

Radioactive Seed Localization

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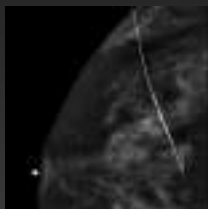


Outline

- Background
- Program development
 - Radiology
 - Surgery, path, radiation safety
- Outcomes data
- Potential pitfalls

Background: Preoperative Wire Localization

- Current standard
 - >1/3 cancers not palp
- Advantages
 - Safe
 - Effective
 - Well established
 - MG, US, MR



Preoperative Wire Localization- Disadvantages

- Must be placed on day of surgery
 - OR and radiology schedule and locations linked
 - Patient is fasting and anxious
- Wire external to patient
 - Dislodge/migrate
 - Kink or fracture (3%)
 - Transect during surgery
- Entry site vs preferred skin incision site
 - Larger excision volumes than necessary
 - Worse cosmesis

Radioactive Seed Localization

- 1st described as alternative to wire loc in 1999
 - MG or US
- Iodine-125 (I-125) labeled titanium seed
 - ~ 5 mm
- Activity: 0.075-0.125 mCi
 - Exposure monitoring not required

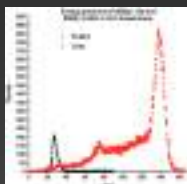


Radiation Safety

- Licensing for I-125 seed localization from state
- Authorized Users (radiologists and pathologists) must receive didactic training and be proctored
- Written directive (order) must be placed before insertion
- An emergency response team (radiation safety) on standby at all times
- Staff are not required to wear radiation badges as exposure dose is quite low.

RSL: Advantages

- Half life: ~59 days
 - Can be performed days/weeks prior to surgery
 - More organized radiology schedule
 - More efficient OR schedule
- Energy: 27keV photopeak
 - Tc99m: 140 keV
 - Compatible with SLN mapping



RSL: Advantages

- Contained within breast
 - No displacement during mammography and transfers
 - No bearing on incision site
 - ?? Smaller lumpectomy volumes
 - ?? Improved margin status

RSL: Disadvantages

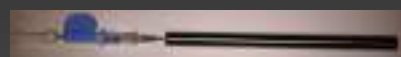
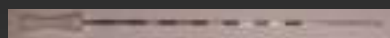
- Cannot adjust once deployed
- No MRI guided localizations
 - No MR-compatible Geiger counter or delivery needle
- Multiple seeds

RSL: Seed Selection

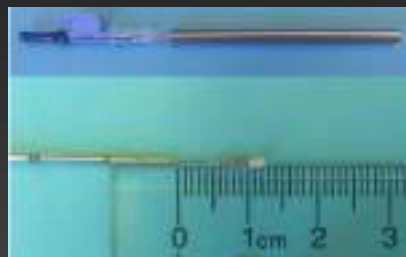
- Standard:
 - Smooth-surfaced
- Stranded:
 - Coated with bioabsorbable co-polymer
 - Increased surface area
 - Decreased chance of migration (<2% all seeds)

RSL: Components

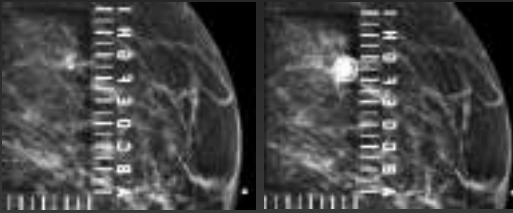
- 18-gauge needle with pre-loaded seed
- Stylet
- Safety/stopper
- Shielding



Spacer- Seed- Wax

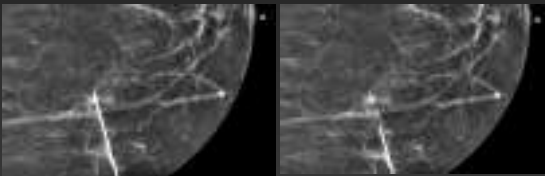


RSL: Mammographic Loc



- Select approach (shortest distance)
- Image target
- Place needle

RSL: Mammographic Loc



- Image in orthogonal plane
- Tip at or ~4 mm proximal to target
- Remove stopper and deploy
- Final pictures – annotate number of seeds

RSL: Ultrasound Loc



After RSL

- Measurements to document activity level at skin and 1 meter away
- Patients given Guidelines info sheet
 - If flying, given card indicating they had a procedure at MSKCC and levels of radioactivity may be detectable

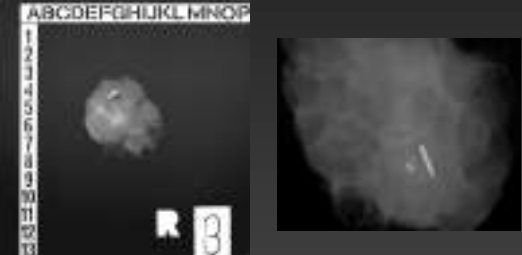
RSL: Surgical Procedure

- Guide by handheld gamma probe/ion chamber
- Verification of seed removal:
 - Counts in specimen
 - No residual activity in breast
 - Specimen radiograph



Clin. Adv. Surg. Oncol. 2003 Nov; 1(5): 109-47.

