An Improved Method for Marking the Surgical Cavity During Partial Mastectomy

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Abstract

Purpose: Improvements in surgical techniques such as breast conservation and oncoplastic surgery have resulted in significant improvements for patients with breast cancer. In most cases, breast conservation requires post-operative radiotherapy, which can be burdensome, costly and can cause significant complications. Recent technological advances have made it feasible to perform external beam radiation in a more targeted and accelerated fashion. However, many of these methods are not widely used in the breast due to difficulty in defining the margins of the lumpectomy cavity. In this pilot study, we evaluated the utility of a new method to delineate the margins of the surgical cavity for radiation treatment planning and clinical follow-up.

Objectives: To determine the benefits of a 3-dimensional bioabsorbable tissue site marker after intra-operative placement.

Methods and Materials: Fifteen patients were selected to have the BioZorb™ tissue marker implanted at the time of lumpectomy. Pre-operative imaging studies including mammography, ultrasound and magnetic resonance imaging (MRI) were used to determine extent of disease. All patients requiring adjuvant radiation therapy were referred for evaluation that included standard and 4-D CT to evaluate dose planning including respiratory motion. Multiple treatment plans were generated and compared, including standard tangent pairs, 3-D non-coplanar conformal, split arc conformal VMAT, and a variant of split arc conformal VMAT. All treatment protocols were in compliance with ASTRO guidelines per the NSABP B-39/ RTOG 04-13 trial.

Results: The marker was easily identified and clearly delineated the margins of the lumpectomy cavity post-operatively. It allowed for 3-dimensional characterization of the borders surrounding the cavity, and it was easily distinguishable from the seroma and other surgical tissue changes. Respiratory motion was easily tracked using the device making it possible to apply advanced radiation treatment methods, such as IMRT and accelerated protocols. When compared to conventional methods of determining the target area, use of the marker resulted in treatment volumes that were reduced by >60%. In appropriate patients, the marker also facilitated the use of an accelerated protocol, decreasing total treatment time from 6 weeks to 5 days. No complications have been reported in this series.

Conclusions: The utility of this 3-dimensional, bioabsorbable tissue marker was confirmed. The marker was consistently visualized without difficulty, was readily incorporated into standard and advanced dose planning methods, and had appreciable benefits when designing optimal dose treatment plans. The unique features of this marker also proved valuable for long-term clinical follow-up with standard methods of breast imaging.

Materials & Methods

Sixteen patients were consecutively selected to have the BioZorb™ tissue marker (Figure 1) implanted at the time of partial mastectomy (PM). The 3-dimensional marker is comprised of two materials (PLA and titanium) both of which have a long history of widespread clinical use in various medical devices. The marker is available in multiple shapes and sizes in order to accommodate various configurations of surgical cavities that might be encountered.

Figure 1. 3-dimensional tissue marker: spiral bioabsorbable material holds six titanium clips in a fixed array during healing. The clips allow for permanent marking of the excised tumor location.
All patients had pre-operative imaging studies including mammography, ultrasound and magnetic resonance imaging (MRI) in order to determine extent of disease. All 16 patients in this pilot series met the accepted criteria for breast conservation therapy. Following informed consent, each patient had PM and sentinel lymph node biopsy, with one patient requiring a completion axillary dissection for a positive lymph node. In each case, an appropriate sized tissue marker was selected, and sutured in position at the surgical site of tumor excision (Figure 2). Oncoplastic techniques including glandular tissue flaps were used to close the surgical cavities, and the surrounding margins of tissue were sutured directly to and through the 3-dimensional tissue marker. As standard procedure, monofilament bioabsorbable sutures were placed in at least 4 aspects of the surrounding breast tissue, and these sutures were then secured to the device in order to prevent the possibility of rotation and/or migration of the marker. Of note, the marker was useful in partial breast reconstruction using oncoplastic surgical techniques to bridge the area of the defect created by tumor excision.

Final pathology findings were reviewed weekly by a multidisciplinary tumor board, and recommendations for adjuvant chemo and/or radiation therapy were formulated. All patients requiring adjuvant radiation therapy were referred for evaluation. Pre-treatment planning CT scans were generally performed 4-6 weeks following implantation, although timing varied considerably due to individual patient considerations (e.g. chemotherapy regimens). Multiple treatment plans were generated and compared, including standard tangent pairs, 3-D non-coplanar, split arc conformal VMAT, and a variant of split arc conformal VMAT. All treatment plans were in compliance with clinical guidelines as accepted per the NSABP B-39/RTOG 04-13 trial. Optimal treatment plans were selected and administered using various methods as deemed appropriate for each patient (whole breast or partial breast irradiation techniques). In addition, selected patients were subject to 4-D CT to evaluate respiratory motion, the findings of which have been previously reported.5

Results

In this series of patients, the marker was easily incorporated into the surgeons’ routine and did not prevent or exclude any necessary diagnostic or treatment efforts. There was no report of post-operative infection, however, one patient had a small hematoma (unrelated to the device) that was drained in the office. No other complications were noted. Excellent cosmetic outcomes have been noted after one year of follow-up with no reports of pain or discomfort (Figure 3).

