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Redefining Margin Assessment in Breast Conservation Surgery: Surgeon-Performed Intraoperative Ultrasound as a Reliable Alternative to Radiologic and Mammographic Assessment

Tabrej Alam¹, Arvind Baghel¹, Devashish Mishra², Ranu Tiwari Mishra³, Shyam Ji Rawat⁴,
Sanjay Kumar Yadav¹, Dhananjaya Sharma¹

¹Department of Surgery, NSCB Medical College, Jabalpur, India

²Department of Radiology, NSCB Medical College, Jabalpur, India

³Department of Pathology, NSCB Medical College, Jabalpur, India

⁴Department of Radiotherapy, NSCB Medical College, Jabalpur, India

ABSTRACT

Objective: Accurate intraoperative margin assessment during breast-conserving surgery (BCS) is essential to minimize re-excision and preserve cosmesis. In resource-constrained settings, advanced imaging and frozen section analysis are often unavailable, and surgeons frequently rely on visual-tactile judgment. This study compared the diagnostic accuracy of surgeon-performed intraoperative specimen ultrasound (IOSpUS-S), radiologist-performed specimen ultrasound (IOSpUS-R), specimen mammography, and gross inspection against final histopathology.

Materials and Methods: This prospective study included 40 patients with early breast cancer undergoing wide local excision at a tertiary centre in central India. Each excised specimen was evaluated intraoperatively, *ex vivo*, by gross inspection, IOSpUS (surgeon and radiologist), and specimen mammography. Diagnostic parameters, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and correlation with the final histopathological margins, were calculated. Receiver operating characteristic analysis was performed to determine discriminative performance.

Results: Both surgeon- and radiologist-performed IOSpUS achieved identical diagnostic performance: sensitivity 100%, specificity 100.0%, PPV 100.0%, NPV 97.5%, and accuracy 97.6%. Specimen mammography showed similar results, whereas gross inspection had zero sensitivity but 100% specificity, with an overall accuracy of 95.0%. The mean histopathological margin width was 13.2±3.7 mm. IOSpUS showed a strong correlation with histopathology ($r = 0.87$ for surgeon-performed and $r = 0.83$ for radiologist-performed; $p < 0.001$). Only one patient (2.5%) had a close margin that was correctly identified by both IOSpUS modalities and mammography, but was missed on gross inspection.

Conclusion: Surgeon-performed IOSpUS provides real-time, workflow-efficient intraoperative margin assessment, with diagnostic performance comparable to that of radiologist-performed ultrasound and specimen mammography in this prospective cohort. In low-resource environments, gross examination, though less sensitive, remains a viable adjunct when imaging facilities are limited. A combined approach has the potential to reduce re-excision by supporting intraoperative decision-making.

Keywords: Breast cancer; intraoperative ultrasound; specimen mammography; margin assessment; gross examination; low-resource setting

Corresponding Author: Sanjay Kumar Yadav MD;

E-mail: sky1508@gmail.com **ORCID:** orcid.org/0000-0002-0682-4970

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KEY POINTS

- Surgeon-performed intraoperative specimen ultrasound (IOSpUS-S) is oncologically reliable: It demonstrates diagnostic accuracy and margin correlation equivalent to radiologist-performed ultrasound and specimen mammography, validating surgeons as effective real-time margin assessors during breast-conserving surgery.
- Workflow efficiency without diagnostic compromise: IOSpUS-S significantly reduces intraoperative time and dependency on radiology services, enabling immediate margin-directed decision-making without loss of accuracy, critical in high-volume and resource-limited settings.
- Gross inspection alone is insufficient but remains a pragmatic adjunct: while gross examination has poor sensitivity for close/positive margins, its high specificity supports its role as a supplementary tool where imaging is unavailable, especially when combined with surgeon-performed ultrasound.

