Original Article

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Radiological Underestimation of Tumor Size Influences the Success Rate of Re-Excision after Breast-conserving Surgery

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ABSTRACT

Objective: Failure to achieve adequate margins after breast-conserving surgery often leads to re-excision, either by repeat breast-conserving surgery (BCS) or by mastectomy. Despite the high frequency of this problem, the success rate of achieving adequate margins by repeat BCS is not well documented. The objective of this study was to determine the success rate of repeat BCS and identify the factors influencing that rate.

Materials and Methods: A retrospective review was performed of all women undergoing repeat BCS for inadequate margins after initial BCS in our breast unit between 2013 and 2019. Univariate and multivariate analyses were carried out to identify the factors influencing how often adequate margins were achieved after repeat BCS.

Results: One hundred fifty-four patients underwent repeat BCS after initially inadequate margins, of which adequate margins were achieved in 82%. Patients with successful repeat BCS had smaller tumors, had less underestimation of tumor size on imaging, and were less likely to have had cavity shaves taken at their initial BCS. A tumor size more than 50% larger than predicted by imaging was independently associated with failure of repeat BCS in multivariate analysis (odds ratio: 3.6, 95% CI: 1.41–9.20, p = 0.007). Underestimation of tumor size by imaging was commoner and more extensive in patients with larger tumors and those with ductal carcinoma in situ.

Conclusion: Re-excision by cavity shaves has a high success rate and should be offered to all patients who are deemed suitable for the procedure. Patients whose tumors are more than 50% larger than predicted by imaging should be counseled about the higher risk of failure.

Keywords: Breast-conserving surgery, breast imaging, breast neoplasms, margins of excision, re-excision

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Key Points

- In patients in whom initial breast-conserving surgery has not achieved adequate margins, repeat breast-conserving surgery is successful in 82% of cases.
- Underestimation of tumor size by imaging reduces the probability that repeat breast-conserving surgery will be successful.
- Underestimation of tumor size by imaging is commoner in patients with larger tumors and ductal carcinoma *in situ*.

Introduction

Breast-conserving surgery (BCS) is now firmly established as the standard of care for early breast cancer where feasible, with long-term follow-up demonstrating oncological safety (1). With ever-improving adjuvant treatment and understanding of tumor biology, local recurrence rates after BCS are low. Re-excision rates, on the other hand, despite improvement in recent years, remain high (2). With BCS performed on 180,000 women in the USA each year and a significant number of those requiring further surgery to obtain adequate margins, re-excision is clearly an area where improvements could have a significant impact on healthcare delivery (3).

For women requiring re-excision, a decision needs to be made on whether to perform repeat BCS, with further shaves of tissue removed at the inadequate margins, or proceed to mastectomy. Mastectomy guarantees that surgical treatment is complete and delivers an extremely high rate of margin clearance but is associated with an increased risk of short- and long-term morbidity and poorer body image (4, 5). Repeat BCS, on the other hand, allows the opportunity for conservation of the breast, although persistent inadequate margins may lead to a third or even a fourth operation, with increased operative risk, increased cost, poorer cosmesis, and a possible delay in adjuvant treatment (6-8). The decision on the type of re-excision is based primarily on the chance of repeat BCS successfully achieving an adequate margin, although the expected cosmetic

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result, the woman's attitude toward the risk of additional surgery, her suitability for an oncoplastic technique, and her degree of aversion to undergoing mastectomy also play a role. Given how often re-excision is necessary, the evidence base addressing factors that affect the success rate of repeat BCS is small.

The aim of this study was to determine the success rate of repeat BCS in achieving adequate margins and to identify clinical factors available at the time when the decision on the method of re-excision is made that would allow us to more accurately define that rate for each individual patient, allowing better informed decision making by patients and their surgeons on the method of re-excision.

