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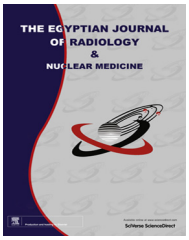

ORIGINAL ARTICLE

Comparative study between breast tomosynthesis and classic digital mammography in the evaluation of different breast lesions

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KEYWORDS

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Abstract *Objective:* To evaluate the impact of adding 3D Tomosynthesis to Full Field Digital Mammography (FFDM) in the detection and diagnosis of breast lesions.
Subjects and methods: The study included 166 mammograms with indeterminate findings selected from 1600 mammograms. They were classified into two groups: group 1 'Diagnostic mammograms' of symptomatic women and group 2 'Screening mammograms'. Dense breasts assigned as ACR3 and ACR4 presented 69% (n = 114/166) of the studied cases. FFDM and 3D tomosynthesis examination was done and imaging findings were evaluated before and after the use of 3D tomosynthesis images.
Results: Both modalities were compared regarding detection and diagnosis, each individually assessed, using the Pearson Chi Square tests. Detection (P value: 0.006) and diagnosis (P value: 0.048) of breast lesions dramatically improved when 3D tomosynthesis images were considered in the evaluation. The sensitivity, specificity, and accuracy of digital mammography was 60%, 20.7% and 48% have significantly enhanced on applying tomosynthesis to be 94.5%, 74% and 89.7%.
Conclusion: Three-dimensional tomosynthesis significantly enhanced the detection and characterization of breast lesions on digital mammography especially in the context of dense breast parenchyma (ACR 3&4).

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1. Introduction

Mammography is an effective imaging tool for the detection of early-stage breast cancer, and it is the only screening modality proved to reduce mortality from breast cancer (1–3). However, the appearance of overlapping tissue on mammograms poses a significant obstacle to interpretation (4–7).

Breast tomosynthesis is a new tool that can be expected to ameliorate this problem by reducing or eliminating tissue overlap (8).

The purpose of this study is to evaluate the potential impact of adding 3D Tomosynthesis to Full Field Digital Mammography on the *detection* and *diagnosis* of breast lesions.

2. Material and methods

This study is a prospective analysis approved by the Ethics Committee in Wadi El-Neel Hospital, where radiological examination of the study cases had been performed in a well equipped and organized breast imaging unit incorporation with Institute Gustave-Roussy (IGR), the leading European anticancer center. Included cases have given informed consents.

2.1. Material

The study included 166 consecutive mammograms with positive findings on the standard mammography examination. Studies were performed during the period of 13 months. Included cases were classified into two groups according to the objective of their referral: *Group 1:* 'Diagnostic mammograms' of symptomatic women. *Group 2:* 'Screening mammograms' of non symptomatic women referred for their regular annual check up.

2.2. Methods

2.2.1. Mammography examination

A combined FFDM and 3D tomosynthesis examination was done by Hologic Selenia Dimensions Digital Tomosynthesis System using the following steps:

- *Position views*: Images are taken both in the cranio-caudal (CC) and medio-lateral oblique (MLO) views.
- *Acquisition*: The system attains a ''Combo-mode'' imaging technique (2D + 3D imaging) that acquires a traditional digital mammogram and a tomosynthesis scan in the same compression. During a tomosynthesis scan, multiple (11–15), low-dose images of the breast are acquired at different angles while the X-ray tube moves in an arc across the breast. These images are then used to produce a series of one-millimeter thick images (from 60 to 90 slices) that can be reconstructed to a three dimensional image of the breast.
- *Display methodology*: Images are displayed on dedicated high resolution workstations with special capabilities that are tailored for breast imaging. The re-constructed tomosynthesis images can be viewed as one slice at a time or in a cine loop.

2.2.2. Ultrasound examination

A complementary ultrasound examination was performed for all cases using both B-mode and elastography ultrasound on Aplio XG device (Toshiba, Japan) to confirm or exclude mammography identified abnormalities. Examination was done by 6–9 MHz high frequency probes.

2.3. Image analysis

According to the ''Breast Imaging Data and Reporting System'' (9) mammograms of all patients were assigned an *initial BIRADS category* in view of their Full Field Digital mammography (FFDM) findings by two independent readers (A.L. and M.S. of 18 and 15 years experience) into: (i) BIRADS 3 or BIRADS 4 mammograms: with indeterminate benign or malignant mammography findings, (ii) BIRADS 1 and BIRADS 2 mammograms: if the tomosynthesis images added new undetected lesions in BIRADS 1 or changed the category of detected ones in BIRADS 2 and (iii) BIRADS 5 cases: when additional findings were reported on reviewing the tomosynthesis images (e.g. additional undetected lesions or wider tumor extent).

