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ORIGINAL ARTICLE – BREAST ONCOLOGY

A Multi-institutional Study to Evaluate the Effectiveness and Safety of a Supine MRI-Based Guidance System, the Breast Cancer Locator™, for Breast Conserving Surgery in Patients with Nonpalpable Breast Cancer

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ABSTRACT

Background. The Breast Cancer Locator™ (BCL) has been demonstrated to be a safe and effective guidance system for breast-conserving surgery (BCS) in patients with palpable breast cancer, but its effectiveness in patients with nonpalpable breast cancer has not been evaluated.

Patients and Methods. Supine magnetic resonance imaging (MRI) images were used to generate (1) an interactive three-dimensional (3D) virtual image of the tumor in the breast and (2) a plastic bra-like form (BCL) that enabled the surgeon to place wires that bracketed the tumor volume. The primary objective was to determine the proportion of patients undergoing margin negative resections.

Results. A total of 35 subjects were enrolled at 5 sites by 9 surgeons. In the 33 patients treated per protocol, 31 had margin negative resections (94%). All 31 patients with negative margins had negative margins on the primary lumpectomy specimen resected with BCL guidance. Additional shave margins were taken in 4 of the 31 patients; no cancer was present in the shaves. A total of 25 patients had invasive ductal carcinoma, 7 invasive lobular carcinoma, and 3 ductal carcinoma en situ (DCIS). The mean tumor diameter was 3.1 cm and specimen volume was 56 ml. The median actual/targeted specimen volume ratio was 1.18. There was no significant difference in preop versus postop Breast-Q scores: 66.5 versus 64.0, $p = 0.58$. Surgeons judged the BCL guidance system to be easy to use in 91% of cases.

Conclusions. The BCL guidance system enabled surgeons to do precise BCS: margin negative resections were obtained in a high proportion of cases, resected specimen volumes were relatively low, and patients' satisfaction with their breasts was not adversely effected by surgery.

Keywords Supine MRI · Breast conserving surgery · Breast cancer · Lumpectomy · Guidance device

Positive margins after breast-conserving surgery (BCS) remain a problem even after the adoption of consensus guidelines.[1,2] A total of 15–20% of patients with nonpalpable invasive cancer who undergo BCS with a variety of localization techniques have positive margins.[3-6] The problem is even greater for patients with palpable cancer or pure ductal carcinoma en situ (DCIS), where positive margins occur approximately 30% of the time.[6-9]

Guidance derived from supine magnetic resonance imaging (MRI) has been demonstrated to decrease positive

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margin rates after BCS for invasive cancer and DCIS in two randomized controlled trials.[10,11] Studies have shown that spatial guidance information derived from supine MRI can be provided to the surgeon via a three-dimensional interactive image that shows the surgeon the shape of the breast cancer combined with a patient-specific bra-like form (Breast Cancer Locator™, BCL), which allows the surgeon to place bracketing wires around the tumor.[12,13] In two pilot studies of BCS in 33 patients with palpable breast cancers, the BCL enabled margin negative resections in all patients.[12,13]

The primary purpose of the current study was to test whether the BCL guidance system and the supporting workflow (supine MRI, transmission of image data, BCL design and fabrication, and surgeon use) could be deployed safely and effectively by several surgeons at multiple sites to guide breast conserving resections of nonpalpable invasive breast cancer and DCIS.

PATIENTS AND METHODS

This study was approved by the ethics committees of Italy (Comitato Etico Territoriale Regione Toscana - Area Vasta Nord Ovest (CEAVNO), Germany (Ethik-Kommission bei der Landesärztekammer Hessen) and Switzerland (Comitato Etico Cantonale Ticino). The study was listed at clinicaltrials.gov (NCT06461663).

