An improved method for marking the surgical cavity during partial mastectomy

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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.

Methods and Materials

Sixteen 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. Each patient had lumpectomy and sentinel lymph node biopsy, with one patient requiring a completion axillary dissection for a positive lymph node. 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 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, 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 3-dimensional marker is comprised of two materials both of which have a long-standing history of use in various medical devices. The clear portion is a bioabsorbable material formed into a spiral shape that is either spherical or elongated. There are also 6 titanium clips arranged in a fixed array at the perimeter of the device (Figure 1). These were noted to remain in place during the healing process for at least a year's time which was quite beneficial in patients that received chemotherapy prior to radiation and/or when minimal seroma was present for targeting. The marker was available in different sizes which accommodated the various sizes of lumpectomy cavities that were encountered.
In this series of patients, the marker was easily incorporated into the surgeons’ routine and did not prevent or exclude any diagnostic or treatment efforts necessary. Figure 2 illustrates placement into the surgical site by the surgeon. As standard procedure, monofilament bioabsorbable sutures were placed in at least 4 aspects of the glandular breast tissue, and these were then secured to the device in order to prevent rotation and to minimize seroma. 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. In this series of 16 patients there was no report of post-operative infection, however one patient had a small hematoma that was drained in the office under ultrasound guidance. No other complications were noted. Excellent outcomes have been noted after one year of follow-up with no complaints of pain or discomfort (Figure 3). A few patients noted that they were able to palpate the marker. None required additional surgical intervention.

The marker was easily identified and clearly delineated the margins of the lumpectomy cavity post-operatively. Figures 4-7 show various images of the marker in the post-operative period including mammography, ultrasound and CT scan. Visibility on mammography was useful to the radiologist in post-op followup of patients, and helped to distinguish the area of the tumor bed from surrounding scar tissue (Figure 4). While clearly visible with ultrasound, the bioabsorbable component was noted to have significant echogenicity (Figure 5). The most useful aspect of the 3-dimensional marker was in regards to targeting for radiation therapy using conventional and advanced methods of CT scanning.

In using the marker for radiation treatment planning, 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 that can occur secondary to surgical rearrangement of glandular tissues and/or tunnelling to regions distant from the incision site. All methods of imaging for treatment planning were used including standard CT scan, 4-D CT and cone beam CT. The marker was easily visible with each of these methods as well as mV and KV imaging.

Figure 6 shows the marker in the medial aspect of the breast adjacent to the chest wall and the heart, although surgical changes can be seen throughout the breast most notably under the areola due to the periareolar approach. In this series of patients, treatment plans were compared using three methods as described. This case illustrates the comparison of the treatment volumes when planning whole breast irradiation using standard methods (Figure 6) versus an accelerated treatment protocol for partial breast irradiation (Figure 7). The isodose curves for the accelerated plan are shown in Figure 8.

When comparing the planned treatment volumes using the three methods mentioned above, this case illustrates nicely the sparing of adjacent tissues from unnecessary radiation exposure (Figure 9). On average the PTVs were significantly reduced when
using the marker as a target for planning, and in fact, a sampling of these patients revealed a >60% decrease in PTV when the marker was used to determine the treatment region (Table 1).

Furthermore, the marker allowed the radiation oncologist to confidently exclude areas of tissue changes on CT that were clearly located outside the region of the marker. Since the marker was easily visible with onboard imaging, using the device for daily setup and positioning made this aspect of patient treatment more efficient and accurate, further eliminating additional uncertainties involved in radiation treatment planning and delivery. Respiratory motion was also easily tracked thus enabling the use of advanced radiation treatment methods such as IMRT/IGRT.

**Figure 10** shows example of patient following completion of lumpectomy, sentinel lymph node biopsy and radiation treatment.

**Images for this section:**
**Fig. 1:** 3-Dimensional tissue marker comprised of two components: bioabsorbable (poly-lactic acid) and six titanium clips in a fixed three dimensional array. The marker was cleared by the US FDA for clinical use as a marker for surgical excision sites in soft tissue.
Fig. 2: 3-D marker placed in lumpectomy cavity and sutured to glandular tissue to prevent rotation and secure margins of the surgical cavity to the device. Oncoplastic techniques can be used to complete partial breast reconstruction while accurately marking the cavity with the permanent clips which are held in a fixed array. This technique provides a standardized method for marking and targeting the post-operative region requiring radiation.
Fig. 3: Several patients following lumpectomy, insertion of the 3-dimensional tissue marker and adjuvant radiation treatment. Arrows indicate treatment area and shows excellent results
**Fig. 4:** 6 month post-op MLO view on mammography showing marker with fixed array of titanium clips that served as fiducial targets for radiation treatment planning. These clips are also helpful in long-term follow-up in area of surgical tumor removal.

**Fig. 5:** Ultrasound image of 3-D marker 6 months post-implantation showing that marker is clearly visible.
**Fig. 6:** Planning CT scan showing BioZorb tissue marker is clearly visible in surgical bed. In this treatment plan, the region outlined in pink indicates the standard treatment volume for whole breast irradiation with a total volume of 1190cc.
Fig. 7: The tissue marker is clearly visible in the area where the tumor was removed. The pink outline shows the treatment plan using the marker to determine the precise treatment volume. The marker enables the radiation oncologist to confidently exclude areas of tissue changes from the treatment volume that do not require radiation (e.g. "tunneling areas" used by surgeons to reach the site of the tumor). In this particular patient, the presence of the marker facilitated the use of an accelerated protocol and the planned treatment volume was 88cc as compared to 1190cc if she were to have received whole breast irradiation.
**Fig. 8:** CT scan showing isodose curves. This illustrates the utility of the 3-dimensional marker to assist with accelerated partial breast irradiation (APBI) protocols. Excellent dose distribution is possible while sparing adjacent normal tissues from exposure to radiation unnecessarily.
Fig. 9: Example of dosimetric comparisons that were performed on patients. Orange area shows standard volume for whole breast irradiation plan, yellow indicates treatment volume using standard seroma-based techniques, and pink area indicates planned treatment volume using the 3-dimensional tissue marker.

Table 1: Table 1 shows the average differences in comparative planned treatment volumes (PTV) using different methods of determination. Treatment plans were determined using either standard whole breast protocols, current methods using seroma-
based changes on CT scan, or using the BioZorb tissue marker as the target treatment area. Note that the average PTVs using the 3-dimensional marker were ~77% lower than those planned for whole breast irradiation.

**Fig. 10:** Patient 6 months after right breast lumpectomy, sentinel lymph node biopsy and adjuvant radiation treatment.
Conclusion

Accurately identifying and delineating the surgical site of partial mastectomy is a difficult task and is well known to create uncertainties in the treatment planning for adjuvant radiation therapy\(^1,2,3\). The use of an implantable device at the time of surgery placed and secured to the margins of the cavity helped to eliminate some of the uncertainty, and facilitated the use of advanced techniques in radiation therapy. In this pilot series of patients, we assessed the utility of a novel 3-dimensional, bioabsorbable tissue marker and confirmed its usefulness in clinical imaging and radiation treatment planning. 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, and it fit easily into the routine practices of all specialists involved in the multidisciplinary care of the breast cancer patient.

Personal Information

References

