast. ABUS has three distinct benefits compared to DBT: ultrasound waves are safe; there is no painful breast compression; and ultrasound can penetrate dense breast tissue to reveal malignant lesions not seen by DBT. This begs the question: How do the two modalities perform in a head-to-head comparison? The purpose of the current review paper is to answer this question. Based on 7 published articles in which 5,550 women were studied, the evidence was clear: ABUS was equal to or better than DBT for the important measure of sensitivity, suggesting it has significant potential in future, especially in women younger than 40.

Abstract

Background: For the past four decades, mammography—an X-ray of the breast—has served as the gold standard for the early detection of breast cancer. Within the past 15 years, two other imaging modalities have emerged, receiving regulatory approval from the FDA, and challenging 2D mammography. These are digital breast tomosynthesis (DBT), often referred to as 3D mammography, and automated breast ultrasound (ABUS) which produces 3D images of the whole breast. Since ABUS has three distinct advantages over DBT—ultrasound waves are safe, there is no painful breast compression, and ultrasound can penetrate dense breast tissue to reveal cancers not seen by DBT—this leads to the question: Which of the two modalities performs best for early detection of breast cancer? **Methods**: First, to provide historical context, the development, testing, patenting and FDA approval of the two modalities were reviewed. Next, employing publicly available databases such as PubMed and Google Scholar, a search was conducted to identify articles in which both DBT and ABUS images were gathered and independently compared for various clinical measures, including sensitivity, specificity, and accuracy. **Results**: Based on 7 published articles in which 5,550 women were examined, ABUS was equal to or better than DBT for sensitivity, and often outperformed DBT for the other measures. Importantly, ABUS was better than DBT in detecting more invasive cancers and for women with dense breasts. **Conclusions**: Although the FDA has mandated that ABUS may only be used as an *adjunct* to DBT, for women younger than 40, and especially those with a family history of breast cancer, ABUS should ideally be applied first.

Keywords: breast cancer; screening; dense breast tissue; digital breast tomosynthesis; DBT; automated breast ultrasound; ABUS

1. Introduction of Digital Breast Technology (DBT)

In 1960, Egan [1] first described the potential of mammography—an X-ray of the breast—to screen healthy women for breast cancer. Over the following four decades, analogue (also called screen-film) mammography gained popularity in both the USA [2] and Europe [3], proving to be a

 doi:10.20944/preprints202603.1310.v1

successful tool for reducing breast cancer mortality. The 1990s saw the development by manufacturers of full-field digital mammography (FFDM) to overcome some of the limitations of analogue mammography [4].

However, FFDM performed poorly in dense breasts because an X-ray is created from the superposition of overlapping tissue structures, and a malignant lesion shows up white on a background of dense parenchymal tissue that is also white. A potential solution to acquire images of the various layers of breast tissue was a technique known as tomosynthesis. This technique has its origins in Holland in the 1930s when the neuroradiologist and electrical engineer George Ziedses des Plantes showed that by translating the X-ray source, it was possible to create in-focus images at a range of depths [5].

Tomosynthesis only became a practical reality with the advent of digital X-ray detectors in the early 1990s. Daniel Kopans, who was head of radiology at Massachusetts General Hospital (MGH) in Boston at the time, had read about analogue tomosynthesis and surmised that digital tomosynthesis applied to the breast could reveal cancers hidden within a mammogram because the tissues were superimposed on one another [6]. In 1992, Kopans enlisted two physicists, Loren Niklason and Rick Moore, to bring his concept to a functional reality. He gave them an article on tomosynthesis and said it was his priority to apply the principle to the breast.

The collaborators decided to utilize the flat panel X-ray detector made by GE because it had the necessary readout speed. As Kopans recalled, "We used their detector and manually moved the tube to show that we could synthesize planar images." Niklason, together with his wife Laura Niklason and Brad Christian, worked out the mathematics and, on 23 July 1996, the team filed for patent protection. United States Patent 5,872,828 was granted on 16 February 1999 and assigned to their employer, MGH [7]. Seen in Figure 1 is an illustration from this patent, showing the basic geometry, with the X-ray tube (numbered 60) being moved through an angle of 2Φ degrees.

