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Multidisciplinary Intra-Operative Assessment of Breast Specimens Reduces Number of Positive Margins

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Abstract

Background—Successful breast conserving surgery requires achieving negative margins. At our institution, the whole surgical specimen is imaged, then serially sectioned with repeat imaging. A multi-disciplinary discussion then determines need for excision of additional margins. The goal of this study was to determine the benefit of each component of this approach in reducing the number of positive margin.

Methods—This single-institution prospective study included 10 breast surgical oncologists who were surveyed to ascertain whether they would have taken additional margins based their review of whole specimen images (WSI), and review of serially-sectioned images (SSI). These results were compared to the multidisciplinary decisions (MDD) and pathology results. Margin status was defined using consensus guidelines.

Results—One hundred surveys were completed. Margins on the original specimen were positive or close in 21%. After WSI, surgeons reported they would have taken additional margins in 26 cases reducing the number of positive/close margins from 21% to 13% ($p < 0.001$). After SSI, 52 would have taken additional margins, however the number of positive/close margins remained 13%. MDD resulted in additional margins taken in 56 cases reducing the number of positive/close margins to 7% ($p < 0.001$ compared to SSI).

Conclusions—While surgeon review of specimen radiographs can decrease the number of positive or close margins from 21% to 13%, more rigorous multi-disciplinary intra-operative margin assessment reduces the number of close or positive margins to 7%.

Breast conserving surgery (BCS) provides equal oncologic outcomes to mastectomy for the management of breast cancer with added benefits of lower operative morbidity and higher patient satisfaction.^{1,2} A critical element for successful BCS is achieving negative margins.^{3,4} Patients with positive margins often require a second operation for re-excision which

results in increased costs, patient anxiety, delays in adjuvant therapy, and impacts on cosmetic outcomes.^{5,6}

Reoperation rates have been suggested as a quality metric for breast cancer surgery,⁷⁻⁹ however methods to reduce re-operations require added costs.¹⁰ To address this, institutions have introduced heterogeneous approaches to intra-operative assessments of breast specimens.^{7,10-12} Recently, the American Society of Breast Surgeons convened a consensus conference with the mission “to reduce the national reoperation rate”.¹³ Their report outlines tools that may reduce the number of positive margin, some of which focus on the intra-operative assessment of surgical specimens.

One recommended approach is for the surgeon to perform and interpret an intra-operative x-ray of the whole specimen to ensure removal of the lesion and localizing clip as well as to determine if additional margins should be taken.¹³ However, at our institution intra-operative assessment is performed which includes a whole specimen radiograph followed by serial sectioning of the specimen with repeat imaging. Images are then reviewed by a multi-disciplinary team including the surgeon, pathologist and radiologist. This multi-disciplinary approach requires increased OR time for specimen processing, pathology support for inking and appropriate sectioning of specimens, and radiology support for interpretation of specimen x-rays. Additionally, because the assessment is made on radiographic and gross evaluation, there is a possibility of removing additional margins which may be unnecessary.

The goal of this study was to determine if surgeon interpretation alone of specimen imaging differs from that of the multi-disciplinary approach currently used.

Methods

This prospective survey study was performed after Institutional Review Board approval. Surgeons performing BCS for patients with invasive breast cancer or DCIS were asked to participate in the study over a 4 month period in 2016. Ten surgeons participated completing surveys for a total of 100 cases.

Pre-operative localization of non-palpable breast tumors was performed with needle or I¹²⁵ seed localization. Specimens were oriented by the surgeon and then transported to the pathology suite. First, whole specimen imaging (WSI) was performed in the pathology suite. Specimens were then serially sectioned, and these serial sections were imaged (SSI). The radiologist, pathologist, and surgeon reviewed the images together (either in person or on phone) and compared findings to gross examination of the specimen. The surgeon made the final decision to resect additional margins after the MDD based on this multi-disciplinary discussion (MDD).

Participating surgeons were asked to complete a survey after reviewing the WSI to indicate if they would anticipate taking additional margins based on their intra-operative findings and WSI. If they indicated that they would anticipate taking additional margins, they were asked which margins they would excise. They were then asked to review the SSI and answer the same questions. Surgeons were required to complete the surveys prior to discussions with radiology or pathology. The results from the MDD were also recorded. Finally, these results

were compared to the surgical pathology report to determine the proportion of patients that would require re-excision based on the surgeon survey and MDD results. (Figure 1)

Imaging and pathology reports were reviewed in the electronic health record to record tumor characteristics. Surgical records were reviewed to determine method of localization and whether an oncoplastic procedure (defined as having a plastic surgeon involved in the operation) was performed. Finally, the surgical pathology report was reviewed to assess the volume and margin status of each specimen.