Patient Eligibility

Eligible patients were adult women with a nonpalpable invasive breast cancer or DCIS on preoperative core biopsy who desired BCS. Tumors were required to enhance and be at least 5 mm in diameter on prone MRI. Patients with multifocal tumors were eligible if the other tumor foci were < 2 cm from the primary tumor. Patients with multicentric tumors (additional foci > 2 cm from the primary) were excluded. Patients were excluded if they had contraindications to MRI (implanted metal objects, allergy to gadolinium or impaired renal function (Glomerular Filtration Rate (GFR) < 30 ml/min/1.73 m^2), were pregnant, or had received neoadjuvant chemotherapy. Patients with very ptotic breasts (sternal notch to nipple distance of > 32 cm) and patients who would not fit into an MRI (circumference around chest and arms > 135 cm) were excluded.

Supine MRI

Patients with nonpalpable invasive breast cancer underwent supine MRI at their local institution as previously described.[13] In brief, patients were positioned supine in the scanner with their ipsilateral arm parallel to their body. Foam pads were placed on the chest to support a rectangular flex body coil without causing breast compression. MRI scanners (1.5T and 3T) were used to obtain an axial T1 large field of view non-fat saturation sequence. Then, axial T1 fat saturated dynamic sequences pre- and post-gadolinium contrast injection were acquired. Image data from the supine and standard of care-prone MRIs were transmitted to the study radiologist (TR), who marked the tumor edges on consecutive supine MRI slices using an open source, commercial off-the shelf (COTS) software package (3Dslicer, www.slicer.org).[14,15]

BCL Design and Manufacturing

BCLs were fabricated as previously described.[13] Briefly, using off-the-shelf software (3Dslicer and MeshMixer: www.meshmixer.com) and proprietary software (Planner, CairnSurgical, NH), three-dimensional (3D) digital models of the breast surface, radiologist-defined tumor extent and chest wall surface were created and used to design the patient-specific BCL device for each subject. Each BCL was then fabricated using an additive manufacturing (3D printing) process (ProJet 7000HD, 3Dsystems, CO) from a transparent plastic material (Accura Phoenix, 3Dsystems, CO) using stereolithography (SLA) 3D printer (ProJet 7000HD, 3Dsystems, CO) and were sterilized using ethylene oxide (Sterivac GS8X, 3M, MN). BCLs were then packaged and shipped to the surgeon. BCL design, manufacturing, and delivery take approximately 7–10 days.

Use of BCL and Visualizer to Guide Surgery

The BCL surgical guidance system consists of two components. Component 1, the Visualizer, is an interactive, virtual 3D view of the cancer in the breast with tumor dimensions and distances from the skin to the tumor and from the tumor to the chest wall (Fig. 1). Component 2, the BCL, is a patient-specific bra-like plastic form (Fig. 2). The BCL is aligned on the breast using a cut-out for the nipple and two cut-outs for marks left at sites of two fiducials placed during supine MRI. It contains small holes on its surface that allow the surgeon to mark the projected edges of the cancer on the skin surface. It also has up to five ports (one central and four peripheral), which allow the surgeon to place wires (Ghiatis® Beaded Breast Localization Wires from Bard Medical Products) into the breast. The peripheral bracketing wires were designed to be placed 1 cm cranial, medial, caudal, and lateral to the MRI-defined tumor edges (Fig. 2). The tip of the needle used to deploy the wire was designed to be no closer than 1 cm from the chest wall; if the distance from the skin to the chest wall was < 2.5 cm, no port was placed at that location.