Materials and Methods

All patients undergoing initial BCS in our breast unit between January 2013 and October 2019 were identified from a prospectively compiled database. Those undergoing re-excision by repeat BCS were included in the study. The exclusion criteria were patients undergoing neoadjuvant chemotherapy; patients where the initial BCS was an excision biopsy for diagnosis; patients undergoing repeat BCS by an oncoplastic reduction technique; patients with phyllodes tumors; patients undergoing repeat surgery to the axilla only; and patients undergoing repeat surgery to the breast for multifocal disease, early recurrence, or surgical complications. Approval was given by the local research governance committee. Patients routinely underwent preoperative digital mammography using Hologic Selenia Dimensions (Hologic, Marlborough, MA, USA) and ultrasound using Toshiba Xario (Toshiba, Tokyo, Japan) equipment. Magnetic resonance imaging (MRI) was not used routinely but was employed in scenarios where it was felt likely to alter management, particularly in patients with lobular tumors or with a marked discrepancy in tumor size between the mammography and ultrasonography results. When used, MRI was performed with either GE Optima (GE Healthcare, Chicago, IL, USA) or Siemens Sola (Siemens, Munich, Germany), both 1.5 tesla wide bore with 16 and 18 channel coils, respectively.

The choice of initial surgical approach, either mastectomy or BCS, was made by the multidisciplinary team in conjunction with the patient, taking into account factors such as radiological prediction of tumor size, breast size, tumor biology, genetic status, and comorbidities. The decision on whether to perform re-excision in patients with inadequate margins, as well as whether to achieve this by mastectomy or repeat BCS, was also made by the multidisciplinary team in conjunction with the patient, taking into account factors such as the number of involved margins, pathological tumor size, and perceived cosmetic outcome.

The multidisciplinary team followed the United Kingdom guidelines for adequate margin distance in invasive and non-invasive disease. The minimum adequate margin decreased to 1 mm during the study period, with the policy of the multidisciplinary team also changing to mirror these guidelines. Patients with an unsatisfactory deep or superficial margin were not routinely re-excised if the initial excision was known to extend to the pectoral fascia or subcutaneous tissue. The technique of planned circumferential cavity shaving in addition to wide local excision was not used in this study. Unplanned targeted cavity shaves were taken during the initial BCS at the operating surgeon's discretion if it was felt that a particular margin was at risk of being involved, either because of visualization or palpation of the tumor at the edge of the wide local excision specimen or breast cavity, or because of concern on intraoperative specimen radiology. Intraoperative radiology was performed for all wire-localized excisions but not for excisions where the tumor was palpable. No intraoperative pathological assessment of margins was performed.

The potential factors predicting the success of BCS investigated were age at the time of initial surgery; radiological tumor size; presence of ductal carcinoma *in situ* (DCIS); presence of DCIS only; pathological tumor size; Bloom-Richardson-Elston grade; tumor type; multifocality; axillary lymph node involvement; number of involved radial margins; whether targeted cavity shaves were taken at initial surgery; presence of lymphovascular invasion; estrogen receptor (ER) status; and human epidermal growth factor receptor 2 (HER2) status.

Assessment of the maximum diameter of the radiological malignancy was made by a consultant breast radiologist while performing the breast ultrasound or reporting the images of the mammogram and, if performed, the MRI. The radiological tumor size was defined as the largest of these measurements, irrespective of modality. This measurement was chosen as it is likely to be the measurement used both to decide whether to perform BCS initially and to plan the size of the resection specimen removed if BCS is performed.

Pathological tumor size was defined as the greatest diameter of the whole tumor, including any DCIS, as measured by a consultant pathologist. If tumors were multifocal, the size of the largest focus was used. If any additional tumor was found in targeted cavity shaves at the initial BCS, this was added to the pathological tumor size. Additional tumor removed at the repeat BCS was not added to the pathological tumor size for the purpose of the results of this study as this information is not available at the time when the decision on the method of re-excision is made and so could not contribute to the aims of this study. It was, however, used in determining the total tumor size used in planning the patients' adjuvant treatment.

The pathological tumor size to radiological tumor size ratio (PRR) was used as a measure of the degree of radiological underestimation or overestimation of tumor size. This was calculated by dividing the pathological tumor size by the radiological tumor size. A higher PRR signifies a greater degree of radiological tumor size underestimation.

Patients with Paget's disease of the breast were excluded from analysis involving radiological tumor size. Patients with pure DCIS were excluded from analysis involving grade, ER status, HER2 status, and lymphovascular invasion as these are not routinely recorded in our institution for these patients. Pathology reports from the re-excision specimen were examined for the presence of any DCIS or invasive carcinoma and whether the re-excision had achieved adequate margins.

The authors state that the study protocol has been approved by the Northern Health and Social Care Trust research committee (decision number: NT20-274636-02 date: June 10th, 2020).