A second look of the mammograms established by another individual reader (M.O. of 20 years experience) and another *BIRADS category* assigned after a combined review of both the tomosynthesis and the regular digital mammography images.

The authors were blinded regarding the image analysis performed by each of them and both the initial mammogram (only regular mammogram) and re-evaluation (combined tomosynthesis and regular mammography images) were performed without knowledge of the pathology results. At the stage of final evaluation, there was multidisciplinary discussion of findings with the authors and the breast surgery consultant (O.O.).

On reporting the mammogram, we answered the following questions before and after evaluating the 3D tomosynthesis images:

1. **Can we detect any abnormality?** (mass lesions, parenchymal distortion, focal asymmetries, micro calcifications or diffuse breast edema pattern).
2. **Can we characterize/ diagnose this abnormality?** (i.e. classify as benign, indeterminate or malignant).
3. **Which BIRADS category could we assign?**
4. **Should we recommend or deter further biopsy?**
5. **Does the FFDM findings whether or not combined with 3D tomosynthesis concomitant with the pathology results?**
6. **Do we need a follow up study for confirming the current mammography findings?**

Ultrasound guided core biopsy using a 14G biopsy needle was performed in 63% (n = 104) for malignant looking (BI-RADS 5), suspicious (BI-RADS 4) and indeterminate lesions (BI-RADS 3). The remaining BI-RADS 3 category (n = 26) and BI-RADS 2 category (n = 35) lesions were managed according to the ACR guideline which is determined during the follow up: a one year stable lesion was considered of benign nature.

2.4. Statistical analysis

Imaging findings were tabulated and categorical results of Full Field Digital Mammography and 3D Digital Tomosynthesis

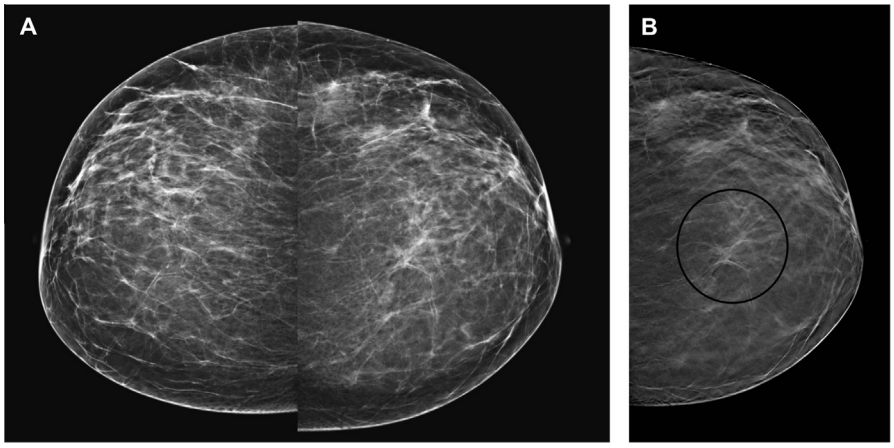

Fig. 1 Tiny carcinoma that could be only identified on the tomosynthesis images (circle in B).

were included. Both modalities were compared in the context of *detection* and *diagnosis*, each was individually assessed, using the Pearson Chi Square tests. The sensitivity, specificity, accuracy and positive and negative predictive values of either modality were also calculated. P value <0.05 is considered to be significant.

3. Results

The study included two groups of patients. *Group 1* patients (94 cases, 56.4%) were symptomatic cases. *Group 2* patients (72 cases, 43%) were asymptomatic ones coming for their regular annual check-up (Fig. 1).

Increased breast density significantly affected the diagnostic ability of mammography. Such cases were misinterpreted in mammograms and were assigned with breast densities of ACR3 (48.2%, $n = 80/166$), and ACR4 (20.5%, $n = 34/166$).

The capability of FFDM and 3D tomosynthesis in the detection of breast pathologies was simplified in Table 1. Tomosynthesis significantly enhanced the detection of the breast lesions on mammography images especially in the context of dense breast parenchyma (P value: 0.006) (Fig. 2). The detection of multicentric lesions was also accessible in the tomosynthesis images (Fig. 3).

Using of tomosynthesis slices also significantly helped in better lesions characterization and consequently verified benign or malignant impression of the identified masses (P value: 0.048) (Table 2, Fig. 4). Based on tomosynthesis images, tumor margins were better assessed ($n = 101$). Also clusters of microcalcifications ($n = 66$) were better identified (Fig. 4b) especially in dense breasts.

Table 1 Comparison between the detection capability of FFDM before and after 3D tomosynthesis imaging application in the assessment of breast lesions.

