

American Society of Breast Surgeons MammoSite® RTS Patient Registry

Part Number 87822-001

MammoSite
Targeted Radiation Therapy 

Next ➔

This presentation provides an overview of the ASBS MammoSite RTS patient registry study, which was initiated by the manufacturer after clearance of the device by the FDA in May of 2002.

ASBS MammoSite® RTS Patient Registry

- Managed by the American Society of Breast Surgeons
- Single largest compilation of clinical data of partial breast irradiation patients
- Anticipate 7 years of follow-up
- Enrollment from 2002–2004

← Previous

Next →

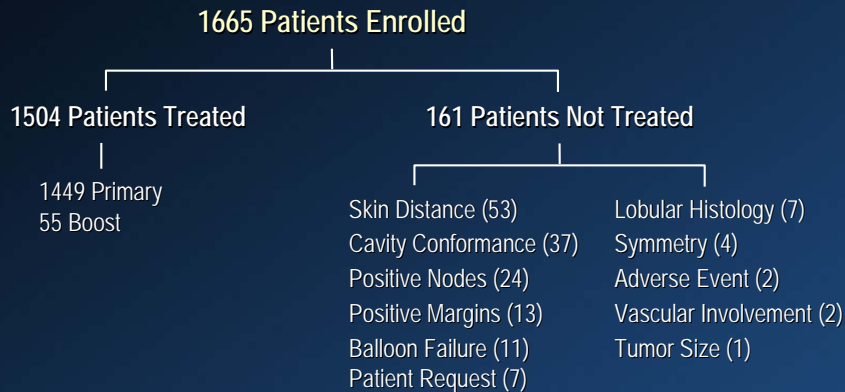
The American Society of Breast Surgeons assumed primary management of the trial in November of 2003 and has since accumulated additional data and follow-up. This registry represents the single largest compilation of clinical data on patients who have received partial breast irradiation.

The ASBS responded to the interest from the clinical community in partial breast irradiation with selection criteria for treatment with partial breast irradiation. Patients meeting these guidelines were enrolled in the registry. The Patient Selection Module of this course will discuss these criteria in detail.

Accrual into the ASBS Registry began in 2002 and was completed in July 2004. Although the original goal was to enroll 1500 patients, 1665 patients were enrolled. Patients will be followed for 7 years, and as of November 2006, the median time for patient follow-up is 14 months.

ASBS MammoSite® RTS Patient Registry¹

Patient Enrollment



1. ASBS Registry Newsletter, June 27, 2006. Data on File American Society of Breast Surgeons.

← Previous

Next →

This chart reviews the distribution of patients enrolled in the Registry.

Of those, 90% (or 1504 patients) have been treated using the MammoSite RTS device. Among the 10% (161 patients) not eligible for treatment with the MammoSite device, reasons include a lack of skin to catheter distance, poor cavity conformance, and a later finding of positive nodes.

The Registry data are relevant as they represent longitudinal community experience, which provides a valuable comparator or index to “actual use” versus results reported in tightly controlled clinical trials.

1. ASBS Registry Newsletter, June 27, 2006. Data on File American Society of Breast Surgeons.

ASBS MammoSite® RTS Patient Registry

Clinical Experience¹

- Initial published results
- Demographics:
 - 1419 patients
 - 5 months median follow-up
 - Median age 65
 - Range 35–93 years
- Clinical findings
 - 91% of invasive carcinoma patients had a negative lymph node status
 - 99% of all patients had negative margins
 - 1 ipsilateral breast local recurrence
 - Outside target area, new primary

