ORIGINAL ARTICLE

Postlumpectomy Insertion of the MammoSite Brachytherapy Device Using the Scar Entry Technique: Initial Experience and Technical Considerations

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■ **Abstract:** For women undergoing breast-conserving surgery, recent reports suggest that in selected cases accelerated partial breast irradiation may yield results equal to that of whole breast irradiation. Over 31 months, 19 patients underwent accelerated partial breast irradiation using the MammoSite as the sole radiation treatment following breast-conserving surgery. Seventeen patients had the MammoSite inserted postoperatively using the scar entry technique (SET). Treatments were delivered using high dose rate iridium 192 given twice a day for 5 days. Three complications (two minor, one major) occurred. Late radiation morbidity and overall cosmetic results were evaluated. Eighty percent of patients had either no change from baseline or slight change in skin pigment. More than 90% had good or excellent overall cosmetic outcomes. Patients undergoing accelerated partial breast irradiation with the MammoSite inserted using SET had excellent overall cosmetic results. Advantages of the SET over intraoperative placement are presented. ■

Key Words: breast cancer, brachytherapy, radiation, surgery, treatment

Whole breast irradiation following lumpectomy has become the standard treatment for women choosing breast conservation (1,2). This therapy is able to treat undetected foci of cancer not removed during surgical excision. More recently, however, several reports of accelerated partial breast irradiation have suggested that in many instances whole breast radiation may not be necessary (3–5). Currently the options for accelerated partial breast irradiation include three-dimensional conformal external beam and brachytherapy either with interstitial catheters or, more recently, utilizing the MammoSite device (Proxima Therapeutics, Alpharetta, GA). Placement of the MammoSite device can be accomplished at the time of lumpectomy or during the postoperative period. We chose to examine our initial experience with the MammoSite catheter in patients in whom it was the sole radiation modality and in whom the catheter was inserted in the postoperative period by the scar entry technique (SET).

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METHODS

Scar Entry Technique

Within the first 1–2 weeks after breast-conserving surgery, ultrasound of the lumpectomy cavity is carried out in order to determine if the cavity is of appropriate size and shape to hold the MammoSite, and to determine whether there is an adequate bridge of tissue between the lumpectomy cavity and the skin (skin bridge) (Fig. 1). To protect the skin from excessive radiation, an attempt was made to provide a skin bridge of at least 1 cm of breast or fibrofatty tissue. The minimum accepted skin bridge was 5 mm. Insertion of the device is carried out in the outpatient clinic setting under local anesthesia without sedation. Ultrasound is generally performed just prior to insertion and the cavity is rechecked for appropriate size, shape, and cavity-to-skin distance. The cavities were measured in three dimensions. Cavities that measured more than 4 cm in two dimensions were considered too large for the 4–5 cm MammoSite balloon. (Subsequent to this study, a 5–6 cm MammoSite balloon has become available.) A minimal balloon-to-skin distance was 5 mm, although 7 mm was more desirable.

A 1–1.5 cm area of skin is anesthetized and 10 cc of 1% xylocaine is instilled into the lumpectomy cavity

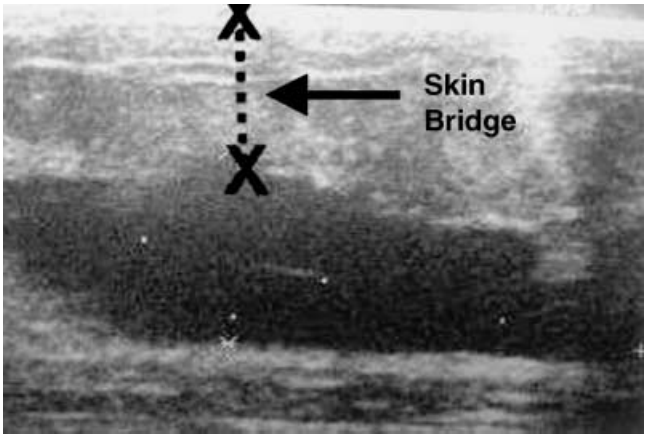

Figure 1. The skin bridge is the distance between the edge of the seroma cavity and the skin.

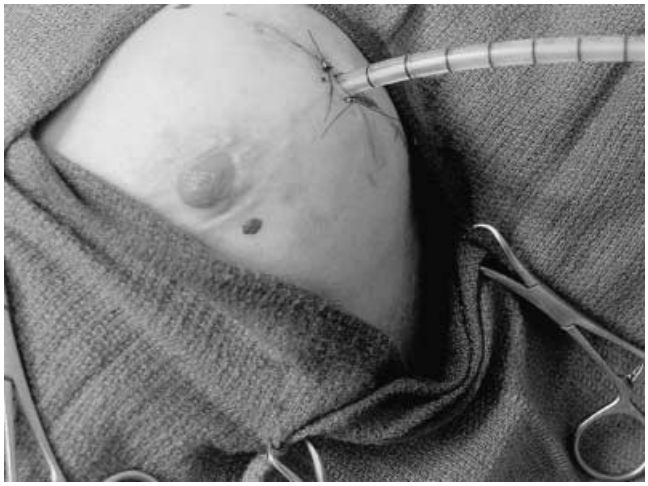

Figure 2. The MammoSite device is inserted through the area of the incision with the narrowest skin bridge; in this instance the center.