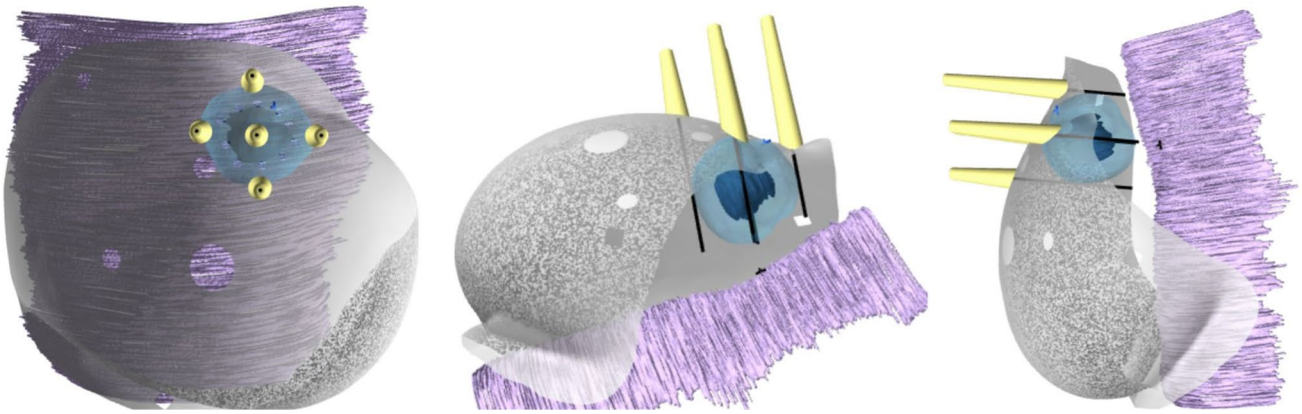

FIG. 1 Depiction of images obtained from the Visualizer, demonstrating the shape, size, and location of the MRI-defined tumor in the breast; tumor volume is dark blue, tumor volume plus 1 cm is light blue, gray is breast skin, purple is chest wall; ports that extend from the BCL are in yellow, and black lines indicate the location of bracketing wires; surgeon has access to an interactive web-access model that can be moved in any direction

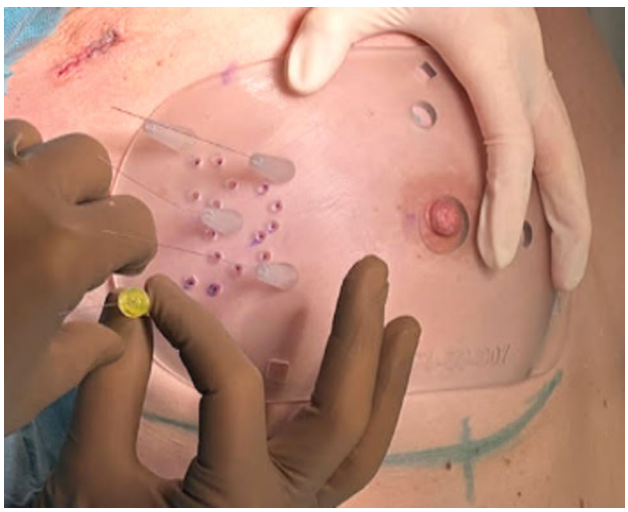

FIG. 2 The BCL device, showing key functional features including **A** a cut-out for the nipple, **B** two alignment holes for intraoperative positioning, **C** multiple small holes to mark the projected edges of the tumor on the skin surface, and **D** up to five ports to place bracketing wires into the breast 1 cm from the MRI-defined tumor edges

After the patient is anesthetized, she is prepped with her arm parallel to the OR table. The surgeon places the BCL on the breast, marks the projected edges of the tumor on the skin surface and then deploys the bracketing wires through the ports. The BCL is removed, the breast is re-prepped and the surgeon performs a partial mastectomy, guided by the bracketing wires and the Visualizer. If gross palpation of the specimen was concerning for a close margin or if the specimen radiograph indicated that the tumor was < 2 mm from an edge, a selected shave excision could be performed at the surgeon's discretion.

Study Objectives and Outcome Measures

The primary objective of the study was to ascertain the positive margin rate when the BCL System is used to guide a surgeon performing partial mastectomy. The main outcome measure was the positive margin rate. A margin was considered positive for invasive cancer if tumor was present on ink and for DCIS if tumor was < 2 mm from the specimen edge.[1,2]

Secondary study objectives were:

1) to determine the specimen volume after BCL-guided partial mastectomy and compare this value to the targeted specimen volume. To measure its volume, the specimen (plus shave specimens, if taken) was placed in a cylinder containing water and the water displacement was determined. The targeted specimen volume was calculated from the 3D model of the tumor in the breast to be the tumor volume plus 1 cm in all directions.
2) to determine patients' satisfaction with their breasts by using the validated BREAST-Q score at 6 weeks after surgery.[16]
3) to evaluate safety of the BCL.
4) to evaluate the surgeon's satisfaction with and perception of ease of use of the BCL system, using a five-point Likert scale.

