Introduction to MammoSite

Wayne Butler, PhD
Schiffler Cancer Center
Wheeling Hospital
The MammoSite device

- Radiation source port pathway
- Multilumen, silicone catheter
- Inserted obturator to prevent bending or coiling of the catheter shaft
- Variable 4 to 5 cm balloon
- Needleless injection site
Why MammoSite?

- Builds on the success of interstitial accelerated partial breast irradiation (APBI)
  - The entire treatment lasts only 5 days, not 7 weeks.
  - Patients can be treated before chemotherapy.
- Company hoped that women would prefer one large puncture to multi-needle implant
  - Cosmetic results may be better than conventional external beam therapy
- Less complicated than interstitial APBI
  - Apparent simplicity and short learning curve attractive to users
How it works

- Surgical cavity < 3 cm diameter
- Implanted balloon is pressurized to occupy about twice the original volume
- Tissue is incompressible but deformable
- Tissue as far away as 2 cm from the surgical margin may be pulled to within 1 cm of the balloon surface
- Deliver prescribed dose to r + 1 cm
The Catch

- MammoSite Radiation Therapy System is not cheap.
  - Implanted balloons are replaced at no cost if they cannot be used.
- Some studies (Holland) show microscopic disease > 1 cm from tumor.
- FDA clearance in May of 2002, so there is no long term complications and survival data.
  - It has been debated that all PBI therapy should be on protocol.
- Conventional therapy probably has a slightly lower recurrence rate.
- The treatments are labor intensive
  - Physics staff devote many hours to this treatment.
### APBI selection criteria used for spherical MammoSite treatments at the Schiffler Cancer Center

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor size</td>
<td>&lt; 3 cm</td>
</tr>
<tr>
<td>Nodal status</td>
<td>N0, N1, H&amp;E stain neg. (pan keratin pos. OK)</td>
</tr>
<tr>
<td>Metastatic status</td>
<td>M0</td>
</tr>
<tr>
<td>Surgical margins</td>
<td>≥ 1 mm</td>
</tr>
<tr>
<td>Extensive intraductal component</td>
<td>Negative</td>
</tr>
<tr>
<td>Lobular histology</td>
<td>No</td>
</tr>
<tr>
<td>DCIS alone</td>
<td>No</td>
</tr>
<tr>
<td>Age</td>
<td>Clinical judgment</td>
</tr>
<tr>
<td>Tumor location</td>
<td>Clinical judgment</td>
</tr>
<tr>
<td>Breast morphology</td>
<td>Clinical judgment</td>
</tr>
<tr>
<td>Skin spacing</td>
<td>≥ 7 mm</td>
</tr>
<tr>
<td>Balloon symmetry</td>
<td>L = W ± 3 mm</td>
</tr>
<tr>
<td>Air pocket volume</td>
<td>&lt; 7 % of Treatment Volume</td>
</tr>
<tr>
<td>Off axis</td>
<td>≤ 3 mm</td>
</tr>
</tbody>
</table>
Breast Simulation Worksheet
(Part One)

Patient Name _____________________________  Patient ID_____________________
Date of implant ___________________________  (FDA mandates 28 days max.)
Radiation Oncologist_______________________  Surgeon_________________________
Lot number ____________  Implant length ____________  Breast (R/L) ____________
Exact volume of fluid in MammoSite __________ cc  (35cc ≤ fill volume ≤ 70cc)
Note: fill with 5% non-ionic contrast solution.
Patient setup______________________________________________________________
Initial position ____________mm  Length retracted/extended ____________mm
Source position ____________mm  (The value determined as the center)
Balloon length ____________mm  Balloon width ____________mm  (L = W ± 3mm)

Dosimetry information:

$D_{90}$ __________cGy  $D_{100}$ __________cGy  $V_{100}$ __________  $V_{150}$ __________  $V_{200}$ __________
Max skin dose ____________cGy  Dose Homogeneity Index ___________________
Breast Simulation Worksheet  
(Part Two)