Definition of Margin Status

Margins were classified based on consensus guidelines.^{4,14} For invasive cancer, margins were considered positive if tumor was found on ink. For DCIS with no associated invasive carcinoma or < 1 mm of invasive disease, margins were positive if DCIS was on ink and close if margins were < 2 mm.

Statistical analysis

Clinicopathologic data was tabulated and surgeon survey results and final pathology results were compared by Fisher's exact test. Tests were two-sided with p-values <0.05 considered significant. All statistical analyses were performed in SAS (Enterprise Guide 5.1, Cary NC).

Results

Surgeons completed surveys on 100 cases. Tumor size on pre-operative imaging was ≤ 2 cm in 66 cases, 2.1–5 cm in 30, and > 5 cm in 4 cases. A mass was seen in 81 cases and calcifications (either with or without a mass) were seen in 40. Sixty-five cases had invasive ductal histology (50 of these were associated with DCIS), 25 were pure DCIS, and 10 had lobular histology. Twenty-seven patients received neoadjuvant therapy (either chemotherapy or endocrine). Seventy-four cases used I¹²⁵ seed localization, 23 used wire-localization, and 3 used no localization because they were palpable lesions. Twenty six cases were done as a joint procedure with a plastic surgeon who performed an oncoplastic closure. Table 1 summarizes the clinicopathologic features. Thirteen patients underwent a second operation for re-excision of margins.

Margin Status

The pathologic evaluation of the original surgical specimen (before any additional margins taken) revealed positive or close margins in 21 (21%) patients. After the WSI, surgeons reported they would have resected an additional margin in 26 cases which would have reduced the number of positive or close margins to 13% (p<0.001). Following review of SSI, surgeons reported they would have taken additional margins in 52 cases. The number of positive or close margins remained the same at 13, however 2 cases with pure DCIS that had a positive margin were converted to close margins. Finally, the MDD resulted in additional margins being taken in a total of 56 cases which reduced the proportion of cases with a final positive or close margin to 7% (p<0.001 compared to WSI) (Table 2 and Figure 2). In 13 cases, the surgeon considered taking an additional margin after review of images, but decided against taking that margin after the MDD. In the 44 cases where no additional

margins were taken, none were found to have a positive or close margin on pathology. The positive predictive value of the MDD was 21/56 (37.5%) and the negative predictive value was 44/44 (100%).

Volume removed—One concern with removing additional margins is the excess breast volume resected that might impact cosmetic outcomes. We analyzed the volume of breast tissue removed in cases that did not include a plastic surgeon as this may have impacted the volume removed. The mean volume of breast tissue removed in cases involving a plastic surgeon was 177.4 cm³. We also excluded cases from this analysis in which the surgeon reported that they would have taken a margin in their WSI or SSI survey that was not taken after MDD since the volume of this specific margin could not be determined (n=13). The mean volume of the original specimen in these remaining 61 cases was 53.3 cm³. After evaluation of WSI, surgeons would have removed a mean volume of 55.4 cm³ and 57.7 cm³ after review of SSI. MDD resulted in removal of 59.6 cm³.

Variables Impacting Evaluation—Finally, we evaluated features which might impact the surgeons' ability to predict which margins should be removed compared to the MDD, which is summarized in Table 3. While we hypothesized that MDD review may be less helpful in cases with a mass on imaging compared to calcifications, this was not the case. In 81 cases with a mass seen on imaging, the proportion of patients with positive or close margins on the original specimen was 19.8% (6/81) which would have been reduced to 11.1% (9/81) after surgeon review and 4.9% (4/81) after MDD. In the 40 cases with calcifications, 17.5% (7/40) had positive or close margins on the original specimen, 12.5% (5/40) would have been positive or close based on surgeon assessment, and 10% (4/40) had positive or close margins after MDD. Thus MDD reduced the number of positive or close margins compared to surgeon assessment by 6.1% (11.1% versus 4.9%, p=0.25) in cases with a mass, but only reduced the number by 2.5% (12.5% versus 10%, p=1.0) in cases with calcifications.

Discussion

Many methods of intra-operative specimen assessment have been utilized in an attempt to decrease re-excision rates after BCS. In this study, we found that removal of a surgical specimen without any intra-operative evaluation of margins would have resulted in positive or close margins in 21% of cases. This was reduced to 13% by surgeons assessing specimen radiographs. Surgeon assessment of serially-sectioned images was not superior to evaluation of the whole specimen image. However, adding multidisciplinary evaluation reduced this number to 7%.

