INTRA-OPERATIVE RADIATION THERAPY FOR EARLY STAGE BREAST CANCER IN DENVER, COLORADO, USA

BARBARA S. SCHWARTZBERG, M.D.

Associate Professor of Surgery - University of Colorado
Sarah Cannon Research Institute at Rose Medical Center
Denver, Colorado
SEQUENCE OF EVENTS

May 25, 2011  Cancer Committee Presentation
July 15, 2011  AXXENT system purchase
October 31, 2011  IRB approval
November 2, 2011  First IORT case
January 10, 2013  Completed accrual with 51 patients
XOFT AXXENT SYSTEM OVERVIEW

Axxent System Controller

Balloon Applicators

X-RAY source
INCLUSION CRITERIA

1. Women > 40 years old
2. Single lesion
3. Infiltrating ductal carcinoma
4. Cancer ≤ 2.5 cm on preoperative radiographic imaging
EXCLUSION CRITERIA

1. Multifocal cancer
2. Lymphovascular invasion
3. Extensive intraductal component
4. History of breast cancer and/or radiation
5. Neo-adjuvant therapy
6. Pregnancy or lactation
7. Scleroderma, active lupus, ipsilateral pacemaker
RADIOGRAPHIC WORKUP
SLN BIOPSY FOLLOWED BY LUMPECTOMY
BALLOON PLACEMENT
BALLOON PLACEMENT
DELIVERY OF ELECTRONIC BRACHYTHERAPY
PROCEDURE RESULTS

- **51 patients** - to OR for IORT
- **1 patient** - technical difficulties
- **5 patients** - positive intra-operative SLNs
- **3 patients** - IORT but positive SLNs on final pathology
- **2 patients** - Positive margins

- **40 (78%)** patients completed IORT per protocol
- **Average age** - 63.8 years
- **Average tumor size** - 1.04 cm
<table>
<thead>
<tr>
<th>Procedure Characteristics</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Average total procedure time</td>
<td>1 hour 47 minutes</td>
</tr>
<tr>
<td>Average radiation delivery time</td>
<td>512.4 seconds (8.5 mins)</td>
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<tr>
<td>Average balloon size</td>
<td></td>
</tr>
<tr>
<td>3 to 4 cm balloon</td>
<td>37 patients</td>
</tr>
<tr>
<td>4 to 5 cm balloon</td>
<td>3 patients</td>
</tr>
<tr>
<td>Average balloon fill</td>
<td>31.75 ml</td>
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<tr>
<td>Average radiation dose</td>
<td>20 Gy</td>
</tr>
<tr>
<td>Average skin-to-balloon distance</td>
<td>1.21 cm</td>
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FOLLOW UP

- 40 patients have completed IORT protocol
- Average follow up - 29 months
- One patient has been diagnosed with a brain metastases at two years
- 2 patients have died of unrelated causes
- No evidence of any local recurrences
IORT - One Year Follow Up

NORMAL BREAST

1 YEAR POST IORT
IORT – ONE YEAR MAMMOGRAPHIC FOLLOW UP

SCREENING MAMMOGRAM

ONE YEAR POST-OP
CONCLUSION

Early results of intra-operative radiation therapy using the Axxent Electronic Brachytherapy System in the United States support the use of IORT for treatment of early stage breast cancer.
A Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft® Axxent® eBx™ System at the Time of Breast Conservation Surgery for Early Stage Breast Cancer

“ExBRT”