Statistical analysis

Statistical analysis was performed using SPSS (SPSS Statistics for Macintosh, Version 24.0; IBM Corp, Armonk, NY, USA). Continuous variables were assessed by the Student's t-test for parametric data and Mann-Whitney U and Kruskal-Wallis tests for non-parametric data, where appropriate. Categorical data was assessed by Pearson's chi-square test and Fisher's exact test, where appropriate. Univariate analysis was performed to assess the associations between potential predictive factors and whether repeat BCS achieved an adequate margin. Odds ratios (ORs) for failure of repeat BCS were calculated for each variable. Variables found to affect the success of repeat BCS in univariate analysis, with a threshold of p<0.10, were included in a multivariate binary logistic regression analysis, with a significance threshold of p<0.05.

Strengthening the reporting of observational studies in epidemiology (STROBE) reporting guidelines were followed when reporting this study.

Results

One thousand one hundred thirty-four patients underwent initial BCS during the study period. Two hundred twenty (16.5%) of these underwent reoperation for inadequate margins. Sixty-six underwent mastectomy, leaving 154 patients undergoing repeat BCS. These 154 patients formed the study group. All patients had ultrasonography and mammography, and seven had MRI. Not all patients with a lobular element had preoperative MRI, as the core biopsy had suggested ductal carcinoma, but the final pathology confirmed mixed ductal and lobular carcinoma. The cohort's surgical treatment is shown in Figure 1. One hundred twenty-six patients (82%) had successful repeat BCS, 104 who had no residual disease and 22 who had residual disease but adequate excision margins. One patient had a successful third BCS, while 27 patients underwent mastectomy as a third procedure.

Thirty-two patients (21%), including one with Paget's disease of the breast, had pure DCIS and were excluded from analyses on ER and HER2 status, lymphovascular invasion, and grade. All 122 patients with invasive disease had lymph node excision, 16 by axillary clearance and 106 by sentinel node biopsy. The patient with Paget's disease also had sentinel node biopsy.

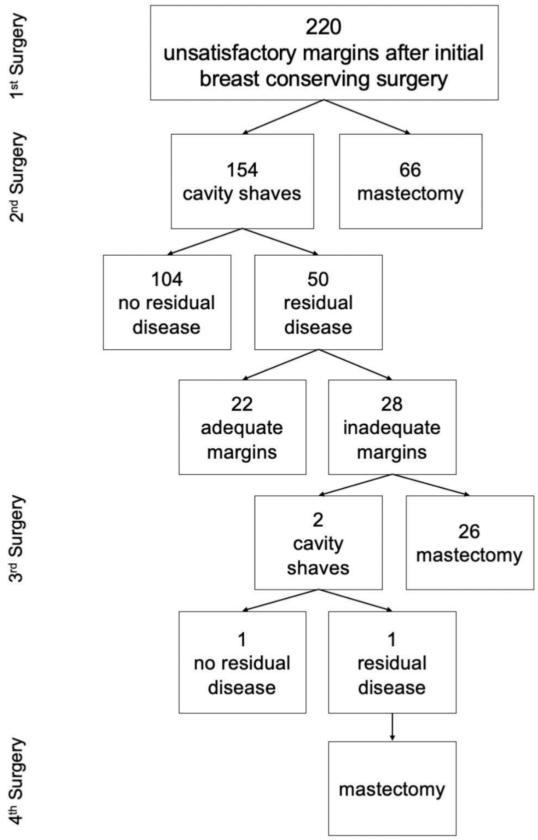

Figure 1. Study group assignment by surgical treatment. In all, 16.5% of patients had a second operation after initial BCS, 2.1% had a third operation, and 1 patient (0.07%) underwent a fourth

BCS: Breast-conserving surgery

Patient characteristics and pathological factors for the groups with successful and unsuccessful BCS are shown in Table 1. Patients with successful repeat BCS had smaller tumors and a lower PRR and were less likely to have had targeted cavity shaves taken at their initial BCS. They also tended to be of a lower grade, but this trend did not reach significance. The success rate of repeat BCS decreased as the degree of tumor size underestimation by radiology increased (Figure 2).

Ninety-four percent of patients with two or three of the factors predicting successful repeat BCS did have successful repeat BCS, whereas only 61% of patients with none of these factors had successful repeat BCS (OR for failure with no factors predicting success was 9.58, 95% CI: 2.94–31.21, p = 0.0001).