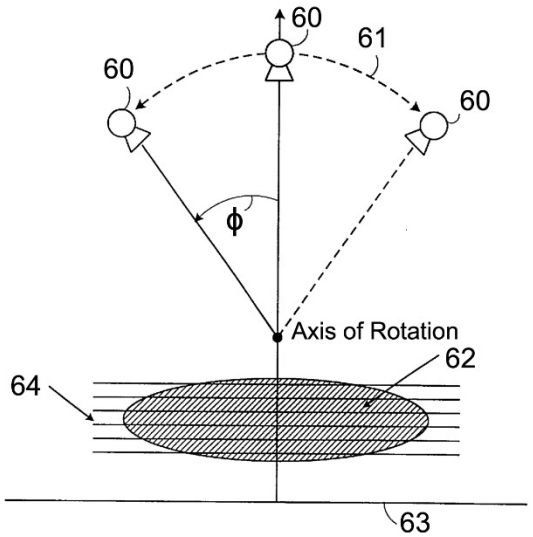

Figure 1. Diagram from the DBT patent awarded to Niklason et al. [7], illustrating how the X-ray source (62) is rotated through an angle of 2Φ degrees, thus yielding tomosynthesis images.

The MGH team published a pivotal paper based on their prototype system entitled "Digital tomosynthesis in breast imaging" in *Radiology* on 1 November 1997 [8] and to date it has garnered more than 1,200 citations. Kopans held a contest among his research group to find a name for their new device, and the descriptive acronym DBT was eventually adopted. As Kopans remembers, "We got a grant from the US Army and paid GE to build the first prototype and began using it in 1999" [6]. By May 2001, the world's first DBT system was in regular use by Kopans and his colleagues in Boston and featured in a newscast that is currently available on the Vimeo platform [9].

 doi:10.20944/preprints202603.1310.v1

MGH licensed their patent to GE but, for still unexplained reasons, the company sat on it for eight years, enabling Hologic to beat GE in bringing a DBT system to market. Hologic hired Loren Niklason, together with another member of Kopans' team, Tao Wu, who had just published a key paper on DBT in *Medical Physics* [10]. On 11 February 2011, Hologic received pre-market approval (PMA) from the Food and Drug Administration (FDA) for their Selenia Dimensions mammography system [11]. The research that underpinned Hologic's FDA approval was not based on a published article; in fact, the pivotal evidence came from proprietary clinical data submitted as part of the PMA application as detailed in the FDA's Summary of Safety and Effectiveness Data [12]. Post-approval by the FDA, a landmark multi-centre screening study by Rafferty et al. [13] reported a 29% increase in cancer detection rate (CDR) for DBT vs FFDM.

During the past 15 years, DBT has become the *de facto* breast screening platform in the United States. In 2011, the year Hologic received FDA approval for its DBT system, there were approximately 19,000 FFDM systems accredited by the Mammography Quality Standards Act (MQSA), while by March 2025 there were 26,539 systems accredited, of which 13,759 were FFDM units, while there were 12,780 accredited DBT units [14]. Aside from Hologic (see Figure 2), other manufacturers to have received FDA approval for their DBT systems include Siemens Healthineers, GE HealthCare, Fujifilm, Planmed, United Imaging and Canon. Although the uptake in Europe has been a little slower, most of the countries that offer state-sponsored breast screening to their women have adopted DBT systems in the past decade. This shift was influenced by the European Commission Initiative on Breast Cancer (ECIBC) which in 2020 recommended that women with dense breast tissue could benefit from the use of DBT [15].

Figure 2. The genius3D device manufactured by Hologic, the most widely deployed DBT system in the United States [14].

