

## ABSTRACT

**Background:** Marking the site of the excised tumor bed during partial mastectomy is critical for radiation targeting and surveillance for breast cancer recurrence. However, delineating the lumpectomy cavity margins is challenging, and dense fibrosis and scarring often present obstacles when reviewing post-operative mammograms for signs of early recurrence. To determine whether implantation of a "mini" breast implant used for partial breast reconstruction adversely affected post-operative breast imaging, we reviewed clinical imaging of 100 patients that had been implanted with a new bioabsorbable breast implant over a three year period.

**Methods:** Following informed consent, 110 patients were implanted at the time of partial mastectomy with a bioabsorbable implant with a primary purpose of marking the surgical site of tumor excision for radiotherapy. In each case, the surgeon sutured the implant into the cavity at the location believed to be at greatest risk for recurrence. Implants were used for partial breast reconstruction, a guide for radiation treatment planning and routine mammographic follow-up. Mammograms were reviewed for implant visibility, presence of artifacts and other diagnostic criteria.

**Results:** In all cases the implant was rated as easily visible on mammography and CT without appreciable artifact or interference with diagnostic capabilities. In addition, there was notably less dense fibrotic tissue visualized on mammographic imaging at the tumor excision site containing the implant. In some cases, the marker clips coalesced in the center of the surgical cavity. The marker was also seen on US and MRI during routine follow-up.

**Conclusions:** Mammographic imaging in patients implanted with this new device was not adversely affected by its presence. The implant visually assisted with verification of the excised tumor bed without introducing any artifact or diagnostic interference and there was notable in-growth of normal breast tissue clearly seen on mammography. In this group of patients there were no abnormal calcifications in or around the implant and there were no recurrent cancers detected within this 36 month period.

## BACKGROUND

The concept of marking the lumpectomy site during surgery is important in order to:

- 1) address difficulties in identifying the tumor excision site for radiotherapy planning<sup>1</sup>
- 2) provide a visual cue of the tumor bed for follow-up monitoring via clinical imaging
- 3) locate the tumor bed if re-excision of margins is necessary.

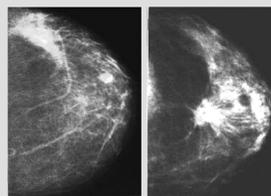
Many surgeons use clips to mark the cavity for radiation treatment planning, however, for the radiologist, these clips cannot be distinguished from clips that may have been used to control bleeding during surgery, and therefore, clips are not a reliable method of marking as a reference for the radiologist. In fact, currently, there is no standardized method for providing a visual cue for monitoring the tumor bed site during post-operative surveillance.

Scarring at the lumpectomy site is an additional challenge that complicates long term surveillance, particularly after radiotherapy. Unfortunately, scarring after lumpectomy and radiation can be severe in up to 30% of women, and these complications can cause painful and disfiguring results (see Figure 1).



**Figure 1**  
Scarring post lumpectomy & RT

When these women undergo regular screening after cancer treatment, areas of very dense fibrotic tissue are seen on mammography which significantly complicate monitoring for recurrence<sup>2</sup> and in many cases leads to additional imaging and/or biopsies adding to healthcare costs (see Figure 2).



**Figure 2**  
Dense fibrotic tissue seen on mammography limits diagnostic ability

Our local community surgeon began implanting a new 3-dimensional, bioabsorbable implant with the intent of marking the tumor excision site in a standardized and reliable fashion. The implant is comprised of a bioabsorbable helix that absorbs slowly, and 6 permanent titanium marker clips that are secured to the helix (see Figure 3).