Univariate and multivariate analyses for failure of repeat BCS are shown in Table 2. Underestimation of tumor size by radiology, with a PRR of over 1.5, independently predicted failure of repeat BCS in multivariate analysis.

Underestimation of tumor size by radiology was commoner in patients whose specimens contained DCIS. The average PRR was 1.21 in patients with invasive disease only and 1.99 in patients with DCIS (p = 0.00398). Eighty-eight percent of patients with invasive disease had a PRR below 1.5, whereas only 54% of patients with DCIS did (p = 0.00266).

Underestimation of tumor size by radiology was more likely as the pathological tumor size increased (Figure 3). Targeted cavity shaves were more likely to have been taken at the initial BCS where the tumor size was underestimated by radiology (p = 0.00988, Figure 4).

Tumor size measurement was similar between mammography and ultrasonography (mean 15.5 mm vs 16.2 mm, p = 0.271). In the seven patients undergoing MRI, the mean MRI tumor measurement was larger than that in the cohort as a whole at 26.3 mm, but these seven patients also had larger tumor measurements on mammography (mean 26 mm, p = 0.95) and ultrasonography (mean 21 mm, p = 0.41).

There was no difference in the degree of underestimation of tumor size between mammography and ultrasonography, with a mean PRR of 1.91 for mammography and 1.92 for ultrasonography (p = 0.60).

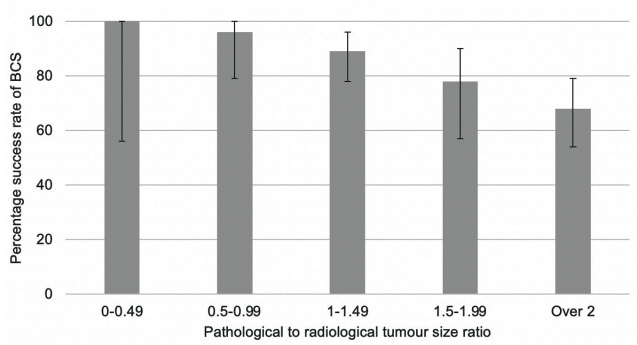

Figure 2. Success rate of repeat BCS by PRR. Repeat BCS was less likely to be successful in patients with a higher degree of tumor size underestimation by radiology

BCS: Breast-conserving surgery, PRR: Pathological tumor size to radiological tumor size ratio

In the small number of patients undergoing MRI, the mean PRR calculated on the basis of the MRI measurement was lower at 1.48, corresponding to a lesser degree of tumor size underestimation, but this was not significant (p = 0.234 vs mammogram and p = 0.238 vs ultrasound).

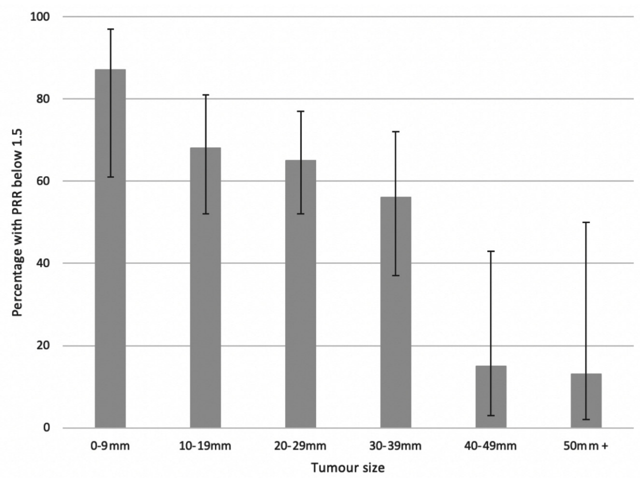

Figure 3. PRR by pathological tumor size. Patients with larger tumors were more likely to have tumor size underestimation by radiology

PRR: Pathological tumor size to radiological tumor size ratio

Discussion and Conclusion

This study focused on the common problem of re-excision after BCS, in particular the method of that re-excision. We found a high rate of success of repeat BCS but showed that underestimation of the tumor size by imaging independently predicted failure.

