Registry Study of 337 Bio-Absorbable 3-D Implants Marking Lumpectomy Cavity Benefit Cosmesis While Targeting Radiation

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Abstract

Introduction: Oncoplastic procedures at the time of lumpectomy have become commonplace. A 3-D bioabsorbable implant placed during lumpectomy may deliver solutions to three common problems; providing a dependable tumor bed target for radiation, providing a scaffold for oncoplastic closure resulting in better cosmesis and identifying re-excision sites after tissue rearrangement. An IRB-approved Registry started in 2012 collected 337 cases to assess these issues.

Methods: A bioabsorbable 3-D implant was sutured to the tumor excision site during lumpectomy and was utilized for planning and targeting breast irradiation. Data includes patient demographics, breast size, tumor characteristics, surgical and radiotherapy techniques, cosmesis and follow-up.

Results: As of September 2016, there are 337 patients from 14 centers involving 17 physicians from 12 states enrolled in the implant registry. Tumor characteristics are similar to other reports involving early breast cancer regarding patient age, size, location, tumor histology, prognostic indicators, node positivity (12%), and location (upper outer 48%). Cancers were T-1 (56%), T-2 (18%) and DCIS (20%). In most cases, implant sizes mirrored the size of the original tumor, 2X2cm (39%) and 2X3cm (33%). The radiation oncologist verified implant as “easily seen” on CT in 92% of cases and 96% found “improved accuracy” in boost targeting and set up. Oncoplastic procedures were used in 90% of patients with 41% using the device as a scaffold for tissue support. Cosmesis was highly rated as “good” or “excellent” at 6, 12, and 24 months by surgeons (94%, 97%, 90%) and by patients (95%, 94%, 87%). The device contributed to the cosmetic benefit for each time period (78%, 80%, and 80%). See Figures.

Conclusion: An IRB approved Registry reports the benefits of a 3-D bioabsorbable implant placed during lumpectomy to provide a dependable target for radiation, a scaffold for oncoplastic tissue rearrangement and to enhance cosmesis over time. This report of 337 patients describes early evidence that this device may achieve multiple goals. Further collection of data over time will validate these early impressions.
Improved Targeting Decreases Treatment Volume – Less Fibrosis

Breast Volume Replacement – Improved Cosmesis, Less Scarring

Ultrasound Visualizes the Tissue Implant (Double Arc)
Little Fibrosis at Imaging at 6–12 Months – Dissolves Beyond 12 Months

Maintains contour, fills void, little fibrosis.

Radiation Oncologists report:
- Easily seen in Rx Planning 90%
- Very Useful in Rx Planning 81%
- Improved Accuracy in Targeting 90%

All charts based on 443 patients

Tumor Size

Size Implant Used

Surgeon’s Stated Reason to Use Implant

Age Distribution

Cup Size (%)

Quadrant of Breast

National Data
- Over 10,000 implanted over 3 years
- Over 490 patients in National Registry to follow for 36 months
- Over 400 sites using the device

3-D Tissue Implant Results
1. Radiotherapy Targeting
2. Visual Marker on Imaging
3. Breast Volume Replacement
4. Good/Excellent Cosmesis
5. Patient Satisfaction

Preop MLO

Postop MLO @ 12 mos

JAC @12 mos

Radiation Target
Improve Cosmesis
Mark Excision Site
Scaffold for Closure
Re-Excision Location

Preop Estimate Pathological Size

DCIS T1a T1b T1c T2 T3

2 x 2 2 x 3 3 x 3 3 x 4 4 x 4 4 x 5

Delta Cosmetic Impact
3 mos. 6 mos. 12 mos. 24 mos.

BZ Cosmetic Impact Physician Opinion Patient Opinion

<60 years >60 years 50–59 years 40–49 years <40 years

A cup B cup C cup D cup >D cup

Upper Outer Lower Outer Lower Medial Upper Medial

Preop MLO Postop MLO

>60 years 59%
50–59 years 27%
40–49 years 12%
<40 years 12%

>60 years 29%
50–59 years 33%
40–49 years 20%
<40 years 14%

>60 years 47%
50–59 years 33%
40–49 years 29%
<40 years 14%

Ongoing Data

<60 years 4%
50–59 years 10%
40–49 years 19%
<40 years 24%

>60 years 10%
50–59 years 20%
40–49 years 29%
<40 years 47%

<60 years 12%
50–59 years 27%
40–49 years 12%
<40 years 12%

>60 years 29%
50–59 years 33%
40–49 years 20%
<40 years 14%

>60 years 47%
50–59 years 33%
40–49 years 29%
<40 years 14%