Statistical Analysis

The positive margin rate (PMR) with the use of BCL was expected to be < 5% on the basis of previous studies.[12,13] We assumed a true PMR of 3% and applied the exact or Clopper–Pearson method for a single binomial proportion to derive a sample size of $N = 35$ patients who have undergone

surgery with the BCL and have had a margin assessment, which will achieve a confidence interval with total width of 15%.

Descriptive statistics were used to describe the data. Comparisons between groups were evaluated with two-tailed *t*-tests.

RESULTS

Subjects

A total of 35 patients were enrolled between June 2022 and February 2024. Patients were enrolled at 5 sites: Agaplesion Markus Krankenhaus, Frankfurt, Germany (15); Brustzentrum an der Klinik St. Elisabeth, Heidelberg, Germany (8); Azienda Ospedaliero Universitaria Pisana, Pisa, Italy (6); Spital Zollikerberg, Zurich, Switzerland (5); and Humanitas Research Hospital, Milan, Italy (1). Nine surgeons enrolled patients: K.K. 7, M.R. and M. Ghilli 6, M.T. 6, H.F. 5, M. Golatta 4, J.H. 4, V.H. 2, and A.S. 1.

Patients ranged in age between 42 and 83 years (median 63 years) (Table 1). A total of 59% had bra sizes A or B; 30% had bra size C; 11% had bra sizes D or greater. Median body mass index (BMI) was 24.7, range 18.7–32.7. Maximal tumor diameters on supine MRI ranged from 1.5 to 6.0 cm (median 2.3 cm, mean 2.7 cm). Seven patients had multifocal tumors (additional enhancing masses < 2 cm from the primary tumor) identified on MRI.

BCL Use in Surgery

In total, 24 BCLs (69%) were designed with 5 ports, 2 were designed with 4 ports, 1 with 3 ports, 1 with 2 ports, and 7 with no ports, due to skin to chest wall distances < 2.5 cm. Wire lengths were 5 cm in 6 patients, 7 cm in 15 patients, 9 cm in 6 patients, and 14 cm in 1 patient.

In total, 33 patients were treated per protocol. Major protocol deviations occurred in two cases. In both of these patients, the instructions for use of the BCL were not followed: the surgeon cut far inside the bracketing wires such that the actual specimen volumes were only 40% of the targeted specimen volumes.

Main Outcome Measure

Considering the 33 patients treated per protocol, 2 patients (6%) had a positive margin and 31 patients (94%) had negative margins. All 31 of the patients with negative margins had negative margins on the primary lumpectomy specimen resected with BCL guidance, and 4 of the 31 patients with negative margins had additional shave margins excised in addition to the primary specimen; no cancer was found in these shave specimens. A total of 27 of 31 patients (87%) had excisions that were guided by the BCL and after palpation of the specimen and specimen imaging, the surgeon did not determine that any additional shaves were necessary. In total, 30 patients had invasive carcinomas (23 ductal, 7 lobular) and 3 had solely DCIS (Table 2). The largest tumor diameter as determined by pathology ranged from 0.6 to 8.5 cm, median 2.0 cm, mean 3.1 cm.

Secondary Outcome Measures

Considering the 33 patients treated per protocol, the targeted specimen volume (the tumor volume plus 1 cm of

TABLE 1 Patient, imaging, and tumor characteristics

Patients treated, *N*	35
Sites, *N*	5
Surgeons, *N*	9
Patient age, years, median (range)	63 (42–83)
Bra size	
A or B, %	59%
C or greater, %	41%
BMI, median (range)	24.7 (18.7–32.7)
Largest tumor diameter, cm, median (range)	
Supine MRI	2.3 (1.5–6.0)
Pathology	2.0 (0.6–8.5)
Multifocal tumor on MRI, *N* (%)	7 (20%)
Histology	
Invasive ductal carcinoma, *N* (%)	25 (71%)
Invasive lobular carcinoma, *N* (%)	7 (20%)
DCIS, *N* (%)	3 (9%)

