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Achieving clear margins. Directed shaving using MarginProbe, as compared to a full cavity shave approach

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ABSTRACT

Background: Following lumpectomy, full cavity shaving approach is used to reduce positive margin rates, among other issues previously studied by others, at an expense of increase in tissue volume removed. We present our experience after switching from full cavity shaving to a targeted shaving approach using MarginProbe, an intra-operative margin assessment device.

Methods: Specimen excision was performed according to standard of care. Additional shavings were taken based on device readings on the lumpectomy specimen. Intra-operative imaging was used, as required.

Results: We compared 137 MarginProbe cases to 199 full cavity shave cases. The re-excision rate was reduced by 57% ($P = 0.026$), from 15.1% to 6.6%. The overall tissue volume removed was reduced by 32% ($P = 0.0023$), from 115 cc to 78 cc.

Conclusions: MarginProbe enabled a change in the lumpectomy technique from full cavity shavings to directed shavings guided by the device. There was a significant reduction in re-excisions and in the overall tissue volume removed. The lower amount of shavings also contributed to a reduction in pathology work.

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1. Introduction

The incidence of breast cancer from 2003 to 2012 has been stable at 29% of new cancer diagnoses, which is now similar between white and black women. While the incidence has remained stable, mortality has decreased 1.9% and 1.4% per year in white and black women, respectively. This is attributed to improved detection and treatment.¹ Total mastectomy and breast conserving surgery (BCS) are the two main modalities for treating breast cancer. BCS attempts to decrease the amount of tissue removed while obtaining negative surgical margins to improve quality of life, survival, and body image. For BCS to be considered successful, the surgical margins (i.e. the outer extent of the removed tissue) have to be clear of cancer cells. In 1991, NIH made a consensus statement to perform

BCS over mastectomy for early stage breast cancer given the equivalence of survival with preservation of more breast tissue.² Subsequent to the NIH consensus statement, studies have continued to show that overall survival is similar between mastectomy and BCS. Recently, Chen et al. have shown that in non-metastatic N0 or N1 breast cancer overall survival is actually increased in women treated with BCS. In N2 and N3 breast cancer overall survival was similar between total mastectomy and BCS.³ Thus, BCS is as effective, if not more, at increasing overall survival in patients with early stage breast cancer.

After the NIH consensus statement, rates of BCS went from 54.3% in 1998 to 59.7% in 2006. This increase was greatest in patients aged 52–70 years old compared to younger patients.⁴ While utilization of BCS increased after the 1991 consensus statement, recently the rate of usage has been decreasing. In a recent review by Recio-Saucedo et al., younger age and genetic testing affected a patient's desire for bilateral mastectomy rather than BCS as patients were concerned about recurrence and body image.⁵ As the NIH consensus statement stated, "A woman's body image and her beliefs and concerns may determine her preference for breast conserving treatment or mastectomy." Thus, a prime goal of BCS is

Keywords: BCS, breast conserving surgery; IDC, invasive ductal carcinoma; DCIS, ductal carcinoma in situ; ER, estrogen receptor; PR, progesteron receptor; HER2, human epidermal growth factor receptor 2.

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to maintain excellent cosmetic outcomes while maintaining overall survival equivalent or better than total mastectomy.

Overall survival is related to local-regional recurrence. A study by Guidroz et al. has shown that recurrence within 4 years was twice as high in patients with inadequate compared to adequate margins (12% vs. 6%, respectively).⁶ While inadequate margins are associated with higher recurrence of cancer, a survey of 382 surgeons in 2009 throughout the nation found there to be no consensus in the acceptable width of margins for resection to avoid re-operation.⁷ In many cases, re-operations are required to achieve clear margins. National rates are reported as being at about 28–31%.^{8,6} Re-operation rates are lower if additional cavity margins are taken during the initial surgery, and this is related to a lower chance of local regional recurrence.⁶ Full cavity shaving is an intra-operative method in which additional margins/shavings are systematically removed from all aspects of the lumpectomy cavity. This technique has been shown to decrease re-excision rates by about half.^{9–12} However, a concern is that a greater volume of tissue is removed, which may affect cosmetic outcome.

