Factors Associated with Reoperation in Breast-Conserving Surgery for Cancer: A Prospective Study of American Society of Breast Surgeon Members

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ABSTRACT

Background. More than 20% of patients undergoing initial breast-conserving surgery (BCS) for cancer require reoperation. To address this concern, the American Society of Breast Surgeons (ASBrS) endorsed 10 processes of care (tools) in 2015 to be considered by surgeons to de-escalate reoperations. In a planned follow-up, we sought to determine which tools were associated with fewer reoperations.

Methods. A cohort of ASBrS member surgeons prospectively entered data into the ASBrS Masteryregistry on consecutive patients undergoing BCS in 2017. The association between tools and reoperations was estimated via multivariate and hierarchical ranking analyses.

Results. Seventy-one surgeons reported reoperations in 486 (12.3%) of 3954 cases (mean 12.7% [standard deviation (SD) 7.7%], median 11.5% [range 0–32%]). There was an eightfold difference between surgeons in the 10th and 90th percentile performance groups. Actionable factors associated with fewer reoperations included routine planned cavity side-wall shaves, surgeon use of ultrasound (US), neoadjuvant chemotherapy, intra-operative pathologic margin assessment, and use of a pre-operative diagnostic imaging modality beyond conventional 2D mammography. For patients with invasive cancer, ≥24% of those who underwent reexcision did so for reported margins of <1 or 2 mm, representing noncompliance with the SSO-ASTRO margin guideline.

Conclusions. Although ASBrS member surgeons had some of the lowest rates of reoperation reported in any registry, significant intersurgeon variability persisted. Further efforts to lower rates are therefore warranted. Opportunities to do so were identified by adopting those processes of care, including improved compliance with the SSO-ASTRO margin guideline, which were associated with fewer reoperations.
In a parallel effort to reduce rates, the ASBrS convened a multidisciplinary conference in 2015. During this “Collaborative Attempt to Lower Lumpectomy Re-Excisions” (CALLER), conference participants reviewed more than 100 publications relevant to reoperations and then recommended 10 processes of care to serve as tools surgeons could potentially employ to reduce rates of reexcision.

Subsequent to the CALLER Conference, a prospective study of reoperation rates reported by ASBrS member-surgeons was conducted. The primary purpose was to determine the efficacy of the tools in the CALLER toolbox at lowering rates of reoperation in patients undergoing BCS for cancer.

METHODS

The principal investigator’s (PI) Institutional Review Board (IRB), the ASBrS Research Committee, selected members of the ASBrS Patient Safety and Quality Committee, and study co-investigators approved the study design.

Surgeons signed an attestation document to prospectively enter information into the ASBrS patient registry (Mastery®/C210) on consecutive patients undergoing initial BCS. Surgeons received a $500.00 stipend. Participation was voluntary. Recruitment occurred by an ASBrS newsletter and member email.

Patients

Patients included those undergoing BCS initially or after neoadjuvant treatment for Stage 0–III breast cancer in 2017 (Fig. 1). All patients had a preoperative diagnosis of malignancy by a core needle biopsy or other minimally invasive technique.

One surgeon provided transparency of one patient to the PI by nonpassword-protected email. After institutional review board notification, the patient was excluded.

Independent variables

Univariate tests of association and model components included in the final multivariate (MV) model of risk of reoperation are shown in Table 1. Multiple different uses of breast ultrasound were treated as independent variables.

Outcome

The primary outcome was reoperation (either re-excision or mastectomy) within 90 days after initial BCS.

Analyses

On preliminary review, a significant portion of missing data was associated with a small subset of seven participating physicians, who were excluded from the subsequent analyses. The remaining cases with missing data were included in the univariate (UV) but not in the MV analysis. Descriptive statistics were reported as proportions, medians (ranges), and means (standard deviations). Chi square, Fisher’s exact, and Wilcoxon rank-sum tests were used to compare demographic and clinical characteristics between patients who did and did not undergo reoperation. Factors that were significant on UV were included as candidate variables in the MV models. The preliminary MV model was constructed stepwise from the list of candidate variables, requiring \( p < 0.20 \) for initial inclusion and \( p < 0.10 \) for the variable to remain. The final mixed effects MV model was constructed by adding physician-level random intercepts. Expected rates of reoperation and physician contribution to the odds of reoperation were calculated using the final mixed effects MV model. All analyses were performed with the SAS 9.4 software suite (SAS Foundation, Cary, NC).

Hierarchical Ranking

The relative strengths of association between explanatory variables and reoperation within 90 days were ranked by the F statistic, derived from the type III test of fixed effects (Table 2).

Data Validation

Seven surgeons (~10% of participants) were blinded to study co-investigators and randomly selected for a detailed audit. They voluntarily provided medical records for comparison to their previously self-reported data in Mastery®. Any discordances were reported to the surgeons in a password-protected format and were reconciled by supporting documentation. Cases that failed reconciliation were discarded.

The rate of discordance between surgeon entry and medical record review was 1.3% (34/2840). Following surgeon agreement, corrections were made in Mastery® for these cases. No discordance occurred for documentation of reoperation.