2. Introduction of Automated Breast Ultrasound (ABUS)

It is remarkable to realise that ultrasound of the breast has been performed clinically for the past 75 years [16]. In her book *Naked to the Bone*, Bettyann Kevles described the work of early pioneers who, building on the applications of sonar during World War II, set about finding medical applications for high-frequency ultrasound [17]. One of these was an eccentric Englishman named John Wild who emigrated to Minnesota after the war. In 1951 he described the acoustic characteristics of two breast tumours, one benign and the other malignant, using a hand-held—and hand-made—sonography device [18].

 doi:10.20944/preprints202603.1310.v1

Wild then developed an automated breast ultrasound (ABUS) device in which the woman lay on top of a water bath with her breasts submerged in the bath. An ultrasound transducer was moved rapidly in a semi-circular reciprocating motion through the water under the control of a hydraulic motor. With this system he successfully characterised 12 out of 12 malignancies and 9 benign tumours [19]. The next major development of ABUS systems came in the 1960s from a group of researchers at the Ultrasonics Institute in Australia led by George Kossof and Jack Jellins [20]. The patient lay on the bed and a water bath was lowered onto her breasts. The ultrasound transducer, located within the bath, was then moved under automated control on a set of rails (see Figure 3).

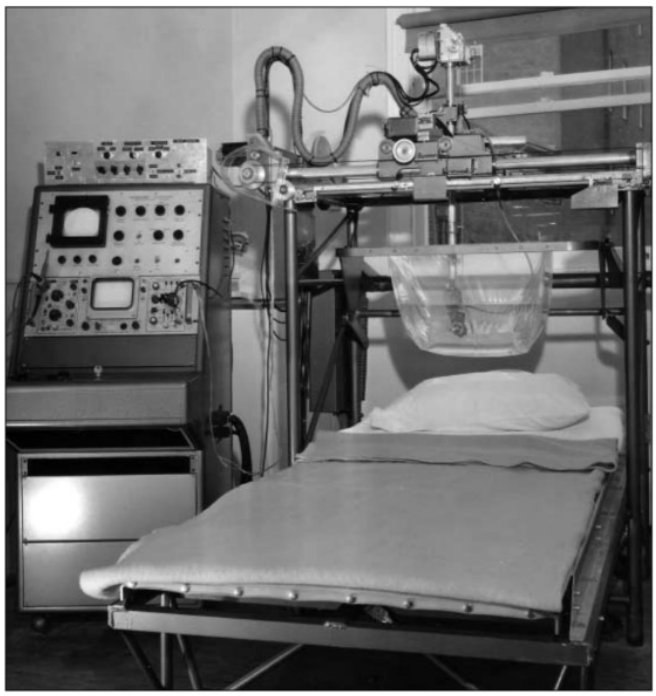

Figure 3. An early ABUS system designed by George Kossof and Jack Jellins in Australia, showing the enclosed water bath that was lowered across the patient's chest [16]. The ultrasound transducer can be seen in the water bath. © American Institute of Ultrasound in Medicine.

In the 1970s the Australians introduced another system called the Octoson that used eight separate transducers located beneath the bed with the woman now lying face down, similar to the system developed by Wild twenty years earlier. A noteworthy pioneer from this era was Elizabeth Kelly-Fry in Indiana whose innovative designs were commercialised by an Australian company called Labsonics [21]. On 25 February 2003, Kevin Kelly and his partners in California were granted a US patent for a screening tool in which an ultrasound probe was moved under 3D mechanical control, generating a complete set of images of the whole breast [22]. This patent was assigned to SonoCiné which was granted FDA approval on 14 October 2008 under the 510(k) predicate device notification [23]. This system, which was designed to function with multiple ultrasound platforms, was used by Kelly to compare his ABUS system and FFDM to detect malignant tumours in women with dense breast tissue, and he reported a doubling of cancer detection rates from 3.6 to 7.2 per 1,000 women who were screened [24].

During the early 2000's, a California company called U-Systems developed a range of ABUS devices, and on 9 November 2010 they were granted US Patent 7,828,733 [25]. This system, where the woman lay supine on a bed while an ultrasound transducer scanned across her breast under automated control, received pre-market approval (PMA) by the FDA on 18 September 2012 for use as an adjunct to mammography in asymptomatic women with dense breast tissue [26]. As with Hologic and its DBT system, the evidence that underpinned the approval was based on proprietary

 doi:10.20944/preprints202603.1310.v1

data [27]. A subsequent publication by Brem et al. [28] reported a 30% increase in CDR for the U-Systems ABUS device when added to FFDM. Shortly after FDA approval, GE HealthCare acquired the ABUS technology from U-Systems [29] and subsequently rebranded the device as Invenia (see Figure 4) which is now the most widely deployed ABUS system in clinical centres around the world.