TABLE 2 Outcome measures, per-protocol patients, $N = 33$

Positive margin, *N* (%)	2 (6%)
No additional shave excisions performed at primary operation, *N* (%)	29 (87%)
Histology	
Invasive ductal carcinoma, *N* (%)	23 (70%)
Invasive lobular carcinoma, *N* (%)	7 (21%)
DCIS, *N* (%)	3 (9%)
Largest tumor diameter on pathology, cm	
Median (range)	2 (0.6–8.5)
Mean (SD)	3.1 (2.2)
Targeted specimen volume, ml	
Median (range)	28 (18–97)
Mean (SEM)	36 (3.3)
Actual specimen volume, ml	
Median (range)	45 (12–211)
Mean (SEM)	56 (5.0)
Actual/targeted specimen volume, median, range	1.18 (0.6–4.8)

breast tissue surrounding the tumor) ranged from 18 to 97 ml (median 28 ml, mean 36 ml) (Table 2). The actual specimen volumes ranged from 12 to 211 ml (median 45 ml, mean 56 ml). The ratio of the actual/targeted specimen tumor volumes was 1.18 (0.6–4.8) (Fig. 3). A total of 26 patients (79%) had actual/targeted resection volumes between 1 and 1.5 (Fig. 3). One patient had an actual/targeted resection volume less than 1; six patients had actual/targeted resection volumes of 2 or greater.

Breast-Q scores were obtained from 28/33 patients. The Breast-Q score preop was 66.5 (SEM 3); the Breast-Q score postop was 64.0 (SEM 2.2). There was no difference between the Breast-Q score preop versus postop (66.5 versus 64.0, $p = 0.58$) (Fig. 4).

Surgeons were satisfied with the 3D interactive image of the tumor in the breast (Visualizer) in 94% of cases, and were very satisfied in 61% of cases. Surgeons were satisfied with the BCL device in 88% of cases. They felt that it was very easy to use in 30% of cases, easy in 36%, neither easy nor complicated in 24%, and complicated in 9% of cases.

Safety Outcomes

When considering all 35 patients enrolled, 13 adverse events occurred: 4 patients had positive margins, 3 reported pain, 2 patients experienced anxiety during the prone MRI, 2 patients developed seromas (1 in the breast and 1 in the axilla from a sentinel node excision), 1 underwent axillary dissection for positive sentinel nodes, and 1 developed breast cellulitis. No serious or unanticipated adverse events were recorded.

Patients with Positive Margins

In one case, the tumor was multifocal and the maximal tumor diameter on MRI was 5.5 cm. The BCL was designed with five ports and specimen target volume of 98 ml. The actual specimen volume was 125 ml. Pathologic evaluation identified a 7 cm background of lobular carcinoma in situ (LCIS). Three macroscopically identifiable tumor foci and multiple microscopic foci of invasive lobular carcinoma were seen. The largest focus of invasive cancer was 2.4 cm. The margins on the main lumpectomy specimen were

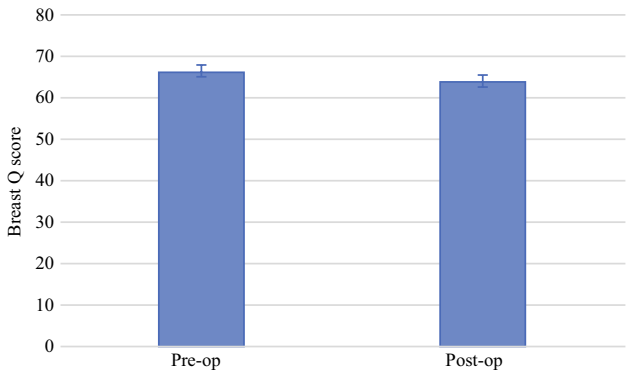

FIG. 4 Preoperative and postoperative Breast-Q scores; $p = 0.58$

negative. The anterior margin felt concerning to the surgeon, thus an anterior shave margin was removed, and this contained a small focus of invasive lobular carcinoma that focally abutted the anterior margin over a 1 mm area.