Re-excision rates following BCS have been found to be highly variable ranging from 3–50%.^{7,10–12} Re-operation increases the costs and risks of complications associated with breast cancer surgery. A review of private claims data on 9837 women undergoing BCS showed that 23% underwent at least one additional surgery. The likelihood of a surgical complication was 47% higher with repeated surgery, and the mean 2-year health care costs increased by \$11,621 for patient undergoing repeat BCS and \$26,276 for those converting to mastectomy.¹⁵

One reason for such variability in re-excision rates is that there has been historical debate defining optimal margins for BCS. In one survey of 418 surgeons performed in 2010, 11% felt no tumor on ink was adequate, 42% felt that 1–2 mm was required, 28% felt 5 mm was necessary, and 19% required > 1 cm.¹⁶ Another survey of 100 surgeons found that 15% would accept any negative margin, 28% a 1 mm margin, 50% would accept 2 mm, 12% would accept 5 mm, and 3% would accept 1 cm.¹⁷ In order to provide guidance on this issue, consensus guidelines have recently been published based on meta-analyses of available literature. These guidelines specify that no tumor on ink is sufficient in cases of invasive cancer⁴ and that a 2 mm margin is optimal in DCIS in patients undergoing BCS with adjuvant radiation.¹⁴ Two studies have shown a 13.6–16% decrease in the number of second operations after BCS for patients with invasive breast cancer after publication of the consensus guidelines.^{18,19} Importantly, these guidelines do not apply to patients who receive neoadjuvant therapy or who do not receive adjuvant radiation.

In an effort to give surgeons methods to reduce the number of patients undergoing re-operation, the American Society of Breast Surgeons convened a consensus conference and published a toolbox of approaches that reduce re-operation rates as well as the data supporting these practices.¹³ In this conference, 100% of attendees recommended specimen imaging and surgeon review classifying this as a strong recommendation. We found surgeon evaluation of the WSI reduced the number of positive/close margins from 21% to 13%. Others have described a similar reduction in the need for re-excision from 31% to 20% with the use of specimen radiography following BCS.²⁰ In our study, surgeon evaluation of SSI did not reduce the number of positive/close margins compared to the use of WSI. While the reduction from 21% to 13% is clinically significant, the addition of multidisciplinary discussion appears to be the best practice based on our data as it reduced the number to 7%.

In addition to this toolbox, other institutions have also reported on methods to reduce number of positive margins. One study compared the national NSQIP re-excision numbers to re-excision numbers for a single institution using frozen section analysis. They found the 30-day reoperation rate was 13.2% nationally compared to 3.6% ($p<0.001$) for the institution using frozen section.¹⁰ Another approach has been to routinely take shave margins, or additional margins circumferentially around the tumor bed. In a randomized trial comparing shave margins to selective margin removal, the number of positive margins was significantly lower in the shave margin cohort (19% vs 34%, $p=0.01$) and the number of re-operations was reduced (10% vs 21%, $p=0.02$).²¹ However, the total volume of tissue excised was significantly larger in the shave margin group (115.1 cm³ vs. 74.2 cm³, $p<0.001$). Another randomized trial of patients with ER-negative tumors, found a reduction in positive margins with cavity shave margins (45% vs 16%, $p=0.005$).²² Our study was not designed to compare our multi-disciplinary approach to other methods, although this could be studied in the future.

In this study, we report that 13% of patients ultimately underwent re-excision while only 7% had positive/close margins on final surgical pathology. Multiple factors may have impacted the decision to re-excise. First, 27% of the study cohort had neoadjuvant therapy. For the purpose of this analysis, we defined negative margins as no tumor on ink. However, given the lack of consensus guidelines, some of these patients underwent re-excision in order to

obtain 2 mm margins. In the 5 patients who received neoadjuvant therapy who underwent re-excision, 4 had positive margins at their first operation. One had multiple close margins (2 mm) even after additional margins were taken which influenced the decision to re-excise. The second factor that may have impacted the re-excision rate was that this survey was conducted before the publication of the DCIS margin consensus guidelines. In 5 of the cases, DCIS associated with invasive cancer was < 2 mm from the final margin. The number of surgeons who decide to re-excise in this scenario may now be reduced since the consensus guidelines state that DCIS associated with at least 1 mm of invasive carcinoma should be treated according to the invasive guidelines (no tumor on ink).¹⁴

This study is limited by the fact that the survey answers may not accurately predict what would be done in a real-world scenario. It is also a single institutional study and therefore may not be applicable at other institutions. The multi-disciplinary specimen evaluation we described has been established as a longstanding collaboration at our institution.^{23–25} Other centers may not be able to immediately reproduce the same results. We recognize that this approach requires significant resources that may not be possible in lower volume centers. We did not evaluate the cost effectiveness of this approach in the current study, however this will be important to study in the future.