RESULTS

After excluding cases from surgeons with fewer than 10 cases/year, the overall reoperation rate for the remaining 71 surgeons was 12.3% (486/3954), mean 12.7% [SD 7.7%],
median 11.5% [range 0–32%], unadjusted performance percentiles 3, 8, 12, 17, and 25% for the 10th, 25th, 50th, 75th, and 90th percentiles [10th–90th difference = 8.3X; IQR 0.17–0.08]. The per annum case volume of surgeons in the highest quartile ranged from 74 to 180 (mean 115, median 107). Their unadjusted reoperation rates were 10.6% compared with 13.9% for lower-volume surgeons. Thirty-one surgeons (44%) had rates of 10% or less. The reoperation rate in five surgeons with <10 cases in 2017 was 3.2% (1/31). The association of all covariates with reoperation, intersurgeon variability and ASBrS member rates over time are shown in Table 1 and Figs. 2 and 3. Of seven different uses of breast ultrasound, only the breast surgeon characteristic of “I preform breast US” was associated with fewer reoperations.

In 130 cases of reexcision after BCS for DCIS, the reasons for reexcision (by margin status) were ink + in 59 (45.4%), < 1 mm in 55 (42.4%), 1–2 mm in 14 (10.8%), and “other” causes in 2 (1.6%) cases. For 349 cases with invasive cancer (± synchronous DCIS), the reasons for reexcision (by margin status) were ink + in 248 (71.1%), < 1 mm in 63 (18.1%), 1–2 mm in 22 (6.3%), and other causes in 16 (4.6%).

The hierarchical ranking of those factors associated with fewer reoperations were, in descending order, tumor focality (unifocal), estimated tumor size (smaller), neoadjuvant systemic therapy (receipt), a composite measure of pathologic tumor size and histology (smaller, invasive ductal), use of a preoperative diagnostic imaging modality beyond conventional 2D mammography, surgeon practice type (solo/academic versus group/hospital), surgeon use of ultrasound (US) [in their practice setting], intraoperative pathologic margin assessment [any type other than margin devices], patient age (> 80), surgeon case volume (highest quartile), cavity side-wall shaves (routine planned), and insurance type (Medicare; Table 2).
### Table 1: Association of patient, tumor, process of care, and surgeon practice characteristics with reoperations after breast conserving surgery for breast cancer, CALLER Registry, American Society of Breast Surgeons Mastery database

|                      | Univariate | Multivariate |
|----------------------|------------|--------------|
|                      | Patient    |              |                      |
|                      | Receipt of reoperation (n = 486) | Total (n = 3954) | Rate (12.3%) | p value | Odds ratio | 95% CI | p value |
| Age (yr)             |            |              |            |          |        |        |        |
| 80+                  | 24         | 344          | 7          | < 0.001  | Reference |
| 70–79                | 116        | 988          | 11.7       | 2.22     | 1.27    | 3.86    | 0.005   |
| 60–69                | 178        | 1288         | 13.8       | 1.94     | 1.19    | 3.17    | 0.008   |
| 50–59                | 91         | 859          | 10.6       | 1.90     | 1.17    | 3.09    | 0.010   |
| < 50                 | 77         | 475          | 16.2       | 1.25     | 0.74    | 2.13    | 0.408   |
| Race                 |            |              |            |          |        |        |        |
| African American     | 50         | 323          | 15.5       | 0.200    |         |        |        |
| Caucasian/Hispanic   | 425        | 3530         | 12         |          |         |        |        |
| Other                | 31         | 250          | 12.4       |          |         |        |        |
| Primary insurance    |            |              |            |          |        |        |        |
| Medicare traditional | 125        | 1319         | 9.5        | 0.002    | Reference |
| Commercial           | 319        | 2247         | 14.2       | 1.58     | 1.19    | 2.09    | 0.002   |
| Medicaid/state-managed | 23       | 187          | 12.3       | 1.22     | 0.69    | 2.16    | 0.488   |
| Tricare              | 6          | 42           | 14.3       | 0.79     | 0.24    | 2.58    | 0.691   |
| No insurance         | 4          | 24           | 16.7       | 2.36     | 0.67    | 8.25    | 0.180   |
| Unknown              | 29         | 283          | 10.3       | 1.02     | 0.56    | 1.84    | 0.956   |
| Missing              | 0          | 1            | 0          |          |         |        |        |
| Tumor                |            |              |            |          |        |        |        |
| Surgery side         |            |              |            |          |        |        |        |
| Left                 | 253        | 2114         | 12         | 0.470    |         |        |        |
| Right                | 253        | 1989         | 12.7       |          |         |        |        |
| Mean size ± standard deviation (mm)b | No reexcision: 15.4 ± 11.4; Reexcision: 18.8 ± 13.8 | < 0.001 | 1.02 | 1.01 | 1.03 | < 0.001 |
| pT stage             |            |              |            |          |        |        |        |
| T1mi/a/b             | 88         | 1175         | 7.5        | < 0.001  |         |        |        |
| T1c                  | 143        | 1279         | 11.2       |          |         |        |        |
| T2                   | 102        | 611          | 16.7       |          |         |        |        |
| T3/T4                | 8          | 36           | 22.2       |          |         |        |        |
| Tis (DCIS)           | 135        | 636          | 21.2       |          |         |        |        |
| TX                   | 1          | 88           | 1.1        |          |         |        |        |
| Missing              | 29         | 278          | 10.4       |          |         |        |        |
| pN stage             |            |              |            |          |        |        |        |
| N0                   | 329        | 2892         | 11.4       | 0.003    |         |        |        |
| N1                   | 51         | 364          | 14         |          |         |        |        |
| N2                   | 12         | 59           | 20.3       |          |         |        |        |
| N3                   | 2          | 16           | 12.5       |          |         |        |        |
| NX                   | 83         | 494          | 16.8       |          |         |        |        |
| Missing              | 29         | 278          | 10.4       |          |         |        |        |
| Histology            |            |              |            |          |        |        |        |
| IDC                  | 127        | 1651         | 7.7        | < 0.001  |         |        |        |
| IDC and ILC          | 14         | 89           | 15.7       |          |         |        |        |
| ILC                  | 44         | 266          | 16.5       |          |         |        |        |
| IDC and DCIS         | 156        | 1105         | 14.1       |          |         |        |        |
| TABLE 1 continued | Univariate | Multivariate<sup>a</sup> |
|-------------------|------------|-----------------------------|
|                  | Receipt of reoperation (n = 486) | Total (n = 3954) | Rate (12.3%) | p value | Odds ratio | 95% CI Lower | 95% CI Upper | p value |
| Other            | 5          | 91                          | 5.5          |
| DCIS only        | 131        | 633                         | 20.7         |
| Missing          | 29         | 268                         | 10.8         |