The second case with a positive margin was DCIS on core biopsy and had a maximal tumor diameter of 2.9 cm. The BCL was designed with five ports and targeted excision volume was 43 ml. The actual volume of the excised specimen was 45 ml. Pathologic evaluation of the excised specimen revealed DCIS with a maximal diameter of 2 cm and one focally positive margin.

Margin negative resections were obtained in 6 of 7 (86%) per-protocol patients with invasive lobular carcinomas, and in 4 of 5 (80%) per-protocol patients with tumors that appeared multifocal on MRI.

The two cases that did not have surgery according to protocol had invasive carcinomas resected with positive margins. In both cases the surgeon excised a volume of tissue that was only 40% of the volume targeted to be excised by the BCL.

DISCUSSION

The goal of breast-conserving surgery is to resect cancer with negative margins and to obtain an optimal cosmetic result. For surgeons to accomplish this goal, understanding the size, shape, and location of the cancer in the breast is required. We have utilized MRI to obtain this spatial

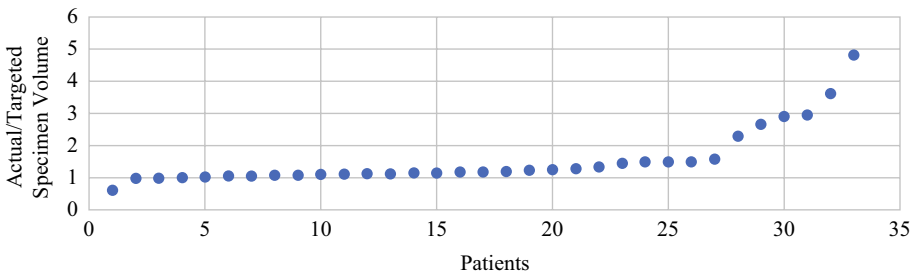

FIG. 3 Actual/targeted specimen volume ratios, per-protocol patients

information because MRI is more sensitive than mammography or ultrasound for detection of invasive cancer and DCIS.[17-20] Breast cancer size, as determined by histopathology, is also defined more accurately by MRI than mammography or ultrasound.[21-23] Furthermore, supine MRI gives the surgeon a view of the cancer that is directly relevant to patients undergoing surgery in the supine position. Several groups have demonstrated that supine MRI of the breast is feasible, well tolerated by patients, and can produce images of excellent quality using clinically available MRI machines and coils.[24-26]

Current methods of localization, whether they be a wire or other point localizing device, attempt to identify the center of the tumor, but do not provide additional spatial information to the surgeon. If surgeons have only one marker that localizes the center of tumors and do not have information about tumor shape, they may assume cancers are spherical, and subsequently either miss extensions of irregular tumors and have positive margins, or resect much more tissue than is necessary to remove the disease. Both radiologic and pathologic studies of the shape of breast cancer indicate that most cancers are not spherical.[24-27] One study used supine MRI to classify the shape of 83 breast cancers: only 19% of breast cancers were spherical.[24] In a pathologic study, only 6 of 165 patients (4%) had spherical-shaped tumors.[27]

Two randomized prospective trials have compared supine MRI-guided breast-conserving surgery to wire localized partial mastectomy. In one study of patients with small foci of DCIS, the positive margin rate was significantly lower with supine MRI-guided surgery (12% versus 39%) and specimen volumes were lower in the supine MRI-guided surgery group.[10] In a study of 138 patients with invasive cancer and DCIS that utilized an optical tracking system in the MRI-guided surgery arm, the proportion of subjects with positive margins in the MRI-guided surgery group was less than half of that observed in the wire localization group (9% versus 19%) and specimen volumes were not significantly different.[11]

In two pilot studies of breast-conserving surgery in 33 patients with palpable breast cancers, the Breast Cancer Locator™ Guidance system was safe and enabled margin negative resections in all cases.[12,13]

We have now tested the BCL guidance system in patients with nonpalpable invasive breast cancer and DCIS. We have shown that supine MRI can be acquired at several different imaging sites and transferred via a web-based process to a central Radiologist. BCL design, manufacture, and delivery were accomplished successfully across multiple sites in a timely fashion that did not cause delays in patient care. The BCL was utilized safely and successfully by multiple surgeons at several sites.

