Routine Use of a Real Time Margin Assessment Device

Alice M Police MD,FACS, Medical Director of Pacific Breast Care Center an affiliate of University of California Irvine, Assistant Clinical Professor of Surgical Oncology.
Vivian Le DO, PGY2 General Surgery University of California Irvine School of Medicine

Introduction

Surgical margins in breast conserving surgery (BCS) of DCIS as well as invasive cancer are a subject of intense discussion. A positive margin is still the strongest predictor for risk of local recurrence of intraductal and invasive breast cancer.

Patient concerns over high re-excision rates are one possible factor affecting the recent increase in patients opting for mastectomy as the initial surgical procedure. Our historical re-excision rates are 15%-30%. We report our initial experience in routine use of a real-time intraoperative tool, MarginProbe®, for margin identification.

Materials and Methods

The MarginProbe® System (**Figure 1**) is comprised of two components; a console and a hand-held probe. The probe is a detachable, sterile, single-use, single-patient component. The system utilizes radiofrequency spectroscopy to characterize breast tissue in real-time, measuring differences in dielectric properties between normal and malignant breast tissue.

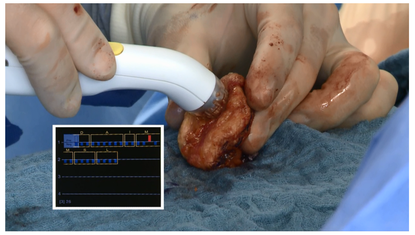

Figure 1 – MarginProbe in use

MarginProbe® was used as part of routine use in a series of consecutive cases of BCS at our center. All patients were pre-diagnosed with cancer, which was histologically confirmed by biopsy. Preoperative wire localization was performed in all cases. Specimens were excised and oriented per routine lumpectomy procedure. MarginProbe was used as an adjunctive tool on all aspects (margins) of the main specimen, but not on additional shavings. The main lumpectomy specimen was oriented and inked in the operating room by the surgeon. Additional shavings of the corresponding cavity face were performed when device reading was positive. Intraoperative imaging by X-ray was performed and, in some cases, intraoperative gross pathology was performed. Where indicated, additional shavings were taken, in addition to the margins which were indicated positive by the device.

Results

Between March 2013 and Jan 2014, 34 Lumpectomy patients were treated.

Each measurement takes approximately 1.5 seconds and measuring the whole specimen took less than 5 minutes.

Subjects' baseline characteristics are presented in **Table 1**.

Age (mean, range)	61 (37 - 83)
Lesion size (mean, range)	1.9 (0.1- 6.9) cm
Tumor Histology	
IDC	71% (24/34)
DCIS component	62% (21/34)
DCIS	21% (7/34)
ILC	3% (1/34)
Receptor status	
ER Positive	85% (29/34)
PR Positive	68% (23/34)
Her2 Positive	21% (7/34)
Specimen volume (mean, range)	28.1 (5.0 – 68.8) cc

Table 1- Subjects baseline characteristics

Using a <1mm definition for a positive margin for both invasive and DCIS, in 13 cases use of the device resulted in identification of the positive margins, sparing these patients a re-excision procedure.

In 4 of these cases there was more than a single involved margin on the main specimen.

In 7 cases, shavings taken due to device readings were found to have cancer present, while the main specimen was clear on final pathology.

Using the new SSO guidelines of "no tumor on Ink" as positive margin, in 5 cases use of the device resulted in identification of the positive margins.

Additional surgeries performed following the lumpectomy are summarized in **Table 2**. Two patients (5.9%, 2/34) underwent a re-excision lumpectomy procedure. In one of these patients the main specimen was all clear by pathology, but the shavings taken based on device readings contained cancer, reaching the new excised margin.

For one additional patient use of the device resulted in identification of extensive disease in 4 shavings leading to a direct conversion to Mastectomy, sparing an intermediate re-excision procedure.

Re-Excision Lumpectomy procedures	5.9% (2/34)
Due to failed detection of margins on specimen	2.9% (1/34)
Due to margins on shavings	2.9% (1/34)
Mastectomy as a second procedure	2.9% (1/34)

Table 2 – Additional Surgeries

Discussion

Use of MarginProbe led to a reduction in re-excision procedures, to single digit re-excision rate. In one case where extensive disease was present use of the device expedited the appropriate surgical procedure - Mastectomy.

Additional studies of device utility in the Neo-Adjuvant setting, as well as skin sparing mastectomies are of interest.