Assessment of a new method for localization of non-palpable breast lesions

Cary S Kaufman MD, January Lopez MD, Michael Cross MD, Kelly Pierce MD, Gail Lebovic MD

University of Washington, Bellingham, WA; Hoag Memorial Hospital Presbyterian, Newport Beach, CA; Breast Treatment Associates, Fayetteville, AR; Medical Associates of Northwest Arkansas, Fayetteville, AR; Focal Therapeutics, Inc. Aliso Viejo, CA

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ABSTRACT

Background/Objective: Wire localization has long been the standard of care to assist surgeons with accurately locating and excising non-palpable lesions of the breast. However, difficulties associated with the procedure have prompted development of alternative technologies. The challenges to address include scheduling conflicts, accuracy in targeting lesion, and development of the wire, delays in surgery start time, and overall inconvenience for patients and clinicians. Valuable features of wire localization for the surgeon include tactile and visual cues during dissection however, these benefits are lost with the new platforms being introduced. Also, these new devices are costly, as they are complex consisting of an implantable percutaneous marking device, and a required complex intra-operative detection system. In this pilot series of patients, we examined an alternative approach that encircles the suspected lesion providing a perimeter to visually and palpably guide the surgeon during dissection, allowing placement of remote incisions and a more familiar and cost-effective procedure. The device is based on a simple needle deployment platform which may occur days before the procedure. In this study, we examine the utility of this new method of percutaneous localization.

Methods: Following informed consent, 28 patients undergoing partial mastectomy for a non-palpable lesion in the breast were evaluated in a prospective manner. The localization device consists of a needle cannula that houses a nitinol ring. The needle is advanced into the breast under ultrasound guidance, and the ring is manually deployed into the breast forming a circle around the target lesion, leaving a highly flexible tail portion emerging from the skin. The deployed nitinol ring encircles the lesion as opposed to penetrating the center or localizing a single point near the edge of the lesion. Performance data of the device were collected for both the placement and surgical removal in 28 patients. Two patients had more than 1 lesion localized prior to surgery.

DEVELOPMENT OF DEVICE

Extensive pre-clinical testing was performed using mammography and ultrasound as methods for placement. Figure 2 (left) shows images of pre-clinical mammographic testing. The handle has indicators to show directionality of the ring deployment as well as the extent of ring deployment. The handle mechanism allows the ring to be retracted for repositioning during deployment if necessary. Below Figure 3 illustrates a case example showing pre-op mammogram with lesion, technique for ultrasound guided deployment of PERL device, surgical excision and confirmation with specimen radiography.

RESULTS

Results: Surrounding the lesion in this manner provided visual and tactile cues for the surgeon while the shape of the nitinol ring and flexible tail portion provided protection against migration or discomfort when placed prior to surgery. Four patients had the device placed more than 24 hours prior to surgery. Sixteen of 30 placements were performed by the surgeon, and 14 of 30 were placed by the radiologist. All placements were performed using ultrasound guidance with an average placement time of 6.7 minutes. All deployments were accurately situated at the intended target with no evidence of migration or hematomas.

CONCLUSIONS

This pilot study describes a novel method of localization for non-palpable breast lesions. The ring is easily deployed under ultrasound or mammographic guidance and can be placed several days prior to surgical removal allowing for maximum flexibility in scheduling for patients, surgeons, and radiologists. The device has excellent retention force and showed no evidence of migration after placement. These data confirm that the Percutaneous Ring Localization (PERL®) device has potential as a cost-effective improvement over currently used devices for wire localization procedures. Further evaluation of this unique device is warranted.

Disclosures
Dr. Cary Kaufman and Dr. Michael Cross are consultants to Focal Therapeutics, Inc. Aliso Viejo, California (manufacturers of the PERL localization device). Dr. Lebovic serves as Chief Medical Officer of Focal Therapeutics.

Table 1: Details of PERL placement

<table>
<thead>
<tr>
<th>Parameter/Medical Device</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Radiologist</td>
<td>45%</td>
</tr>
<tr>
<td>Surgeon</td>
<td>34%</td>
</tr>
<tr>
<td>Histology Caner</td>
<td>51% Cancer</td>
</tr>
<tr>
<td>LC</td>
<td>45% Benign/unknown</td>
</tr>
<tr>
<td>Density</td>
<td>66% Fatty</td>
</tr>
<tr>
<td>Equividity Sub Areola</td>
<td>58% UOQ</td>
</tr>
<tr>
<td>Ring Plane</td>
<td>56% 44%</td>
</tr>
<tr>
<td>Needle visualization</td>
<td>100% Excellent</td>
</tr>
<tr>
<td>Place time</td>
<td>6.5 minutes avg</td>
</tr>
<tr>
<td>Confirm image</td>
<td>53% US 35% Mamm 12% Both</td>
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</table>

Table 2: Surgical removal of PERL device

<table>
<thead>
<tr>
<th>Parameter/Medical Device</th>
<th>Details of Surgical Removal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophcrac approach</td>
<td>47%</td>
</tr>
<tr>
<td>Time until surgery</td>
<td>15% &gt;18-48 hours</td>
</tr>
<tr>
<td>Margin</td>
<td>No reported positive margin</td>
</tr>
<tr>
<td>Lymphectomy time</td>
<td>22 minutes avg</td>
</tr>
</tbody>
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Figure 2 A,B,C. Pre-clinical mammographic images

A. Shows phantom with PERL device deployed
B. Shows mammo image of ring and partial deployment confirmation
C. Shows ring deployed in fixed tissue specimen

Figure 3: Case Example – Dr. Kaufman

A. Pre-op mammography showing lesion
B. Ultrasound confirmation of ring around tumor
C. Technique for ultrasound PERL placement
D. Surgical excision (partial mastectomy)
E. Mammographic specimen x-ray

Figure 4: Close-up of nitinol ring and needle tip

Figure 5: Close-up of nitinol ring and needle tip

Figure 6: Case Example

A. Pre-op mammography showing lesion
B. Ultrasound confirmation of ring around tumor
C. Technique for ultrasound PERL placement
D. Surgical excision (partial mastectomy)
E. Mammographic specimen x-ray

Physician reported observations:
- Allows uncoiling of localization procedure from surgical removal (partial mastectomy)
- Can be placed on a separate visit by either radiologist or surgeon
- No evidence of migration after placement (under mammographic compression and/or overnight)
- Assists with oncoplastic resection using tactile feedback (makes non-palpable lesion palpable)
- Potential to decrease re-excision rates by surrounding tumor as opposed to locating centering
- Cost effective, disposable
- Uses current techniques, no radioactivity or new equipment needed