**Focality**

|                  | Unifocal | 348 | 3358 | 10.4 | < 0.001 | Reference |
|                  | Multifocal/multicentric | 124 | 444 | 27.9 | 3.64 | 2.77 | 4.78 | < 0.001 |
| Uncertain        | 5         | 31  | 16.1 | 2.85 | 0.88 | 9.19 | 0.080 |

**Stage and histology composite<sup>c</sup>**

|                  | T1mi/a/b IDC | 35  | 613  | 5.7  | < 0.001 | Reference |
|                  | T1mi/a/b ILC | 3   | 77   | 3.9  | 0.62 | 0.18 | 2.14 | 0.448 |
|                  | T1mi/a/b Mixed/other | 50 | 484 | 10.3 | 1.86 | 1.15 | 3.01 | 0.011 |
|                  | T1c IDC      | 55  | 659  | 8.4  | 1.42 | 0.90 | 2.26 | 0.134 |
|                  | T1c ILC      | 13  | 109  | 11.9 | 1.67 | 0.81 | 3.44 | 0.162 |
|                  | T1c Mixed/other | 75 | 510 | 14.7 | 2.63 | 1.67 | 4.14 | < 0.001 |
|                  | T2 IDC       | 31  | 295  | 10.5 | 1.53 | 0.89 | 2.65 | 0.127 |
|                  | T2 ILC       | 25  | 69   | 36.2 | 7.84 | 4.04 | 15.21 | < 0.001 |
|                  | T2 Mixed/other | 46 | 247 | 18.6 | 3.12 | 1.86 | 5.24 | < 0.001 |
|                  | T3/T4 All types | 8 | 36  | 22.2 | 2.15 | 0.79 | 5.83 | 0.134 |
|                  | Tis (DCIS)   | 135 | 636  | 21.2 | 3.71 | 2.43 | 5.67 | < 0.001 |
|                  | Missing      | 29  | 280  | 10.4 |     |     |     |     |

**Surgeon practice setting/characteristic**

|                  | Solo private practice | 90  | 1013 | 8.9  | < 0.001 | Reference |
|                  | Academic              | 30  | 251  | 12   | 0.92 | 0.39 | 2.17 | 0.843 |
|                  | Group private practice | 268 | 1650 | 16.2 | 2.31 | 1.45 | 3.69 | < 0.001 |
| Hospital employed practice | 118 | 1189 | 9.9  | 1.60 | 0.95 | 2.70 | 0.075 |

**Length of time in practice**

|                  | 10 years or less | 145 | 1101 | 13.2 | 0.009 |
|                  | 11–20 years      | 167 | 1371 | 12.2 |
|                  | 21–30 years      | 170 | 1280 | 13.3 |
|                  | More than 30 years | 24 | 351  | 6.8  |

**Proportion of practice breast surgery**

|                  | 100% | 367 | 3197 | 11.5 | 0.005 |
|                  | > 50% | 122 | 763  | 16   |
|                  | 25–50% | 13 | 90   | 14.4 |
|                  | < 25% | 4   | 53   | 7.6  |

**I perform breast ultrasound<sup>d</sup>**

|                  | No   | 105 | 681  | 15.4 | 0.007 | Reference |
|                  | Yes  | 401 | 3422 | 11.7 | 0.57 | 0.35 | 0.92 | 0.022 |