MarginProbe (Dune Medical Devices, Paoli, PA, USA) is a hand-held intra-operative device for identification of positive margins, enabling the surgeon to perform immediate additional shaves to obtain negative margins. It uses radio frequency spectroscopy to identify tumor cells.^{13,14} Prospective randomized controlled studies have shown that MarginProbe decreases the re-excision rate by up to 56%.¹³ Recently, use of the device was shown to decrease re-excision rates by 62%.^{15,16} This decrease was not dependent upon grading, tumor size, breast-density, age, body-mass-index or wire-marker application. Also, use of the device maintained cosmetic outcome as 80% and 92% of surgeons and patients, respectively, reported excellent cosmetic outcome.^{13,17} Cosmetic outcome was not different from the control arm (standard of care without MarginProbe) as there was only an average of 8.5 mL more tissue removed.¹⁴ Thus, our hypothesis was that MarginProbe compared to full cavity shave would decrease the amount of tissue removed while maintaining negative margins.

2. Methods

We retrospectively analyzed two sets of consecutive lumpectomy cases performed at the Hall-Perrine Cancer Center at Mercy Hospital in Cedar Rapids, Iowa. MarginProbe cases and full cavity shave approach cases. Specimen excision was performed according to standard of care. For the MarginProbe set, additional specimen shavings were taken based on device reading from the lumpectomy sample. For the full cavity shave set, additional shavings were taken circumferentially from all aspects of the cavity. For both sets, intra-operative imaging was used as required. Re-excision rate, volume excised, and additional shavings removed were compared between the two sets. Positive margins were defined as ink within the specimen.

All patients were incorporated in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database of our institution. Data was collected from participant use files for the NSQIP database, including operative notes, pathology reports and hospital records. Data on device readings was obtained from operative notes. Historical data was collected from a consecutive set of patients in the period before the device was put into use. As this was a retrospective chart review and observational study of NSQIP participant files no further review by the institutional review board was required.

For the statistical analysis numerical variables were tabulated using mean, standard deviation, and ranges. Categorical variables were tabulated using number of observations and percent. All statistics were performed at $\alpha = 0.05$ two-sided significance level.

Rates between sets were compared using Fisher's exact test for dichotomous variables, and Wilcoxon rank sum test for continuous variables. Missing data were not imputed.

3. Results

A total of 137 patients received BCS with MarginProbe between the 19-month period of January 2014 until July 2015. This was compared to a historical set of 119 patients who received BCS with full cavity shaving during the full year of 2013. MarginProbe added about 3–5 min to each case. The patient demographics (Table 1) and tumor characteristics (Table 2) were similar between the two methods. The mean age was 63.7 (± 11.5) for the patients who received BCS with MarginProbe and 61.5 (± 11.4) for patients who received BCS with full cavity shaving. For both surgical methods, the main tumor type was IDC with 75% of the MarginProbe cases positive and 87% of the full cavity shaving cases positive. Invasive lobular carcinoma was 10% and 4% for MarginProbe and full cavity shaving, respectively, while DCIS was 15% and 9%, respectively. The majority of cases were ER+ with 93% and 82% positive for MarginProbe and full cavity shaving, respectively, and 89% and 59% of the cases were PR+. Most of the cases were not HER2+ as only 10% and 13% of MarginProbe and full cavity shaving cases were positive, respectively. Table 2 shows the tumor grade was almost evenly divided between grades 1 through 3. The percent of cases for MarginProbe were 28%, 36%, and 36% for grades 1 through 3, respectively. Full cavity shaving was 30%, 25%, and 45% for grades 1 through 3, respectively. Most of the cases were stage 2 or less as 97% and 92% of MarginProbe and full cavity shaving cases, respectively, were stage 2B or less. Tumor size was similar between groups as the mean size of the MarginProbe cases was 1.4 (± 1) cm while the full cavity shaving cases were 1.7 (± 1.3) cm.

