

Breast Conserving Surgery with a 3D Bioabsorbable Marker (BioZorb®): A Surgeon's 5-Year Experience

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For the past several years, I have replaced the use of surgical clips to mark the lumpectomy excision site with a bioabsorbable implant that serves as both a surgical marker for future medical procedures (such as radiation targeting, radiation therapy planning, mammographic follow-up, etc.), and as a scaffold to support tissue healing and breast contour (BioZorb® 3D Bioabsorbable Marker). Over the last 5 years, this device has been an excellent marker for our radiation oncologists to target during whole breast irradiation as well as partial breast irradiation. In an attempt to share the pivotal lessons I have learned from experience gained in my private surgical practice, I submit this short review that covers several clinical areas of interest where questions frequently arise: resorption and palpability, pain, infection, imaging over time, and cosmesis.

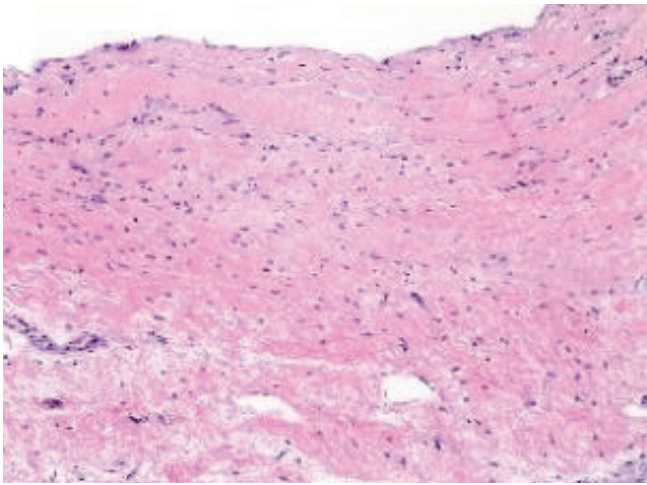
RESORPTION AND PALPABILITY:

This bioabsorbable marker is composed of two materials: a bioabsorbable framework composed of PLA, and 6 embedded titanium clips. In my experience with the device, the complete absorption time of PLA can vary considerably from patient to patient, it is best to counsel patients that the device will dissolve slowly over time, as opposed to making reference to a specific timeframe.

There are several clinically meaningful reasons for the bioabsorbable marker to remain intact for a prolonged period following surgery. Initially, the primary reason for the device to maintain its structure is to function as a 3D marker indicating the margins of the tumor excision site during future medical procedures. After initial surgery, there may be repeat surgery, extra time for healing, second opinions, and perhaps months of chemotherapy, finally followed by radiation therapy. In those patients who have such prolonged multidisciplinary treatments, the marker needs to be structurally intact for at least 10 months.



The device consists of a PLA-derived bioabsorbable spiral framework and 6 titanium clips. It is available in 6 sizes, as well as a low-profile design (right).



Pathology Results: At 12 months, the device is embedded in established fibrosis and mild inflammation

The long resorption time is an advantage by providing a “scaffolding” to support tissue in and around the device during healing^{1,2}. The common fibrotic depression that occurs following seroma absorption, even with oncoplastic tissue advancement, is not seen in most patients implanted with the device. When the device dissolves, we have not seen the cosmetic collapse of the lumpectomy site. It appears that the slow absorption process allows time for the ingrowth of fibrous tissue to fill the interior space of the device and become mature and organized. If the device were to dissolve too quickly, there is a potential for the unorganized interior tissue to be resorbed and preservation of the breast contour would be lost.

When a bioabsorbable marker implanted for a long time is removed from the breast for other reasons, one sees bland fibrous tissue occupying the center and periphery of the device. Unlike the capsule that typically forms around a smooth-surfaced round implant (such as a brachytherapy balloon or breast implant), the tissue that forms around the device exterior appears histologically similar to the fibrous tissue that fills the cavity (see image).

