Implementing Radioactive Seed Localization in Your Practice

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Disclosure

• Gary J. Whitman, MD
• Book contract – Cambridge University Press
Special Thanks

• Piyanoot Woodtichartpreecha, MD
• Helped to prepare this presentation
Radioactive Seed Localization (RSL)

• Introduced in 1999
• An alternative method to standard wire localization (WL) for preoperative localization of nonpalpable breast lesions
Radioactive Seed Localization

• Implantation of an Iodine-125 seed in the tumor under mammographic or ultrasound guidance

• Intraoperative transcatheter tracking of Iodine-125 counts using a gamma probe
Starting a Program

Regulatory compliance

• Investigate state-specific nuclear regulatory compliance (NRC) issues and gain approval for use
• Train involved personnel in radiation safety and handling
• Develop a written protocol
• Design and implement a seed tracking system and recovery procedure
Starting a Program

• Involve multidisciplinary coordination
  – Radiation safety officer (RSO)
  – Nuclear medicine physicians
  – Radiologists
  – Surgeons
  – Pathologists
State Regulations

• Guidelines specifically for RSL of breast lesions
  – Limit the length of time to 5 days (Texas) that the seed may remain in the patient before surgical excision

• Proper handling, use, and disposal of the radioactive seed requires the oversight of a RSO and proper facility licensing
Licensing Process

- Applying for RAM license if not pre-existing
- Amend RAM license to add use I-125 seed for RSL
- Key members
- Logistics of in-house program
Radiation Safety Officer (RSO)

• Regulatory guidance
• Oversight and radioactive material (RAM) protocol
• Develop policies and procedures for RAM use
• Training based on ALARA principles (time, distance, shielding)
NRC RSL Licensing Guideline

• 10 CFR 35.1000:
  – Other medical uses of byproduct material or radiation from byproduct material
Radioactive Seed

• Iodine-125
  – 60-day half-life
  – 27-keV gamma radiation emission peak
Radioactivity Level

• Radioactivity levels ranging from 0.1 to 0.3 mCi are considered by the Nuclear Regulatory Commission (NRC) to be safe for human exposure
Seed Type

Preloaded seed

Self-loaded seed (loose seed)
Seed Type

Preloaded seed

• Two FDA approved needles: IsoAid® and Best®
  – 18 g needles are currently available in 5, 7, 10, and 15 cm lengths
  – With stopper

http://www.teambest.com/
Preloaded Seed

Stopper

http://www.teambest.com/
Loose Seeds

Self-loading seed into needle

• Scrape the tip of the needle across the surface of the wax until the tip is just covered with a thin layer of wax

  ➢ Too much wax risks the seed sticking to the needle tip during deployment or remaining within the needle
  ➢ Too little wax risks the seed being expelled prematurely
Seed size: 4.5-mm x 0.8-mm

http://rpc.mdanderson.org/
Gamma Detection Probe

- Neoprobe® gamma detection system (Devicor Medical Products, Cincinnati, Ohio)
  - Handheld probe
  - Can select either Tc-99m (used for lymph node mapping) or I-125 (used for seed localization)
RSL: Advantage

• Improved scheduling

• Decouples surgical schedule from breast imaging procedure schedule
  – Can place seed in breast on a day prior to surgery
    • Can be placed up to 5 days before surgery (in Texas)
RSL: Advantage

• Results in better patient satisfaction
• Surgeons have found RSL easier to perform than WL
• Radiologists have not reported a difference in difficulty (technique similar to WL)

Sharek et al. AJR 2015; 204:872-877
RSL: Advantage

- Extremely low likelihood of migration after placement

Sharek et al. AJR 2015; 204:872-877
RSL: Disadvantage

• The seed is a source of radiation
• The patient receives an extremely low dose of radiation to the tissues immediately adjacent to the seed

Sharek et al. AJR 2015; 204:872-877
RSL: Disadvantage

• Regulatory considerations
  – Strict oversight by the radiation safety officer (RSO)
  – Need a comprehensive safety plan for tracking, handling, and management of each seed

• Once a seed is deployed within the breast, it cannot be adjusted
  – Must be removed surgically
Comparison Between RSL versus WL

**Advantages**
- Can perform 1-5 days before surgery
- Positive margin status is equal or lower in RSL compared to WL
- No difference in specimen size and operative time compared to WL
- Patient satisfaction improved

**Disadvantages**
- Cannot be repositioned
- Radiation exposure to patient and staff

Studies Comparing Margin Status for RSL Versus WL

<table>
<thead>
<tr>
<th>References</th>
<th>Wire (N)</th>
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<th>Final margin positive</th>
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Studies Comparing Various Aspects: Seed Versus WL

<table>
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<tr>
<th>References</th>
<th>Positive margins</th>
<th>Specimen size</th>
<th>Operative time</th>
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</tbody>
</table>

\(^a\) Randomized, controlled trial

Authorized User (AU)

