

MarginProbe® Use Reduced Positive Margins and Lumpectomy Volumes

Introduction

The MarginProbe® System (Fig 1) utilizes radiofrequency spectroscopy to identify microscopic residual cancer and DCIS at the surface of lumpectomy specimen. The device is FDA approved to detect differences in the dielectric properties of cancerous and normal tissues arising from such cellular changes as ion concentration, water content, cellular membrane anatomy, vasculature, and nuclear DNA content.¹

Used intraoperatively during breast conserving surgery, these “real time” results enable surgeons to immediately react by taking selective cavity shavings for any suspect margins.

Previous studies have reported reductions in positive margin rates of 50-60%.³ after using MarginProbe®.

Cosmesis is also important to breast conserving therapy. Cosmetic outcome is known to be inversely proportional to the volume of tissue removed.⁴

This NAPBC quality study measured outcomes from our first year of MarginProbe® use, reporting on the device's impact on final positive margin rates, as well as volume of breast tissue excised.



Figure 1: Margin Assessment with MarginProbe Radiofrequency Spectroscopy

Methods

After institutional board approval, we prospectively collected data on our first 111 lumpectomies performed during the first 12 months of MarginProbe® use from April 2015 through March 2016. This was compared to a historical cohort of 87 lumpectomies from April 2014 through March 2015.

All 197 patients were treated post adoption of the joint SSO/ASTRO “No Tumor on Ink” margin consensus guideline announcement of 2014.

Results

Patient age and tumor histology from each arm are presented in Table 1.

	MarginProbe	SOC
Age (mean, SD)	67±2.1	69±2.8
Tumor Histology		
Invasive	35%	36%
in-Situ	13%	15%
Mixed	52%	49%

Table 1: Patient baseline characteristics

Implementing MarginProbe® for intraoperative margin assessment resulted in a statistically significant 56% relative reduction in positive margins, from 10.3% to 4.5% with a P-Value of 0.016 using 2-tailed Fisher's exact test. (Figure 2)

The mean specimen tissue volume decreased by 34% (P<0.00001) from 132 +/-13 cc to 87+/-13 cc (95%CI). We observed a steady decrease in lumpectomy volume as experience with the device increased. (Fig 3)

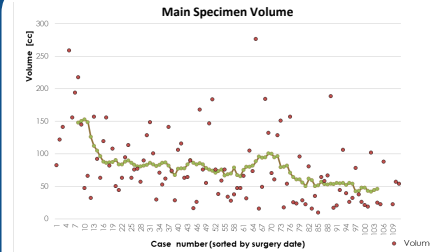


Figure 3: Lumpectomy Volume Reduction with MarginProbe

Conclusions

These results demonstrated statistically significant favorable outcomes reducing positive margin rate while simultaneously reducing the volume of excised tissue when using MarginProbe® for intraoperative margin assessment.

Most centers using the device report a reduction in positive margins by ≥ 50% compared to their previous methods. This study was unique in that it included an assessment of the reduction of tissue removed as well.

Further studies randomizing the utility of this device compared to other methods of intraoperative assessment would be valuable.

Bibliography

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Final Positive Margin Rates

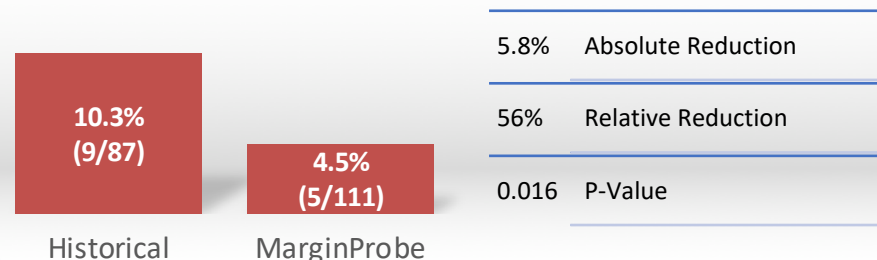


Figure 2: Reduction in positive margin rates