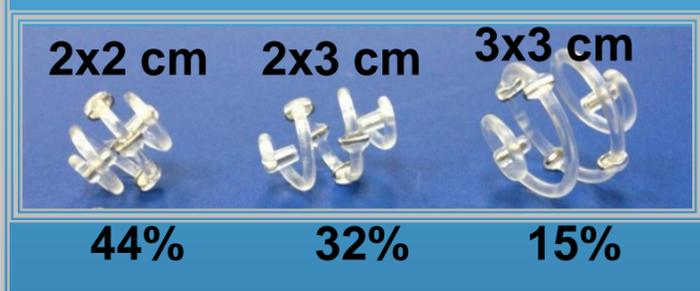




Long Term Value of 3-D Bioabsorbable Tissue Marker on Radiation Planning & Targeting, Cosmesis and Follow-up Imaging

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Abstract:

Background/Objective:

Early breast cancer is most often treated with breast conservation lumpectomy followed by radiation therapy. With long term survival, desired outcomes include both cancer survival and optimal cosmetic results. Despite oncoplastic surgery and focused radiation techniques, some patients will be left with less than optimal cosmetic results. Accurate radiation targeting may decrease the overall volume of breast tissue treated, helping to decrease the negative cosmetic effects of radiation. We used a 3-D bioabsorbable marker (3DM) to aid in radiation targeting and have followed the long term results on cosmetic outcome and follow-up imaging.

Methods:

Between May 2014 and September 2016 we implanted a 3DM in 79 {now 117} patients at lumpectomy for breast cancer often combined with oncoplastic reconstruction (reconstructive lumpectomy). Radiation Oncologists assessed impact on radiation planning & targeting. Of the entire group, 36 patients have been followed for at least one year with serial exams, follow-up mammograms, and assessment of cosmesis by clinician and patients.

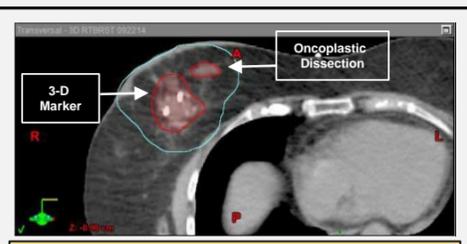
Results:

All 79 patients were evaluated for use of the 3DM. There were no cancer recurrences nor problems with the 3DM requiring removal in any patient. Overall, radiation oncologists felt the 3DM was useful for treatment planning in 85% of patients. Figure one demonstrates the value in planning and targeting by radiation oncologists. Use of 3DM targeting for boost or partial breast irradiation occurred in 69%. The 3DM allowed more exact targeting in patients receiving boost or partial breast radiation, allowing treatment volumes to decrease by an average of 24% in partial radiation patients. Of the 36 patients that have completed at least 1 year follow-up, cosmesis was rated as excellent/good by clinicians (96%) and patients (96%), and 100% excellent/good by 20 patients at 2 years. Mammograms taken at one year revealed minimal increase in fibrotic density in the area of the 3DM when compared with the similar area on the opposite breast.

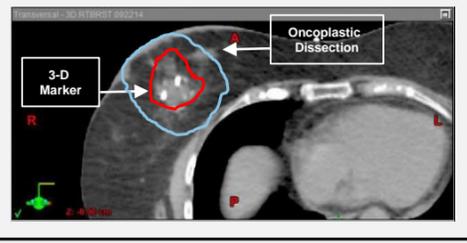
Conclusions:

Use of a 3-dimensional bioabsorbable marker (3DM) positively contributes to radiation treatment planning and targeting. This is followed by long term excellent/good cosmetic results with minimal changes on mammograms. Use of this 3DM is associated with a positive long term effect on breast cancer patients receiving breast conserving surgery. An ongoing registry study using 3DM may verify these findings in multiple centers.