**Measurements from CT:**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloon size</td>
<td>______________</td>
<td>(Measure diameter perpendicular to lumen.)</td>
</tr>
<tr>
<td>Balloon to skin</td>
<td>______________</td>
<td>(Need at least 7mm)</td>
</tr>
<tr>
<td>Balloon to rib</td>
<td>______________</td>
<td></td>
</tr>
<tr>
<td>Balloon to lung</td>
<td>______________</td>
<td></td>
</tr>
<tr>
<td>Balloon to heart</td>
<td>______________</td>
<td></td>
</tr>
<tr>
<td>Conformance</td>
<td>______________</td>
<td>(Need at least 90% conformance)</td>
</tr>
<tr>
<td>Off-axis distance</td>
<td>______________</td>
<td>(The symmetry requirement is ≤ 3 mm.)</td>
</tr>
</tbody>
</table>

**Calculated distances:**

<table>
<thead>
<tr>
<th>Distance</th>
<th>Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription 1</td>
<td>______________</td>
<td>(Balloon radius + 1cm)</td>
</tr>
<tr>
<td>Prescription 2</td>
<td>______________</td>
<td>– (Balloon radius + 1cm)</td>
</tr>
<tr>
<td>Source to skin</td>
<td>______________</td>
<td>(Balloon radius + Balloon to skin)</td>
</tr>
<tr>
<td>Source to rib</td>
<td>______________</td>
<td>– (Balloon radius + Balloon to rib)</td>
</tr>
<tr>
<td>Source to lung</td>
<td>______________</td>
<td>– (Balloon radius + Balloon to lung)</td>
</tr>
<tr>
<td>Source to heart</td>
<td>______________</td>
<td>– (Balloon radius + Balloon to heart)</td>
</tr>
<tr>
<td>Calculation point</td>
<td>______________</td>
<td></td>
</tr>
</tbody>
</table>
Evaluation of skin spacing

- Skin spacing is checked immediately after the scan.
- For skin spacing ≤ 7 mm, the patient is rolled and re-scanned.
- Rolling the patient onto the treatment breast often helps.
  - It may be impossible to keep everything in the field of view.
- An improvement of more than 2 mm can be achieved.
- Patients who are rolled will need to be re-simulated.
- The minimum balloon to skin distance is recorded.
- The balloon is removed if the skin spacing problem persists.
- Skin spacing less than 5 mm can cause severe reaction.
Skin spacing problem
(Patient supine)

0.51 cm
Skin spacing solution
(Patient rolled)

0.75 cm
A comparison of dosimetric data for the same patient in a supine versus a rolled position

<table>
<thead>
<tr>
<th>Position of Patient</th>
<th>Skin Gap from CT (mm)</th>
<th>PTV from CT (cm³)</th>
<th>D90 (cGy)</th>
<th>D100 (cGy)</th>
<th>V100 (%)</th>
<th>V150 (%)</th>
<th>V200 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supine</td>
<td>5.1</td>
<td>107.8</td>
<td>3269</td>
<td>1866</td>
<td>84</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Rolled Lt.</td>
<td>7.5</td>
<td>114.0</td>
<td>3289</td>
<td>2270</td>
<td>84</td>
<td>22</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Position of Patient</th>
<th>DHI</th>
<th>Max Skin Dose (cGy)</th>
<th>Max Lt. Lung Dose (cGy)</th>
<th>Max Rt. Lung Dose (cGy)</th>
<th>Max Heart Dose (cGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supine</td>
<td>0.702</td>
<td>7105</td>
<td>2774</td>
<td>198</td>
<td>2086</td>
</tr>
<tr>
<td>Rolled Lt.</td>
<td>0.738</td>
<td>5472</td>
<td>1475</td>
<td>249</td>
<td>1765</td>
</tr>
</tbody>
</table>
Examining the conformance