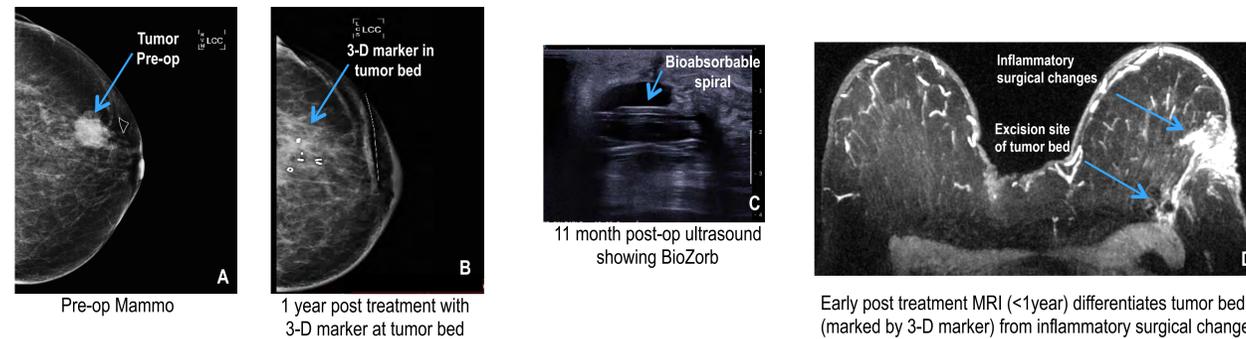


**Figure 3**  
3-D marker

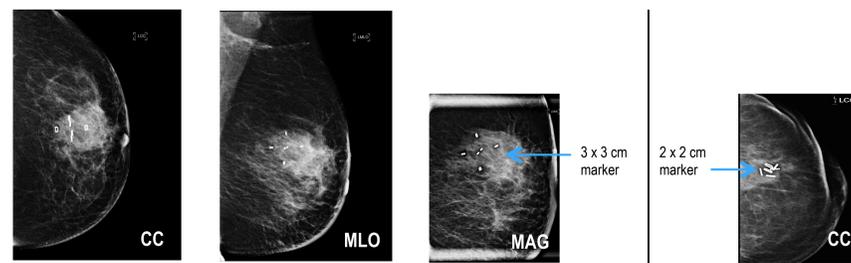
## RESULTS

In all cases the implant was rated as easily visible on mammography and CT without appreciable artifact or interference with diagnostic capabilities (see Figures 4-7). In addition, as shown in the case examples below, there was notably less dense fibrotic tissue commonly seen on post BCT mammographic imaging. This visual decrease in the post-surgical artifact at the tumor excision site was a clear and consistent finding within this group of patients implanted with the 3-D marker.

**Figure 4.** Post-operative clinical Imaging with Mammography, Ultrasound and MRI

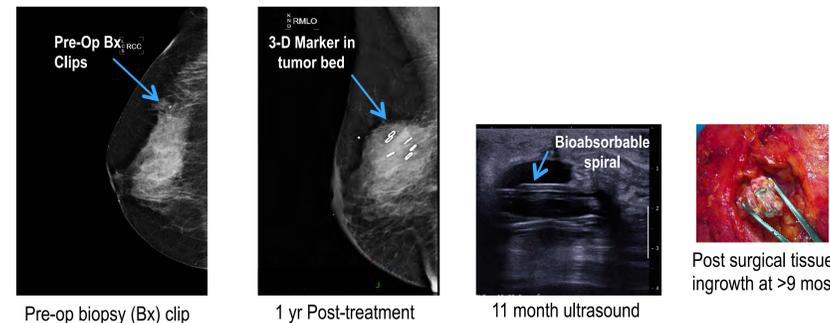


**Figure 5.** Post-operative Mammograms illustrating marker clips in 3-D array secured to bioabsorbable spiral



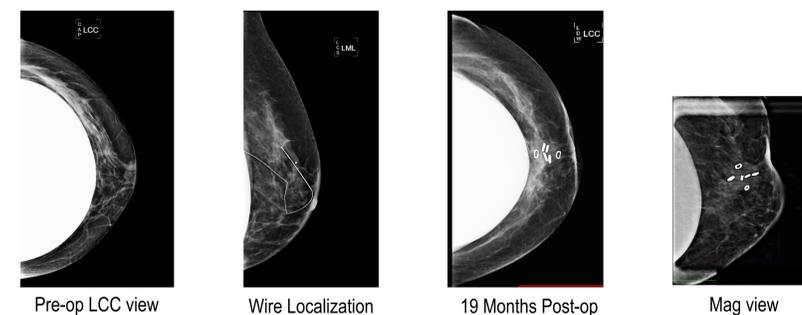
**Figure 5** shows a patient's post treatment mammograms (3 left panels) - a typical example within this group of 110 patients. Images show 3-D array of clips and magnification view with growth of normal tissue within the central region of the 3-D helix. Scarring within the breast and distortion is notably minimal. In some instances (right panel), the individual marker clips were observed to coalesce over time, in response to mild contracture of the surgical cavity.