Introduction

Breast cancer is the most common malignancy among women worldwide and remains a major health burden in India (1, 2). Wide local excision (WLE) is an integral part of breast-conserving surgery (BCS) for early breast cancer, as it aims to remove the tumor completely while preserving breast shape and cosmesis (3, 4). The adequacy of surgical margins is crucial in preventing local recurrence, and positive margins often require re-excision or mastectomy, procedures that adversely affect both oncological and cosmetic outcomes (5, 6). Several intraoperative techniques have been developed to evaluate margins and reduce reoperation rates (7-10). Traditionally, specimen mammography has been used, particularly in cases of ductal carcinoma *in situ* (DCIS) (11, 12). Radiologist-performed specimen ultrasound (IOSpUS-R) has been employed to evaluate soft-tissue tumors more accurately than mammography; however, it requires specimen transfer and radiology input, which can prolong the operative workflow (13-16).

Surgeon-performed intraoperative specimen ultrasound (IOSpUS-S) has emerged as a pragmatic alternative, particularly in settings where dependence on radiologists, frozen section facilities, or dedicated imaging infrastructure limits real-time decision-making (17-19). This approach has the potential to reduce re-excisions, operative delays, and costs, particularly in resource-constrained settings. In low- and middle-income countries, the resources required for advanced intraoperative imaging are scarce, and breast cancer surgery often relies on the surgeon's experience and visual-tactile judgment. Gross examination of excised specimens, though simple and cost-neutral, is inherently subjective and hence is considered to have limited ability to detect close margin involvement (16, 20, 21). The present study was therefore undertaken to compare the diagnostic performance of gross examination, specimen mammography, radiologist-performed *ex vivo* (IOSpUS-R), and surgeon-performed *ex vivo* (IOSpUS-S) against final histopathology, the gold standard.

Materials and Methods

This prospective observational study was conducted in the Department of Surgery, Netaji Subhash Chandra Bose Medical

College, Jabalpur (MP), India, over 18 months (August 2023 to December 2024). Ethical approval was obtained from the Netaji Subhash Chandra Bose Medical College Jabalpur Institutional Ethics Committee (approval no: IEC/2023/7335-143, date: 18.08.2023), and informed consent from all participants were obtained. This prospective study included 40 consecutive patients with biopsy-proven invasive breast carcinoma undergoing WLE. Patients with pure DCIS, multifocal or multicentric disease, prior neoadjuvant chemotherapy, or non-mass lesions with calcification-dominant imaging were excluded.

All patients underwent standard preoperative mammography and ultrasound for localization and surgical planning. During surgery, WLE was performed with adequate margins in accordance with oncological principles. Each excised specimen was assessed intraoperatively using four margin-assessment methods. First, gross examination and surgeon-performed *ex vivo* ultrasound were carried out in the operating room using a portable high-frequency ultrasound probe to examine the specimen and assess margin status. Second, specimens were evaluated using radiologist-performed *ex vivo* ultrasound after transfer to the radiology department. Third, specimen mammography was performed to assess for calcifications and to evaluate margin clearance.

The findings of each modality were documented and compared with the final histopathology, which served as the gold standard; a close margin was defined as tumor not on the inked margin, with the closest margin measuring <2 mm. The primary outcome was the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of each imaging modality. Interobserver agreement between surgeon-performed and radiologist-performed ultrasound was also assessed. The radiologist was not informed of the surgeon's ultrasound interpretation. The final histopathological assessment was performed, blinded to all intraoperative margin assessments. While complete blinding of the surgeon to the specimen was not feasible, bias was mitigated using a standardized scanning protocol and predetermined cut-off values for close margins.

Statistical Analysis

Data were analyzed using an Excel spreadsheet and MedCalc Statistical Software (MedCalc Software Ltd., Ostend, Belgium).