1. Vicini et al. *Cancer*. 2005;104(6):1138-1148.

← Previous

Next →

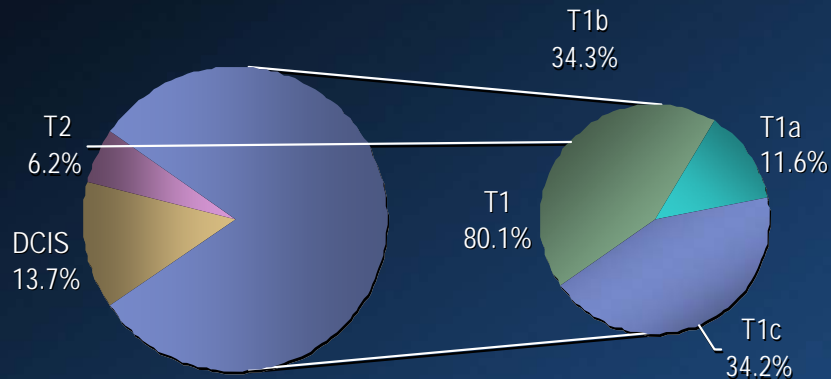
The first peer-reviewed published results appeared in the September 2005 issue of *Cancer* and reported on 1419 patients enrolled in the ASBS Registry Study. The median follow-up was 5 months. The median age was 65 with a range of 35 to 93 years. Ninety-one percent of the invasive cancer patients had negative lymph node status and 99% of all patients had negative margins. At the time of this publication, one ipsilateral breast local recurrence was reported. This recurrence was outside the target area and was reported as a new primary occurrence.

1. Vicini FA, Beitsch P, et al. First analysis of patient demographics, technical reproducibility, cosmesis and early toxicity, results of the American Society of Breast Surgeons MammoSite Breast Brachytherapy Registry Trial. *Cancer*. September 15, 2005;104(6):1138-1148.

ASBS MammoSite® RTS Patient Registry¹

AJCC Tumor Status

Initial Published Results



1. Vicini et al. *Cancer*. 2005;104(6):1138-1148.

← Previous

Next →

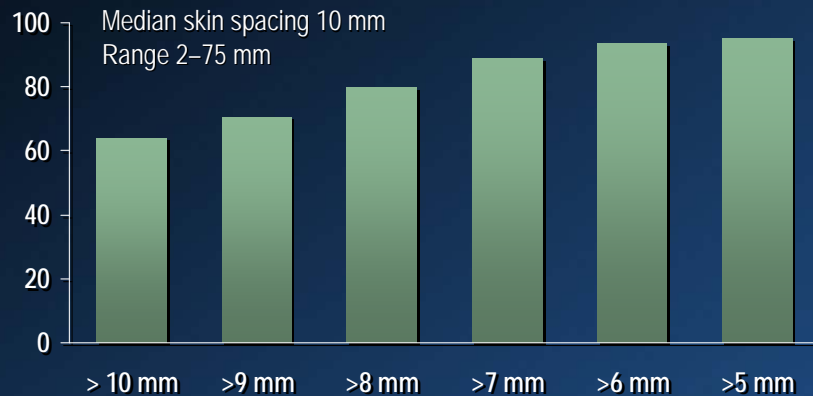
As you see in this chart, using the American Joint Committee on Cancer (AJCC) criteria for tumor status, approximately 80% of the Registry patients had T1 tumor status while 6% had T2. Thirteen percent of the patients in the registry were classified as having DCIS.

1. Vicini FA, Beitsch P, et al. First analysis of patient demographics, technical reproducibility, cosmesis and early toxicity, results of the American Society of Breast Surgeons MammoSite Breast Brachytherapy Registry Trial. *Cancer*. September 15, 2005;104(6):1138-1148.

ASBS MammoSite® RTS Patient Registry

*Skin Spacing*¹

Initial Published Results



1. Vicini et al. *Cancer*. 2005;104(6)1138-1148.

← Previous

Next →

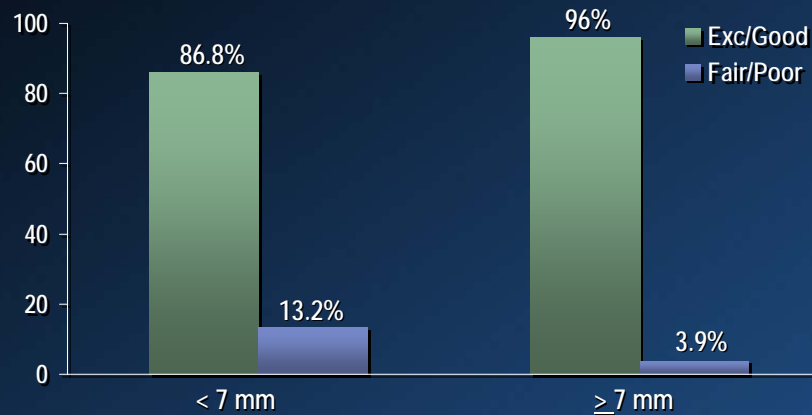
Skin spacing ranged from 2 to 75 mm, with a median of 10 mm. In 89% of the patients there was a minimum balloon to skin distance of 7 mm, with 2% of patients with distances less than 5 mm. Increased skin spacing was associated with a good/excellent cosmetic result, and this result corresponds with the initial study data.