Mammography detection	Tomosynthesis detection		Total
	Yes	No	
Yes	125 (75.3%)	3 (1.8%)	128 (77.1%)
No	33 (19.9%)	5 (3.0%)	38 (22.9%)
Total	158 (95.2%)	8 (4.8%)	166 (100%)

All mammograms were assigned an initial BI-RADS category, then the 3D tomosynthesis images were re-viewed and the BIRADS score was re-adjusted by being either upgraded, downgraded or remained unchanged (Table 3).

Adding the 3D tomosynthesis images to the regular mammography significantly enhanced accurate BIRADS scoring (P value: 0.00). In reference to Table 3 we can deduce the following:

- Three-dimensional tomosynthesis images significantly decreased the number of *indeterminate/suspicious lesions,* (BIRADS 3 & 4) by either supporting a benign (downgrading) or a malignant (upgrading) diagnosis.
- In BI-RADS 5 (28.9%, $n = 48$) cases, 3D tomosynthesis showed more accurate tumor extension and allowed better prediction of subtle microcalcific clusters especially in dense breast parenchyma (Fig. 5).
- Pathologically proved BIRADS 6 lesions (3%, $n = 5$) that were under neoadjuvant chemotherapy could not be identified on mammography. Tomosynthesis allowed better depiction of such pathologies by providing the possibility of recognizing post therapy residual tumor tissue (Fig. 6).
- Tomosynthesis did not only allow a more confident malignant diagnosis of some mass lesions but it helped in confirming the benign nature of BIRADS 2 (31.3%, $n = 52$) lesions as well. The presence of well defined margins, the typical benign radiolucent halo and the intra-lesional fat density verified the benign diagnosis of these lesions.
- Operative bed recurrence could be excluded from extensive scars (4.8%, $n = 8$). In such cases, no recurrent masses were identified in any of the tomosynthesis slices and moreover in five cases, associated central fat density could be elicited which further excluded tumor recurrence (Fig. 7).

Recommendation of biopsy for detected lesions was based on the combined evaluation of FFDM, 3D tomosynthesis and ultrasound examinations (Table 4). Revision of pathology specimens revealed 77 malignant lesions (46.4%) and 89 benign lesions (53.6%). Ten cases (6%) of those benign lesions were found to be precancerous. With the aid of tomosynthesis slices, 62 cases (37.3%) were saved from unnecessary biopsy.

The sensitivity, specificity, and positive and negative predictive values of FFDM when assessed individually and when combined with 3D tomosynthesis were illustrated in Table 5.