**Figure 6.** Mammography, Ultrasound and surgical specimen



**Figure 6** shows another example of minimal scarring after BCT. The 3-D marker is nestled within and sutured to the tissue immediately adjacent to the region of tumor excision. This surgical technique helps to approximate the margins (at greatest risk for recurrence) up against the marker. In addition, the open architecture of the helix permits tissue ingrowth within and around the device. The clips provide a permanent visual cue for radiographic follow up long-term. Ultrasound reveals the presence of the bioabsorbable framework, which can remain echogenic for a year or more during the resorption process.

**Figure 7.** Mammography with submuscular implants



**Figure 7** shows a patient with bilateral submuscular silicone gel implants who underwent wire localization and BCT for a 1.2 cm invasive ductal CA. Mammographic imaging can be especially challenging for patients with breast implants who undergo BCT. The 3-D marker is associated with minimal scarring within the breast. Minimal scarring may be the result of multiple factors including the surgeon's ability to re-approximate the tissue around and within the device to help promote healing, as well as optimization of radiotherapy regimens.

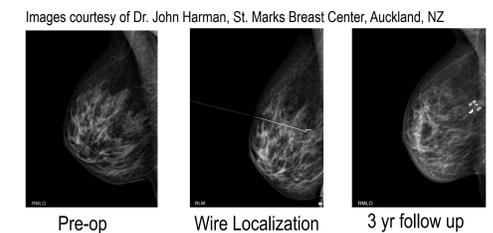
## METHODS

Following informed consent, 110 patients were implanted with the 3-D bioabsorbable marker at the time of partial mastectomy with the primary purpose of marking the surgical site of tumor excision. In each case, the device was surgically placed into the cavity at the location believed to be at greatest risk for recurrence and was sutured into position. The device demonstrated utility in assisting with partial breast reconstruction, as a guide for radiation treatment planning and for follow-up imaging. Mammograms were reviewed for implant visibility, presence of artifacts and other diagnostic criteria.

## DISCUSSION

The potential for improved cosmetic outcomes with the use of this 3-D marker during BCT has been previously described, with a reduction in the severity of scarring as seen on clinical exam and with preservation of breast shape and contour.<sup>3</sup> This observation has been noted at other centers that have adopted use of the marker as well. The mammographic images in Figure 8 are consistent with the observation of reduced scarring after BCT. The authors note that mammographic images of patients implanted with the marker and followed long term reveal notably less visible scar tissue in the region of the excised tumor, correlating the internal and external reduction in scar and fibrosis of the breast.

**Figure 8.** Mammography pre and post BCT



## CONCLUSIONS

Mammographic imaging in patients implanted with this new 3-D marker was not adversely affected. The implant visually assisted with verification of the excised tumor bed without introducing artifact or diagnostic interference and there was notable in-growth of normal breast tissue observed on the mammographic images.

Of note, this initial experience suggests that use of this device may be associated with a reduction in the dense fibrotic scar tissue commonly seen as surgical artifact on post BCT mammography. Hence, a more clearly visible view of the surgical excision site can be seen on mammography. This observation has been noted by others and warrants further comparative study. In this group of patients there were no abnormal calcifications in or around the implant and there were no recurrent cancers detected within this 36 month period.

## REFERENCES

1. Landis DM, Luo W, Song J, et al. Variability among breast radiation oncologists in delineation of the postsurgical lumpectomy cavity. *Int J Radiat Oncol Biol Phys.* 67(5):1299-308, 2007.
2. Ackerman S, Lin EC, Baron LF, et al. Postsurgical breast imaging. *Medscape.* June 25, 2015.
3. Cross M, Ross J, Jones S, et al. Identifying the surgical cavity after oncoplastic breast surgery. *ASCO Breast Cancer Symposium* 2014.