• Must be board certificated in either nuclear medicine, radiation oncology or diagnostic radiology
  – Completed appropriate training and supervision of a requisite number of cases as documented in NRC Form 313A
Authorized User

• Surgery and pathology personnel work under the supervision of an authorized user
  – Must complete radiation safety training, which is provided by either the AU or the RSO
The AU and the RSO

• Ensure that new radiology, surgery, or pathology personnel who intend to handle radioactive seeds are identified

• Ensure that the requisite training is complete as part of a quality maintenance plan
Written Directive

• The brachytherapy source can deliver a therapeutic dose

A written directive is required
Written Directive

• Must meet the requirements detailed in 10 CFR 35.40
  – The patient’s name
  – Treatment site
  – Dose and type of radionuclide
  – Number of sources implanted
  – Total source strength and exposure time.

• The form must be dated and signed by an AU
Written Directive

• To track the seed throughout the entire RSL process

Documentation of

– The number of seeds removed during surgery
– The number of seeds retrieved from the specimen
– The number of seeds retrieved by the RSO for decay and disposal
RSL Workflow

- RSO
- Pathologist
- Nuclear Medicine
- Surgeon
- Radiologist
Sequence of Events in Tracking Seeds During RSL

RSO and Nuclear Medicine

• Seed pockets received by RSO from vendor
• Seed pockets wipe-tested and logged in database
• Seed pockets stored in secure location
• Seed pockets transported in lead envelope to procedure room
Sequence of Events in Tracking Seeds

Radiology

- Seed pockets opened and seed placed on tray, radioactivity confirmed by Geiger counter (load loose seed or use preloaded seed)
- Seed(s) deployed into breast
- Dual confirmation of seed deployment with Geiger counter and mammography
- Number of seeds implanted into patient documented in written directive
Sequence of events in Tracking Seeds

Surgery

• Patient arrives in operating room
• Seed(s) localized in patient with gamma detection probe
• Seed(s) excised within tissue specimen, radioactivity confirmed
• Number of seeds within breast specimen documented in written directive
Sequence of Events in Tracking Seeds

Pathology

- Seed(s) localized within specimen by using a gamma detection probe
- Seed(s) removed from specimen with hemostat
- Seed(s) placed in lead pig and stored in a secure location
- Number of seeds removed from breast specimen documented in written directive
Sequence of Events in Tracking Seeds

RSO

• RSO collected seeds for disposal
• Seed(s) returned by RSO to vender or sent for long-term decay
• Completed written directive collected by RSO
Seed Workflow in Radiology

Decision making and planning

• Type of seed
• Number of seeds per breast
• Imaging modality for guidance
  – Mammography or ultrasound

The seed is deployed into the breast by using a technique similar to traditional wire localization.
Utilization of Multiple Seeds in the Same Breast

Purposes

• Bracketing or localization of multiple lesions
  – Similar to wire localization
Multiple Seeds: 3 Seeds Bracketing the Lesion
All 3 Seeds are Removed in 1 Specimen
Utilization of Multiple Radioactive Seeds in the Same Breast

- A Geiger counter cannot reliably confirm placement of additional seeds once the first seed has been placed if the seeds are close to one another.
- Distance between seeds should be > 2 cm
  - Enable the surgeon to more effectively detect separate radioactive sites.
Utilization of Multiple Seeds in the Same Breast is Safe and Feasible

For bracketing purpose

• The mean distance between the seeds on bracketing cases was 45 mm (range 8-110 mm)

• Seed retrieval and removal of the targeted lesion was successful in all cases, and 96% of the bracketed lesions were removed as a single specimen

Utilization of Multiple Seeds in the Same Breast is Safe and Feasible

• Overall re-excision rate of 28.2%
  – 18% for re-excision of margins and 10.2% proceeding to mastectomy
  – Patients with multiple lesions in the same breast, multifocal and multicentric cancer, and extensive disease requiring bracketing at a higher likelihood of failing to obtain negative margins

Ultrasound Guidance

• The seed is deployed at the target site during real-time observation, with care taken to avoid any adjacent biopsy clip

• RSL allows one to use any angle or approach
US-Guided Seed Localization

mass with biopsy clip

seed was placed
Post-procedural Mammography
Specimen Radiography
Mammographic Guidance

Digital mammography guidance

- Alphanumeric grid in mammography unit or stereotactic guidance
- The needle is not completely withdrawn from the patient until the seed is confirmed to be within the breast on at least one image
  - If the seed is not successfully deployed, this technique allows for repositioning the needle and attempting to deploy the seed again
Imaging Guidance

MRI

• Cannot be used to guide seed placement
• The gamma detector probe used to locate a lost or dropped seed is not MRI compatible
Seed Workflow in Radiology

• After seed deployment, regardless of the guidance method, and before anyone exits the procedure room, the patient is assessed for radioactivity with a Geiger counter to confirm placement of the seed within the breast.
Seed Workflow in Radiology