In conclusion, we found that an intra-operative specimen evaluation involving a multi-disciplinary team of surgeons, pathologists, and radiologists was able to significantly decrease the rate of positive margins in patients undergoing BCS. This collaborative approach increased the number of additional margins taken intra-operatively, but the additional volume resected was minimal.

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Synopsis

We evaluated an intra-operative, multi-disciplinary margin assessment strategy for patients undergoing breast conservation surgery. Specimen imaging with serial sectioning and multidisciplinary review reduces the number of close or positive margins from 21% to 7%.

Figure 1.
Study Design

Intra-operative specimen assessment included whole specimen imaging followed by serial sectioning of the specimen with repeat imaging. The pathologist and radiologist review the images and specimen and discuss findings with the surgeon to guide selective removal of additional margins. In this study, surgeons were surveyed after reviewing the whole specimen and serially sectioned images to determine if they would have taken additional margins based on these findings before discussion with radiology and pathology.

	Review of Whole Specimen Imaging	Review of Serial Section Imaging	Multi-disciplinary Review

Number of cases in which additional margins would be removed	26	52	56
Number of margins removed for each patient:			
1 margin	16 (62%)	31 (60%)	29 (52%)
2 margins	8 (31%)	14 (27%)	13 (23%)
3 margins	1 (4%)	6 (12%)	11 (20%)
≥4 margins	1 (4%)	1 (2%)	3 (5%)

Figure 2.

Additional margins after intra-operative Assessment

Summary of the number of margins that would have been taken after each step of intra-operative evaluation and the margin status based on this information.

Table 1

Clinicopathologic Features

	Number
Size of lesion on imaging	
0–2 cm	66
2.1–5 cm	30
>5 cm	4
Description on imaging	
Mass	81
Calcifications	40
Asymmetry or distortion	22
Method of localization	
Seed	74
Wire	23
None (palpable lesions)	3
Neoadjuvant therapy	
None	73
Chemotherapy	23
Endocrine therapy	4
Histology	
DCIS	25
Ductal	65
Lobular	10

Table 2**Margin Status After Specimen and Imaging Review**

Margin status based on review of specimen and imaging. Positive margins defined as tumor seen on ink. Close margins defined as pure DCIS (or associated with < 1 mm invasive carcinoma) with a margin < 2 mm.

	Number
Original surgical specimen	
Pathologic margin status of this specimen	
Positive	17
Close	4
Negative	59
Survey results after review of whole specimen imaging	
Cases in which additional margins would have been resected Margin status based on this evaluation:	26
Positive	11
Close	2
Negative	87
Survey results after review of serial section imaging	
Cases in which additional margins would have been resected Margin status based on this evaluation:	52
Positive	9
Close	4
Negative	87
Survey results after multidisciplinary discussion	
Cases in which additional margins would have been resected Margin status based on this evaluation:	56
Positive	6
Close	1
Negative	93

Table 3
Number of positive or close margins based on clinicopathological characteristics or surgical technique

		Number of Positive or Close Margins based on this evaluation				
		N	Original Specimen	Whole Specimen Image	Sectioned Specimen Image	Multidisciplinary Discussion
Size of lesion						
	0-2 cm	66	11 (16.7%)	7 (10.6%)	7 (10.6%)	4 (6.1%)
	2.1-5 cm	30	9 (30%)	5 (16.7%)	5 (16.7%)	2 (6.7%)
>5 cm	4	1 (25%)	1 (25%)	1 (25%)	1 (25%)	1 (25%)
Mass						
	Yes	81	16 (19.8%)	9 (11.1%)	9 (11.1%)	4 (4.9%)
No	19	5 (26.3%)	4 (21.1%)	4 (21.1%)	3 (15.8%)	
Calcifications						
	Yes	40	7 (17.5%)	5 (12.5%)	5 (12.5%)	4 (10%)
No	60	14 (23.3%)	8 (13.3%)	8 (13.3%)	3 (5%)	
Neoadjuvant Therapy						
	Yes	27	6 (22.2%)	6 (22.2%)	6 (22.2%)	4 (14.8%)
No	73	15 (20.5%)	7 (9.6%)	7 (9.6%)	3 (4.1%)	
Histology						
	Ductal	65	9 (13.8%)	5 (7.7%)	5 (7.7%)	3 (4.6%)
	Lobular	10	5 (50%)	5 (50%)	5 (50%)	1 (10%)
DCIS	25	7 (28%)	3 (12%)	3 (12%)	3 (12%)	
Oncoplastics						
	Yes	26	8 (30.7%)	5 (19.2%)	5 (19.2%)	2 (7.7%)
No	74	13 (17.6%)	8 (10.8%)	8 (10.8%)	5 (6.8%)	