<sup>a</sup> Odds ratio, 95% CI, p value

<sup>c</sup> Stage and histology composite

<sup>d</sup> I perform breast ultrasound
| Univariate Multivariate \(^a\) |
|---------------------------------|
| | Receipt of reoperation \((n = 486)\) | Total \((n = 3954)\) | Rate \((12.3\%)\) | \(p\) value | Odds ratio | 95\% CI | \(p\) value |
|---|---|---|---|---|---|---|---|
| I perform ultrasound-guided office breast procedures\(^d\) | | | | | | | |
| No | 136 | 901 | 15.1 | 0.004 | | | |
| Yes | 370 | 3202 | 11.6 | | | | |
| I perform ultrasound-guided breast procedures in the operating room\(^d\) | | | | | | | |
| No | 136 | 1025 | 13.3 | 0.300 | | | |
| Yes | 370 | 3078 | 12 | | | | |
| I perform stereotactic-guided breast procedures | | | | | | | |
| No | 318 | 2461 | 12.9 | 0.150 | | | |
| Yes | 188 | 1642 | 11.5 | | | | |
| Surgeon per annum case volume in top quartile | | | | | | | |
| No | 301 | 2173 | 13.9 | 0.001 | Reference | | |
| Yes | 205 | 1930 | 10.6 | 0.68 | 0.48 | 0.98 | 0.038 |
| National Consortium of Breast Centers participation | | | | | | | |
| No | 412 | 3146 | 13.1 | 0.007 | | | |
| Yes | 94 | 957 | 9.8 | | | | |
| Preoperative imaging modalities | | | | | | | |
| 2d diagnostic mammography | | | | | | | |
| No | 313 | 2311 | 13.5 | 0.004 | Reference | | |
| Yes | 173 | 1650 | 10.5 | 1.4 | 1.07 | 1.84 | 0.013 |
| Missing | 20 | 142 | 14.1 | | | | |
| Film mammography | | | | | | | |
| No | 484 | 3947 | 12.3 | 0.810 | | | |
| Yes | 2 | 14 | 14.3 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| 3d diagnostic mammography | | | | | | | |
| No | 251 | 1907 | 13.2 | 0.100 | | | |
| Yes | 235 | 2054 | 11.4 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| Ultrasound (US)\(^d\) | | | | | | | |
| No | 114 | 651 | 17.5 | < 0.001 | | | |
| Yes | 372 | 3310 | 11.2 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| Magnetic resonance imaging (MRI) | | | | | | | |
| No | 295 | 2270 | 13 | 0.110 | | | |
| Yes | 191 | 1691 | 11.3 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| None | | | | | | | |
| No | 486 | 3960 | 12.3 | 0.710 | | | |
| Yes | 0 | 1 | 0 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
### TABLE 1 continued