• Post procedure mammography with two orthogonal images
  – Reconfirms seed placement
  – Evaluation of seed location
  – Successful placement: seed within 1 cm of target lesion
Seed Workflow in Radiology

• If the patient has been recently injected with Tc-99m for sentinel lymph node mapping before seed localization, confirmation of seed placement must be done with imaging
  – Ideally, the seed placement should be done before Tc-99m is injected
Seed Workflow in Surgery

• Surgery within 1-5 days after seed implantation
• The surgeon relies on radioactivity counts during excision to recover the seed
• The surgeon must use the gamma probe to:
  – Ensure that the seed is within the excised specimen before passing the specimen off the field
  – Assure no remaining I-125 activity within the breast
Seed Workflow in Surgery

• Some surgeons prefer to avoid suction until the seed is confirmed to be removed and within the specimen.
• The surgeon must handle the specimen with care during excision to avoid seed extrusion.
• A post-excision specimen radiograph provides confirmation that the seed has been recovered.
Specimen Radiography

• A specimen radiograph is obtained to confirm the presence of the radioactive seed and the presence of the lesion and/or the marker clip within the specimen
Seed Workflow in Pathology

• Laboratory safety
  – Safety equipment included gloves, tweezers, shielded containers, and caution radioactive material (CRAM) labels
  – Survey meter with sodium iodine (NaI) detector
Seed Workflow in Pathology

Handling the specimen

• Specimen radiograph to document seed removal
• Use the specimen radiograph for guidance to the seed location
• Retrieval of the seeds
  – The seed should be placed into a lead lined container with a patient identifier denoting which patient’s specimen the seed was retrieved from
Safety and Emergency Procedures

- Written procedures for routine monitoring and emergency procedures
  - Radiation levels still present after seed removal
  - Lost seed during placement or removal procedure
  - Transected seed
Safety and Emergency Procedures

• Describe the procedures if the patient does not return for excision of the seed
  – Make every effort to locate the individual
  – A licensed medical physicist should document the calculated radiation dose that the patient would receive from the decay of the seed
Pitfalls and Potential Issues

• Deployment failure: 0.3-7.2%
  – Seed adheres to the tip of the localization needle due to abundance of bone wax at the needle tip (used in loose seeds)
• Clinically important seed migration is rare (<1% of cases)

Goudreau et al. Radiographics. 2015; 35:1319-1334
Mishaps and Misplanted Seeds

- Bone wax mimics seed
- Inadvertent deployment of seed
- Problematic seed locations

Goudreau et al. Radiographics. 2015; 35:1319-1334
Bone Wax Mimics Seed

- An abundance of bone wax at the needle tip may mimic the US appearance of the seed
- Nondeployment is more likely to go unrecognized when using US guidance than when performing localizations with mammographic or stereotactic guidance

Goudreau et al. Radiographics. 2015; 35:1319-1334
Inadvertent Deployment of Seeds

• Seeds can be deployed inadvertently, particularly when using self-loaded seeds
  – Preloaded seeds are designed with rubber stoppers to safeguard against premature deployment
  – It is advisable to remove the stopper only after the needle is well-positioned at the target site

Goudreau et al. Radiographics. 2015; 35:1319-1334
Problematic Seed Locations

- Placing a seed within the gelatinous substance of a clip
  - Recovery of the seed more difficult at the time of surgery: slippery nature of the bioabsorbable polymer surrounding the metallic clip
  - Place the seeds adjacent to, rather than within, biopsy clips

Goudreau et al. Radiographics. 2015; 35:1319-1334
Problematic Seed Locations

• Place the seed adjacent to, rather than within a fluid collection
• Placing seeds into a fluid collection may lead to seed migration, especially in a large collection.

Goudreau et al. Radiographics. 2015; 35:1319-1334
Problematic Seed Locations

• Confirmation of seeds placed in suspicious axillary lymph nodes or in lymph nodes known to contain metastases can be challenging to document mammographically, particularly if the localized nodes are positioned superiorly or deep within the axilla.
  – It is advisable to place a radioactive seed in the axilla before any additional seeds are placed in the breast

Goudreau et al. Radiographics. 2015; 35:1319-1334
Patient Does Not Return for Surgical Excision

- This can almost be completely avoided by:
  
  Placing seeds after:
  - The patient is seen by the surgeon
  - An operation is scheduled
  - The patient has committed to surgical excision of the seed

Goudreau et al. Radiographics. 2015; 35:1319-1334
Conclusion

• Seed program requires collaboration and coordinated planning and workflow
Conclusion

• Seed placement requires planning
• US or mammographic guidance
• Type of seed localization device
• Number of seeds
Conclusion: Seed Localization

- Decouples needle localization schedule and surgery schedule
- Seed can be placed up to 5 days before surgery
- Improved patient satisfaction
- Well accepted by surgeons