Comparing the re-excision rate between the MarginProbe and full cavity shave cases, Table 3 shows there was a 8.5% absolute reduction in re-excision; 9 out of 137 (6.6%) and 19 out of 119 (15.1%) of MarginProbe and full cavity shaving cases, respectively. This corresponds to a relative reduction in re-excision cases of 57% by using MarginProbe compared to full cavity shaving, which was statistically significant (P-value 0.026). Comparing the volume of the main specimen excised, Table 4 shows that using MarginProbe compared to full cavity shavings had a relative reduction of 22% (P-value 0.034). With use of the device, the number of shaving taken was reduced from 3.5 (± 1.4) to 1.9 (± 1). This corresponded to a relative reduction of 46% (P-value <0.0001) in the number of shavings taken per case. Thus, use of MarginProbe compared to full cavity shaving decreased, by the combined contribution of the above two effects, the mean total volume of tissue excised during

Table 1
Patient demographics.

	MarginProbe (N = 137)	Historical set (N = 119)
Age		
Mean (STD)	63.7 (11.5)	61.5 (11.4)
<50	13%	25%
50 to 60	20%	18%
60 to 70	36%	32%
>70	31%	25%
Tumor Type		
Invasive Ductal	75%	87%
Invasive lobular	10%	4%
DCIS	15%	9%
Receptor Status		
ER+	93%	82%
PR+	89%	59%
HER2+	10%	13%

Table 2
Tumor characteristics.

	MarginProbe set (N = 137)	Historical set (N = 119)
Tumor grade:		
1	28%	30%
2	36%	25%
3	36%	45%
Cancer Stage:		
0	17%	12%
1A	56%	56%
1B	2%	0%
2A	11%	9%
2B	11%	15%
3	2%	3%
4	1%	5%
Tumor/lesion size:		
Mean (STD) [cm]	1.4 (1)	1.7 (1.3)
<1 cm	42%	32%
1 cm–2 cm	40%	35%
>2 cm	18%	33%

BCS by 38 cc, from 116 (± 53) cc to 78 (± 33) cc. This corresponding to an overall relative reduction in volume of 33% (P-value 0.0023).

4. Discussion

The purpose of this study was to determine if MarginProbe could further improve surgical technique during BCS by minimizing the amount of tissue removed and lowering the rate of re-excision. We have shown that— with the same surgeon, similar patient demographics, and similar tumor characteristics— switching from a full cavity shaving approach to selective shavings based on MarginProbe readings decreased the rate of re-excision from 15.1% to 6.6%. This resulted in a statistically significant reduction of 57%, and is in line with data previous published regarding MarginProbe.^{13,14,17} Prior studies with using full cavity shavings have shown a re-operation rate of 5.5–35.9%. However, the total volume excised during BCS with cavity shaving in these studies ranged from 55.5 cm³ to 115 cm³.^{18,11,19,20,21,9} A study by Coopey et al. showed that full cavity shaving compared to partial mastectomy decreased total volume excised from 106 (± 87.7) cm³ to 76.3 (± 60.2) cm³. However, this decrease was due to smaller original lumpectomy volume removed with the shaving group, and it did not decrease the re-excision rate while we have shown MarginProbe does.¹⁸ In a recent randomized study, Chagpar et al. showed that full cavity shaving decreased the re-excision rate from 21% to 10%, while the total volume removed was increased from 74.2 cm³ to 115.1 cm³.²² We have shown that MarginProbe significantly decreases the total volume of tissue excised by 33% from 116 cm³ to 78 cm³. The volume excised with use of the device is similar to that reported in

Chagpar when not using full cavity shavings, while the re-excision rate with use of the device (6.6%) was lower than the rate reported in Chagpar when full cavity shave was performed.

