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A new simplified cost-effective technique for localization of non-palpable breast lesions

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ABSTRACT

Introduction: Wire localization has long been the standard of care to assist surgeons with locating and excising non-palpable breast lesions identified by imaging. Significant challenges include scheduling conflicts, delays in surgery, accuracy in targeting the lesion, wire displacement or migration, and overall inconvenience for patients, clinicians and facilities. In an attempt to address these challenges, a number of complex "wireless" approaches have emerged. However, they are costly and require the purchase of multiple pieces of capital equipment. Additionally, these wireless approaches lose the benefits of visual and tactile cues for the surgeon during excision and risk dislodgement or migration of the embedded seed or marker. In this multi-centered pilot series, we report on a novel method of percutaneous localization that secures the target lesion, may be placed prior to the day of surgery and provides the surgeon with tactile guidance during dissection without the challenges of standard wire localization.

Methods: Following informed consent, 55 patients undergoing partial mastectomy or excisional biopsy were evaluated in a prospective manner. The localization device (PERL™ Hologic, Sunnyvale, CA) consists of a needle cannula with a handle deployment mechanism housing a sharp Nitinol Ring. Following infiltration of local anesthetic in the skin and target region, the introducing needle was advanced into the breast under image guidance and the Ring was deployed and securely seated at or around the target. The Ring is attached to a highly flexible, suture-like tail emerging from the skin. When the Ring device was placed the day before surgery, the flexible tail external to the skin was coiled under an adhesive dressing allowing the patient to return to work or home. Confirmation of target localization was imaged by ultrasound, mammography and specimen x-ray. Procedure characteristics were noted at placement and surgical removal.

Results: 39 (71%) of 55 placements were performed by surgeons and 16 (29%) were placed by radiologists. 34 (83%) of devices were placed under ultrasound guidance while 7 (17%) were placed using mammo/tomo or stereotactic imaging. Average placement time for the PERL was 5.7 minutes including infiltration of local anesthesia. All deployments were successfully directed to the intended target without migration including those placed on a different day/time from the surgery. Localization using the Ring enabled 100% successful surgical targeting and lesion removal. There were no technical complications, infection or significant patient discomfort associated with placement or removal of the device. For the 55 lesions with a pre-operative cancer diagnosis, all but one had clear margins. The one patient represents 3% of this patient cohort and the re-excision was for DCIS at the surgical margin.

Conclusions: Percutaneous Ring Localization (PERL™) is a novel approach to lesion localization in the breast that solves issues associated with standard wire localization. This multi-center experience demonstrates that PERL can be utilized to guide the excision of non-palpable lesions, provides visual and tactile cues during surgery, and avoids repeated intraoperative handling of expensive scanning devices. The Ring and flexible tail allow placement at a time and location separate from the surgery with minimal discomfort and without migration. This pilot series illustrates that PERL can provide a cost-effective solution to issues with wire localization using a familiar clinical platform. Further studies are warranted based on these results.

METHODS

Methods: Following informed consent, a total of 55 patients undergoing partial mastectomy or excisional biopsy were evaluated for lesion localization using this novel device in a prospective manner. Patient demographics are listed in **Table 1**. Placement was performed using image guidance with ultrasound, mammography, tomosynthesis or stereotactic mammography using the **Affirm Arm®** system **(Hologic, Danbury CT)**. The localization device **(PERL® Hologic, Sunnyvale, CA)** consists of a needle cannula with a handle deployment mechanism housing a sharp Nitinol Ring **(Figure 1A-C).** Placement of the PERL device was performed by a radiologist or surgeon trained on using the device properly. The placement procedure was scheduled on the day of surgery, or prior to the day of surgery and the procedures were performed in the office, breast imaging center or operating room. Following infiltration of local anesthetic in the skin and target region, the needle was advanced into the breast under image guidance and the Ring was deployed and securely seated at the target leaving a highly flexible, suture-like tail emerging from the skin. Procedure characteristics were noted at placement and surgical removal.

RESULTS

TABLE 1: Number of Patients	55
Surgeon Placements	39 (71%)
Radiologist Placements	16 (29%)
Age	64
Invasive Cancer	29 (53%)
DCIS	8 (15%)
Phylloides	1
Benign/Atypica or Unspecified	11 (27%)
Mammo/Tomo/Stereotactic	7 (17%)
Ultrasound	34 (83%)
Unspecified Imaging Method	14
Average Procedure Time PERL Placement	5.7 mins
Average Procedure Time PERL Lumpectomy	21.5 mins
Flexible Tail used during surgery	44 (80%)
Targeted Lesion Removed	55 (100%)
Re-excision	1 (3%)

Figure 1 A-C:

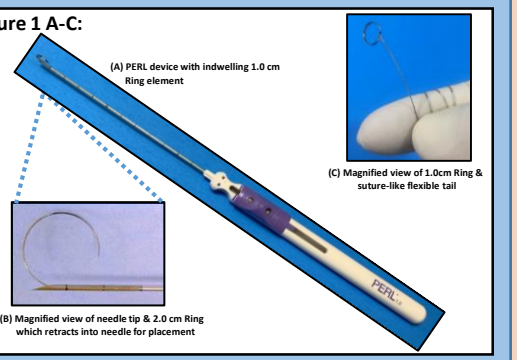
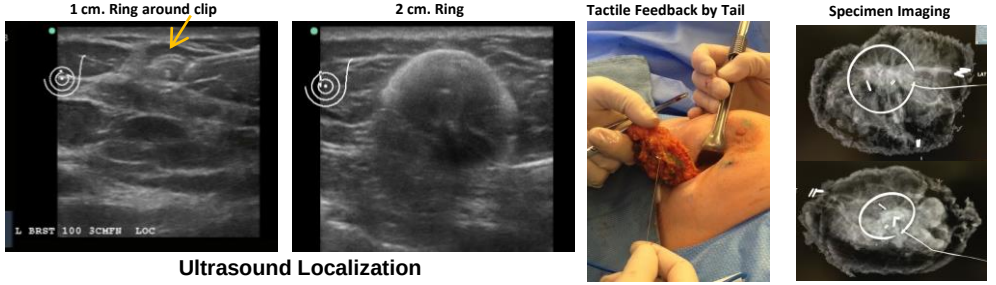
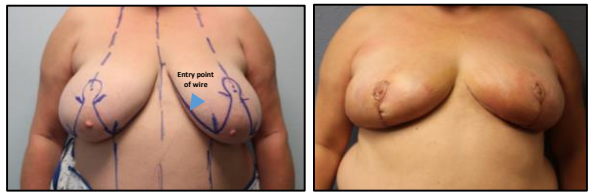


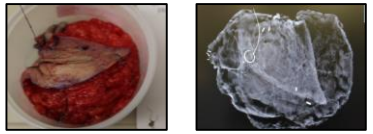
Figure 2: Use of PERL device with methods of image guidance



Ultrasound Localization

Figure 3: Use of PERL device with Oncoplastic Reduction





Intra-operative specimen from Oncoplastic Reduction Mammoplasty performed day after placement of **PERL** showing accurate lesion localization and no migration even though **PERL** placed on different day and at different location

Case Example: The **PERL** was placed by the Radiologist at the Breast Center of NW Arkansas the day prior to surgery under US guidance. The patient tolerated the procedure well and the surgeon was able to schedule this lengthy case first thing in the morning without having to wait for localization. Margins were widely negative.

Table 2: Physician Reported Observations

- ✓ There were no technical complications or infections
- ✓ Placement & overnight indwelling of Ring was well tolerated by patients
- ✓ Allows uncoupling of lesion localization from surgical removal thereby accommodating flexible scheduling for radiology and surgery
- ✓ Placed by either radiologist or surgeon in office, breast center or operating room with accuracy by ultrasound or mammography
- ✓ No evidence of migration after placement (under mammographic compression and/or overnight)
- ✓ Flexible tail provides surgeons tactile and visual cues to locate lesion during surgery. Particularly useful for Oncoplastic (hidden) incisions
- ✓ 1 patient with DCIS required re-excision. Represents 3% of cohort - well below national average
- ✓ 100% of targeted lesions were successfully located and removed
- ✓ Cost effective, disposable, no capital equipment, no radioactivity
- ✓ Uses current known placement techniques for radiologists and surgeons

CONCLUSIONS

In this cohort of 55 consecutive patients, radiologists and surgeons reported their clinical experiences using this novel device (**PERL**) for percutaneous image guided localization of non-palpable breast lesions. **Table 1** summarizes the demographic information as well as the results of the placements and surgical removal showing 100% of targeted lesions were successfully removed with 1 patient requiring re-excision for DCIS at the margin. Procedure placement and partial mastectomy required on average 5.7 and 21.5 minutes respectively.

The majority of surgeons (80%) used the tail in order to facilitate tactile and visual cues during surgery which differentiates this method of localization from the "wireless" technologies. Additionally, there is no capital equipment required for use with this disposable device thereby eliminating the expense and training associated with other methods. The **PERL** uses current techniques familiar to both radiologists and surgeons for accurate placement prior to and during surgical removal, and the stability of the ring placement allows for uncoupling of the procedures achieving flexible/independent scheduling of localization and surgery. **Table 2** captures the physicians' reported comments and the images shown in **Figures 1-3** illustrate use of the device under mammographic and ultrasound guidance. Intra-operative specimen x-ray confirmed accurate localization of 55/55 cases (100%) with no evidence of migration in any case evidenced by mammographic and/or specimen x-ray at surgery. **Figure 3** shows utility of the **PERL** with Oncoplastic reduction and accuracy of localization without migration of the ring even in the large breast overnight.

This limited clinical experience illustrates ease of adoption of the **PERL** device in a series of patients with excellent accuracy in placement, retention of the ring in vivo and during surgical excision. Positive responses from surgeons and radiologists offer encouraging evidence for future adoption and opportunities for additional studies using this novel device.

Disclosure: This research was supported by Hologic, Inc (Danbury, CT) and several of the authors serve as consultants to Hologic for educational and training purposes. Dr. Lebovic is a co-inventor of the PERL device, and formerly VP of Clinical Innovations at Hologic, Inc.