|                                                                 | Univariate | Multivariate<sup>a</sup> |
|-----------------------------------------------------------------|------------|---------------------------|
|                                                                 | Receipt of reoperation \(n = 486\) | Total \(n = 3954\) | Rate \(12.3\%) | \(p\) value | Odds ratio | 95% CI Lower | 95% CI Upper | \(p\) value |
| Receipt of reoperation \(n = 486\)                              |            |                           |                |              |            |              |              |              |
| **Radiologist-surgeon communication by report**                  |            |                           |                |              |            |              |              |              |
| Surgeon-radiology communication-did radiologist indicate size(s)? |            |                           |                |              |            |              |              |              |
| No                                                              | 176        | 1434                      | 12.3           | 0.990        |            |              |              |              |
| Yes                                                             | 310        | 2527                      | 12.3           |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| Surgeon-radiology communication-did the radiologist indicate distance(s) to nipple, skin, other? |            |                           |                |              |            |              |              |              |
| No                                                              | 426        | 3349                      | 12.7           | 0.040        |            |              |              |              |
| Yes                                                             | 60         | 612                       | 9.8            |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| **Breast conservation localization technique**                   |            |                           |                |              |            |              |              |              |
| Hematoma guided US<sup>d</sup>                                  |            |                           |                |              |            |              |              |              |
| No                                                              | 483        | 3881                      | 12.5           | 0.019        |            |              |              |              |
| Yes                                                             | 3          | 80                        | 3.8            |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| Ultrasound (US)<sup>d</sup>                                     |            |                           |                |              |            |              |              |              |
| No                                                              | 315        | 2327                      | 13.5           | 0.004        |            |              |              |              |
| Yes                                                             | 171        | 1634                      | 10.5           |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| Palpation                                                       |            |                           |                |              |            |              |              |              |
| No                                                              | 410        | 3336                      | 12.3           | 0.93         |            |              |              |              |
| Yes                                                             | 76         | 625                       | 12.2           |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| Single wire                                                     |            |                           |                |              |            |              |              |              |
| No                                                              | 253        | 2010                      | 12.6           | 0.540        |            |              |              |              |
| Yes                                                             | 233        | 1951                      | 11.9           |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| Multiple wires                                                  |            |                           |                |              |            |              |              |              |
| No                                                              | 372        | 3330                      | 11.2           | < 0.001      |            |              |              |              |
| Yes                                                             | 114        | 631                       | 18.1           |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| Any wire (simplified)                                           |            |                           |                |              |            |              |              |              |
| No                                                              | 146        | 1412                      | 10.3           | 0.006        |            |              |              |              |
| Yes                                                             | 340        | 2549                      | 13.3           |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| Radioactive seed(s)                                             |            |                           |                |              |            |              |              |              |
| No                                                              | 472        | 3840                      | 12.3           | 0.810        |            |              |              |              |
| Yes                                                             | 14         | 121                       | 11.6           |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| Magnetic resonance imaging (MRI)                                |            |                           |                |              |            |              |              |              |
| No                                                              | 484        | 3946                      | 12.3           | 0.900        |            |              |              |              |
| Yes                                                             | 2          | 15                        | 13.3           |              |            |              |              |              |
| Missing                                                         | 20         | 142                       | 14.1           |              |            |              |              |              |
| TABLE 1 continued | Univariate | Multivariate<sup>a</sup> | Multivariate<sup>a</sup> |
|-------------------|------------|--------------------------|--------------------------|
|                   | Receipt of reoperation (n = 486) | Total (n = 3954) | Rate (12.3%) | p value | Odds ratio | 95% CI | p value |
| Mammography stereotactic | | | | | | | |
| No                | 386 | 3295 | 11.7 | 0.018 | | | |
| Yes               | 100 | 666 | 15 | | | | |
| Missing           | 20 | 142 | 14.1 | | | | |
| SAVI SCOUT<sup>®</sup> radar | | | | | | | |
| No                | 461 | 3757 | 12.3 | 0.990 | | | |
| Yes               | 25 | 204 | 12.3 | | | | |
| Missing           | 20 | 142 | 14.1 | | | | |
| Other             | | | | | | | |
| No                | 481 | 3926 | 12.3 | 0.610 | | | |
| Yes               | 5 | 35 | 14.3 | | | | |
| Missing           | 20 | 142 | 14.1 | | | | |
| Surgeon intraoperative practice (receipt) | | | | | | | |
| Cavity side wall shaves performed? | | | | | | | |
| No                | 197 | 1383 | 14.2 | < 0.001 | Reference | | |
| Selective based on intra-op findings | 161 | 1225 | 13.1 | 0.86 | 0.64 | 1.15 | 0.299 |
| Routine planned   | 127 | 1334 | 9.5 | 0.58 | 0.39 | 0.85 | | < 0.001 |
| Missing           | 21 | 161 | 13 | | | | |
| Oncoplastic resection and any type closure | | | | | | | |
| No                | 359 | 2728 | 13.2 | 0.017 | Reference | | |
| Yes               | 124 | 1189 | 10.4 | 0.76 | 0.57 | 1.00 | 0.054 |
| Missing           | 23 | 186 | 12.4 | | | | |
| Dune MarginProbe<sup>®</sup> device | | | | | | | |
| No                | 486 | 3901 | 12.5 | 0.280 | | | |
| Yes               | 20 | 202 | 9.9 | | | | |
| Margin evaluation type | | | | | | | |
| Beyond gross      | 19 | 122 | 15.6 | 0.001 | | | |
| Gross             | 72 | 836 | 8.6 | | | | |
| None              | 395 | 3003 | 13.2 | | | | |
| Missing           | 20 | 142 | 14.1 | | | | |
| Any type of intra-operative pathologic margin assessment excluding margin device<sup>®</sup> | | | | | | | |
| Yes               | 91 | 965 | 9.4 | 0.002 | 0.66 | 0.46 | 0.95 | 0.027 |
| No                | 395 | 2996 | 13.2 | Reference | | | |
| Missing           | 20 | 142 | 14.1 | | | | |
| Gross evaluation margin | | | | | | | |
| No                | 410 | 3082 | 13.3 | < 0.001 | | | |
| Yes               | 76 | 879 | 8.7 | | | | |
| Missing           | 20 | 142 | 14.1 | | | | |
| Frozen selective margin(s) | | | | | | | |
| No                | 475 | 3902 | 12.2 | 0.130 | | | |
| Yes               | 11 | 59 | 18.6 | | | | |
| Missing           | 20 | 142 | 14.1 | | | | |
| TABLE 1 continued | Univariate | Multivariate<sup>a</sup> |
|-------------------|------------|--------------------------|
| Receipt of reoperation | Total | Rate | p value | Odds ratio | 95% CI Lower | 95% CI Upper | p value |
| (n = 486) | (n = 3954) | (12.3%) | | | | |
| Touch-prep cytology margin | | | | | | |
| No | 477 | 3918 | 12.2 | 0.080 | | | |
| Yes | 9 | 43 | 20.9 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| Specimen orientation (# sides)<sup>f</sup> | | | | | | |
| 0 | 5 | 54 | 9.3 | 0.740 | | | |
| 1–2 | 120 | 997 | 12 | | | | |
| 3 or more | 361 | 2899 | 12.5 | | | | |
| Missing | 20 | 153 | 13.1 | | | | |
| Ultrasound (US) by surgeon in operating room<sup>d</sup> | | | | | | |
| No | 448 | 3670 | 12.2 | 0.680 | | | |
| Yes | 38 | 291 | 13.1 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| Specimen mammography | | | | | | |
| No | 371 | 3208 | 11.6 | 0.005 | | | |
| Yes | 115 | 753 | 15.3 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| Specimen imaging single view | | | | | | |
| No | 218 | 1705 | 12.8 | 0.390 | | | |
| Yes | 268 | 2256 | 11.9 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| Specimen imaging multiple views | | | | | | |
| No | 316 | 2671 | 11.8 | 0.230 | | | |
| Yes | 170 | 1290 | 13.2 | | | | |
| Missing | 20 | 142 | 14.1 | | | | |
| Was the specimen compressed for imaging? | | | | | | |
| No | 386 | 3245 | 11.9 | 0.070 | | | |
| Yes | 98 | 680 | 14.4 | | | | |
| Missing | 22 | 178 | 12.4 | | | | |
| Guidance technique used? | | | | | | |
| No image guidance | 44 | 351 | 12.5 | 0.330 | | | |
| Pre-op localization | 135 | 1115 | 12.1 | | | | |
| Intra-op localization | 32 | 342 | 9.4 | | | | |
| Image guidance | 295 | 2295 | 12.9 | | | | |