1. Vicini FA, Beitsch P, et al. First analysis of patient demographics, technical reproducibility, cosmesis and early toxicity, results of the American Society of Breast Surgeons MammoSite Breast Brachytherapy Registry Trial. *Cancer*. September 15, 2005;104(6)1138-1148.

ASBS MammoSite® RTS Patient Registry

Cosmesis by Skin Spacing¹

Initial Published Results



1. Vicini et al. *Cancer*. 2005;104(6)1138-1148.

← Previous

Next →

In the group of patients with greater than or equal to 7 mm skin spacing, cosmetic outcome was excellent to good in 96% of the patients, while in the patient group with skin spacing less than 7 mm, the excellent to good cosmetic outcome was only 86.8%. Likewise, the percentages of patients reporting fair to poor cosmetic outcomes grew with smaller skin spacing: with 13.2% of those patients with less than 7 mm skin spacing reporting fair to poor cosmetic outcomes, compared with only 3.9% of patients reporting fair to poor cosmetic outcomes in the group where skin spacing was greater than or equal to 7 mm.

1. Vicini FA, Beitsch P, et al. First analysis of patient demographics, technical reproducibility, cosmesis and early toxicity, results of the American Society of Breast Surgeons MammoSite Breast Brachytherapy Registry Trial. *Cancer*. September 15, 2005;104(6)1138-1148.

ASBS MammoSite® RTS Patient Registry¹

Initial Published Results

<i>Time of Placement</i>	<i>% (n)</i>
Open Cavity	44.8% (545)
Closed Cavity	55.2% (683)
SET Technique	24.9% (70)
Ultrasound Guidance	74.4% (508)
Unknown	0.7%

1. Vicini et al. *Cancer*. 2005;104(6)1138-1148.

← Previous

Next →

This chart discusses the placement techniques for the MammoSite catheter. As you can see, both open and closed techniques have been used, with a small preference for closed cavity placement.

Five hundred forty-five patients, or about 45%, had the MammoSite balloon placed with an open cavity at the time of the lumpectomy, while 683 patients, or 55%, had the MammoSite balloon placed with a closed cavity (post lumpectomy).

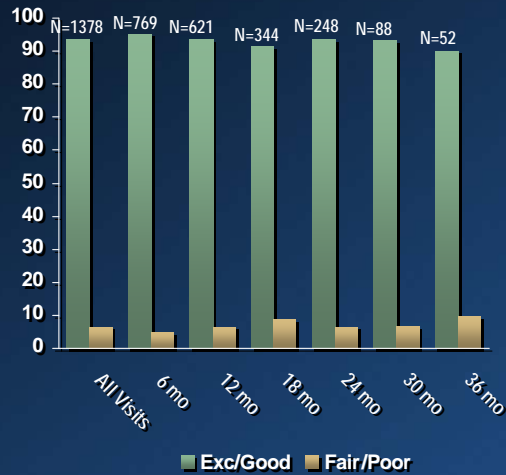
Among the patients where the MammoSite catheter was placed in a closed cavity 70 patients, or about 25%, were placed using the scar entry technique (SET) while the majority, 508 patients, or 74%, were placed using ultrasound guidance.

1. Vicini FA, Beitsch P, et al. First analysis of patient demographics, technical reproducibility, cosmesis and early toxicity, results of the American Society of Breast Surgeons MammoSite Breast Brachytherapy Registry Trial. *Cancer*. September 15, 2005;104(6)1138-1148.