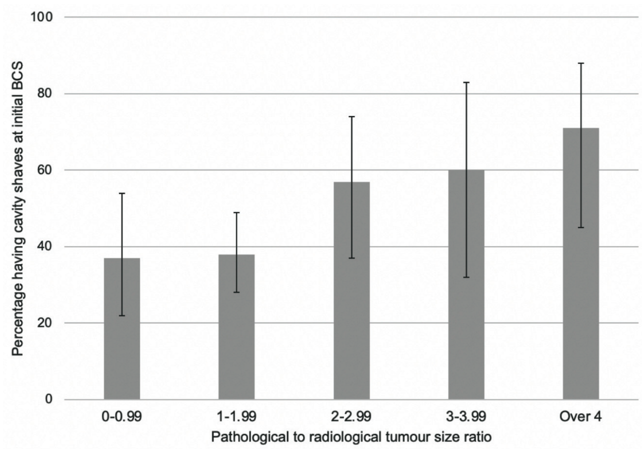

Figure 4. Rate of cavity shaves taken at initial BCS by PRR. Tumor size underestimation by radiology made it more likely that surgeons took unplanned targeted shaves at initial BCS

BCS: Breast-conserving surgery, PRR: Pathological tumor size to radiological tumor size ratio

Table 1. Comparison of patients with successful and unsuccessful repeat BCS

Factor	Successful 127 patients	Unsuccessful 27 patients	p-value
Mean age (range)	56 (32–83)	59 (46–79)	0.1172
Any DCIS present	105/127 (83%)	25/27 (93%)	0.2532
Pure DCIS	27/127 (21%)	5/27 (19%)	0.7499
Mean radiological tumor size (range)	16 mm (3–40)	14 mm (2–27)	0.3030
Mean pathological tumor size (range)	23 mm (2–75)	29 mm (6–50)	0.0274
Mean PRR (range)	1.72 (0.3–8)	2.56 (0.9–7)	0.0005
Multifocal tumor present	12/127 (9%)	3/27 (11%)	0.7194
IDC	91/100 (91%)	21/22 (95%)	0.6881
Mean specimen weight (range)	50 g (5–164)	51 g (11–140)	0.6312
Grade			
1	25/100 (25%)	2/22 (9%)	
2	47/100 (47%)	10/22 (45%)	0.1469
3	28/100 (28%)	10/22 (45%)	
ER positive	87/100 (87%)	19/22 (86%)	0.9361
HER2 negative	85/100 (85%)	17/22 (77%)	0.3754
LVI present	33/100 (33%)	6/22 (27%)	0.6020
Involved nodes present	32/101 (32%)	6/22 (27%)	0.6891
Mean number involved margins (range)	0.55 (0–2)	0.74 (0–2)	0.2713
Any involved margin	56/127 (44%)	15/27 (56%)	0.2780
Targeted shaves taken at initial surgery	52/127 (41%)	17/27 (63%)	0.0367

DCIS: Ductal carcinoma *in situ*, PRR: Pathological tumor size to radiological tumor size ratio, IDC: Infiltrating ductal carcinoma, ER: Estrogen receptor, HER2: Human epidermal growth factor receptor 2, LVI: Lymphovascular invasion

Table 2. Univariate and multivariate analysis of factors predicting failure of repeat BCS

Factor	Failure rate of BCS	Univariate analysis			Multivariate analysis		
		OR for BCS failure	95% CI	p-value	OR for BCS failure	95% CI	p-value
Age							
≥50	19%	1					
<50	14%	0.67	0.25–1.79	0.4201			
DCIS							
Present	8%	1					
Absent	19%	2.62	0.58–11.88	0.2532			
Pure DCIS							
Yes	18%	1					
No	16%	0.84	0.29–2.43	0.7518			
Tumor size							
<20 mm	9%	1					
≥20 mm	22%	2.67	0.95–7.53	0.0554	2.10	0.71–6.20	0.178
PRR							
≤1.5	8%	1					
>1.5	29%	4.34	1.71–11.03	0.0011	3.60	1.41–9.20	0.007
Multifocal tumor							
No	17%	1					
Yes	20%	1.20	0.31–4.57	0.7283			
Tumor type							
IDC	19%	1					
ILC or mixed	10%	0.48	0.06–4.01	0.6881			
Grade							
1	7%	1					
2	18%	2.66	0.54–13.09	0.3216			
3	26%	4.46	0.89–22.36	0.1020			
LVI							
Absent	19%	1					
Present	15%	0.76	0.27–2.13	0.6033			
Axillary nodes							
Not involved	19%	1					
Involved	16%	0.81	0.29–2.26	0.6892			
Any margin involved							
No	14%	1					
Yes	21%	1.58	0.69–3.66	0.2774			
Margins involved							
0	14%	1					
1	19%	1.41	0.56–3.54	0.4666			
2	26%	2.11	0.64–6.95	0.3024			
Any targeted shaves taken at initial BCS							
Yes	12%	1					
No	25%	2.45	1.04–5.78	0.0368	1.91	0.77–4.71	0.162