<sup>a</sup> Adjusted for receipt of reoperation.
DISCUSSION

Variation of reoperation rates after BCS for cancer represents an opportunity for process improvement at both the surgeon and facility level. Recognizing high rates and variation as early as 2012, a “plan-do-study-act” performance improvement project was initiated by the ASBrS the following year.29 This initiative included ranking and specifying reoperation rates along with other domains of care, incorporating a reoperation metric into the ASBrS patient registry for auditing, and providing a web-based platform for benchmarking.30 During benchmarking, surgeons compared their personal rates in real-time to the de-identified rates of all other ASBrS surgeons entering data. Two planned data reviews indicated persistently high rates and inter-surgeon variability.4,6 Further action plans to reduce rates were therefore undertaken. First, a national multidisciplinary consensus conference (CALLER) was convened to endorse ten specific processes of care, or “tools,” found by others to be associated with fewer reoperations.18 This toolkit was then communicated to other surgeons by publication and by presentation at the national ASBrS meeting. Second, after the CALLER consensus conference, new data fields were incorporated into the ASBrS patient registry to capture receipt of which endorsed tools were used for each patient undergoing an initial BCS. Another planned prospective analysis of sequential patients undergoing BCS for 1 year followed, and we report the results of this analysis here. We sought to determine which of the tools endorsed by the ASBrS in 2015 were utilized by its members in 2017 and which were associated with fewer reoperations after BCS.

In 2013 and 2015, the rates of reoperation were 21.6% and 16.5% respectively for ASBrS members participating in Mastery/C210.4,6 In the current study year (2017), the overall rate of reoperation by 71 surgeons was 12.3% (Fig. 3). To our knowledge, this is the lowest rate yet identified in a national registry. Furthermore, more than one in three surgeons achieved the ASBrS recommended target goal of 10%.18 Of note, the highest rate in the current study of 32% is a very low “peak” rate compared with other publications.1–8,10–16 However, significant intersurgeon variability was identified, and there was greater than a eightfold difference between surgeons at the 10th and 90th performance percentiles. Thus, future efforts to reduce variability are still indicated. We are unaware of any professional organization recommending use of a specific reoperation target goal for accountability purposes, such as for pay for performance incentives or patient steerage.

| TABLE 1 continued |
|-------------------|
|                    | Univariate | Multivariate^a |
| Receipt of reoperation (n = 486) | Total (n = 3954) | Rate (12.3%) | p value | Odds ratio | 95% CI | p value |
| Treatment          |            |              |            |          |         |        |         |
| No                | 448        | 3553         | 12.6       | 0.007    | Reference |
| Yes—Chemotherapy  | 27         | 356          | 7.6        | 0.45     | 0.28     | 0.73   | 0.001   |
| Yes—Endocrine therapy | 18     | 104          | 17.3       | 2.1      | 1.14     | 3.86   | 0.017   |
| Missing           | 13         | 90           | 14.4       |          |          |        |         |

DCIS ductal carcinoma in situ; IDC infiltrating ductal carcinoma; ILC invasive lobular carcinoma; CI confidence interval

^aCovariates not significantly associated with reoperation, after accounting for the effects of other relevant covariates, were excluded from the final multivariate reoperation model by the stepwise selection process and are left blank in the right column

^bLargest estimated pre-operative tumor size. The odds ratio for reexcision is for each 1 mm increase in tumor size

^cComposite covariate to reflect final pathologic stage and histology; histology as an independent variable had many cells with small numbers

^dSeven different uses of breast ultrasound (US) are shown in Table 1. On multivariate analysis, only the surgeon characteristic of “I perform breast US” was associated with fewer reexcisions

^eComposite measure of any of the different methods of intraoperative margin assessment—gross pathologic, frozen section or touch prep cytology but excluding margin devices. Margin devices are commercial products available for intraoperative margin assessment such as but not limited to the MarginProbe™

^fSpecimen orientation not expected to impact reoperation rates. Purpose is to aid targeted re-excision in patients undergoing re-excision
Opportunities