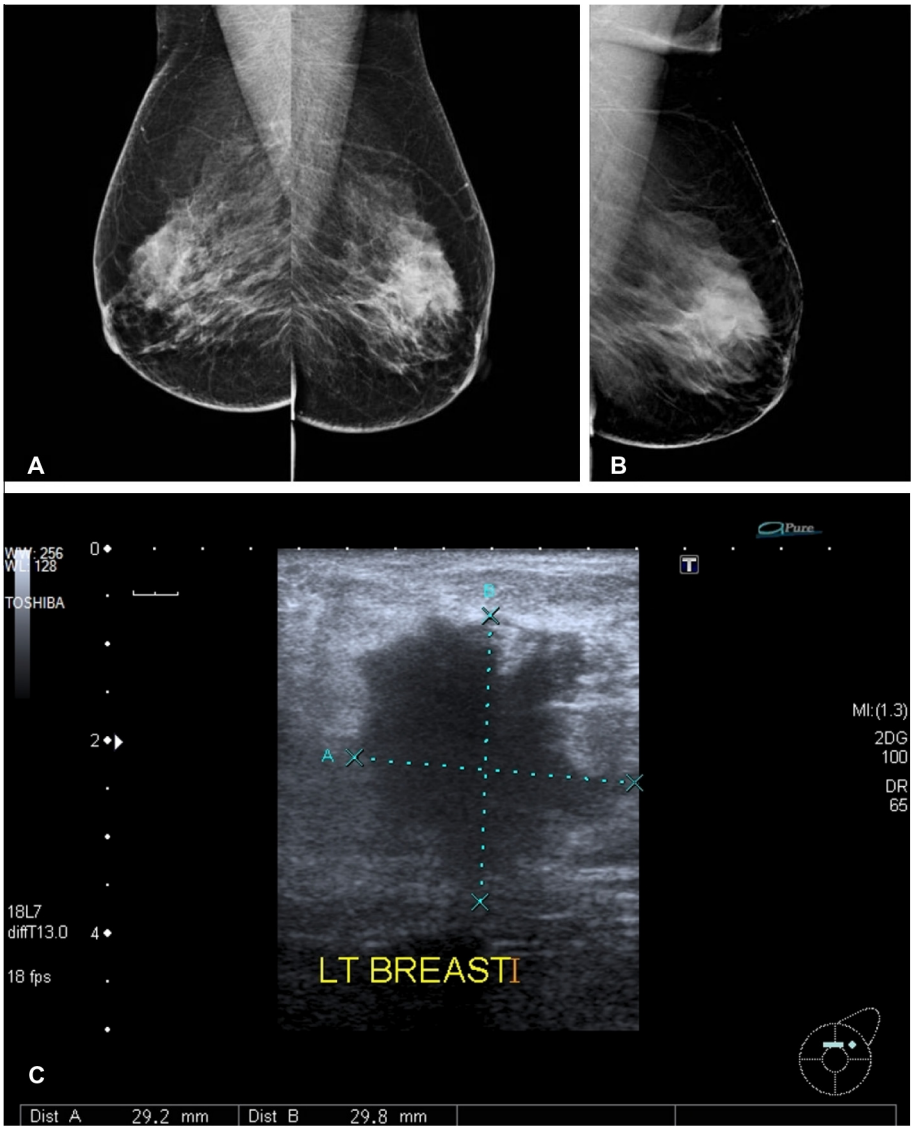

Fig. 2 Left breast large invasive duct carcinoma that is hardly seen on the FFDM images (A). It was assigned as BIRADS 4. The carcinoma appears more evident on the tomosynthesis slice (B) and was upgraded to BIRADS 5. Complementary ultrasound (C) confirmed the tomosynthesis findings.

False negative tomosynthesis results included six benign breast lesions in heterogeneous breast parenchyma and one case of duct carcinoma in situ (DCIS) in an ACR4 breast.

False positive results included two cases of granulomatous mastitis, four benign precancerous lesions, one case of post operative fat necrosis and three cases with atypical fibroadenomas.

4. Discussion

Breast tomosynthesis is considered one of the most challenging and promising up to date mammography technologies. Tomosynthesis is expected to resolve mammography drawbacks by eliminating tissue overlap due to its ability to acquire 3D images of the breast (8).

A number of investigators believe that 3D tomosynthesis has a potential impact in both screening and diagnostic settings. The use of tomosynthesis could alter the diagnostic protocol substantially (10).

Several studies had considered breast tomosynthesis an entrance for a 3D imaging capability that allows more accurate evaluation of lesions by enabling better differentiation between overlapping tissues (8,11–14). Most of the articles reviewed its role literally. There was a paucity of references that had discussed its use in routine clinical practice.

A prospective study (12), examined the effect on radiographers' and radiologists' workload when implementing 3D mammography in screening by comparing image acquisition time and screen-reading time for 2D mammography with that of combined 2D + 3D mammography.

The main issue of their study focused upon time consumed versus accuracy in interpretation of the mammograms of the selected cases. They found out that combined 2D + 3D mammography prolongs image acquisition time and screen-reading

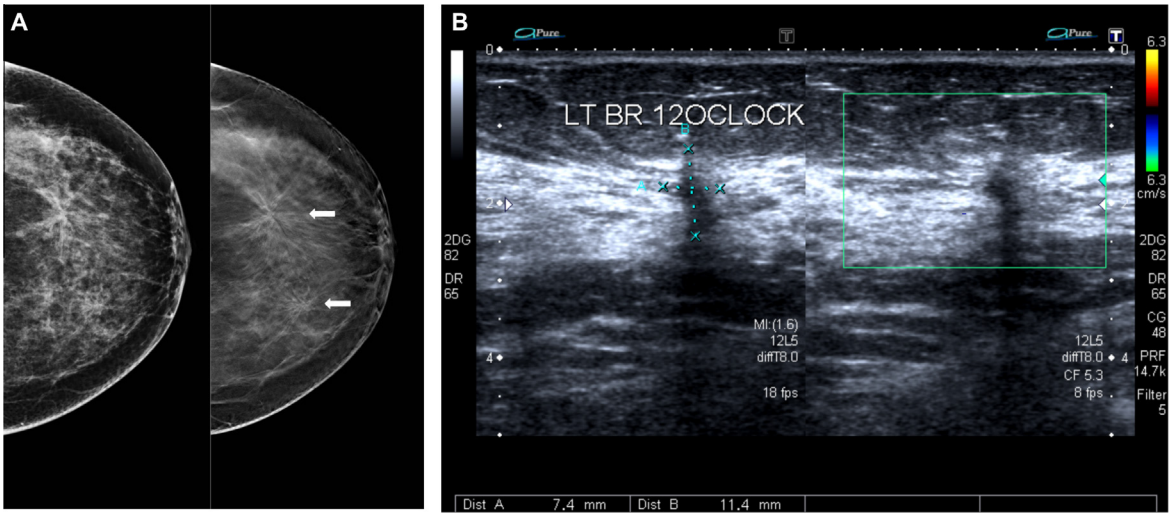

Fig. 3 Screening mammogram showed a subtle mid upper breast area of parenchymal distortion that became more apparent on one of the tomosynthesis slices in addition to another lesion (arrows). Complementary ultrasound proved the presence of an underlying two tiny spiculated mass lesions.

