Combined experience at three breast centers with routine use of an intraoperative margin assessment device including comparison to historical re-excision rates

Molly Sebastian, MD, FACS & Stephanie Akbari, MD, FACS; Reinsch Pierce Family Center for Breast Health, Virginia Hospital Center, Arlington, VA.
Beth Anglin MD, FACS; Complete Breast Care, The Medical Center of Plano, Plano, TX.
Alice M Police MD,FACS; Pacific Breast Care Center, University of California Irvine, CA.

Introduction

Obtaining clear margins following a lumpectomy surgery for breast cancer is an important factor in the treatment of breast cancer while conserving the breast (BCS). Historically, high rates, 26%, of surgical interventions to obtain clear margins have been reported[1].

This study is the first compilation of data from three breast centers in the USA, to assess the impact of an intraoperative margin assessment tool on re-excision rates since this technology received FDA approval. We present a retrospective, observational, review from sets of consecutive patients in each of these breast centers – before and after the implementation of routine intraoperative use of the device during lumpectomy procedures.

Materials and Methods

The MarginProbe® System (**Figure 1**) consists of a console and a hand-held, sterile, single-use probe. The system measures the differences in dielectric properties between normal and malignant breast tissue, thereby characterizing breast tissue in real-time.

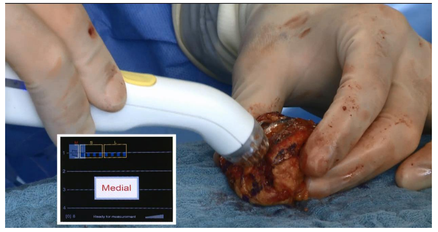

Figure 1 - The device in use

[1]Morrow M, Jagsi R, Alderman AK, et al. JAMA. 2009;302(14):1551-6

Patients were pre-diagnosed with cancer, histologically confirmed by biopsy. Lesions were localized and excised by standard methods. The intraoperative margin assessment device was used on all circumferential margins of the main specimen, but not on any additional shavings. A positive reading by the device led to an additional shaving of the corresponding cavity location. Specimens were also, when feasible, imaged intra-operatively by X-ray, with additional shavings taken if needed based on clinical assessment.

Historical re-excision rates of each surgeon were established on a consecutive set of patients in a corresponding period just before we began using the device.

Results

From Mar 2013 to Apr 2014 the device was routinely used in a series of consecutive BCS cases, by 4 surgeons in 3 centers. The historical comparison sets were established for similar duration of practice, immediately prior to initiation of routine device use. Subjects' baseline characteristics are presented in **Table 1**.

Table 1 - Subjects baseline characteristics

Age (mean, STD)	60.5 (12.4)
Lesion size (mean, STD)	1.5 (1.1) cm
Tumor Histology	
IDC	72% (119/165)
ILC	7% (12/165)
DCIS	20% (33/165)
DCIS component	67% (110/165)
Receptor status	
ER / PR Positive	89% / 76%
HER2 Positive	14%

	Device Procedures			Historical Set			Reduction		
	Lumpectomy procedures	Re-excision procedures	Re-excision rate	Lumpectomy procedures	Re-excision procedures	Re-excision rate	Absolute Reduction (% points)	Relative reduction	P-value
Total	165	16	9.7%	186	48	25.8%	14.6%	62%	< 0.0001
Per Surgeon									
1	39	3	8%	51	8	16%	8.0%	51%	
2	42	7	17%	48	21	44%	23.8%	62%	
3	39	4	10%	46	14	30%	20.2%	66%	
4	45	2	4%	41	5	12%	7.8%	64%	

Table 2 - Re-excision procedures, comparison to Historical set

Re-excision procedures are presented in **Table 2.** With use of the device, positive margins resulted in additional re-excision procedures in 9.7% (16/165) of the cases. The matching historical set consisted of 186 Lumpectomy cases, in which there were additional re-excision procedures in 25.8% (48/186) of the cases. The reduction in the rate of re-excision procedures was significant 62% (P<0.0001). The reduction was similar across surgeons, irrespective of the per surgeon nominal rates of re-excision procedures.

Using the recently updated SSO guidelines of positive margin defined as tumor on ink, in 18% (30/165) of the cases the primary (main) lumpectomy specimen, prior to intra-operative assessment, had positive margins. In 73% (22/30) of these cases use of device led to identification of the positive margins.

In 3.6% (6/165) of the cases follow-up re-excision procedures were performed due to margins on ink. Of these, only 2.4% (4/165) were due to failed detection of positive margins on the main specimen, where the device was used.

Table 3 summarizes the breakdown of additional surgical procedures performed following the initial lumpectomy. In some cases the shavings taken based on device readings contained cancer, leading to a re-excision procedure.

Re-Excision Lumpectomy procedures	9.7% (16/165)
Due to failed detection of margins on specimen	6.1% (10/165)
Due to margins on shavings	3.6% (6/165)
Mastectomy as a second procedure (due to extensive disease)	1.8% (3/165)

Table 3 - Break-down of additional surgical procedures

Discussion

Use of an intraoperative margin assessment device contributes to achieving clear margins at a higher rate, and reducing re-excision procedures.

As in some cases positive margins were found on shavings, future studies of interest may include an analysis of the effect of using the device on the shavings intra-operatively.