The actionable processes of care associated with fewer reoperations in the current study were, in descending order of influence, receipt of neoadjuvant chemotherapy (NAC), use of a preoperative diagnostic imaging modality beyond conventional 2D mammography, surgeon use of ultrasound (US), intraoperative pathologic [margin] assessment [of any type other than margin devices], and routine planned cavity side-wall shaves (Tables 1 and 2). These findings are consistent with selected prior randomized trials, meta-analyses, and observational studies.18,31–40 Thus, all are consistent with selected prior randomized trials, meta-analyses, and observational studies.18,31–40 Thus, all are recommended for consideration of adoption by breast surgeons when appropriate given a patient’s presentation and tumor subtype. Of note, selective cavity shavings (based on intraoperative findings) were not associated with fewer reoperations. Selective shaving is a different process compared to a priori planned all side-wall shaves, as demonstrated to be successful in two randomized trials.31,32

For some tools, such as cavity shaves and NAC, there are few barriers to implementation. For patients in whom NAC is appropriate based on the tumor type, size, and nodal status, there are additional benefits beyond reducing reoperations. NAC de-escalates the overall chance of mastectomy and axillary dissections, especially for patients with subtypes known to have high response rates.41–44 The use of intraoperative imaging with US has not always been available to the vast majority of surgeons performing breast surgery. The ASBrS has addressed this concern by providing education and certification programs.45 Our findings of fewer reoperations with surgeon use of US reinforce the importance of the ASBrS US training and accreditation programs.

For each of the processes described, there are opportunities for improvement based on the frequencies of their use by ASBrS members (Table 1). For example, planned cavity shaves—a procedure that requires no equipment and adds minimal additional time to the length of the procedure—were utilized in only 1334 (34%) of 3942 cases. For those surgeons with a higher than average rate of reoperation, incorporating this tool into their standard operative approach could be advised. Adoption of every process of care shown here to be associated with fewer reoperations is not recommended. The selection of which to adopt will depend on patient factors, surgeon setting, resource availability, and facility-specific barriers. If rates are at or below target goals with current practices, then adopting new processes may not be value-added.

Another opportunity for improvement identified in the current study is increased compliance with the SSO-ASTRO guideline.20 This guideline was based on a meta-analysis that demonstrated that reexcisions wider than no-ink on tumor did not lessen in-breast cancer recurrence in patients with invasive disease.19 After reviewing reasons for reexcision in patients with invasive cancer in the current study, we found that more than 20% of reexcisions were performed in patients with an ink-negative margin. In contrast, surgical care was guideline-compliant with the 2016 margin guideline for DCIS.21 Reexcision for margins > 2 mm rarely occurred.

Some factors associated with reoperations are immutable; i.e., they are not modifiable upon patient presentation and therefore not actionable to improve rates. These include tumor histology, tumor focality, and surgeon practice type. There were fewer reoperations in solo- and academic-practice surgeon settings compared with other settings, and rates were higher with lobular histology and multifocality. Tumor size also is fixed at patient presentation; however, in select eligible patients, NAC can be considered and is associated with fewer reoperations.35,36 Lastly, commercial insurance, compared with no or “other” insurance, was another fixed factor associated with higher rates. Wilke et al. also reported an association between insurance type and reoperation rates in the NCDB; no coverage was associated with the lowest rates.3 The association between reimbursement incentives, provider practice, surgical volume, and surgical outcomes is complex and requires greater depth of information than what is provided in this patient registry.46

Factors not Associated with Reoperations

Notable factors not associated with fewer reoperations included patient race, preoperative breast magnetic resonance imaging (MRI), and the method of tumor localization. A recent meta-analysis also demonstrated no improvement in reoperations with MRI.47 Other processes of care were investigated, because recent studies had demonstrated their effectiveness in reducing reoperations. For example, two randomized trials demonstrated fewer reoperations with the MarginProbe® device.48,49 In our analysis, reoperation rates with and without the device [9.9% and 12.5%; \( p = 0.280 \)] did not achieve statistical significance. Onco-plastic surgery also has been associated with fewer positive margins and reoperations in other studies.33,50–52 In the current study, the unadjusted rates with and without receipt of it were 10.4% and 13.2% \( (p = 0.017) \). After adjustment, the odds ratio was 0.76 [95% CI 0.57–1.00; \( p = 0.054 \)]. If positive margins occur after oncoplastic surgery, identification of the location for reexcision may be challenging.
Determining the frequency of use of various processes of care within the CALLER toolbox to decrease reoperations was not the primary focus of the current study; however, they are shown in Table 1 and reflect the distribution of their use in a contemporary cohort of surgeons that collectively had a very low rate of reoperation. The profile of the processes of care that they employ may differ from non-ASBrS member surgeons.

Study strengths included prospective data entry, a very low error rate of surgeon-entered data, a sample size larger than that in five recent publications comparing reoperation rates before and after the SSO-ASTRO margin guideline, and collection of covariates beyond the typical patient and tumor factors used for risk adjustment.\(^9\)\(^-\)\(^14\) Additionally, those processes of care that are important predictors for reoperations, such as surgeon use of US, cavity shaves, and reasons for reoperation (including margin status), were able to be captured. This granularity of information is not available in other commonly used national data sets.

### Limitations

All patient registry studies can have unmeasured confounders that introduce bias. We limited this risk by including covariates for processes of care. Risk adjustment in many past investigations was restricted to patient, tumor, and treatment characteristics. Also, we were unable to explain the reasons why surgeons who perform breast US have fewer reoperations.