Table 2 Comparison between the diagnostic ability of FFDM before and after combining the 3D tomosynthesis imaging in the assessment of breast lesions.

Mammography diagnosis	Tomosynthesis diagnosis		Total
	Yes	No	
Yes	51 (30.7%)	4 (2.4%)	55 (33.1%)
No	90 (54.2%)	21 (12.7%)	111 (66.9%)
Total	141 (84.9%)	25 (15.1%)	166 (100%)

time (at initial implementation), yet appears to be associated with improved screening accuracy, which consequently help in detection of more cancers (12).

Skaane et al. compared digital mammography and digital breast tomosynthesis (DBT) in a side-by-side feature analysis for cancer conspicuity, and assessed whether there is a potential additional value of DBT to standard conventional imaging regarding the detection of additional malignancies. The study included 129 women and actually biopsied 45 breasts (the remaining 84 cases were dismissed with a normal/definitely benign finding that presented no need for biopsy). According to their work; the side-by-side feature analysis showed higher conspicuity scores for tomosynthesis compared to conventional 2D for cancers presenting as spiculated masses and distortions (15).

Hakim et al. (10) subjectively compared additional mammographic views to DBT when characterizing known masses, architectural distortions, or asymmetries. The study considered mammography of 25 women with known masses. After review of the examinations, radiologists rated their relative preference in terms of classifying the finding in question twice; one time when aided by the additional views and another when aided by DBT. The diagnostic BI-RADS rating of both examinations was correlated. They found that FFDM and DBT (combined) were perceived to be better for diagnosis in 50% of cases. Finally they concluded that DBT may be an alternative to obtaining additional mammographic views in most cases especially if the presentation of the concerned lesion is not by calcification.

During our experience; the 3D tomosynthesis images had increased the sensitivity and accuracy of mammography and significantly enhanced accurate BIRADS scoring (P value: 0.00). The proved malignant lesions ($n = 77$) were correctly diagnosed by mammography in 14 cases (18.1%), such estimation became more accurate when 3D tomosynthesis included in the evaluation to be 48 cases (62.3%). Even when malignant mass lesions were identified on mammograms, 3D tomosynthesis still has a role in defining actual tumor size and extension (Fig. 5). We have to admit that the diagnostic accuracy percentage for FFDM was very low to be accepted on a standard basis; yet it is a unique situation in this study as most of the malignant cases were of dense breast categories.

Tomosynthesis significantly enhanced the cancer detection rate of mammography as it showed a sensitivity of 94.5% compared to only 60% in solo mammography evaluation. This was coupled with its impact on the diagnostic accuracy of mammography that had upgraded from 48% to 89.7%. Improved depiction of clustered microcalcifications, together with better margin delineation and superior resolution has paved way for making an accurate diagnosis (Fig. 4b).

In a study done in 2012, DBT was compared with mammographic spot views (MSVs) in characterizing 67 breast masses as benign ($n = 37$) or malignant ($n = 30$). In this small-sample study, mass characterization in terms of visibility ratings, reader performance, and BI-RADS assessment with DBT was similar to that with MSVs. Preliminary findings suggest that MSV might not be necessary for mass characterization when performing DBT (16).

From our point of view, tomosynthesis being a ''slice folding'' technique has only the capability to locate the site of calcific clusters but not to accurately suggest the possible pathology of clusters. Regarding this issue spot magnification view is a better method of evaluation.

Kontos et al. in 2011 presented a correlation between the parenchymal texture features at DBT and digital mammography with breast percent density (PD) in a screening population