In regard to palpability, one issue may occur when patients are told that the device will dissolve “within” a year. Creating such an expectation can easily lead to disappointment. I tell my patients that it is necessary for the device to dissolve slowly over time so that the cosmetic benefits can mature to their optimal position. I advise patients not to check repeatedly to see if they can feel the device – and that if they do feel it, that it is a good sign that the incubation of cosmetic benefits is currently occurring. Patients have reported that after a year they can tell the device is dissolving as it doesn’t feel as hard. Yet they point out that the shape of the

breast has been maintained despite the decreased ability to feel the device. Properly informed patients are quite satisfied to wait for the ultimate outcome as long as they understand the healing process and know that it is normal for full reabsorption to take a year or longer.

PAIN:

When introducing a new variable to surgery – such as a bioabsorbable marker – some patients assume that there will be additional pain involved in the procedure or post-operative period. Similarly, some surgeons may be concerned that their patients will experience increased amounts of pain with this rigid 3D device implanted in the otherwise soft breast. Selection of the appropriate device size and technique of device placement are the crucial surgical decisions in this equation, and there is a degree of skill in determining the right choice. When these two items are properly addressed, I have not seen an increase in the amount of pain experienced in my patients.

Most surgeons instinctively want to place a device that matches the size of the lumpectomy cavity. This seems most intuitive and it is often done at the first or second BioZorb placement if the surgeon is not instructed otherwise. Ideally, the size of the device should reflect the size of the tumor, NOT the size of the lumpectomy cavity. When sized to the lumpectomy cavity, the device will end up being too large for the size of the breast and will most likely be palpable and perhaps even painful. It is also important to recall that the device is used to identify the specific region for follow-up procedures post-lumpectomy and should therefore approximate the size of the excised tumor, not the entire lumpectomy specimen.

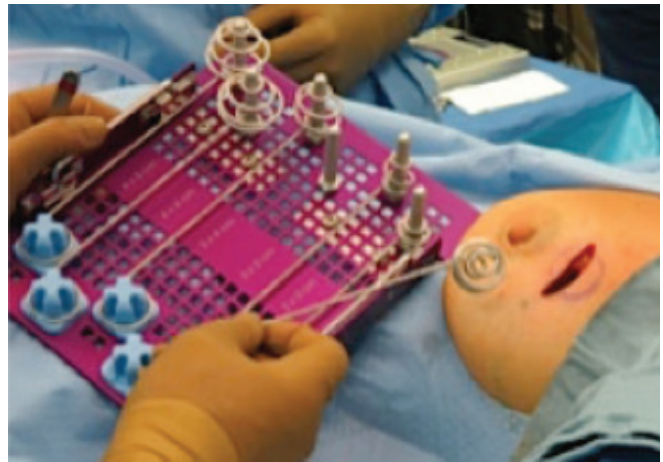
Proper placement should allow breast tissue to be closed circumferentially around the device. Even after mobilization of surrounding breast tissue, it becomes very difficult to have the device totally encased by breast tissue if the selected device size is equal to the size of the lumpectomy cavity. However, if the selected device size is equal to the size of the tumor, surrounding breast tissue can readily be mobilized to surround the device in an envelope of breast tissue. Covering the device with a generous amount of subcutaneous or breast tissue is desirable to avoid a superficial, and possibly tender, position. With proper device sizing and tissue coverage, patients will not have any significant sensation that there is a device in place.

I have asked my patients whether they experience pain long term or feel the device when they lie down on their stomach or are hugged. Most patients respond that they don't feel it at all, even in those specific situations. None of my patients have had to change their sleeping habits from sleeping on their stomach. No pain has been noticed that was unexpected or increased from typical post-operative surgical discomfort, and our standard pain medication regimen is unchanged regardless of whether the device is used or not. The message I have taken away from my experience is that this device functions as an inert traveler within the lumpectomy cavity.