Whereas the ABUS systems manufactured by SonoCiné [30] and GE [31] require the woman to lie supine on a bed with her breast naturally compressed under gravity, there are two commercial ABUS systems where the woman lies in a prone position with her breast protruding through an aperture in the bed. In these systems a circular ultrasound transducer immersed in water moves upward from the nipple to the chest wall. Delphinus Medical Technologies [32] first received 510(k) approval from the FDA for its SoftVue system on 19 December 2013 [33] based on extensive clinical research at the Karmanos Cancer Institute in Detroit [34]. QT Imaging [35] received 510(k) approval for its QT Scanner system on 6 June 2017 [36] based on early clinical studies [37]. While both SoftVue and QT Scanner have proven to be successful in detecting breast cancers not seen with mammography, neither system is yet in widespread clinical use compared to GE's Invenia.

Figure 4. The Invenia device manufactured by GE HealthCare, the most widely deployed ABUS system in the world [31].

3. DBT Plus ABUS

As summarized in the two sections above, both digital breast tomosynthesis (DBT) and automated breast ultrasound (ABUS) have demonstrated that they can independently increase the cancer detection rate (CDR), particularly for women who have dense breast tissue. In a review article published in 2019, Vaughan [38] suggested that a logical next step would be to integrate DBT and ABUS in a single common platform. With a generous multi-year grant from the National Institutes of Health, and the technical support of GE HealthCare, a research group at the University of Michigan led by Paul Carson was the first to build a successful prototype. Their system was based on one of

 doi:10.20944/preprints202603.1310.v1

GE's early DBT prototypes, together with a hand-held ultrasound transducer sitting atop a motorized carriage built into the compression paddle [39].

This original prototype was tested clinically on 27 patients and, despite the difficulty in identifying lesions that were close to the chest wall, plus the 30 minutes required to capture dual-modality images of both breasts, the researchers successfully fused the DBT and ABUS images in 3D. A decade later the Michigan team built a second prototype in which they combined two of GE's commercial systems—SenoClaire DBT and Invenia ABUS—and where the compression paddle was constructed from a flexible polyester mesh. They reduced the acquisition time to 15 minutes and, in a clinical trial of 13 patients, again successfully demonstrated co-registration of lesions in both the DBT and ABUS views [40]. It would appear GE HealthCare has not yet developed this successful fusion of DBT plus ABUS into a commercial product.

There were two separate research groups located in Germany, one based in Heildelberg [41] and the other in Erlangen [42], that built similar prototypes designed around commercial system manufactured by Siemens: The Mammomat Inspiration DBT system and the Acuson S2000 ABUS system. Similar to the Michigan protypes, the ultrasound probe was incorporated within the compression paddle which was located above the breast. The Heildelberg group evaluated 23 patients and successfully demonstrated co-registration of lesions in both image modalities; however, while all 6 malignant lesions were identified with DBT, ABUS revealed only 4. This problem may have been because coverage by ABUS was just 66% of DBT coverage, and probably stemmed from the ultrasound probe being positioned above the breast, thus limiting acoustic coupling. Since Siemens has recently discontinued manufacture of their Acuson ABUS system, it would appear the company is not planning to release a dual-modality DBT + ABUS product in the future.

4. DBT Versus ABUS

Despite the significant impact that DBT has had on the early identification of breast cancer—and therefore saving women's lives—it does nevertheless suffer from five significant drawbacks: (1) dangerous ionizing X-ray radiation; (2) breast compression causes discomfort and even pain; (3) high end-user price ($250,000 to $500,000); (4) installation requires a large clinical area; and (5) dense breast tissue hides the cancer, leading to false negatives. This last point is undoubtedly the most important and was highlighted in a recent paper by Kniss et al. published in *Academic Radiology* [43]. In this retrospective study of DBT screening examinations, the cohort included 111,143 women whose breast densities were: (A) entirely fatty = 9%; (B) scattered fibroglandular = 50%; (C) heterogeneously dense = 37%; and (D) extremely dense = 4%. Sensitivities were inversely related to breast density, with A = 93%, B = 90%, C = 81%, and D = 62%, emphasizing that DBT misses many cancers in women with dense breast tissue.