Continuous variables were expressed as mean \pm standard deviation, while categorical data were presented as frequencies and percentages. Diagnostic performance parameters, including sensitivity, specificity, PPV, NPV, and overall accuracy, were calculated for each intraoperative modality using final histopathology as the gold standard. Exact 95% confidence intervals (CIs) for sensitivity and specificity were computed using the Wilson score method without continuity correction. Comparative analyses between modalities were performed using the chi-square (χ^2) test or Fisher's exact test as appropriate. Correlations between margin distance measured by intraoperative methods and final histopathological margins were analyzed using the Pearson correlation coefficient(r); the strength of association was interpreted as follows: $r = 0.00$ – 0.30 (weak), 0.31 – 0.70 (moderate), and >0.70 (strong).

Diagnostic performance across modalities was further assessed by constructing receiver operating characteristic (ROC) curves, and the area under the curve (AUC) was calculated, along with its standard error and 95% CI, to evaluate discriminatory ability. All tests were two-sided, and statistical significance was set at $p < 0.05$.

Table 1. Demographic and clinical profile of patients

Variable	Category	Frequency (%)
Age	Mean \pm SD (range)	42.65 \pm 13.36 (32–70)
Occupation	Homemakers	93%
	Others	7%
Menopausal status	Postmenopausal	18 (45%)
	Premenopausal	22 (55%)
Clinical stage	I	6 (15%)
	II	34 (85%)
Molecular subtype	A+B	18 (45%)
	Her 2 enriched	10 (25%)
	TNBC	12 (30%)

TNBC: Triple-negative breast cancer; SD: Standard deviation

Results

Patient Characteristics

Forty consecutive patients with breast cancer undergoing WLE were included. The mean age was 49 \pm 9 years (range 32–68). All lesions were invasive ductal carcinomas; the mean tumor diameter on final histopathology was 2.4 \pm 0.8 cm (Table 1).

Margin Assessment and Diagnostic Performance

Each excised specimen was evaluated intraoperatively by gross inspection, IOSpUS-S, radiologist-performed intraoperative specimen ultrasound (IOSpUS-R), and specimen mammography. Final histopathology served as the reference standard. The sensitivity of IOSpUS-S and IOSpUS-R was 100.0% (95% CI: 21–100); specificity was 100.0% (95% CI: 88.8–100); PPV was 100%; NPV was 97.5%; and overall accuracy was 97.6%. Specimen mammography yielded comparable performance metrics: sensitivity 100.0% (95% CI: 21.1–100); specificity 100.0% (95% CI: 88.8–100); PPV 100%; NPV 97.5%; and accuracy 97.6%. Gross inspection missed the only close-margin case in this cohort; therefore, its sensitivity could not be reliably estimated (0.0%, 95% CI: 0–37.9), and overall accuracy was 95.0% (95% CI: 83.1–99.4). There was no statistically significant difference between IOUS-R and IOUS-S ($p = 0.99$); however, both outperformed gross inspection ($p < 0.05$, χ^2 test) (Table 2).

Figure 1 depicts the ROC curves comparing diagnostic performance among modalities. Both surgeon- and radiologist-performed margin assessments showed near-identical curves with AUC = 0.90. Specimen mammography demonstrated moderate discrimination (AUC = 0.84), whereas gross inspection aligned closely with the reference line (AUC = 0.50).

Margin Distance Correlation

The mean histopathological margin width was 13.2 \pm 3.7 mm. Measurements obtained with surgeon-performed IOSpUS-S correlated strongly with histopathology ($r = 0.87$, $p < 0.001$), while radiologist-performed IOSpUS-R also demonstrated high

Table 2. Diagnostic performance of intraoperative margin assessment modalities (n = 40)

Modality	TP	FP	TN	FN	Sensitivity (%)	Specificity (%)	AUC	95% CI	PPV (%)	NPV (%)	Accuracy (%)
IOSpUS-R	1	0	39	0	100.0	100.0	0.90	0.83–0.98	100.0	97.5	97.6
IOSpUS-S	1	0	39	0	100.0	100.0	0.90	0.83–0.98	100.0	97.5	97.6
Specimen mammography	1	0	39	0	100.0	100.0	0.84	0.73–0.95	100.0	97.5	97.6
Gross inspection	0	0	39	1	0.0	100.0	0.50	0.34–0.65	-	95.0	95.0
Combined (gross+IOSpUS-S)	1	0	39	0	100.0	100.0	-	-	100.0	97.5	97.6