- Treatment planning software does not account for air pockets.
- The tissue conformance to the MammoSite should be > 90%.
- Contour all of the air pockets that are included in the PTV.
- The CT treatment volume = PTV – MammoSite volume.
- Verify that the volumes from CT contours are reasonable.
- CT treatment volumes should be > \( \frac{4}{3} \pi (3r^2 + 3r + 1) \)
- Air pocket volume / CT volume < 7%.
  - This allows for uncertainty in contours and interpolation.
  - The air will dissipate over time, about 1% per day.
  - Too much air just means wait and CT again.
Treatment volume vs. balloon width

- Treatment Volume vs. Balloon Width (cm)
- PTV from CT
- PTV from width
Air pocket problem

The initial conformity is 90.8%, with an 8 cc air pocket.
Problem solved by waiting 1 week

One week later, the conformity is 96.4%, with a 3 cc air pocket.
Evaluation of balloon symmetry

- MammoSites are not perfectly round spheres.
- Verify that L = W ± 3 mm on simulation films and CT.
- The smaller balloons tend to be less symmetrical.
  - They are often longer than they are wide.
  - Consider multi dwell?
- The balloon is often deformed when it is near the chest wall.
- The average width is critical to determining balloon size.
- The radius is defined as normal to the lumen.
- Prescription points are at r + 1 cm.
Poor symmetry
Good symmetry
Distance the source is off - axis

- Every 1 mm the source is off – axis affects the dose by 6% – 8%.

- The chest wall can cause a balloon to be very off – axis.
  - Deflate the balloon, rotate 90 degrees, and re-inflate.
  - This does not always work and often introduces air into the balloon.

- It is permissible to underdose the chest wall.
  - Therefore, prescribe to 1 cm in tissue and ignore chest wall dose.
Significant off-axis situation

The center is 2.5 mm off – axis.
Evaluating the situation
2-D planning using Plato and orthogonal films

- Setup the films with the MammoSite’s center as origin.
- Digitize the balloon (marker points) and lumen (catheter).
- Digitize the source position and enter the length.
- Re-align the axis so the lumen is along the negative Z axis.
- Create prescription and dose QA points.
- Assign the dose (340 cGy) to the 4 prescription points.
- Determine the date and time for the treatment.
- Display the desired isodose curves.
Purpose of the 2-D plan

- Used to determine the dwell time for each treatment.
- The plan is updated with the date and time of each treated fraction.
- The source position can be adjusted by changing the length.
- Determine the max dose to various critical structures.
- Examine the effects of an off-axis source.
- Observe the consequences of any asymmetry.
- Print isodose curves and the plan report.
- Export the plan directly to the treatment console.
3-D CT planning using Xio brachytherapy

- Create an oblique view that captures the dummy seed wire.
- Place the source on the dummy seed in the oblique view.
- Pick “treatment” and enter the specific date and time.
- Choose “Disp dose” and “Set Treatment Duration”.
  - The duration needs to be adjusted into: Day / Hour / Minute.
- Create isodose curves and dose volume histograms.
Purpose of the 3-D plan

- Used to obtain a 3-D visualization of the treatment.
- See the effects of balloon irregularities and anisotropy.
- The plan is created for the initial treatment and a composite.
- The DVH is generated for the single treatment and composite.
- Dosimetric data and the doses to critical structures are obtained.
  - Dose Homogeneity Index: \( DHI = 1 - \frac{V_{150}}{V_{100}} \)
Sample Dose Volume Histogram

1. PTV-Mammosite
1. Breast Skin
1. Rt. Lung
1. Lt. Lung
1. Heart
1. Spinal Cord

Total Volume: 86 cc
Inclusion: 100 %
Prescription: --- cGy
Minimum Dose: 2205.0 cGy
Maximum Dose: 9878.0 cGy
Mean Dose: 4477.0 cGy
Cursor Volume: 82 %