The primary goal of this trial was to determine the positive margin rate when the BCL was used to guide BCS. Patients enrolled in this study spanned a large age range (42–83 years). A substantial proportion of participants had large breasts (41% with bra size C or greater), which may make tumor localization more challenging. The tumor sizes were substantial: ranging on MRI from 1.5 to 6 cm, with a mean of 2.7 cm, and on pathologic assessment ranging from 0.6 to 8.5 cm with a mean diameter of 3.1 cm. Only two patients treated per protocol (6%) had positive margins. One of these patients had a very large multifocal invasive lobular carcinoma, which is a particularly difficult combination of histology and focality to resect with negative margins. Notably, BCL guidance did effectively achieve margin negative resections in 6 of 7 (86%) per-protocol patients with invasive lobular carcinomas, and in 4 of 5 (80%) per-protocol patients with tumors that appeared multifocal on MRI. On further study, BCL guidance may prove to be most useful in patients whose tumors may be hard to define and resect using conventional techniques (such as invasive lobular carcinomas) and for patients with multifocal tumors (where satellite tumors may be missed entirely using conventional techniques).

Importantly, the guidance provided by the BCL was adequate to ensure negative margins in all of the 31 patients resected with negative margins. Only 4 patients had additional shave margins excised due to surgeon concerns on specimen palpation or specimen imaging, and there was no cancer in any of these shaves. Notably, these results were obtained by a large number of surgeons (nine), all of whom had limited experience using the BCL guidance system (the maximal number of cases performed by any surgeon was seven).

Use of the BCL guidance system also facilitated more precise breast-conserving surgery (BCS), as demonstrated by small specimen volumes. The median and mean specimen volumes in our study were 45 and 56 ml, respectively. These volumes are less than half the volume excised in studies evaluating the use of full cavity (six side) shave margins to decrease positive margin rates after BCS.[28,29] In these studies the volume of the primary specimen plus shaves were 115 ml and 101 ml, respectively. Notably, the tumors excised in these shave cavity studies were much smaller than the tumors excised in our study. The median tumor diameter in the shave studies were 1.1 and 1.3 cm, compared with a median tumor diameter of 2 cm in our study. Thus, with the BCL guidance system we were able to excise tumors that were twice as large, on average, with half the specimen volumes obtained in full cavity shave studies. This outcome is important because the volume of tissue excised is well documented to correlate directly with cosmetic results.[30-32] After having more precise breast surgery, our patients were just as satisfied with their breasts (Breast-Q scores) after surgery as they were prior to surgery.

In most cases, the volume of tissue that was excised closely matched the volume that was targeted by the BCL guidance system: 79% of patients had actual/target volume ratios between 1 and 1.5. Surgeons excised substantially more breast tissue than was targeted in six cases. If surgeons had more closely excised the targeted volume in those outlier cases, actual BCL-guided specimen volumes would have been even smaller. The targeted specimen volume itself, since it is derived from the tumor volume plus 1 cm in all directions, is substantially larger than the tumor volume. Design of a BCL to target excision of the tumor volume plus, for example, 5 mm of tissue all around the tumor is technically possible and would result in an even smaller excision volume. The implications of such a design on the positive margin rate would require additional clinical study.

Limitations of this trial include the relatively small sample size and the lack of a control arm. CairnSurgical, Inc. is currently enrolling subjects in a large randomized prospective trial that is designed to compare the positive margin rate in patients with nonpalpable invasive cancer or DCIS undergoing breast-conserving surgery using the BCL guidance system versus standard of care wire localization.

In conclusion, the BCL guidance system is an effective, easy to use, and safe system for guiding breast-conserving surgery for nonpalpable breast cancer.

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