Initial Experience with a Novel 3-D Bioabsorbable Lumpectomy Marker

Cary S. Kaufman1,2, William Hall3, Laurie Hill3, Rebecca Caro4, Sid Nix4, Erik Evans4, Karen Zacharias4, Carol Mahon4, Karen Ness4, Nancy Schaeffer4
1University of Washington Department of Surgery, 2Bellingham Regional Breast Center, 3Department of Radiation Oncology, PeaceHealth St. Joseph Medical Center, Bellingham Ambulatory Surgery Center

Abstract:
Objective: Breast conserving surgery requires adequate excision of the primary tumor (lumpectomy) followed by external radiation to the tumor bed. The surrogate for the tumor bed has been the residual seroma cavity remaining after lumpectomy as well as surgeon placed individual clips. Yet, due to the eccentric removal of tumors, the distortion of the target site by oncoplastic procedures, lack of standard locations for clip placement and variance of the degree of seroma formation, the targeting of the tumor bed can be less than optimal and often larger than desired. A novel three dimensional bioabsorbable device has been developed to facilitate communication between the surgeon and the radiation oncologist to accurately depict where the original tumor resided while avoiding targeting of inadvertent tissue that might simply be dissected on the path toward to target tumor. This device is expected to have an impact on targeting the radiation volume as well as on cosmesis by adding volume and preventing the skin from collapsing into the wound.

Methods: We have placed 22 marker devices after lumpectomy in breast cancer patients, both invasive and non invasive with at least six months follow up. This device consists of a bioabsorbable three dimensional spiral coil with six embedded titanium clips in a fixed pattern. The spiral is sewn in place by the surgeon during the lumpectomy procedure at the exact location where the tumor was removed. Placing this device at the “ghost” site of the tumor allows the radiation oncologist to accurately target the tumor to create additional volume to reduce the lumpectomy cavity and avoid volume limited treatment. At the same time, the device allows the radiation oncologist to avoid breast tissue involved by seroma that was not close to the tumor but was dissected in transit to the tumor site or mobilized during oncoplastic procedures. All patients were evaluated with post-operative imaging, including CT planning. Cosmesis was evaluated with pre and post treatment gaging and photographs and patient and physician satisfaction scores for appearance. The spiral device takes a year or more to dissolve and this will be monitored.

Results: The device is well seen on mammogram, ultrasound and CT planning scans, aiding the targeting of the tissue bed. The device facilitates identification of the original tumor site on radiation treatment planning CT. Preliminary results indicate it may be feasible to reduce the lumpectomy cavity boost target volume based on targeting the tumor marking device, while avoiding CT densities associated with excursion of tumor remnants. Two patients had delayed cellulitis during excision of a single margin leaving the device in place. The third patient required an extensive re-excision of closest margins leaving the device in place. The third patient required an extensive re-excision for persistent cavity persistence and non healing with at least six months follow up. This device consists of a bioabsorbable three dimensional spiral coil with six embedded titanium clips in a fixed pattern. The spiral is sewn in place by the surgeon during the lumpectomy procedure at the exact location where the tumor was removed. Placing this device at the “ghost” site of the tumor allows the radiation oncologist to accurately target the tumor to create additional volume to reduce the lumpectomy cavity and avoid volume limited treatment. At the same time, the device allows the radiation oncologist to avoid breast tissue involved by seroma that was not close to the tumor but was dissected in transit to the tumor site or mobilized during oncoplastic procedures. All patients were evaluated with post-operative imaging, including CT planning. Cosmesis was evaluated with pre and post treatment gaging and photographs and patient and physician satisfaction scores for appearance. The spiral device takes a year or more to dissolve and this will be monitored.

Conclusion: A three-dimensional bioabsorbable device has been used to accurately depict the original tumor site after lumpectomy. The device is particularly valuable for external beam partial breast and radiation boost treatments. Future studies of the device in partial breast radiation protocols should follow. A national registry database is being created to assess and report on additional findings.

Challenges to Targeting:
1) Eccentric location of tumor in lumpectomy specimen
2) Oncoplastic rearrangement of closest margins
3) Extraneous dissecting planes during rearrangement or tunneling
4) Separate clips placed for hemostasis versus localization
5) Clip “migration” by retraction and scarring
6) No generally accepted standardized clip placement protocol
7) Individual patient variance in seroma formation and resorption

Marker Facilitates Targeting Goals:
1) Accurate identification of tumor margins
2) Uniform treatment dose to actual tumor bed
3) Planned treatment volume limited to tumor sites
4) Targeting may avoid fibrosis and tenderness
5) Identify candidates for partial breast radiation
6) Contribute to cosmetic results

Summary:
SUMMARY: LUMPECTOMY MARKER
1) Communicates site of tumor margins
2) Identifies candidates for PBI
3) Visible on all imaging.
4) Patient satisfaction with cosmesis
5) No increase in side effects.

Seroma Targeting: Radiation Oncologist

Tissue Marker Targeting: Radiation Oncologist + Breast Surgeon

Clinical Treatment Volume = CTV

Planned Treatment Volume = PTV

Volume of a sphere = 4/3πr³

<table>
<thead>
<tr>
<th>Size</th>
<th>Diameter (cm)</th>
<th>BioZorb Placed (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2x2</td>
<td>8-10</td>
<td>32%</td>
</tr>
<tr>
<td>2x3</td>
<td>11-13</td>
<td>45%</td>
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<tr>
<td>3x3</td>
<td>14-15</td>
<td>68%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Age (yrs)</th>
<th>Age range (yrs)</th>
<th>Right / Left</th>
<th>Mean Follow-up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>62.8</td>
<td>46 - 77</td>
<td>45% / 55%</td>
<td>5.0 months</td>
</tr>
<tr>
<td>F/U Range</td>
<td>1 - 11 months</td>
<td></td>
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</table>

Sizer set to determine tissue marker size and shape for lumpectomy cavity

Safety Profile:
- hematomas
- bleeding
- re-excision
- migration
- infection
- skin erosion
- pt request removal
- difficulty sleeping
- patient acceptance
- pain - mild
- pain - severe

Tumor Characteristics:
- Cases Reviewed: 22
- Size average (cm): 2.6 ± 0.3
- Size range (cm): 1.4 - 5.0
- Histology: IDC 73%, ILC 27%
- DCIS: Grade High 18%, Moderate 33%, Low 44%
- Prognostics: ER Pos 98%, PR Pos 75%
- Sentinel nodes (+): 2.11 (1-4)
- Positive Sentinel Node: 21% (19)

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(1) Biodegradable marker
(2) Titanium clips
(3) Three-dimensional spiral coil
(4) Oncoplastic surgery
(5) Radiation oncology
(6) Breast surgery
(7) Patient satisfaction
(8) Radiation treatment