Table 2. Continued

Factor	Failure rate of BCS	Univariate analysis			Multivariate analysis		
		OR for BCS failure	95% CI	p-value	OR for BCS failure	95% CI	p-value
ER status							
Positive	18%	1					
Negative	19%	1.06	0.27–4.08	0.9361			
HER2 status							
Negative	17%	1					
Positive	25%	1.67	0.53–5.20	0.5242			

BCS: Breast-conserving surgery, OR: Odds ratio, CI: Confidence interval, DCIS: Ductal carcinoma *in situ*; PRR: Pathological tumor size to radiological tumor size ratio, IDC: Infiltrating ductal carcinoma, ILC: Infiltrating lobular carcinoma, LVI: Lymphovascular invasion, ER: Estrogen receptor, HER2: Human epidermal growth factor receptor 2

Re-excision is currently a widely debated topic in breast surgery. Substantial efforts have been made in recent times to reduce rates of re-excision. Novel surgical techniques, including intraoperative ultrasound, intraoperative cytology, in-theater specimen radiology, and circumferential cavity shaving, have been introduced to reduce margin involvement (9, 10). Much work has also been carried out investigating the size of the resection margin that gives the optimum balance between unnecessary re-excision and future local recurrence. While debate remains over what constitutes an adequate margin, with United Kingdom (UK) guidelines recommending a 1 mm margin for invasive disease, while United States (US) guidelines mandate only no tumor on ink, it is clear that avoiding involved margins is essential in reducing the tumor burden sufficiently so that the combination of surgery and adjuvant therapy can lead to extremely low local recurrence rates (11). The ideal scenario would clearly be to achieve this at initial BCS; however, if this is not achieved, re-excision still reduces local recurrence, although possibly not to the same level as if adequate margins were achieved at the initial BCS, particularly if the re-excision contains residual disease (12–14). Inaccurate targeting of re-excision may at least partially explain this. Particularly with mobilization of glandular flaps to fill the lumpectomy defect at initial BCS, the exact site of margin involvement may not be correctly identified at repeat BCS, potentially leaving residual disease in the breast despite a histologically clear re-excision specimen. The sharing of adverse prognostic indicators between the need for re-excision and local recurrence may also contribute. While local recurrence rates may be higher, overall survival in patients undergoing re-excision is no different to those having successful initial BCS, whether the re-excision is achieved by repeat BCS or mastectomy (15). Although re-excision rates are improving, with a meta-analysis finding a re-excision rate of 14% in recent studies, substantially lower than historic rates, the burden of re-excision remains high (2). Given how frequently the decision on the method of re-excision needs to be made, very few studies have looked at the rate of success of re-excision BCS or investigated the factors that influence it. Our study showed a success rate of re-excision BCS of 82%. It must be borne in mind that this was a group of patients considered appropriate candidates for repeat BCS, and 30% of patients with inadequate margins during the study period chose mastectomy as their method of first re-excision and so were not included in this study group. Fisher et al. also showed a success rate for repeat BCS of 82%, Morrow et al. (16) 93%, and Coopey et al. (17) 91% in registry-based cohort studies, the focus of which was not on factors influencing the success of repeat BCS (15–17). Houvenaeghel et al. (18) showed a success rate of repeat BCS of 87%, with patients under 50 and those with larger or multifocal tumors less likely to have successful repeat BCS. In a cohort of patients with invasive lobular carcinoma, Piper et al. found a success rate of repeat BCS of 74%, with higher success rates in those who were older and had fewer involved nodes. Patients whose repeat BCS was unsuccessful also had larger tumors in their study, but this did not reach significance (19).