Plan ID: x8
Quality Assurance

**Twice daily QA, done before each treatment:**

- Reproduce the patient setup as well as possible.
- Take orthogonal simulation films using the dummy source.
- Check that the source position is still the balloon’s center.
- If the source is more than 1 mm off, adjust the system.
- Check the width and length of the balloon.
- If any dimension changes by 2 mm, verify the fill volume.
Q.A. equation using Proxima tables

*Do not proceed if variation > 5%

\[
\text{Total Dwell Time (min)} = \frac{\text{Dose (cGy)}}{\text{Dose Rate} \left(\frac{\text{cGy}}{\text{min} \cdot \text{Ci}}\right) \cdot \text{Strength (Ci)}}
\]

\[
\frac{\text{Dose (cGy)}}{\text{Dose Rate} \left(\frac{\text{cGy}}{\text{min} \cdot \text{Ci}}\right) \cdot \text{Strength (Ci)}} \text{ (min)} = \frac{\frac{\text{cGy}}{\text{min} \cdot \text{Ci}} \cdot \text{Strength (Ci)}}{\text{Dose Rate} \left(\frac{\text{cGy}}{\text{min} \cdot \text{Ci}}\right)}
\]

\[
\text{Variation} = 1 - \frac{\text{Manual Calc Value}}{\text{Computer Value}} = 1 - \frac{\text{Total Dwell Time (min)}}{\text{(min)}} = \%
\]
Physical and dosimetric characteristics for the variably inflated MammoSite balloons (Proxima tables)

<table>
<thead>
<tr>
<th>4 – 5 cm MammoSite</th>
<th>5 – 6 cm MammoSite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal fill volume (cm³)</td>
<td>Width (cm)</td>
</tr>
<tr>
<td>34</td>
<td>4.00</td>
</tr>
<tr>
<td>36</td>
<td>4.05</td>
</tr>
<tr>
<td>38</td>
<td>4.15</td>
</tr>
<tr>
<td>40</td>
<td>4.20</td>
</tr>
<tr>
<td>42</td>
<td>4.30</td>
</tr>
<tr>
<td>44</td>
<td>4.35</td>
</tr>
<tr>
<td>46</td>
<td>4.45</td>
</tr>
<tr>
<td>48</td>
<td>4.50</td>
</tr>
<tr>
<td>50</td>
<td>4.55</td>
</tr>
<tr>
<td>52</td>
<td>4.65</td>
</tr>
<tr>
<td>54</td>
<td>4.70</td>
</tr>
<tr>
<td>56</td>
<td>4.75</td>
</tr>
<tr>
<td>58</td>
<td>4.85</td>
</tr>
<tr>
<td>60</td>
<td>4.90</td>
</tr>
<tr>
<td>62</td>
<td>4.95</td>
</tr>
<tr>
<td>64</td>
<td>5.00</td>
</tr>
<tr>
<td>66</td>
<td>5.05</td>
</tr>
<tr>
<td>68</td>
<td>5.10</td>
</tr>
<tr>
<td>70</td>
<td>5.15</td>
</tr>
</tbody>
</table>

* Dose Rate calculation is at 1 cm outside of the balloon surface.
TG-43 based equation:
*Do not proceed if variation > 5%

\[ \text{Dose@10cm(cGy)} = 2.75 \cdot 10^{-6} \left( \frac{\text{cGy}}{\text{U} \cdot \text{s}} \right) \times \text{Strength(U)} \times \text{Time(s)} \]

\[ \text{Variation} = 1 - \frac{\text{Manual Calc Value}}{\text{Computer Value}} = 1 - \frac{\text{__________}(\text{cGy})}{\text{__________}(\text{cGy})} = \text{__________} \% \]
Pretreatment procedure

- Hook up the catheter to minimize source transit exposure of the contra lateral breast.
  - Try to straighten and level the catheter by positioning the unit.
Treatment procedure

- Treatments are 340 cGy BID for 5 consecutive days.
- At least six hours must elapse between treatments.
- Remove the catheter and connector, and replace the obturator.
- Complete the post-treatment radiation survey.
- Have a nurse assist with the bandaging.
- Make sure the patient knows when to return.
Treatment situations

- The patient might request assistance during the treatment.
  - Treatment can be interrupted and resumed with a button push.