In contrast with DBT's five significant drawbacks, ABUS compares as follows: (1) ultrasound waves are safe; (2) there is no uncomfortable breast compression; (3) high end-user price for GE's Invenia system ($250,000); (4) installation and operation require a large clinical area; and (5) ultrasound can penetrate dense breast tissue to reveal lesions not seen by X-rays. It is this last point that gives ABUS its greatest advantage over DBT and why there is strong evidence to offer ABUS as a follow-up procedure for women who have dense breast tissue and a negative finding following screening with DBT [44]. In fact, for all the ABUS systems that have been approved by the FDA, the agency has mandated that ABUS may be used as an adjunct to, rather than as a replacement for screening mammography (either FFDM or DBT). This does, however, beg the question: Given the clear benefits of ABUS, is there a case for applying ABUS *before* DBT? And furthermore, how do the two imaging modalities perform in a head-to-head comparison?

In 2019, Kate Madden Yee reported in AuntMinnie.com regarding a clinical study that had just been presented at the European Congress of Radiology by Norran Hussein Said of Cairo University [45]. Said's group used data from the Egypt Breast Cancer National Screening Program to compare the performance of DBT and ABUS in the workup of 242 women with dense breasts who had been recalled following positive screening with FFDM. All women underwent both DBT and ABUS, and

 doi:10.20944/preprints202603.1310.v1

the independent evaluations of the imaging modalities were compared to pathological findings. The key parameters are summarized in Table 1 where ABUS clearly outperforms DBT in specificity (98% vs 92%), positive predictive value (92% vs 76%), and accuracy (97%vs 92%). The two modalities were equivalent for sensitivity (92%) and negative predictive value (98%).

A year later, another group from Cairo University published a prospective study of 32 women with 37 breast masses (16 benign and 21 malignant) detected either by means of clinical examination or by FFDM [46]. All women then underwent DBT and ABUS examinations and the images were independently analyzed by two experienced radiologists, and the results were compared with pathological findings. Their findings have been summarized in Table 2 where the two imaging modalities were equivalent for sensitivity (100%) and negative predictive value (100%), whereas DBT outperformed ABUS for specificity (81.3% vs 75%) and positive predictive value (87.5% vs 84%). The authors concluded that both DBT and ABUS could be implemented as an adjunct modality to FFDM for early diagnosis of breast cancer.

A group at the University of Pittsburgh that was experienced in DBT screening conducted a prospective study of ABUS screening in women with FFDM-based dense breasts [47]. A total of 598 women was initially screened with both DBT and ABUS, having had no prior record of being screened by either modality; of these, 513 women completed the same set of examinations a year later. Of these 1111 examinations, 8 women were diagnosed with breast cancer, leading the authors to conclude that the number was too small to enable any meaningful statistical inference about cancer detection rates. Their findings, which are summarized in Table 3, show that ABUS was more successful than DBT in identifying malignancies. They pointed out that DBT had a recall rate of 10.7%, while the recall rate for ABUS was 15.2% which led to more unnecessary biopsies. The authors concluded that ABUS added benefit to a DBT-based screening practice and raised the possibility of ABUS being used as a standalone modality at alternating time intervals with DBT.

Table 1. Yee [45] reported the results for a study conducted at Cairo University of 242 women with dense breasts who were recalled after positive screening mammography. All women underwent both DBT and ABUS.

Measure	DBT	ABUS
Sensitivity	92%	92%
Specificity	92%	98%
Positive Predictive Value	76%	92%
Negative Predictive Value	98%	98%
Accuracy	92%	97%

Table 2. Hashem et al. [46] conducted a prospective study of 32 women with breast masses detected by clinical exam or mammography. All women underwent both DBT and ABUS.