While no head to head comparison of cosmetic outcome between MarginProbe and the full cavity shave method or total mastectomy has been performed, surrogate data indicates that it would be improved. A study by Taylor et al. has shown that cosmetic outcome is degraded if the total volume excised is higher than 100 cm³.²³ This is important in the treatment of women with early stage breast cancer as cosmetic outcome is a factor in women choosing BCS over mastectomy. Given that total volume excised with MarginProbe is less than 100 cm³ it is likely that good cosmetic outcome was maintained while decreasing re-excision rates, and subsequent keeping overall survival similar to total mastectomy. Furthermore, there is a higher surgical risk, longer recovery time, and more psychological stress with total mastectomy.²⁴

We, as in other studies, use positive margins and re-excision rates as surrogate markers of local-regional recurrence and subsequently overall survival given the limitations of time. There has yet to be a 5-year cancer free survival study comparing MarginProbe to total mastectomy. A randomized prospective study by Jones et al. has shown that decreasing the rate of positive margins by taking more shavings during BCS decreased the rate of re-excision from 17.2% to 2.3%.⁸ A retrospective of data from 2001 to 2010 found local regional recurrence in 10% of patients and positive margins carried a hazard ratio of 9.11.²⁵ Another retrospective analysis of 470 patients undergoing BCS found that obtaining negative margins decreased the chance of local-regional recurrence by half.⁶ Thus, several studies have supported the correlation between positive margins and local-regional recurrence.

Our study had an un-intended bias towards IDC as about 75% of our cases were IDC, though this was not different between our treatment arms. IDC compared to DCIS has been shown to be less associated with positive margins.¹² Jacobson et al. have shown that 27% of pure IDC had positive margins while 65% of DCIS had positive margins.²⁶ Taking additional margins by shaving during BCS has been shown to decrease the rate of re-excision from 32% to 22%. A study by Thill et al. has shown that MarginProbe decreased the re-excision rate of DCIS by 56% as MarginProbe is able to detect DCIS with no difference from invasive cancers.¹⁷ This is important as a study by Cedolini et al. found that the highest prevalence of local-regional recurrence from DCIS was from tissue with minimal DCIS extension (<25% of the neoplastic lesion). Thus, we do not expect our findings with IDC to be different with DCIS as MarginProbe has a similar detection rate and reduced re-excision rate between IDC and DCIS.^{27,28}

From our study we can conclude that adjusting our practice from full cavity shavings to MarginProbe during BCS has decreased

Table 3
Comparison of re-excision procedures between the sets.

	MarginProbe cases	Historical set	Absolute Reduction (% points)	Relative reduction	P-value
Lumpectomy procedures	137	119			
Re-excision procedures	9	19			
Re-excision rate	6.6%	15.1%	8.5%	57%	0.026

Table 4
Comparison of volume excised and additional shavings removed between the sets.

	MarginProbe cases	Historical set	Relative reduction	P-value
Main Specimen volume [cc]; Mean (STD)	61 (27)	78 (35)	22%	0.034
Number of Shavings Taken, per case; Mean (STD)	1.9 (1.0)	3.5 (1.4)	46%	<0.0001
Total volume removed in the lumpectomy procedure [cc]; Mean (STD)	78 (33)	116 (53)	33%	0.0023

the amount of tissue removed and the re-excision rate. Our findings are likely translatable to other surgeons as our volume of excised tissue and re-excision rate for full cavity shaving and MarginProbe were similar to published results. Decreasing the amount of tissue removed will also decrease the work of pathologists, which will be a savings to healthcare. Removing less tissue is also likely to improve cosmetic outcome while maintaining overall survival similar to mastectomy, which is the goal of BCS.

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Conflicts of interest

The authors declare no conflicts of interest.

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