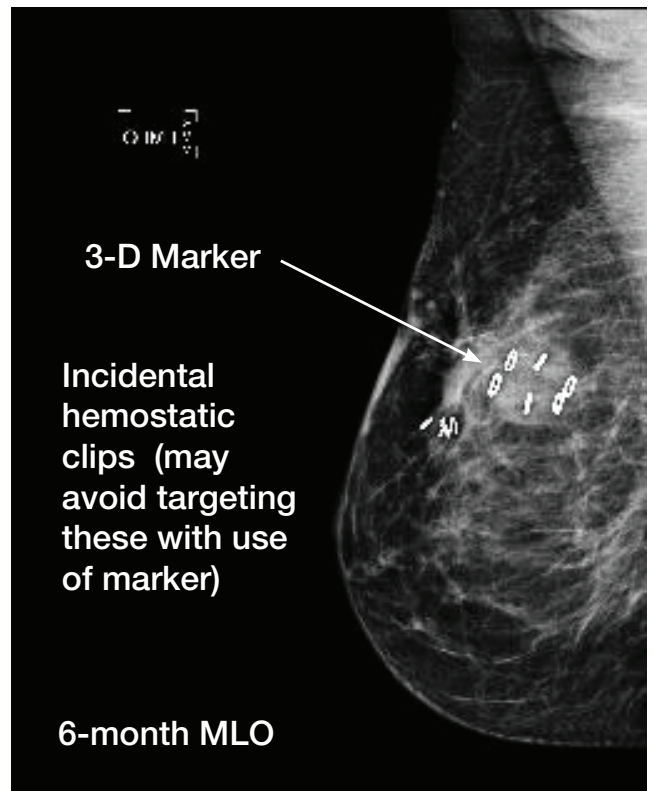
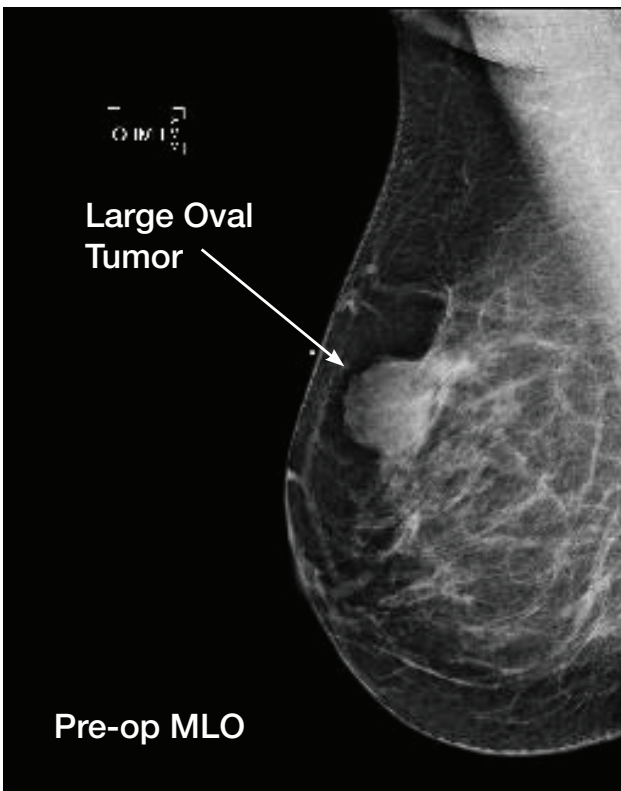
