Handheld Intraoperative Margin Assessment Device for Partial Mastectomy Specimens

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RESULTS

METHODS

An ongoing, international, multicenter, IRB approved, prospective study included 84 patients (87 specimens) undergoing BCS for invasive and non-invasive breast cancer. A probe (Dune Medical Devices, Caesarea, Israel) that detects differences in electrical waveforms reflected from tissue based on its electromagnetic properties. Preliminary establishment of the ability to differentiate malignant from normal tissue. An IRB approved, currently ongoing, multicenter trial was initiated. Patients with diagnosed breast cancer and treated with partial mastectomy were candidates. Probe measurements were taken intraoperatively on 1) slices from 41 fresh breast-lumped lumpectomy specimens (39 patients) or 2) the surface of 46 fresh intact lumpectomy specimens (40 patients). All measured points were then separately evaluated by pathology for the presence of DCIS and/or invasive disease. Surgeons and pathologists were blinded to the probe results and the results were not used to guide excision.

Results: Eighty-four patients have enrolled in the study. A total of 748 points on 85 specimens were analyzed pathologically and compared to probe output data. Overall sensitivity was 78%, specificity 92%, and accuracy is 91%, the positive and negative predictive values were 98% and the positive and negative likelihood ratios were 20 and 0.5 respectively. The 7 mm footprint handheld probe was easy to use, having gentle suction that allowed accurate, reproducible data points. Each measurement took 1-2 seconds for acquisition.

Conclusion: This device holds promise for the detection and assessment of margin intraoperatively. Results of the ongoing trial may help to determine its ability to decrease the number of patients that must return to the operating room. Further evaluation and comparison to other intraoperative methods may also be warranted.

INTRODUCTION

Obtaining clear margins with a single surgical procedure remains a significant challenge in breast conserving surgery (BCS). Re-excision rates are reported as high as 60% and contribute to decreased patient satisfaction, increased health care costs and poorer cosmetic results. Currently available methods for intraoperative margin assessment (frozen section, gross examination, intraoperative ultrasound, touch prep) have met with variable success and often present technical and practical limitations. In this study, we evaluated a novel probe that can easily and reliably differentiate malignant and benign breast tissue intraoperatively (Figure 1) by using a fringing field sensor to collect electromagnetic reflection from a 7 mm wide coin-shape tissue volume on the surface of a lumpectomy specimen. Preliminary work in the pathology lab established the modality’s ability to reliably differentiate benign and malignant breast lesions based on the electromagnetic properties with sensitivity and specificity as high as 95% and 94% respectively. In the current study, the probe is tested intraoperatively, with the main goal of assessing the device performance compared to pathological specimen evaluation for the prediction of margin status and its potential beneficial impact on clinical outcomes.

METHODS

RESULTS

CONCLUSIONS

Results from this ongoing trial show that this probe holds promise for a substantial reduction in re-excision rate. According to this data set, it may yield a 7% re-excision rate. The sampling nature inherent to the use of the device leads to enhancement in device performance at the margin level, and at the patient level. The Dune device provides rapidly, ease of use and reproducible results for intraoperative margin assessment, making it an attractive alternative to currently available methods of intraoperative margin assessment. Larger data sets and future device modifications may help to further improve margin re-excision rates. Future studies may include comparison of the probe to other methods of intraoperative margin assessment.


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