TP: True positives; FP: False positives; TN: True negatives; FN: False negatives; AUC: Area under curve; PPV: Positive predictive value; NPV: Negative predictive value; IOSpUS-S: Intraoperative specimen ultrasonography-surgeon; IOSpUS-R: Intraoperative specimen ultrasonography-radiologist; CI: Confidence interval

correlation also correlated strongly with histopathology ($r = 0.83, p < 0.001$). Specimen mammography showed a moderate correlation ($r = 0.68, p = 0.04$), whereas gross inspection showed a poor correlation ($r = 0.41, p = 0.12$) (Table 3).

Re-Excision Rate and Operative Workflow

Final histopathology confirmed that a single patient (2.5%) had a positive margin. This margin was accurately detected intraoperatively by both IOUS modalities and specimen mammography, but was missed on gross inspection, resulting in one false-negative case that was re-excised in the same sitting, under the same anaesthesia. The overall re-excision rate was 2.5%. The mean additional intraoperative time for IOSpUS-S evaluation was 5.8 ± 1.9 minutes, significantly shorter than that for IOSpUS-R and specimen mammography (16 ± 2 min and 14.2 ± 2.6 minutes respectively, $p < 0.001$). No intraoperative complications or workflow interruptions were encountered.

Discussion and Conclusion

In this study of 40 patients undergoing WLE, we found that surgeon-performed and radiologist-performed *ex vivo* intraoperative ultrasound achieved excellent specificity and

an overall diagnostic accuracy of 97.6% in margin assessment, with both modalities detecting the single close/positive margin that was missed by gross inspection. Importantly, gross visual inspection, despite its low sensitivity, maintained perfect specificity, highlighting that in settings lacking imaging infrastructure, careful gross margin assessment may still offer a pragmatic fallback. In resource-limited settings, where intraoperative imaging or frozen-section analysis is unavailable, gross inspection by an experienced breast surgeon remains a practical adjunct to reduce re-excision rates. Specimen ultrasound is technically less demanding than *in vivo* breast ultrasound and can be adopted by breast surgeons after focused training. The use of a standardized protocol further minimizes operator dependency and enhances reproducibility.

Ex vivo intraoperative ultrasound has been increasingly validated as an effective technique to reduce positive margins and re-excision rates. A systematic review and meta-analysis analyzing palpable infiltrating ductal breast cancers demonstrated that *ex vivo* IOUS guidance was significantly associated with higher rates of clear lumpectomy margins (odds ratio: ~ 2.3) compared to palpation or wire-guided surgery (18, 19, 22). Our results are consistent with this trend: *ex vivo* IOUS can reliably detect margin compromise with minimal operative delay.

On the other hand, gross intraoperative margin assessment (i.e., visual and tactile inspection of the specimen surface) has historically been considered inferior to imaging- or pathology-based intraoperative methods. However, a recent study evaluated the performance of gross intraoperative assessment and found that its use could contribute meaningfully to reducing re-excisions (20). Authors reported modest sensitivity but acceptable specificity and cautioned that performance is operator-dependent. Similarly, Hoekstra et al. (23) examined a registry dataset and concluded that gross margin examination reduced re-excision rates among invasive breast cancer BCS cohorts. Our experience accords with these findings: although our gross inspection missed one close margin, the inspection's perfect specificity suggests that a positive result is reliably predictive and can help triage which margins require further evaluation. When combined with surgeon-performed IOUS, gross examination could help prioritize suspicious zones for imaging or re-excision, thereby optimizing workflow.