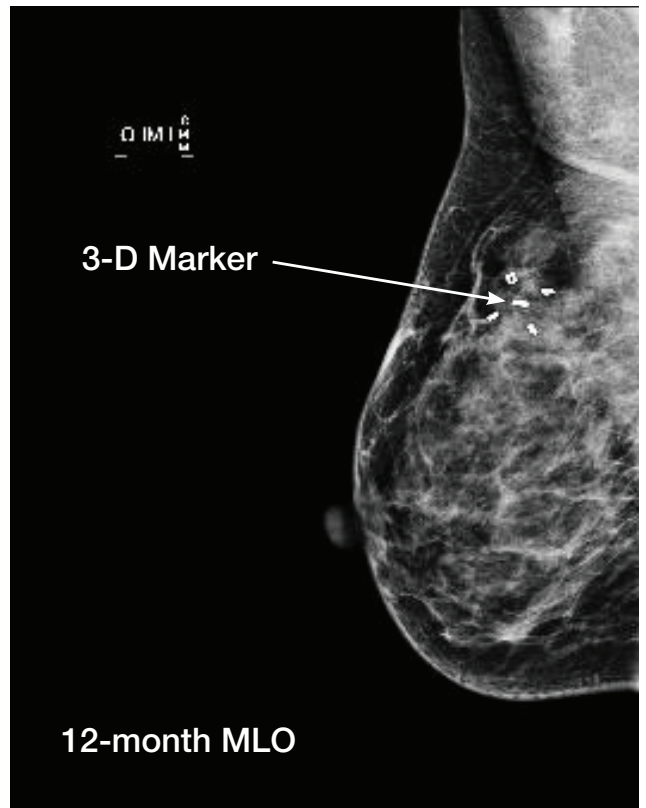
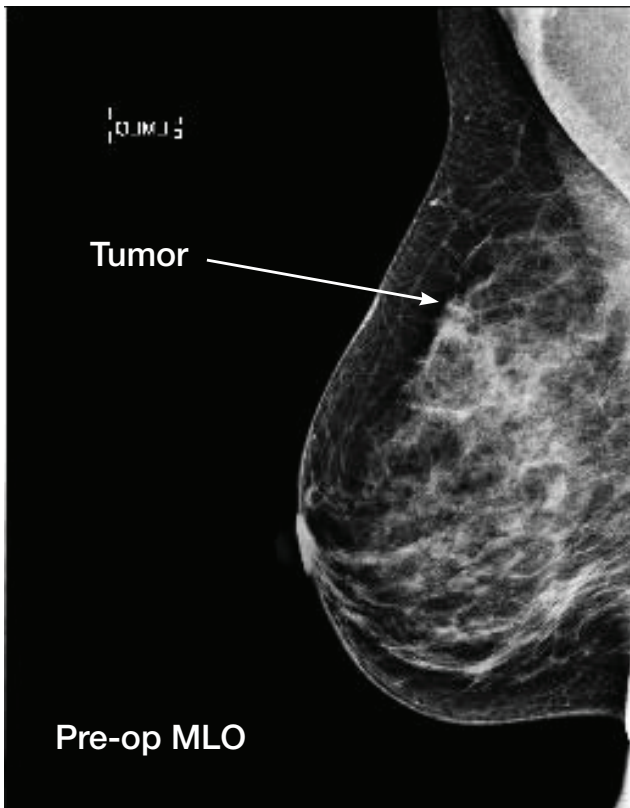
INFECTION:

Infections are relatively rare in breast surgery, typically quoted between 2-5% of cases³⁻⁵. In my experience, this device doesn't affect the infection rate. As with any implantable device, surgeons should use standard patient selection procedures for breast conservation surgery and avoid placing the device in patients that are poor candidates, such as those with significant risk factors. Of note, the device should not be implanted into an area of active infection. And as with any implantable device, one should handle it carefully and treat it with meticulous sterile technique during surgery.

For the few post-surgical infections that I've seen in patients with a bioabsorbable marker in place, I've treated the patient as I would any post-surgical infection, and have not had to remove the device. These have been breast infections, not necessarily at the site of the device. Treatment consisted of antibiotics and aspirations. Of course, standard surgical management suggests that we should have a low threshold to remove any foreign objects that might be in an infected wound. Surgeons need to consider each clinical situation, confer with colleagues, and ultimately decide for themselves based on the extent and location of infection, the status of the patient, and the overall clinical picture as to how to handle potential infections when there is a device in place.



The sizer set can assist in determining the appropriate device size and shape for the tumor size



Little fibrosis is found on imaging at 6 and 12 months, and similar breast volume and contour can be observed compared to pre-lumpectomy imaging

IMAGING OVER TIME:

With over 5 years' experience implanting the BioZorb, I've seen many serial mammograms demonstrating the device over time. The 6-month post-surgery mammogram demonstrates the classic array of the 6 titanium clips. Usually, one doesn't visualize the spiral framework, only the clips. At 12 months, imaging looks similar even though the device may have started to dissolve. By 18 or 24 months, it is clear that the device is dissolving or has completely dissolved, as the array of clips may have moved in relationship to each other and the original pattern array may have changed somewhat as the tissues of the lumpectomy cavity are remodeled during the healing process. The clips usually keep the original distance between them, but the orientation may be less uniform. On occasion, the clips may meet in the center of the lumpectomy site, but most often they simply remain in the general location where the device was sutured in place.

The most impressive mammographic finding over time has been the lack of dense fibrotic scar tissue normally seen at the lumpectomy site. With standard lumpectomy, the image often demonstrates central fibrosis with chronic white scar spiculations radiating from the lumpectomy site—this scarring can make long-term surveillance difficult for tracking potential early recurrence of cancer. However, with most patients implanted with this device, we see that over time, the lumpectomy site is filled with normal fatty breast tissue. This consistent finding is provocative, and makes sense, given the fibrous tissue that fills the center of the device over time. When comparing follow-up images after lumpectomies performed with and without bioabsorbable marker implantation, the mammograms with the marker seem to be easier to read over time, with less fibrosis. Dr. Steve Harms has also reported decreased mammographic scarring around the device⁶, and our imaging experience has echoed that. We've presented our breast contour data at the ASBrS Annual meeting where we demonstrated no change in contour at two and three years post implant placement⁷. We've been pleased at the midterm imaging follow-up at 2-4 years and the ability to visualize the lumpectomy site accurately. We've had no recurrences to date.



1.8 cm invasive ductal carcinoma treated with a 2x3 cm BioZorb at 12 months (upper outer quadrant)

Summary

To summarize, there are five key points to remember in order to achieve the best cosmetic outcome with the BioZorb® 3D Bioabsorbable Marker:

- **Choose the correct device size, most closely matching the size and shape of the tumor removed, not the lumpectomy cavity.**
- **Mobilize the surrounding breast tissue and suture the breast tissue to the device so that it is completely nested within the tumor bed region.** Do not allow the BioZorb to reside immediately below the skin without breast tissue covering it.
- **Educate your patient to expect the device to remain palpable as it dissolves slowly over time.** Explain that while it takes some time to resorb, during this process internal healing of the tissues is occurring, which will help to achieve and maintain a good cosmetic outcome.
- **Closely look at your patients postoperatively to recognize inadequate mobilization of tissue flaps.** Inadequate mobilization will leave bumps and dimples of the skin unrelated to the device, but rather related to the oncoplastic procedure. During the procedure, try to sit the patient up so that you can visualize the final result, taking into account the effects of gravity.
- **Take patient pictures before and after surgery (in upright position) to document your cosmetic outcomes.** Often, surgeons will not have taken pictures and the improvement may not be recognized by the patient.

I hope that sharing my clinical experience will be useful during your initial experience with the device in your practice. Hopefully, these tips will help alleviate some of the questions or concerns you may have. I believe by sharing our experiences we can all benefit our patients' surgical outcomes. Please contact me if you have any questions or comments at breastcare@aol.com.

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Disclaimer: Dr. Kaufman has been the Principal Investigator of the Registry Trial for BioZorb®, is a consultant for Focal-Hologic, and has received research support. Technical editing services were provided by Dana Bentley, medical writer and paid consultant for Hologic.

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