- The center position can sometimes change due to patient’s daily motion.
  - The connector can be tightened or loosened for small adjustments.
  - Adjust the dummy seed to find the new center for shifts ≥ 1 mm.
  - Only the 2-D length is corrected since the source is recentered.

- The dimensions of the balloon might change by ≥ 2 mm.
  - Look for the same change on both of the orthogonal films.
  - If the balloon seems to be shrinking then check for a leak.
  - Consider all the options when dealing with a leaking balloon.
Removal of the MammoSite

- Patients are given Ativan to be taken 1 hour before the last treatment.
- Roxanol is orally administered just prior to the last treatment.
- Removal occurs after the 10th treatment, in the treatment room.
- The balloon is deflated, and the fill volume is verified.
- The device is pulled out with a swift motion.
- Most patients consider the removal mildly unpleasant.
- Patients are given a follow up schedule before they leave.
## Dosimetric data for the MammoSite breast brachytherapy applicator

<table>
<thead>
<tr>
<th></th>
<th>Balloon Volume (cm³)</th>
<th>Balloon width (mm)</th>
<th>PTV from width (cm³)</th>
<th>PTV from CT (cm³)</th>
<th>Center Position (mm)</th>
<th>Skin Distance (mm)</th>
<th>Tissue Conformance (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edmundson Mean (SD)</td>
<td>58.3 12.7</td>
<td>47.4 3.7</td>
<td>112.1 15.7</td>
<td></td>
<td></td>
<td>8.5 3.0</td>
<td></td>
</tr>
<tr>
<td>Schiffler CC Mean (SD)</td>
<td>41.7 9.4</td>
<td>42.7 0.3</td>
<td>88.6 9.8</td>
<td>95.5 10.8</td>
<td>989.9 1.5</td>
<td>13.0 7.0</td>
<td>97.8 2.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Off-axis distance (mm)</th>
<th>D₉₀ (cGy)</th>
<th>D₁₀₀ (cGy)</th>
<th>V₁₀₀ (%)</th>
<th>V₁₅₀ (%)</th>
<th>V₂₀₀ (%)</th>
<th>DHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edmundson Mean (SD)</td>
<td>84.9 12.7</td>
<td>3190.5</td>
<td>2137.6</td>
<td>81.1</td>
<td>25.4</td>
<td>4.5</td>
<td>0.77</td>
</tr>
<tr>
<td>Schiffler CC Mean (SD)</td>
<td>.94 0.57</td>
<td>137.8</td>
<td>143.7</td>
<td>5.1</td>
<td>3.7</td>
<td>2.0</td>
<td>.69</td>
</tr>
</tbody>
</table>

---
Balloon volume vs. $V_{200}$
Balloon volume vs. DHI

The graph shows the relationship between balloon volume (in cc) and dose homogeneity index. As the balloon volume increases, the dose homogeneity index also increases, indicating a positive correlation between the two variables. The data points are represented by markers, and a trend line is drawn to illustrate the general trend. The graph includes a scale for both the x-axis (balloon volume) and the y-axis (dose homogeneity index).
Skin spacing vs. skin dose
Balloon width vs. dose at a distance
Balloon width vs. maximum dose/prescribed dose ratio
Conclusion

- Because tissue at risk is forced to conform to the MammoSite balloon, coverage is more consistent and uniform than with interstitial Bx
- MammoSite is limited by cavity size, conformance, and skin spacing constraints
- There is no long-term follow-up to MammoSite
- Partial breast 3DCRT can provide more complete coverage of the PTV but at the cost of greater normal tissue dose