Impact of a 3D Bioabsorbable Implant on the Rate of Breast Conserving Surgery: Review of 1151 Breast Cancer Patients at Physicians Surgery

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Background

Breast conservation surgery (BCS) provides equivalent survival rates to mastectomy in appropriately selected patients, and if given the choice, most patients would prefer to preserve their natural breast if possible. However, the majority of patients require adequate local control and limit the risk of local recurrence. Unfortunately, due to many factors, women continue to require or choose mastectomy as opposed to BCS.

In our practice, many patients live in rural areas and they must travel a long distance to access treatment. They often choose mastectomy over BCS since they are looking for the most effective and efficient method of treatment. Because breast cancer patients are now achieving excellent long term survival rates, other aspects of survivorship have become equally important such as the patients’ desire for re-attachment of the breast skin envelope, symmetry, etc. Often the cosmetic outcomes following BCS are less than optimal and studies have reported at least 30% of patients are dissatisfied with the cosmetic outcome following lumpectomy.5 6 These factors influence both surgeons and patients during the decision making process when considering mastectomy versus BCS in order to obtain optimal results.

In 2012, we learned of a novel 3-D bioabsorbable surgical implant (BioZorb® marker) designed for use in BCS. The purpose of the device is to mark the tumor excision site for follow-up medical imaging, particularly after BCS in the setting of oncologic surgery where finding the tumor excision site for targeting may be challenging.4 6 Currently, the suture or clips are used to locate the tumor bed, however these may be ambiguous or misleading as targets and may lead to over or under radiation treatment volumes.4 6

Unfortunately, the combination of surgery and radiation often leads to poor aesthetic outcomes for patients having BCS.3 While oncoplastic techniques have improved surgical outcomes, extensive dissection and tissue rearrangement creates difficulty for radiation planning and targeting. Therefore, in mid-2012 we began using the surgical marker and in mid-2013 we began using the 3D marker. Over the course of the next several years we subjectively noted a marked improvement in cosmetic outcomes and thus, we have reviewed our experience with breast conserving surgery before and after integration of the surgical marker into our practice.

This is a retrospective, observational study of 1151 breast cancer patients (Stage I and II).

Methods

Breast conservation surgery (BCS) is associated with increased rates of breast radiation technique failure due to inadequate local control. In order to achieve adequate local control and limit the risk of local recurrence, women continue to require or choose mastectomy as opposed to BCS in order to obtain optimal results.

In this retrospective observational study, we noted an increased use of breast conserving surgery after we began routine use of the 3-D absorbable marker associated with increased cosmetic outcomes which further encouraged routine integration of the device into our practice. With the increased BCS we also observed an associated increase in the use of Oncoplastic breast reconstruction which is facilitated with use of the implant. The device helped to provide:

• A framework that supports tissues during oncoplastic partial breast reconstruction
• Clear identification of the tumor bed even with extensive mobilization of tissue flaps
• A small but significant amount of 3-D volume to preserve breast shape and contour
• A clear and reliable target for optimal radiation treatment planning and targeting

The combination of these factors has resulted in the improved cosmesis seen in our patients and our ability to offer an increased number of patients the option of BCS opposed to mastectomy. In a previous report, we noted that use of the 3-D marker was associated with a shift toward increased use of hypofractionation (shorter course of radiation) at our local radiation oncology center.2 This has made the radiation treatment regimen more attractive and practical for our patients who often travel long distances. We believe this too, may have contributed to the increased use of BCS observed in this study. While use of the BioZorb in our practice has been associated with these observations, additional studies are needed to determine the potential for increasing the rate of BCS in various other practice settings.

Conflicts of Interest: All authors have stated that they have no potential conflicts of interest.

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Conclusions

We observed the following routine use of the BioZorb marker in our practice:

• Increased rate of Breast Conservation Surgery
• Increased use of Oncoplastic partial breast reconstruction
• Excellent/good cosmesis in >80% of patients
• Low complication rate (<5%)
• Low re-excision rate (<5%)

Methods for implementation: The BioZorb marker was introduced into use in mid-2012 and into routine use in August of 2013. Use of the implant began with caution as we were the first center in the United States to begin using the device. Patient selection is critical to achieving good/excellent outcomes and avoiding complications. Typical cautionary procedures should be followed when patients with co-morbid medical conditions such as uncontrolled diabetes, obesity, smoking, etc. are encountered.

We found the implant facilitates use of oncoplastic techniques and allowed BCS in many patients that might otherwise require or choose mastectomy to avoid breast deformity commonly seen after BCS. The lumpectomy is performed in standard fashion, and the implant (sized to mimic the tumor bed) is sutured directly into the tumor bed with monofilament sutures. Oncoplastic techniques such as subcutaneous mastectomy, reduction or other techniques were used for partial breast reconstruction.

Patients were placed in mild compressive garments for at least 2 weeks. Antibiotics and drains were used as needed.

Results:

Table 1 reports on 1151 patients in our practice sorted by year as well as procedure performed (168 mastectomies + BCS). The rate of BCS for the time period prior to routine use of BioZorb (2010-2011) was 37.7% whereas the rate of BCS increased to 49% after routine use of the implant (2012-2013). This reflects a 29.9% increase in the use of BCS over our practice. As expected, this increase was even more pronounced since 2013, the rate of OPS with BCS was noted to increase with use of the 2-D implant as well (Figure 1). In mid-2013 we subjectively noted improved cosmetic outcomes in our BCS patients which coincided with our first experiences using the 2-D implant. To track and report objective post-treatment cosmesis, we enrolled our BCS patients in an IRB approved national registry database (BZCore). Early reports from the registry regarding cosmetic appearance of the breast after placement of the BioZorb implant was judged by healthcare providers and patients. Cosmesis was rated as excellent or good in over 90% of patients at 1 year (cosmetic cosmesis). Patient cosmesis was maintained at >90% follow up in 80% or more of patients at 1 year.

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