Improved Targeting of Radiation Treatment



24% Less Volume ($v=4/3\pi r^3$)



Breast Volume Replacement @ 1&2 yrs 96%-100% Excellent / Good Cosmesis

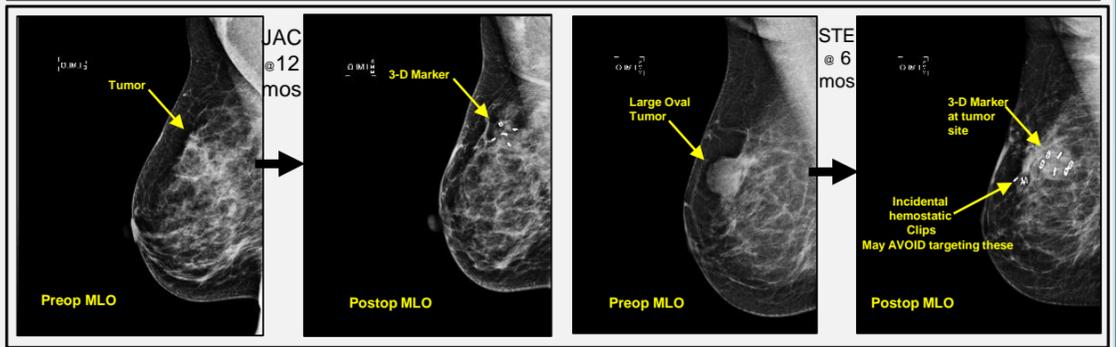


Left @8:00 - 1.9 cm IDC 2x3 cm BZ at 1 year LIN



Left @2:00 - 1.8 cm IDC 2x3 cm BZ at 1 year JAC

Adds Volume & Maintains Contour. Little Fibrosis Found at Imaging at 6-12 months. Absorbs Over Time at 12-24 months



NATIONAL DATA:

- 1) Over 10,000 implanted over 5 years
- 2) Over 500 patients in National Registry
- 3) Over 200 sites using the device

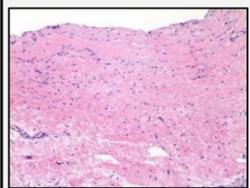
3-D MARKER BENEFITS:

- 1) Radiotherapy Targeting
- 2) Visible on all imaging modalities.
- 3) Breast volume replacement
- 4) Long term patient satisfaction.
- 5) No impact on side effects.
- 6) Bland fibrosis at histology

OVERALL Radiation Oncologist Evaluation (n=34)	
Visibility	
Easily seen	100%
Useful for Treatment Planning	
Useful	85%
Useful in hypofraction regimen	
Very or fairly useful	65%
TARGETING for BOOST (n=34)	
Easily seen	100%
Useful in boost planning	93% very or fairly
Accuracy improvement	100% useful
Useful for field in field	53% very or fairly
Useful during boost setup	60%
Overall benefit	Very useful 60%
	fairly useful 20%
	somewhat 13%
	not used 7%
TARGETING for Partial Breast Irradiation (PBI) (n=8)	
Easily seen	100%
Useful in PBI planning	88% very or fairly
Reduce PTV*	63% able to reduce
Percent reduction in PTV*	24% average
Useful for hypo fx regimen	100%
BZ used for set up	100%
How Useful was BZ?	Very useful 100%
*PTV = Planned Treatment Volume	

Cosmesis assessed by Patients @ 1 year (n=45)	
Excellent / Good	96%
Fair	4%
Cosmesis assessed by Patients @ 2 years (n=20)	
Excellent / Good	100%
Fair	0%
Palpable to patient @ 1 year (n=45)	
No	82%
Barely	9%
Yes	9%
Palpable to patient @ 2 years (n=20)	
No	80%
Barely	15%
Yes	5%
Tender to touch @ 1 year (n=45)	
None	90%
Minimal	5%
Yes	5% (1 = due to radiation)
Tender to touch @ 2 years (n=20)	
None	95%
Minimal	5% (1 = due to radiation)
Yes	0%

Pathology Results: At 1 year tissue marker embedded in established fibrosis and mild inflammation



Left: Mastectomy at 12 months with bland fibrosis and mild inflammation. Right: Marker embedded at 1 year

