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Does three-dimensional intraoperative specimen imaging reduce the need for re-excision in breast cancer patients? A prospective cohort study

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Abstract

BACKGROUND: Standard two-dimensional (2D) specimen radiography may guide intraoperative re-excision of margins in patients undergoing breast conserving surgery. We sought to determine the impact of three-dimensional (3D) specimen imaging in further reducing positive margin rates.

METHODS: A prospective study of 100 patients in which both 2D and 3D specimen radiographies were performed. The impact of orthogonal view on intraoperative surgical management and final margins was assessed.

RESULTS: Ten patients had no residual tumor; therefore, 90 patients formed the cohort of interest. Of them, 21 patients (23.3%) had ductal carcinoma in situ; 18 (20.0%) had invasive cancer; and 51 (56.7%) had both. Median tumor size was 1.7 cm (range, .2 to 8.1 cm). On the basis of 2D imaging, surgeons stated they would take more tissue in 26 patients (28.9%). Three-dimensional imaging changed management in 4 patients (6.3%). One of these patients would have had positive margins if the intraoperative resection done on the basis of the 3D imaging would have been omitted.

CONCLUSIONS: Three-dimensional specimen imaging results in further intraoperative re-excision in 6.3% of patients and may reduce re-excision rates in 2.2%.

Breast conserving surgery is the procedure of choice for primary tumor extirpation in most breast cancer patients, and achieving clear margins is critical to minimizing the risk of local recurrence in these patients. Despite the most recent guidelines indicating that, for patients with invasive disease, a negative margin is considered "no tumor at ink,"[1] roughly 20% to 40% of patients will have positive margins mandating re-excision.[2–4] As a result, there have been a number of initiatives to try to reduce positive margin rates.

Intraoperative specimen radiography has been well accepted to confirm that nonpalpable lesions, often designated with a radiographic marker, are removed. Although this form of imaging can often be used to guide intraoperative re-excision if the malignant lesion in question is found to be close

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to a margin, the image that is routinely obtained is two dimensional (2D). We hypothesized that by obtaining orthogonal images to provide three-dimensional (3D) specimen radiography, further information could be obtained that could guide additional intraoperative margin resection and reduce positive margin rates.

Methods

Patients with Stage 0 to 3 breast cancer, who were more than the age of 18 years and who were candidates for needle-localized partial mastectomy, were eligible for participation in this study. Those with metastatic disease, or in whom a total mastectomy was planned, were excluded. One hundred seven patients who were eligible for the study were approached. No patient refused participation; all signed informed consent. However, 2 patients withdrew before surgery as they decided to proceed with total mastectomy instead of partial and therefore were no longer eligible. One patient changed her mind regarding participation after previously consenting preoperatively. In 4 additional cases, data could not be obtained for a variety of reasons (technical or supply issues [n = 2], surgeon did not do orthogonal specimen radiograph [n = 1], or intraoperative ultrasound instead [n = 1]). This yielded a cohort of 100 patients in whom two intraoperative orthogonal specimen radiographs were obtained.

All patients had standard intraoperative radiography of their partial mastectomy specimen, and surgeons were asked if, based on the 2D picture obtained, they would take additional margins. Orthogonal images of the specimen were then taken (using the Faxitron Wedge system, Faxitron Bioptics LLC, Tuscon, AZ). The surgeon interpreted these images as they were captured in the operating room and were queried as to their disposition as to whether further intraoperative margins should be taken. Surgeons were at liberty to take more tissue regardless of imaging findings. All patients therefore had both 2D and 3D specimen radiography intraoperatively.

Surgeons oriented the primary partial mastectomy with a minimum of two orthogonal orienting sutures or markers; any additional margins that were removed were also oriented as to which face was the true margin. Final pathology results were reviewed to determine the impact of 3D imaging on reducing positive margin rate and need for re-excision. Over the period of this study, there were 4 breast surgeons, 6 pathologists, and 8 breast imagers at our institution. Given the relatively small number of patients in this study, the impact of individual providers was not ascertained. This study was approved by the Yale University Human Investigations Committee. Statistical analyses were performed using SPSS, version 21, software (IBM, Armonk, NY).

Results

Of the 100 patients who were consented for this study, informative data were only available in 90 patients as 10 patients had no further tumor at the time of surgery (either due to neoadjuvant chemotherapy or all tumor being removed at the time of diagnostic core needle biopsy). These patients formed the cohort of interest.

The sociodemographic and clinicopathologic factors for the cohort of interest are summarized in Table 1. The median patient age was 60 years (standard deviation [SD] = 10.0; range, 41 to 88 years). Sixty nine patients had invasive disease, with a median tumor size of 1.2 cm (SD = 1.1; range, .1 to 5.4 cm). Of these patients, 51 (73.9%) had concomitant ductal carcinoma in situ (DCIS), and 21 additional patients had DCIS alone. The median extent of the DCIS was 1.75 cm (SD = 1.4; range, .2 to 8.1 cm). The median tumor size resected (whether of DCIS or invasive cancer, whichever was largest if both coexisted) was 1.72 cm (SD = 1.3; range, .2 to 8.1 cm).

On the basis of 2D imaging alone, surgeons stated they would take additional tissue in 26 patients (28.9%). Of the

Table 1 Sociodemographic and clinicopathologic features of cohort

Characteristic	N (%)
Race	
White	71 (78.9)
African-American	13 (14.4)
Asian	2 (2.2)
Other	4 (4.4)
Ethnicity	
Non-Hispanic	81 (90.0)
Hispanic	6 (6.7)
Unknown	3 (3.3)
Histology of invasive component (n = 69)	
Ductal	62 (89.9)
Lobular	5 (7.2)
Other	2 (2.9)
Grade of invasive component*	
1	27 (30.0)
2	30 (33.3)
3	11 (16.2)
Grade of DCIS (n = 21)	
1	7 (9.7)
2	44 (61.1)
3	21 (29.2)
ER status (either invasive or DCIS)	
Positive	86 (95.6)
Negative	4 (4.4)
PR status (either invasive or DCIS)†	
Positive	80 (99.9)
Negative	9 (10.0)
Her-2 status (invasive cancer)‡	
Positive	4 (4.4)
Negative	58 (84.1)

DCIS = ductal carcinoma in situ; ER = estrogen receptor; Her-2 = human epidermal growth factor receptor 2; PR = progesterone receptor.

*Grade not stated in 1 patient.

†PR status not stated in 1 patient.

‡Her-2 status not stated in 7 patients with invasive disease.