Measure	DBT	ABUS
Sensitivity	100%	100%
Specificity	81.3%	75%
Positive Predictive Value	87.5%	84%
Negative Predictive Value	100%	100%

Table 3. Chough et al. [47] examined 598 women in Year 1, 513 of whom returned for a second examination in Year 2. Eight (8) patients were diagnosed with breast cancer. All women underwent both DBT and ABUS, and the modality that led to the recall and subsequent diagnosis was either Both or ABUS or DBT. The pathologies were either IDC = invasive ductal carcinoma, DCIS = ductal carcinoma in situ, or micro- = microcalcifications.

Patient	Diagnosed	Image Presentation	Modality Recalled	Pathology
1	Year 1	Mass with microcalcifications	Both	IDC, DCIS
2	Year 1	Lobulated nodule	ABUS	DCIS
3	Year 1	Hypoechoic mass	ABUS	IDC, DCIS

 doi:10.20944/preprints202603.1310.v1

4	Year 2	Asymmetry with possible distortions	Both	IDC, micro-
5	Year 2	Aechitectural distortion	Both	IDC, micro-
6	Year 2	Hypoechoic mass	Both	IDC
7	Year 2	Irregular mass	Both	IDC, DCIS
8	Year 2	Microcalcifications	DBT	DCIS

Another group from Egypt conducted a prospective study of 38 women who presented with a palpable breast mass and had FFDM-confirmed dense tissue (either BI-RADS density C or D) [48]. There were 38 lesions (24 malignant and 14 benign), and all patients underwent both DBT and ABUS, with each modality's images being independently assessed. Their findings are summarized in Table 4 where ABUS outperforms DBT for sensitivity (100% vs 87.5%), negative predictive value (100% vs 82.4%) and accuracy (100% vs 92.1%). The two modalities both scored 100% for specificity and positive predictive value. The authors concluded that the addition of ABUS and DBT to FFDM could lead to a "revolution" in screening for women with dense breast tissue.

Radiologists from Turkey were interested in the value of ABUS as a standalone or supplemental modality to DBT [49]. They recruited a cohort of 3466 women aged 39 or older with BI-RADS densities of B to D, and 29 cancers were screen-detected. Both DBT and ABUS exhibited the same cancer detection rate (CDR) of 7.5/1000 whereas DBT + ABUS yielded 8.4/1000. Standalone ABUS outperformed DBT in detecting 12.5% more invasive cancers. The group's findings have been summarized in Table 5, where it is seen that DBT outperformed ABUS in both specificity (95% vs 88%) and accuracy (95% vs 88%). Sensitivity was the same in both modalities (84%) while the recall rate for ABUS was double that of DBT (12.4% vs 6%). The authors concluded that ABUS standalone showed promise in detecting more biologically important cancers with a higher false positive rate as the trade-off.

A team of researchers from Malaysia wished to assess the performance of ABUS as an adjunct to DBT in both the screening and diagnostic setting and conducted a cross-sectional study that included opportunistic and targeted screening cases, as well as symptomatic women [50]. DBT followed by ABUS was performed on 1089 women, of which 909 were screening and 180 were diagnostic examinations. Malignant lesions were detected in 100 patients in the study population, with 29 cases from the screening group and 71 cases from the diagnostic group. In 9 of the cases, the tumours were detected by ABUS alone, with 7 being invasive cancers and 2 being ductal carcinoma in situ (DCIS). In 19 of the cases malignancies were detected by DBT alone, of which 9 were invasive cancers and 10 were DCIS. The authors concluded that ABUS was a useful adjunct to DBT in both the opportunistic screening and diagnostic settings.