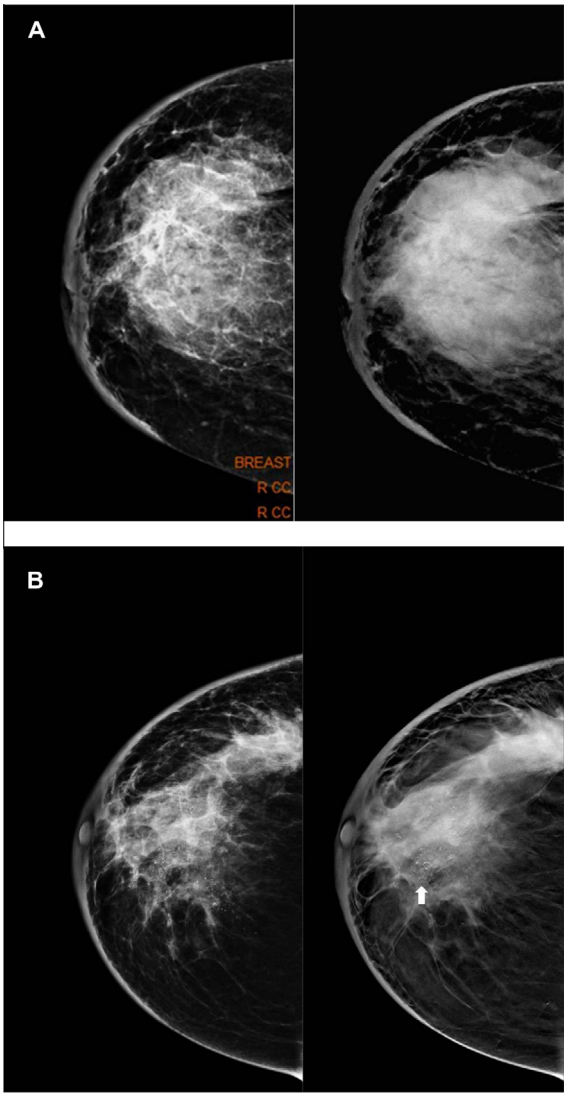

Fig. 4 Two different cases showing diffuse non specific edema pattern of the right breast with coarsened trabeculae, increased breast density and diffuse skin thickening. Case1 (A) is granulomatous mastitis. Tomosynthesis images added no information. Case 2 (B) is an extensive invasive duct carcinoma. Malignant microcalcific clusters and spiculations are excellently demonstrated on the tomosynthesis image.

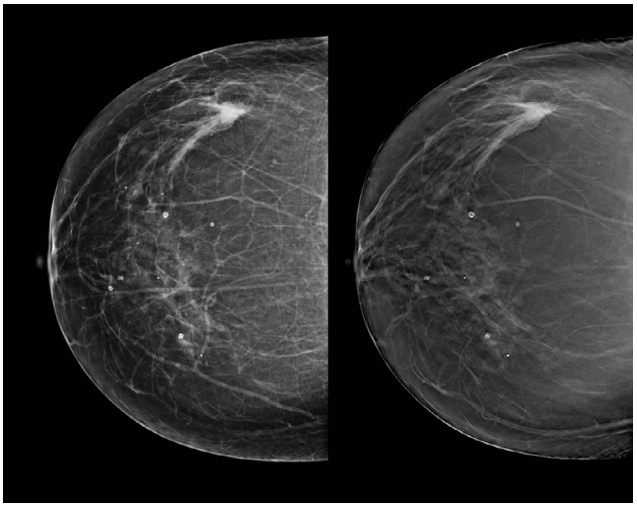

Fig. 5 A typical carcinoma that is easily identified on the CC view of a FFDM examination, yet, wider extension could be depicted on the tomosynthesis slice.

of women. According to their study, parenchymal texture features are more strongly correlated to breast PD in DBT than in digital mammography. The authors' long-term hypothesis is that parenchymal texture analysis with DBT will result in quantitative imaging biomarkers that can improve the estimation of breast cancer risk (17).

The current work included 114 (69%) cases with dense parenchymal texture (i.e. ACR 3 and 4). Lesions in dense breast parenchyma were sometimes upgraded or downgraded on the tomosynthesis images; a fact which had a major impact in the perspective of recall rates in screening mammography and in the perspective of biopsy referral in the diagnostic context. It allowed a more confident diagnosis of both benign and malignant pathologies.

Breast abnormalities were more depicted at 3D-tomosynthesis that detected 158 out of the 166 studied lesions (95.2%) and missed only eight lesions (4.8%), while on the other side digital mammography had missed 38 lesions (22.9%). Also the interpretation of the abnormality was better defined by tomosynthesis which characterized and properly diagnosed 141 lesions (84.9%) while digital mammography hit the target in only 55 lesions (33.1%).

Table 3 Comparison between the initial mammography BI-RADS scoring and the re-adjusted score after re-viewing the 3D tomosynthesis images.

