

The Case for MarginProbe in the Era of No Ink on Tumor

Impact on Re-Excision and Tissue Volume Using Radiofrequency Spectroscopy

Post Consensus Guideline

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Introduction

In an effort to reduce national re-excision rates, in 2014 the Society of Surgical Oncology and the American Society for Radiation Oncology announced a Consensus Guideline of "No Ink on Tumor" to define adequate margins for patients with early stage invasive cancer undergoing breast-conserving surgery (BCS) and whole-breast radiation.¹

Post Consensus Guideline adoption, our re-excision rate was 12.7%. We sought to determine if utilizing MarginProbe Radiofrequency Spectroscopy could further reduce positive margin and subsequent re-excision rate, without increasing excised tissue volume, in the "No Ink on Tumor" era.

Materials and Methods

The MarginProbe Radiofrequency Spectroscopy System (Fig 1) captures the bioelectric signature of tissue at the surface of the lumpectomy specimen, characterizing it as benign or malignant, in real time.



Figure 1 - MarginProbe System

	Historical Control			MarginProbe			Reduction	
	Lumpectomies	Re-excisions	Re-excision Rate	Lumpectomies	Re-excisions	Re-excision Rate	Relative Reduction	P-Value
Total	150	19	12.7%	87	3	3.4%	73.2%	0.0197

Table 2 – Reduction in re-excision vs historical control

We present a retrospective observational review of 237 consecutive cases from Jan, 2016 - Apr, 2018, representing the 150 consecutive patients directly before, and 87 consecutive patients directly after implementation of MarginProbe for intraoperative margin assessment.

All patients were newly diagnosed with invasive cancer or DCIS, scheduled for Breast Conserving Therapy, and received standard of care comprised of image guided localization, intraoperative x-ray specimen imaging, and intraoperative margin color inking for orientation. (Table 1)

	Historical	Device
Age mean (range)	65 (41-88)	64 (27-85)
Tumor size mean (range)	1.5 (0-6.4)cm	1.29 (0-4.5)cm
Tumor Histology		
IDC	73% (109/150)	75% (64/87)
ILC	11% (17/150)	10% (9/87)
Mixed Invasive	2% (3/150)	2% (2/87)
DCIS	14% (21/150)	13% (11/87)
DCIS Component	45% (67/150)	53% (46/87)

Table 1 – Patient Characteristics

Results

Utilization of MarginProbe produced a statistically significant relative reduction in re-excision of 73.2%, from the historical incidence of 12.7% (19/150) to 3.4% (3/87) in the device arm, with a P-value of 0.0197. (Table 2)

Total tissue volume removed was decreased from 69cc to 56cc, a 19% decrease in the MarginProbe group. (Table 3)

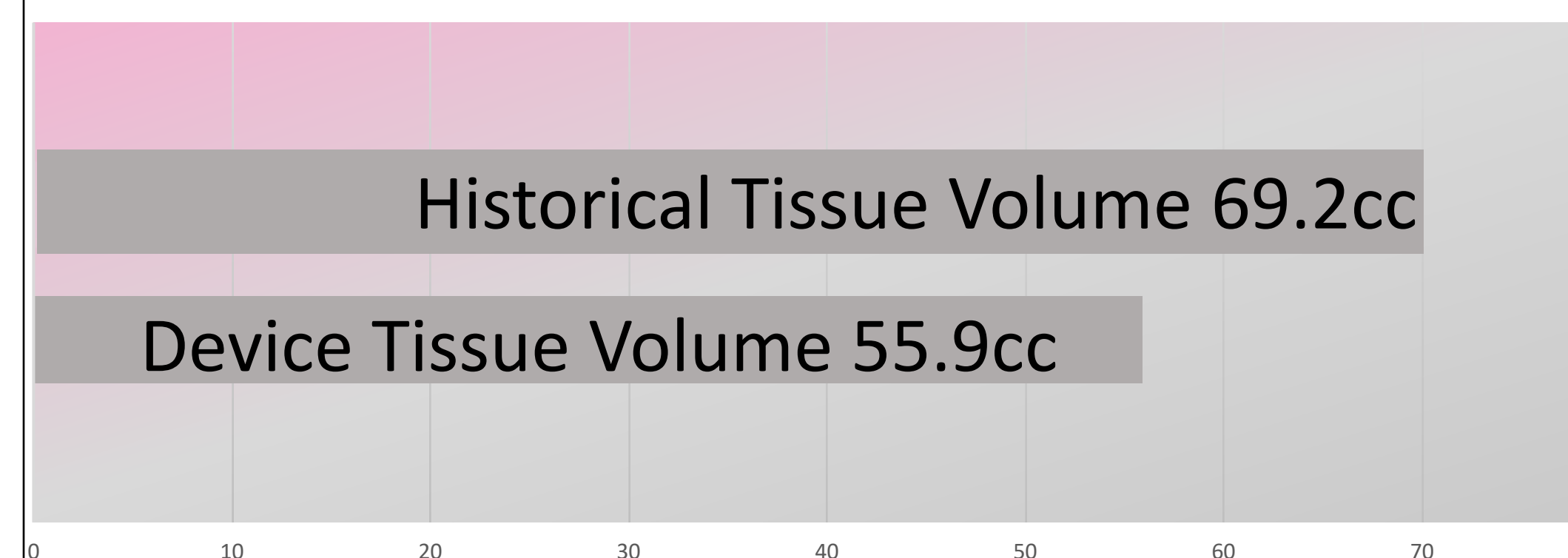


Table 3 – Tissue Volume

Additionally, in 10% (9/87) of the cases, malignant tissue (7 DCIS, 1 IDC, 1 ILC) was reported in MarginProbe directed shavings, although the main lumpectomy specimen was determined to be histopathologically clear. These cases represent disease identified and removed via MarginProbe directed shaving which would have otherwise remained in the breast after a final pathology report indicating clear margins.

Discussion

The 2014 Consensus Guideline of "No Ink on Tumor" to define adequate invasive margin seeks to reduce national re-excision rates and reduce cost to the healthcare system while improving quality of care and patient satisfaction.

Multiple studies to date report the Guideline impact on re-excision for invasive cancer to be a relative reduction of 8-33%, resulting in re-excision rates of 11-21%.^{2,3,4,5,6,7} A recent meta-analysis on Guideline impact reports a 35% odds reduction, with re-excision prevalence decreasing from 22 to 14%.⁸

We found that implementing MarginProbe as an adjunct to standard of care post consensus guideline significantly reduced re-excisions to the low single digits for breast cancer across all subgroups while decreasing total volume of tissue removed.

Importantly, malignant disease which would have been previously unknown, can be identified and removed utilizing MarginProbe for directed shaves.

Future studies should seek to determine if this identification and removal of residual disease will have a positive effect on lowering recurrence rates.

References

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