In a follow up to their earlier work on the characterization of breast masses [46], researchers at the National Cancer Institute in Cairo studied the diagnostic performance of DBT and ABUS in mammographically dense breasts [51]. They enrolled 85 patients with dense breasts (BI-RADS C or D)—as first determined by FFDM—in this prospective study, in which DBT and ABUS were performed in the same session. They detected a total of 100 lesions of which 68 were benign, 31 were malignant, and one lesion was borderline. Their findings have been summarized in Table 6, where DBT and ABUS both yielded equal sensitivities of 93.8%, while ABUS was marginally better than DBT for all four of the other measures. Figure 5 shows how a malignant lesion not seen by DBT was clearly visible by ABUS. The authors concluded that ABUS detected more lesions with higher specificity and better accuracy, while DBT was more beneficial in detecting micro-calcifications, leading them to recommend ABUS being used in combination with DBT for women with dense breasts.

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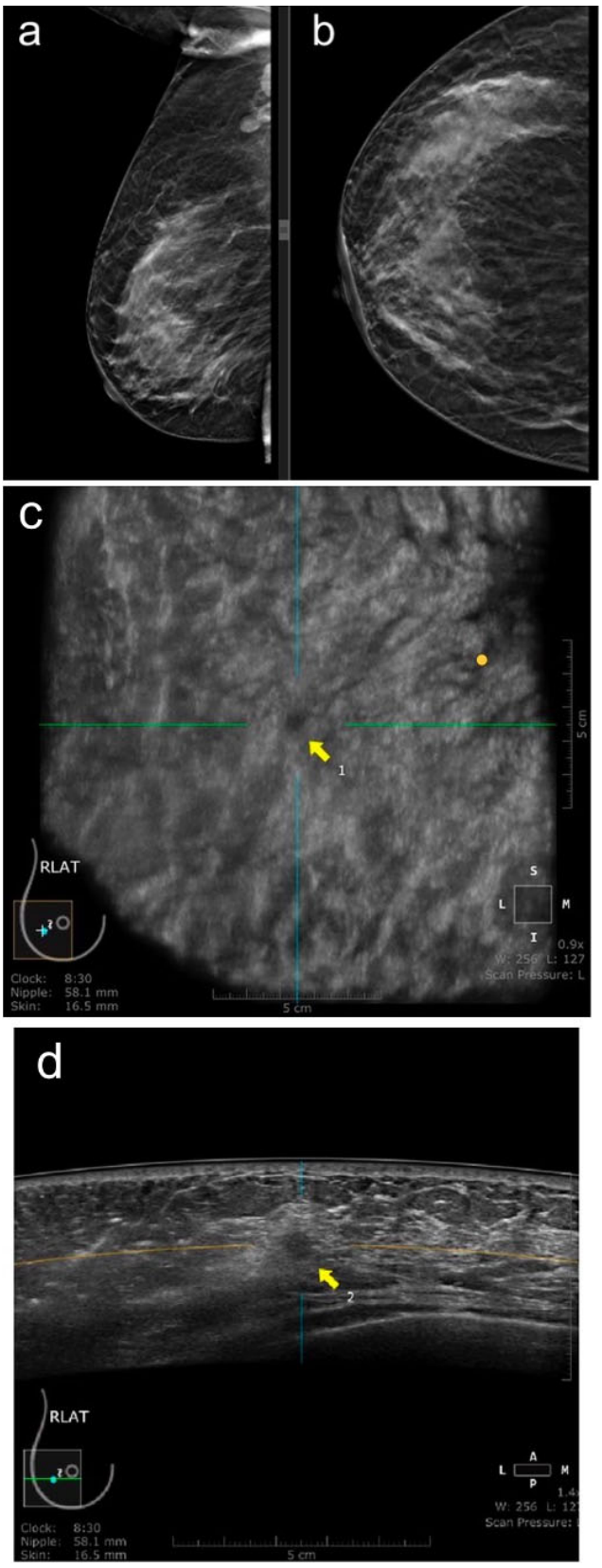

Figure 5. A 41-year-old female presented for screening. (a) right medio-lateral oblique DBT view; (b) right cranio-caudal DBT view. No masses were detected in either of these images. (c) right coronal plane ABUS view; (d)

 doi:10.20944/preprints202603.1310.v1

right transverse plane ABUS view. An invasive ductal carcinoma (IDC), indicated by the yellow arrows, is clearly visible. © Gouda et al. [51].