ASBS MammoSite® RTS Patient Registry¹

Cosmesis over Time

- 1449 patients
 - Reports on 1378
- Median follow-up = 14 months
- Cosmetic outcome remains stable over time



1. ASBS Registry Newsletter, June 2006.

← Previous

Next →

An update on the ASBS Registry was presented at the American Society of Clinical Oncology in June 2006. The median follow-up was 14 months on the 1449 patients.

Cosmetic outcome remains stable over time, with:

93.7% excellent/good cosmetic outcome at 12 months, with an n of 621

93.5% excellent/good cosmetic outcome at 24 months, with an n of 248

90.4% excellent/good cosmetic outcome at 36 months, with an n of 52

1. Presented at the American Society of Clinical Oncology, June 2006, Atlanta, and ASBS Registry Newsletter, June 27, 2006. Data on File American Society of Breast Surgeons.

ASBS MammoSite® RTS Patient Registry¹

Tumor Recurrence

Ipsilateral Breast Tumor Recurrence (IBTR)

	<i># of Events</i>	<i>Crude Rate</i>	<i>2-Year Actuarial Rate</i>
Total Breast Failures	11	0.8%	1.2%
TR / MM	6	0.4%	0.6%
Elsewhere	5	0.4%	0.6%
Isolated Breast Failures	8	0.6%	0.8%
Breast and Axilla	3	0.2%	0.6%

1. ASBS Registry Newsletter, June 2006.

← Previous

Next →

This chart presents ipsilateral breast tumor recurrence rates, or IBTR.

The generally accepted ipsilateral breast tumor recurrence rate is 1.2%. Compared to data from conservative surgery and no radiation therapy, the risk of elsewhere failures ranges from about 1 to 5%. Therefore, the rate of new cancers is 1 to 5%, even with whole breast radiation.²⁻⁶

Overall tumor recurrence rates are very low. In a recent Registry cohort analysis by Vicini and colleagues, 11 PATIENTS, or less than 1%, developed an ipsilateral breast tumor recurrence (ibtr) as some component of their initial failure for a 2-year actuarial rate of 1.2%.⁷

1. ASBS Registry Newsletter, June 27, 2006. Data on file American Society of Breast Surgeons and presented at ASCO, June 2006.
2. Clark RM, Whelan, T, Levine, M, et al. Randomized clinical trial of breast irradiation following lumpectomy and axillary dissection for node-negative breast cancer: an update. Ontario Clinical Oncology Group. *J Natl Cancer Inst.* 1996;88:1659-1664.
3. Veronesi U, Marubini E, Mariani L, et al. Radiotherapy after breast-conserving surgery in small breast carcinoma: long term results of a randomized trial. *Ann Oncol.* 2001;12:997-1003.
4. Holli K, Saaristo R, Isola J, et al. Lumpectomy with or without postoperative radiotherapy for breast cancer with favourable prognostic features: results of a randomized study. *Br J Cancer.* 2001;84:164-169.
5. Fisher ER, Anderson, S, Tan-Chiu, E, et al. Fifteen-year prognostic discriminants for invasive breast carcinoma. *Cancer.* 2001;91:1679-1687.
6. Liljegren G, Holmberg, L, Bergh, J, et al. 10-year results after sector resection with or without postoperative radiotherapy for stage I breast cancer: a randomized trial. *J Clin Oncol.* 1999;17:2326-2333.
7. Vicini F, Beitsch P, Quiet C, et al. Two-year analysis of treatment efficacy and cosmesis by the American Society of Breast Surgeons (ASBS) MammoSite Breast Brachytherapy Registry Trial in patients treated with accelerated partial breast irradiation (APBI). *J Clin Oncol.* 2006;24:529.

Summary

- With over 1500 treated patients, the MammoSite RTS Patient Registry represents the largest clinical data compilation on patients who have undergone partial breast irradiation.
- Patients typically displayed very low levels of local recurrence and infection, and very high levels of cosmesis and patient satisfaction.
- Increased skin spacing was associated with a good/excellent cosmetic result, corresponding with the initial study data.

 [Previous](#)