Study Limitations

Nevertheless, our study has limitations. The present study should be interpreted in light of its small sample size and low event rate, as there was only one close-margin case. Consequently, diagnostic performance estimates should be considered exploratory and hypothesis-generating rather than definitive. Second, our results stem from a single institution with experienced surgeons and radiologists; performance might be lower in less-experienced

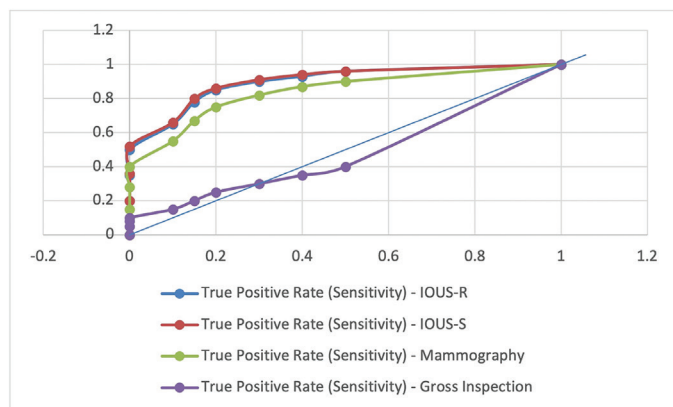


Figure 1. Depicts the receiver operating characteristic curves comparing diagnostic performance among modalities

Table 3. Correlation between intraoperative margin assessment modalities and final histopathological margin width

Modality	Correlation coefficient (r)	p-value
Surgeon-performed (IOSpUS-S)	0.87	0.0003
Radiologist-performed (IOSpUS-R)	0.83	0.0005
Specimen mammography	0.68	0.037
Gross inspection	0.41	0.118

IOSpUS-S: Intraoperative specimen ultrasonography-surgeon; IOSpUS-R: Intraoperative specimen ultrasonography-radiologist

hands. Third, this was a controlled setting; in busy clinical environments, additional time, coordination, or fatigue could affect IOUS performance. Fourth, we did not evaluate long-term local recurrence, cosmetic outcomes, or cost-effectiveness. All lesions in this study were mass-forming invasive carcinomas. The applicability of IOSpUS to pure DCIS or calcification-dominant lesions remains limited; specimen mammography continues to play a critical role.

Despite these limitations, our study has several strengths: we directly compared surgeon- and radiologist-performed IOUS with both specimen mammography and gross assessment in the same cohort, providing an internal control. The real-time integration of surgeon-performed IOSpUS-S demonstrates practical feasibility without disrupting operative flow.

Surgeon-performed IOSpUS provides real-time and workflow-efficient intraoperative margin assessment, with diagnostic performance comparable to radiologist-performed ultrasound and specimen mammography in this prospective cohort. In low-resource environments, gross examination though less sensitive remains a viable adjunct when imaging facilities are limited. A combined approach has the potential to reduce re-excision and may support intraoperative decision-making aimed at reducing re-excision.

Ethics

Ethics Committee Approval: Ethical approval was obtained from the Netaji Subhash Chandra Bose Medical College Jabalpur Institutional Ethics Committee (approval no: IEC/2023/7335-143, date: 18.08.2023).

Informed Consent: Informed consent from all participants were obtained.

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Footnotes

Authorship Contributions

Surgical and Medical Practices: T.A., S.K.Y., A.B., D.M., S.J.R., R.M., D.S.; Concept: T.A., S.K.Y., A.B., D.M., S.J.R., R.M., D.S.; Design: T.A., S.K.Y., A.B., D.M., S.J.R., R.M., D.S.; Data Collection and/or Processing: T.A., S.K.Y., A.B., D.M., S.J.R., R.M., D.S.; Analysis and/or Interpretation: T.A., S.K.Y., A.B., D.M., S.J.R., R.M., D.S.; Literature Search: T.A., S.K.Y., A.B., D.M., S.J.R., R.M., D.S.; Writing: T.A., S.K.Y., A.B., D.M., S.J.R., R.M., D.S.

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