The MarginProbe® System: An Innovative Approach to Reduce the Incidence of Positive Margins Found After Lumpectomy

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The goal of lumpectomy surgery for breast cancer is to completely remove the tumor and have clear margins, reducing the rates of local recurrence. The MarginProbe® System is a new device that can detect microscopic tumor cells at or close to the margin of the surgical resection intraoperatively, providing the surgeon with the ability to re-excite tissue at the time of surgery, reducing the need for a second surgery to obtain clear margins.

At a Glance
- Lumpectomy surgery followed by radiation is the recommended treatment for early-stage breast cancer; however, successful lumpectomy is contingent upon cancer-free surgical margins.
- Current standards of intraoperative margin assessments include visual inspection, palpation, and imaging techniques, which are all less than reliable.
- The MarginProbe® System, used during lumpectomy surgery, has been shown to reduce the need for a second surgery because of positive tumor margins.

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Because of concerns of having different definitions of a negative margin status by surgeons, a multidisciplinary panel of breast experts reviewed data from a meta-analysis, which included a systematic review of 33 studies with 28,162 patients and a median follow-up time of 6.6 years (Moran et al., 2014). The panel of experts looked at margin width and local tumor recurrence in women with early-stage breast cancer. A positive margin was defined as the presence of ink at the surface of the surgical specimen on either invasive tumor cells or ductal carcinoma in situ (DCIS). A positive margin would signify an incomplete resection and a higher risk of local tumor recurrence. The findings of this meta-analysis revealed that a positive margin was associated with a two-fold increase in local tumor recurrence. A second finding revealed that a more widely clear margin (i.e., 1, 2, and 5 mm margin widths) did not significantly decrease the rate of local tumor recurrence compared with no ink on tumor (Moran et al., 2014).

Based on this information, the Society of Surgical Oncology–American Society for Radiation Oncology Consensus Guideline recommends that the standard for an adequate margin in invasive cancer be defined as no ink on tumor (Moran et al., 2014).

During lumpectomy surgery, the goal of clear margins is not always possible. Microscopic involvement of tumor in the margins is not easily assessable through palpation alone. Other methods, such as frozen section and touch preparation cytology, performed during the surgery can be time-consuming and inaccurate.

Breast cancer is the most common type of cancer affecting women in the United States, with an estimated 246,660 women diagnosed with invasive breast cancer and an additional 61,000 new cases of in situ breast cancer diagnosed in 2016 (American Cancer Society, 2016). About 60%–75% of women in the United States with early-stage breast cancer, defined as stages 0–II, opt for a lumpectomy. A lumpectomy involves removal of the tumor and some of the normal tissue surrounding the tumor, called the margin. Although lumpectomy has been a standard procedure since the 1990s, no consensus exists on how a negative margin is defined. About 25% of women undergoing a lumpectomy procedure undergo a re-excision, and about half of these procedures are performed to obtain more widely clear margins in women with negative margins, as defined by no ink on tumor (McCahill et al., 2012). Having to add a second surgery increases discomfort and stress for patients, involves possible surgical complications, has cosmetic implications, and increases cost (King et al., 2011).
Patients must wait about three to seven days for the final pathology report after lumpectomy surgery. If the pathologist finds tumor at the margins of the specimen, the patient will undergo a re-excision procedure. For this reason, a need exists for an improved method for intraoperative margin assessment (Karni et al., 2007; Moran et al., 2014).

The MarginProbe® System

The MarginProbe® System, developed by Dune Medical Devices, is a new device, approved by the U.S. Food and Drug Administration, that identifies cancerous tissue at the margins of the excised lumpectomy tissue intraoperatively. The device is based on radiofrequency spectroscopy, measuring the local electrical properties of breast tissue to identify normal or malignant cells. It consists of a handheld, single-use, sterile probe connected by cables to a console. When the probe tip is placed against tissue, it attaches a sensor to the tissue. The probe applies gentle suction to the tissue, and the console sends radiofrequency waves, which are transmitted to the tissue through the sensor. The signals are analyzed, and each signal is given a positive (cancerous) or negative (not cancerous) result based on an algorithm (Pappo et al., 2010). Each of the six measurements taken by the surgeon using the probe to assess the lumpectomy specimen margin takes about one to five seconds, with all margin assessments completed within three to five minutes. This information guides the surgeon as to whether more tissue needs to be removed during the procedure (Allweis et al., 2008).

The MarginProbe System has been the subject of multiple studies, with a large randomized, controlled trial specifically looking at diagnostic performance of the device. The study involved 76 patients from three medical centers and analyzed 753 measurement sites (Pappo et al., 2010). The results of device performance in determining normal from cancerous breast tissue revealed a high sensitivity of 100% and high specificity of 87% for homogenous measurement sites (single tissue type), with a decrease in sensitivity and specificity measurements for less homogenous measurements (multiple tissue types).

In a multicenter, randomized, controlled trial by Allweis et al. (2008), 300 women from 11 institutions underwent lumpectomy procedure for invasive and preinvasive breast cancer. The study assessed the impact of the MarginProbe System on re-excision rates. Women were randomized into two arms (with or without device use). The repeat lumpectomy rate was significantly reduced by 56% in the device arm as compared to the group without the device.

A retrospective, observational study was done at three centers with four surgeons, all using their routine lumpectomy methods (Sebastian, Akbari, Anglin, Lin, & Police, 2015). The study involved groups of women before and after implementation of the MarginProbe System during lumpectomy procedures. For each surgeon, historic re-excision rates were defined. Using the MarginProbe System during surgery, 165 lumpectomy cases were performed, and positive margins resulted in additional re-excision rates of 9.7% (16 of 165). The corresponding historic data revealed a re-excision rate of 25.8% (48 of 186). This is a reduction in re-excision rate of 62% with the use of the MarginProbe System (p < 0.0001).

Conclusion

The MarginProbe System can provide a fast intraoperative margin assessment during lumpectomy for breast cancer and can lower the re-excision rate for invasive and noninvasive breast cancers by greater than 50%. This reduces the need for a second surgery, which can decrease complication rates and stress involved in a second surgery, improve cosmetic outcomes, and decrease cost to the patient.

References