The generalizability of the current study findings to other surgeons is unknown. The low rate of reoperations demonstrated here may not reflect other surgeon groups. Voluntary participation may have preferentially captured a dedicated group of surgeons with a focus on quality improvement. On the other hand, all the processes of care that we found to be associated with fewer reoperations in this seemingly “exceptional” group of surgeons are potentially available to all breast surgeons.

Our goal is to reduce intersurgeon variability by simple adoption of those tools found to be associated with lower rates. As a cautionary note, we advise that surgeons continue guideline-compliant care to re-excise in patients with positive margins and to continue to offer breast conservation to all eligible patients. Failing to re-excite a positive margin by a surgeon not wanting to report a reoperation would be expected to result in higher rates of cancer recurrence.

### TABLE 2 Hierarchical ranking of patient, surgeon, tumor, and treatment factors for their effect on reoperations after breast conserving surgery for breast cancer

| Effect                                                                 | F value\(^3\) | p value |
|-----------------------------------------------------------------------|---------------|---------|
| Tumor focality (unifocal)                                             | 43.9          | < 0.0001|
| Preoperative estimated tumor size (smaller)                           | 22.0          | < 0.0001|
| Neoadjuvant systemic therapy (receipt)\(^a\)                          | 8.5           | 0.0002  |
| Composite measure pathologic tumor size and histology (smaller, invasive ductal) | 7.6           | < 0.0001|
| Pre-operative imaging (more than traditional 2D)\(^a,\(^b\)             | 6.1           | 0.0133  |
| Surgeon practice type (solo/academic vs. group/hospital)              | 5.3           | 0.0013  |
| Surgeon use of ultrasound (yes)\(^a,\(^d\)                            | 5.3           | 0.0221  |
| Intraoperative pathologist margin evaluation any type (gross/microscopic, but not device)\(^a\) | 4.9           | 0.0266  |
| Patient age (> 80 yr)                                                 | 4.5           | 0.0012  |
| Physician case volume (top quartile)                                  | 4.3           | 0.0382  |
| Cavity shaves (planned routine all sides)\(^a\)                       | 3.8           | 0.0219  |
| Oncoplastic surgery (performed)\(^a\)                                 | 3.7           | 0.0539  |
| Primary insurance type (Medicare)                                     | 2.6           | 0.0231  |

\(^a\)Actionable factor (under surgeon control)

\(^b\)Pre-op imaging included one or more imaging modalities other than traditional 2D imaging (e.g., US, MRI, 3D mammography)

\(^c\)The F-statistic is a measurement of the explanatory power of a given covariate to reoperations, after considering the effects of all other model covariates. To calculate the F-statistic for a specific covariate, the residual sum of squares for the full model is compared to the residual sum of squares for a model without the covariate in question. A larger F-statistic represents a larger contribution to the overall model’s explanatory power.

\(^d\)Surgeon performs US in their practice setting

**Frequencies of Use of Diagnostic Modalities and Processes of Care**

Determining the frequency of use of various processes of care within the CALLER toolbox to decrease reoperations was not the primary focus of the current study; however, they are shown in Table 1 and reflect the distribution of their use in a contemporary cohort of surgeons that collectively had a very low rate of reoperation. The profile of the processes of care that they employ may differ from non-ASBrS member surgeons.

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CONCLUSIONS

To provide a snapshot of the efficacy of those processes of care endorsed by a 2015 consensus conference to lower reoperation rates, 71 member-surgeons of the ASBrS entered data on nearly 4000 patients undergoing BCS for cancer.

Surgeon use of US, routine planned cavity side-wall shaves, and NAC were associated with fewer reoperations. Other opportunities for improvement were identified as well, specifically by increasing compliance with the SSO-ASTRO margin guideline for invasive cancer.
A low overall rate of reoperation (12.3%) was found, but variability persisted. As surgeons and facilities increase participation in benchmarking programs and regional and state collaborative improvement programs expand, further reductions in variability are likely to occur.

ACKNOWLEDGMENT The authors thank Dune Medical Devices® and the Gundersen Medical Foundation for financial support, the American Society of Breast Surgeons staff (Margaret Schlosnagle, Ben Schlosnagle, Mena Jalali, and Sharon Grutman) for their ASBrS patient registry and data support, Himani Naik for assistance with the data validation strategy, Alec Fitzsimmons for manuscript preparation, and the ASBrS surgeon members who entered data. The ASBrS Mastery® database was the source of the de-identified data used in the current study. The ASBrS has not verified and is not responsible for the validity of the data analysis.

DISCLOSURES Andrew Borgert and Dr. Landercasper receive funding from the Gundersen Medical Foundation; however, this is unrelated to the content of this manuscript. Dr. Fayanj is supported by the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH) under Award Number 1KL2TR002554 (PI: Svetkey) and by the Duke Cancer Institute through NIH grant P30CA014236 (PI: Kastan). The content of this manuscript is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. Dr. Cody, Dr. Feldman, Dr. Linebarger, and Dr. Pockaj have no disclosures. Dr. Greenberg is a consultant for Johnson and Johnson on their Global Education Council; this is unrelated to the content of this manuscript. Dr. Wilke is a founder and minority stock owner in Eluant Medical; this is unrelated to the content of this manuscript.

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