Impact of a 3D Bioabsorbable Implant on the Rate of Breast Conserving Surgery: Review of 1155 Breast Cancer Patients in our Practice Setting

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ABSTRACT

Breast conservation surgery (BCS) provides equivalent survival rates to mastectomy in appropriately selected patients. The purpose of the device is to mark the excision site for radiation and follow up medical imaging after BCS. Radiation oncologists use a variety of treatments to achieve 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. We believe this too 

Keywords: breast conservation surgery, tissue rearrangement, radiation oncologists, boost or PBI planning

Objective: To determine the terms in the marker with the device in our practice. We evaluated the impact of the device on our practice and patient outcomes.

Methods: We reviewed our experience with breast conserving surgery before and after integration of the surgical marker into our practice.

Results: The rate of BCS for the April 2011 to April 2013 period was 80.2% (p < 0.001). Early reports regarding cosmetic appearance of the breast are favorable, with good to excellent outcomes maintained in over 90% of patients. Compared to our previous practice, the rate of BCS has increased from 70% to 80% in our current practice. The majority of patients noted satisfaction with the cosmetic appearance of their breasts, and the majority of patients would choose to undergo breast conservation surgery again.

Conclusions: We found that the use of the BioZorb marker facilitated the use of oncoplastic techniques by providing a clear and reliable target for optimal radiation treatment planning and targeting. This has made the radiation treatment regime more attractive and practical for our patients who often travel long distances. We believe this 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.

Impact of 3D Bioabsorbable Implant on the Rate of Breast Conserving Surgery

Table 1: Impact of a 3D Bioabsorbable Implant on the Rate of Breast Conserving Surgery

<table>
<thead>
<tr>
<th>Year</th>
<th>BCS Percentage</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>75.5%</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>80.2%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2014</td>
<td>82.7%</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>85.0%</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>87.3%</td>
<td></td>
</tr>
</tbody>
</table>

In this retrospective observational study, we noted an increased use of breast conserving surgery after we began routine use of the 3D absorbable implant. This has made the radiation treatment regime more attractive and practical for our patients who often travel long distances. We believe this 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.

Breast conservation surgery (BCS) provides equivalent survival rates to mastectomy in appropriately selected patients. The purpose of the device is to mark the excision site for radiation and follow up medical imaging after BCS. Radiation oncologists use a variety of treatments to achieve 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 and they are unable or unwilling to complete the arduous 6-8 week daily radiation regimen often needed with BCS. Because breast cancer patients are now achieving excellent long term survival rates, other aspects of survivorship have become equally important such as the patient's desires and subjective feelings regarding their breast shape, size, symmetry, etc.

The cosmetic outcomes following BCS are less than optimal and studies have reported at least 30% of patients dissatisfied with the cosmetic outcome following lumpectomy. This fact influences both surgeons and patients during the decision making process when considering mastectomy versus BCS in trying to obtain optimal results.

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

Unfortunately, the combination of surgery and radiation often leads to poor aesthetic outcomes for patients having BCS. 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 by mid-2013 all patients undergoing BCS in our practice were enrolled in an IRB-approved national registry (BZcoR). Early reports from the registry regarding cosmetic appearance of the breast before placement of the BioZorb implant indicated that the use of the device facilitates use of oncoplastic techniques by providing a clear and reliable target for optimal radiation treatment planning and targeting. This has made the radiation treatment regime more attractive and practical for our patients who often travel long distances. We believe this 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.

Conclusions:

- 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 a 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. This has made the radiation treatment regime more attractive for our patients who often travel long distances. We believe this 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.

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 >85% of patients
- Low complication rate (<5%)
- Low re-excision rate (<5%)

We believe this to be due to improved cosmetic outcomes with breast conservation surgery, particularly through the use of hypofractionated (shorter course) radiation. This has made the treatment regime more attractive and practical for our patients who often travel long distances. We believe this 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.

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 adjuvant radiotherapy in order to achieve 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 and they are unable or unwilling to complete the arduous 6-8 week daily radiation regimen often needed with BCS. Because breast cancer patients are now achieving excellent long term survival rates, other aspects of survivorship have become equally important such as the patient's desires and subjective feelings regarding their breast shape, size, symmetry, etc. The cosmetic outcomes following BCS are less than optimal and studies have reported at least 30% of patients dissatisfied with the cosmetic outcome following lumpectomy. This fact influences both surgeons and patients during the decision making process when considering mastectomy versus BCS in trying to obtain optimal results.

Methods

We reviewed our experience with breast conserving surgery before and after integration of the surgical marker into our practice.

Results:

Table 1 reports data on 1155 patients in our practice sorted by year as well as procedures performed (16 mastectomy vs 21 BCS). The rate of BCS for the time period prior to routine use of BioZorb (2009-2012) was 37.9% whereas the rate of BCS increased to 43.0% after routine use of the implant (2013-2016). This reflects a 15.1% increase in the use of BCS for our practice. Approximately 15% of our patients were enrolled in an IRB-approved national registry (BZcoR) since 2013, the rate of BCS with BioZorb was increased to use the B2 implant as well (Figure 1). Over time, we have noticed improved cosmetic outcomes in our BCS patients which coincided with our first experiences using the B2 implant. To track and report objective post-treatment cosmesis, we enrolled our B2 patients in an IRB-approved national registry database (BZcoR). Early reports from the registry regarding cosmetic appearance of the breast after placement of the BioZorb implant indicated that the use of the device facilitates use of oncoplastic techniques by providing a clear and reliable target for optimal radiation treatment planning and targeting.

Conclusions:

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