Table 4. Ali et al. [48] conducted a prospective study on 38 patients who presented with palpable breast masses and had mammographically determined dense breast tissue. All women underwent both DBT and ABUS.

Measure	DBT	ABUS
Sensitivity	87.5%	100%
Specificity	100%	100%
Positive Predictive Value	100%	100%
Negative Predictive Value	82.4%	100%
Accuracy	92.1%	100%

Table 5. Aribal et al. [49] conducted a prospective screening study of 3466 women with BIRADS densities B to D. A total of 29 cancers was detected. All women underwent both DBT and ABUS.

Measure	DBT	ABUS
Sensitivity	84%	84%
Specificity	95%	88%
Accuracy	95%	88%
Recall Rate	6%	12.4%

Table 6. Gouda et al. [51] studied 85 patients with dense breasts in this prospective analysis. All women underwent both DBT and ABUS.

Measure	DBT	ABUS
Sensitivity	93.8%	93.8%
Specificity	86.8%	88.2%
Positive Predictive Value	76.9%	78.9%
Negative Predictive Value	96.7%	96.8%
Accuracy	89%	90%

5. Conclusions

The data presented in Tables 1, 3, 4 and 6 which were reported in references [45,47,48,51] respectively, support the hypothesis that ABUS outperforms DBT in early detection of breast cancer, especially for women with dense breast tissue. In contrast, the data in Tables 2 and 5, reported in references [46,49], suggest that DBT is the better modality. That said, in all cases ABUS performed as well if not better than DBT for the important measure of sensitivity. If, following routine screening with DBT, a false negative finding is reported—typically because of dense breast tissue [43]—the consequences of a late diagnosis can be devastating for the woman, both in terms of clinical outcome and cost of treatment. This is why follow-up imaging, either with HHUS or ABUS, is recommended for women with mammographically dense breasts [52].

Given that ABUS has three major benefits compared to DBT—ultrasound waves are safe, the breast is not compressed, and ultrasound can penetrate dense tissue—while the data show that ABUS performs better than DBT, especially for sensitivity, this strengthens the argument that ABUS should be the imaging modality applied first in screening. Of course, this strategy goes against FDA guidelines which mandate that ABUS may only be used as an *adjunct* to DBT. However, for women who are younger than 40 and especially those with a family history of breast or ovarian cancer, it certainly appears to make sense that they would benefit from having access to ABUS being applied as a first evaluation.

A recent publication in *The Lancet Oncology* by the Breast Cancer Collaborators of the Global Burden of Diseases, Injuries, and Risk Factors Study considered the burden of breast cancer from 1990 to 2023, with forecasts to 2050 [53]. They reported that in high-income countries there was a

 doi:10.20944/preprints202603.1310.v1

stable incidence and declining mortality rates of female breast cancer, reflecting success in screening, diagnosis, and treatment. In contrast, there has been a concomitant rise in incidence and mortality in low- and middle-income countries, which led the authors to conclude that without decisive and immediate interventions, many countries would fall short of the targets set by the WHO in their Global Breast Cancer Initiative in 2023 [54]. The key to modifying the trajectory of the heavy burden of breast cancer in developing countries must surely be the introduction of breast screening on a widespread basis. We believe that ABUS, if it can address the dual problems of high cost and large clinical area required, has the potential to impact and improve the lives of many women worldwide.

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Conflicts of Interest: Christopher Vaughan is a shareholder in and Chief Executive Officer of TomoSwiss.AI, a company that is developing a portable 3D automated breast ultrasound (ABUS) system (https://tomoswiss.ai/).

Abbreviations

The following abbreviations are used in this manuscript:

ABUS	Automated breast ultrasound
BI-RADS	Breast Imaging Reporting and Data System
CDR	Cancer detection rate
DBT	Digital breast tomosynthesis
DCIS	Ductal carcinoma in situ
FDA	Food and Drug Administration
FFDM	Full-field digital mammography
HHUS	Hand-held ultrasound
IDC	Invasive ductal carcinoma
MGH	Massachusetts General Hospital
MQSA	Mammography Quality Standards Act
PMA	Pre-market approval
WHO	World Health Organisation

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