Specimen Radiographs



Coordinated Program

- Radioactive seeds tracked at all times
- Arrive and inspected in nuclear medicine
 - Entered into database
- Stored in radiology
 - Locked in secure cabinet
 - Ordered by radiologist before use
 - Database updated once deployed
- Removed at surgery
 - Specimen X-ray
 - Database updated

Coordinated Program

- Pathology:
 - Remove seed with non-puncturing long handled tool (forceps)
 - Stored in lead box
 - Database updated
- Radiation safety:
 - Retrieve seeds from pathology weekly
 - All seeds accounted for and stored for long term decay
 - Database updated



Data – Specimen Volume

Author	Year	Wire – mean volume mL(n)	Seed – mean Volume mL(n)	P-value
Gray	2001	74 (26)	56 (35)	0.48
Lovrics	2011	184 (152)	191 (151)	0.607
Murphy (MSKCC)	2013	21 (256)	19 (429)	0.074

No significant difference in specimen volume, RSL = WGL

Data – Margin Status

Author	Year	Wire – neg margins #(%)	Seed – neg margins #(%)	P-value
Gray	2001	11/26(43)	26/35(74)	0.02
Gray	2004	60/79(76)	75/83(90)	0.01
Hughes	2008	53/99(54)	280/383(73)	<0.001
Rao	2010	24/33(73)	23/33(70)	0.20
Lovrics	2011	135/153(88)	136/152(89)	0.99
Murphy	2013	242/256(95)	398/431(92)	0.38

Involved margins with variable results, some show less likely with RSL

Data – Reoperation rates

Author	Year	Wire – reoperation #(%)	Seed – reoperation #(%)	P-value
Gray	2001	15/26(57)	9/35(26)	0.01
Gray	2004	19/79(24)	8/83(10)	0.01
Hughes	2008	25/99(25)	31/383(8)	<0.001
Rao	2010	18/33 (54)	14/33 (42)	0.46
Lovrics	2011	29/153(19)	23/152(15)	0.389
Murphy	2013	57/256 (22)	99/431 (23)	0.83

Re-operation with variable results, some show less likely with RSL

Time to OR

- Length of time from when the patient arrives for preoperative setup to when in the OR:
 - Wire locs: 243 minutes
 - RSL: 103 min

Data – OR Time for lumpectomy

Author	Year	N	Wire – mean time in min	Seed – mean time in min	P-value
Gray	2001	97	6.1	5.4	0.28
Lovrics	2011	278	22	19	<0.001
Murphy (MSKCC)	2013	142	33	31	0.18

OR time slightly shorter with RSL than WGL, variably significant

Data – Patient Satisfaction – Self-Reported Pain Scores

Author	Year	Wire – Pain score	Seed – Pain score	P-value
Gray	2004	2	2	0.43
Hughes	2008	2.3	2.2	0.9
Lovrics	2011	Not reported	Not reported	0.038

Likert scale from 1 (easiest) to 10 (most difficult)

Lovrics et al report significant improvement in pain scores for RSL over WGL. Other studies no significant difference, RSL = WGL.

Data – Patient Satisfaction – Convenience Scores

Author	Year	Wire – Convenience score	Seed – Convenience score*	P-value
Gray	2004	8.0	10.0	<0.01
Hughes	2008	7.4	8.5	0.02

*For those having seed placed at least one day prior to surgery

Convenience score better for RSL than for WGL

Potential pitfalls

- Patient
 - Noncompliant
 - Does not return for retrieval
 - Not medically cleared for surgery
 - 64 day delay, still successful (0.100 mCi)
 - Not surgical candidate
 - PET scan after RSL showed metastases
 - Surgery no longer needed
 - Internal pathology review

Potential pitfalls

- Surgery/Pathology
 - Cut seed (no scissors)
 - Lose seed (be careful with suction, use reverse tweezers to handle)

Emergency Procedures for Leaking Seed

- Remove all personnel if suspected leak
- Keep all personnel outside to check for radioactive contamination
- Notify Radiation Safety immediately
- Notify Pathology for processing of specimen
- Check all personnel for radioactive contamination using a portable LEG NaI probe
- Exposed personnel/patient obtain thyroid scan

MSKCC Radiation safety policy and procedure #08.12, 2013.

Potential pitfalls

- Radiology
 - Seed misplacement
 - Seed migration
 - Seed not anchored
 - Seed extrusion
 - Body habitus and inferior approach
 - Hard-to-excise location

Conclusion

- RSL is a safe and effective alternative to WGL
- Main advantage is convenience for patient and surgeon and improved OR flow
- Imperative to monitor and account for location of all seeds at all times
- Be aware of potential pitfalls

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