Mammography BI-RADS	Tomosynthesis BI-RADS						Total
	1	2	3	4	5	6	
1	4	14	3	1	0	0	22
2	3	11	1	5	2	0	22
3	9	22	9	4	3	0	47
4	2	5	2	18	29	0	56
5	0	0	0	0	14	0	14
6	0	0	0	0	0	5	5
Total	18	52	15	28	48	5	166

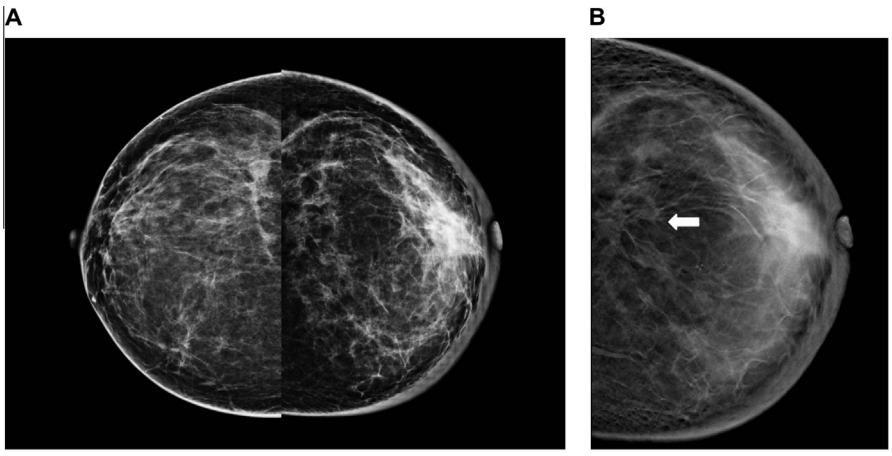

Fig. 6 Proved carcinoma under neo-adjuvant chemotherapy. Tumor is in-apparent on FFDM image (A). It becomes clearly illustrated on the tomosynthesis images (arrow in B).

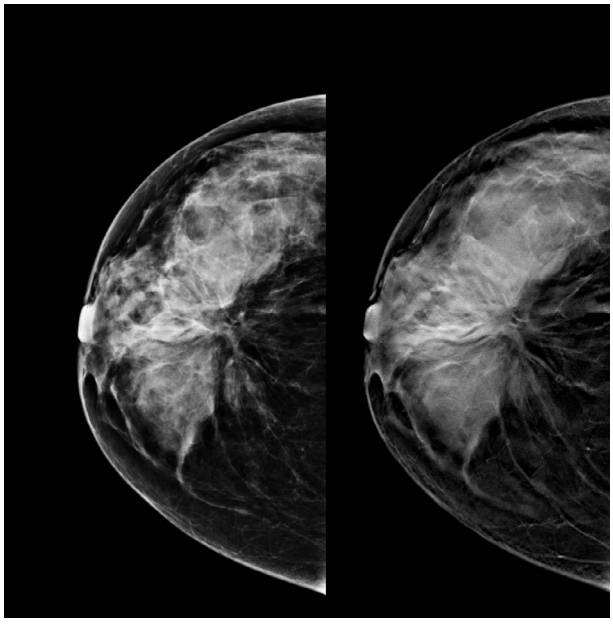

Fig. 7 A 37-year-old female with history of right conservative breast surgery. She recently noticed a palpable operative bed lump. Her mammogram showed operative bed microcalcifications and spiculations. She was assigned BI-RADS 4 score with suspicious recurrence. Tomosynthesis images showed a central radio-lucency with fine egg shell calcifications; a picture that is typical for operative bed fat necrosis. She was downgraded to BI-RADS 2 score.

Nevertheless we have to admit that breast tomosynthesis sometimes does not save the case, it holds the challenge of "absence of mass effect". Lesions with no associate architectural compression and/or distortion may be indiscernible from the related parenchyma in breast with ACR 3&4 categories (Fig. 8). Such condition may present with a number of considered pathologies such as: Intraductal epithelial hyperplasia, lobular carcinoma in situ and ductal carcinoma in situ (DCIS). Presence of an area of abnormal echo pattern on complementary breast US could draw attention to biopsy and consequently solve such problem.

Table 4 Number of performed breast biopsies and results of revision of pathology specimens.

Pathology	Total No. of cases	Biopsy performed	Biopsy deterred
Benign	79 (47.6%)	17	62
Fibroadenomas		5	1
Mammary dysplasia		2	–
Fibrocystic changes		2	25
Mastitis		6	1
Normal		2	9
Scar			8
Duct ectasia			2
Precancerous	10 (6%)	10	–
Malignant	77 (46.4%)	77	–
DCIS		6	
Lobular carcinoma		3	
Malignant phylloids		1	
Invasive duct carcinoma		67	
Total	166	104	62

Table 5 Calculated sensitivity, specificity, accuracy, and positive and negative predictive values of FFDM before and after combining the 3D tomosynthesis in the assessment of breast lesions.