This study did not investigate the type of re-excision to offer if repeat BCS did not achieve adequate margins. In our study, all but two patients in this situation underwent mastectomy. Our policy is to avoid more than three operations on the breast, if possible, based on concerns regarding excess tumor burden, delay to adjuvant therapy, and previous national guidance. Of the two patients who underwent a third BCS in our cohort, one achieved adequate margins, while the other underwent mastectomy as a fourth operation. Other series have addressed this situation, with Cellini et al. (20) showing a 61% success rate and Coopey et al. (17) a 67% success rate at third BCS and 25% at fourth BCS, with a 2% local recurrence rate in those patients at 64-month median follow-up.

Underestimation of tumor size by radiology is a well-recognized problem in the literature. It has previously been shown that radiological tumor size underestimation influences the success of initial BCS, with a greater degree of underestimation leading to a greater need for re-excision (21). Tumor size underestimation has also been shown to increase the probability of residual disease in the re-excision specimen (22). We showed that a pathological tumor size exceeding the radiological measurement by more than 50% independently predicted a higher failure rate of repeat BCS, to our knowledge the first study to demonstrate this in the literature. The rate of underestimation was generally high in this study as it included only patients who had failed initial BCS, a group known to have a higher rate of underestimation (21). The imaging modality may play a role in tumor size underestimation, having previously been shown to be commoner with ultrasonography than with mammography (23). Ultrasonography is operator dependent, and underestimation may be due to factors such as failure to measure the halo around the tumor or the tumor size exceeding the size of the transducer. In tumors with a significant component of DCIS, the tumor extent may be underestimated on ultrasound as the typical microcalcifications are less readily visible or measurable. Noncalcified DCIS may lead to tumor underestimation on mammography (24–26). We found no difference in the degree of size underestimation between mammography and ultrasonography in this study, although we did find that underestimation of tumor size was commoner in patients with DCIS and also with larger tumors, findings echoed in other studies (25, 27). Radiological underestimation of tumor size has been shown to occur less often with MRI, although MRI can also lead to overestimation, possibly due to enhancement of background parenchyma (24, 28). We found that MRI underestimated tumor size to a lesser extent than mammography or ultrasound, although too few patients in this cohort underwent MRI to allow a useful comparison.

The pathological tumor type also influences the degree of radiological size underestimation. Lobular primaries are at higher risk of radiological underestimation, due to their diffuse growth pattern, with less distortion of the breast architecture and a lack of difference in density or echogenicity between the tumor and normal breast tissue. Lobular tumors are also more likely to exhibit irregular contours and more diffuse margins and have a higher likelihood of satellite foci (29). We did not find a higher rate of underestimation in lobular tumors, although they made up only 10 patients of our cohort.

We found that patients with a greater degree of radiological underestimation were more likely to have had targeted cavity shaves taken at the time of their initial BCS. We believe this is because the surgeon's initial excision is guided by the preoperative radiological tumor size, with a larger tumor than expected only being detected intraoperatively, by direct palpation, visualization, or intraoperative specimen radiology and leading to additional tissue being taken. To our knowledge, this is the first time this correlation has been reported in the literature.

A limitation of the study is that patients were from a single center, which limited the number of patients, and the treatment decisions made may not be replicated in other centers. We followed UK guidelines on an adequate margin distance of 1 mm, different to US and other European guidelines, which may make this study less applicable in countries following those guidelines. A further limitation is that we had no data on cosmetic outcomes for patients who had re-excision, relying on margin adequacy as the only marker for success of the repeat BCS.

Further work could explore the extent to which patients value particular factors, such as the risk of additional surgery, cosmesis, delay in adjuvant treatment, or potential avoidance of radiotherapy when making the decision on whether to have repeat BCS or to choose mastectomy.

In conclusion, re-excision by cavity shave has a high success rate and should be offered to all patients who are thought suitable. Patients whose tumors are more than 50% larger than was predicted on imaging should be counseled about the higher risk of failure with consideration given to larger excisions or oncoplastic techniques.

Ethics Committee Approval: The authors state that the study protocol has been approved by the Northern Health and Social Care Trust research committee (decision number: NT20-274636-02 date: June 10th, 2020).

Informed Consent: Patient-level consent was waived by the committee as no treatment decisions were altered by the study.

Peer-review: Externally peer-reviewed.

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Conflict of Interest: No conflict of interest was declared by the authors.

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