The marker was easily identified and clearly delineated the margins of the tumor excision site. Figure 4 shows that the marker is clearly visible post-operatively using mammography, MRI, CT and ultrasound. The most useful property of the 3-dimensional marker was in enabling precise targeting for radiation treatment planning and delivery. The marker assisted with conventional methods of radiation as well as facilitated the use of advanced methods such as accelerated radiotherapy—where the overall course of treatment was shortened from 6 weeks to 5 days.

On average, the planned treatment volumes (PTVs) were significantly reduced when using the marker as a target for planning. Figure 5 shows a case example where the marker identified the tumor excision site and enabled the patient to receive accelerated partial breast irradiation. The presence of the marker allowed the radiation therapy team to confidently exclude tissue changes associated with the surgery (e.g. the surgical tunnel from the peri-areolar incision) from the target volume. When compared to conventional methods of determining the target volume, use of the marker resulted in treatment volumes that were reduced by >60%. Figure 6 illustrates this reduction by comparing different radiation treatment planning techniques, and summarizes the quantitative differences in resultant PTVs.

Case Example #1

Figure 3 (see next page) The tissue marker was placed into the surgical excision site through a peri-areolar incision (blue arrow) at the time of partial mastectomy and was sutured to the surrounding breast tissue. The marker was used as a tool for delineating the location of the tumor bed for radiation treatment planning. The tumor site may often be located distant from the incision (as in this case). The marker helps to differentiate the tumor resection site from other surgical changes (e.g.
tunneling from incision to tumor site). In addition, the tumor resection site may not be visible on CT (e.g. when oncoplastic techniques are used to close the cavity or when there is no seroma for targeting). Panel A shows patient at 2 months post partial mastectomy & sentinel lymph node biopsy, after radiotherapy. Panel B shows patient at 16 months with excellent cosmetic results.

**Figure 3**

**Figure 4 (see below)** The tissue marker is consistently visible with all methods of clinical breast imaging. It provides a standardized array of clips on mammography (center panel) that assists the radiologist in identifying the area of tumor resection. MRI (right panel) shows tissue flaps sutured through interior of spiral structure and healing after surgery.

**Case Example #2**

**Figure 5** This patient had a small invasive carcinoma located in the medial aspect of the left breast diagnosed by percutaneous biopsy (Panel A - white arrow). Partial mastectomy was performed using a peri-areolar incision (blue arrow) with tunneling to the site of the tumor. The BioZorb tissue marker enabled precise targeting of the surgical cavity and facilitated the use of advanced techniques for adjuvant radiation treatment. Panel B shows result after completion of accelerated partial breast regimen.

Panel C shows this patient’s pre-treatment CT scan. The tissue marker is easily seen at the tumor excision site which is notably remote from the incision (blue arrow). No seroma cavity is readily discerned, and a variety of tissue changes make this case challenging for target volume delineation. The 3-D volumetric nature of the BioZorb marker helps to accurately define the PTV for the surgical excision site for treatment planning and delivery (Panel D).

This case example illustrates how the tissue marker facilitated the use of partial breast irradiation thereby sparing adjacent tissues from exposure to unnecessary radiation. A comparison of planned treatment volumes (PTVs) using the marker (Panel E) for accelerated partial breast versus standard whole breast (Panel F) can be seen by the area outlined in pink. This significant volume reduction (>60%) can be achieved because the marker clearly delineates the region requiring radiation treatment.

**Figure 6. Quantitative comparison of three different target volumes, illustrated on this patient’s pre-treatment CT scan. Orange -- whole breast (PTV = 788cc); yellow -- seroma-based, current methods, no BioZorb (PTV = 378cc); pink -- using BioZorb marker (PTV = 84cc).**

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<thead>
<tr>
<th>Whole breast</th>
<th>Current Methods</th>
<th>BioZorb Marker</th>
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<td>788cc</td>
<td>378cc</td>
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Conclusions & Comments

Accurately identifying and delineating the tumor resection site of partial mastectomy is a difficult task and is subject to considerable variability among clinicians in generating treatment plans for adjuvant radiation therapy. In this pilot series of patients, we assessed the utility of a novel 3-dimensional, bioabsorbable tissue marker that served as a “volumetric” marker within the tumor resection site. Placed at the time of surgery and secured to the margins of the tumor resection cavity, the 3-D marker allowed the radiation planning clinician to confidently exclude regions of tissue that would otherwise be included in the planning treatment volume.

We have confirmed the utility of this device in clinical imaging, including radiation treatment planning and delivery. This marker enabled the use of accelerated techniques for delivery of radiotherapy. The reduced number of dose fractions enabled by the new marker offer advantages to the patient in terms of fewer daily visits and faster completion of treatment (e.g. 5-7 days versus 5 weeks). The reduced number of dose fractions also offer advantages to the healthcare system in terms of the total cost of delivering radiation therapy for breast cancer (e.g. $7.5k versus $15k $NZ).

References