Statistics	Mammography (%)	Tomosynthesis (%)
Sensitivity	60	94.5
Specificity	20.7	74
Accuracy	48	89.7
Positive predictive value	62	92
Negative predictive value	20	80

Bernardi et al. (12), in 2012 stated that there is limited evidence on the role of 3D mammography with tomosynthesis in breast screening, although early studies suggest that it may improve specificity. They evaluated the effect of integrating 3D mammography on 158 consecutive recalls to assessment in asymptomatic subjects and finally found out that their study

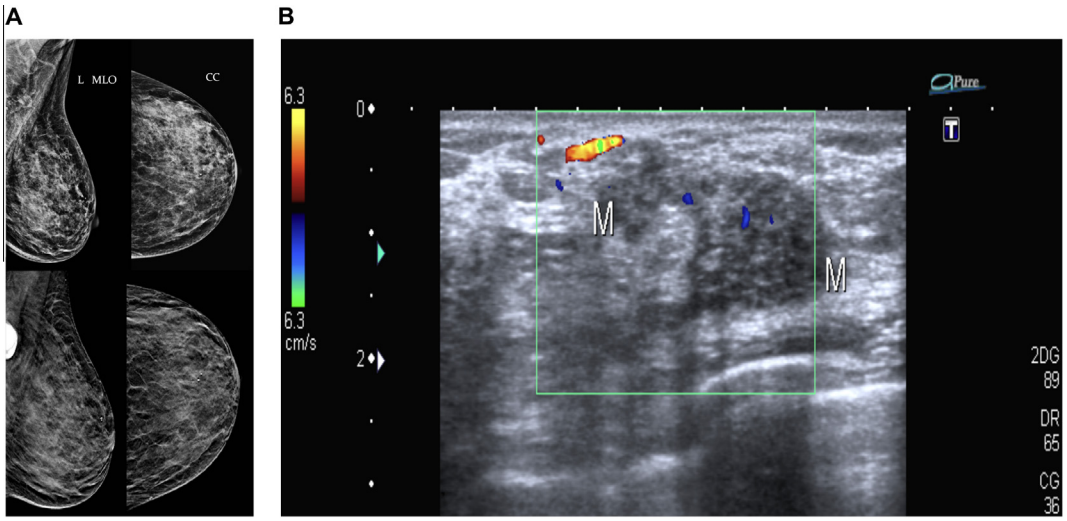

Fig. 8 Patient is 58 years old with history of right breast cancer post mastectomy. One year post therapy follow-up revealed contralateral ductal carcinoma in situ (DCIS) solid and cribriform patterns with stromal microinvasion. (A) Left-sided FFDM and tomosynthesis MLO and CC views show unremarkable findings. (B) Color Doppler US shows ill-defined area of abnormal hypoechoic texture. Note small feeding vessel targeting the lesion. According to the mammography the breast is BI-RADS 1 yet US displays BI-RADS 4a which is the nearer category to the pathology results.

clearly demonstrates the capability of 3D tomosynthesis to improve breast screening specificity and reduce recall rates.

Another experience (18) compared the image quality of tomosynthesis with that of conventional mammography and estimated the recall rate of screening when tomosynthesis is used in addition to mammography. There were 99 digital screening recalls in 98 women. They stated that the image quality of tomosynthesis was equivalent ($n = 51$) or even superior ($n = 37$) to diagnostic mammography in 89% (88/99). Finding type was significantly ($P < 0.001$) associated with equivalence. Approximately half – 52/99 (52%) – of the findings would not have been recalled when digital screening mammography was supplemented with tomosynthesis. When adjusting for confounding conditions, the recall reduction was 40% (37/92). The likelihood of recall was also dependent on finding type ($P = 0.004$).

Our work limited by the fact that it was carried out in a non-screening institute; most of the patients present with well-established breast pathology and needed diagnostic mammogram. Some of the cases had complaints regarding other body system and were sent for check up, in other words sent for Screening mammograms to exclude additional breast disease. Such condition markedly limited recall/assessment option.

From our experience we could recommend breast cancer screening scheme as follows: First, start the screening image with 3D tomosynthesis "Combo-mode" imaging technique using the CC views. If there was any impression of hidden pathology then it is better to continue with 3D tomosynthesis technique. If no abnormality was detected then instead do the MLO views with the regular FFDM. Women with dense breasts, even with negative mammograms (i.e. BI-RADS 1) need additional breast ultrasound examination to exclude malignancy.

5. Conclusion

Three-dimensional tomosynthesis significantly enhances the detection and characterization of breast lesions on digital mammography especially in the context of dense breast parenchyma (ACR 3&4).

Authors' contribution

Study concepts: O.M., L.A. and O.O.
Study design: S.M.
Data acquisition: S.M. and O.M.
Quality control of data and algorithms: S.M.
Data analysis and interpretation: S.M., L.A. and O.M.
Statistical analysis: S.M.
Manuscript preparation: S.M.
Manuscript editing: S.M.
Manuscript review: S.M., O.O.

Sources of support

Wadi El-Neel Hospital.

Conflicting interest

The authors declare that they have no conflict of interests.

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