approximately 10 minutes prior to insertion of the device. Saline is injected into the MammoSite to check for balloon integrity and symmetry. As a general rule, the catheter is inserted through the corner of the incision. However, in many instances the narrowest skin bridge is located in another part of the incision, and if so, the catheter is inserted through that site (Fig. 2). The skin incision is teased open with a hemostat for approximately 1 cm and the cavity identified with the tip of the hemostat. The seroma will drain spontaneously once the cavity is opened. The catheter is inserted through the opening and inflated with a saline-contrast solution to 35–70 cc, depending on the size and pliability of the cavity. Every attempt is made to fill the balloon as much as possible without impinging on the balloon-to-skin distance or creating a problem with balloon symmetry. The volume used to inflate the balloon is recorded.

Ultrasound is then used to check balloon conformance to the surrounding tissues and the distance between the edge of the balloon and the skin is measured to confirm an adequate skin bridge. The catheter is then completely deflated and a skin suture is taken on either side of the catheter in order to prevent the incision from opening further. No sutures are used to secure the catheter, as the filled balloon prevents accidental dislodgment. The catheter is then reinflated to the previously recorded volume. An antibiotic ointment is placed around the catheter exit site, a sterile dressing is applied, and the patient is discharged from the clinic on oral pain medication and a low-dose broad-spectrum antibiotic.

Radiation

Following insertion of the MammoSite, patients were transferred to the Department of Radiation Therapy where computed tomography (CT) scans and orthogonal simulation films were performed to further evaluate conformity of the MammoSite device with the lumpectomy cavity. Treatment proceeded if, on CT scans, the inflated balloon showed good conformance with the lumpectomy margins. This ensured that there were no air- or fluid-filled spaces between the surface of the balloon and the lumpectomy cavity. These scans were also used to verify that the catheter was centrally located in the balloon, thus ensuring that a uniform dose of irradiation would be delivered to the surface of the balloon. Treatment planning was performed using both the CT and orthogonal images. The balloon diameters ranged from 4 to 5 cm. Treatment consisted of 34 Gy delivered to a point 1 cm from the balloon surface in 3.4 Gy fractions given twice a day over 5–7 days.

The daily fractions were separated by 6 hours. Radiation treatments were delivered using the Nucletron (Veenendaal, The Netherlands) iridium 192 HDR remote afterloader. Given that this was our initial experience with placement of the MammoSite catheter with the SET, we elected to repeat the CT scan of the breast daily to verify balloon integrity and placement. At the conclusion of the last fraction, the catheter was pulled in the radiation department. The wound was cleaned and steristrips were applied.

RESULTS

Over the 31-month period from July 2000 to February 2003, 19 patients underwent insertion of the MammoSite for delivering accelerated partial breast irradiation. Two

Table 1. Patient, Tumor, and Lumpectomy Cavity Characteristics

Characteristic	Range	Mean
Patient age	42–84 years	65.6 years
Time from surgery to insertion	13–41 days	22.7 days
Follow-up time	5.6–30.9 months	11.8 months (median 7.9 month)
Tumor size	0.5–2.0 cm	1.1 cm (median 1.0 cm)
Size of surgical specimen	33.2–400 cc	114.4 cc
Surgical cavity volume by ultrasound	4.2–35.8 cc	18.6 cc
Balloon volume	35–70 cc	41.8 cc
Skin bridge by ultrasound	5–16.2 mm	10.7 mm
Skin bridge by CT	3–15 mm	10.1 mm

patients had the MammoSite inserted in the operating room at the time of lumpectomy and 17 had insertion through the surgical scar (SET) during the postoperative period in the outpatient clinic setting. The decision as to whether the device was placed at the time of surgery or after lumpectomy was made by each individual surgeon. In one instance, the intraoperative placement was early in our experience with the MammoSite, and in the second instance, the device was placed at the time of reexcision for a close margin. It is this group of 17 patients undergoing insertion by SET that comprises the study group.

Patient and tumor characteristics can be seen in Table 1. Patients ranged in age from 42 to 84 years (mean age 64.9 years). Ten of the 16 patients (62.5%) were diagnosed with invasive ductal carcinoma, while 4 patients (25%) had ductal carcinoma in situ (DCIS) and 1 each had tubular and invasive papillary carcinoma. All patients had negative surgical margins and those with invasive carcinoma underwent sentinel node biopsy. All patients were sentinel node negative by both hematoxylin-eosin and immunohistochemistry (IHC). Mean follow-up was 11.4 months (median 7.9 months, range 3.2–30.9 months).

An attempt was made to correlate the balloon volume with both preinsertion cavity size as measured by ultrasound and the size of the surgical specimen as measured by the pathologist. Cavity size as measured by ultrasound was available for review in 12 patients and surgical specimen size was available in 14 patients. No conclusions could be drawn between the specimen and cavity size and the fill volume of the MammoSite balloon.

Fourteen of the 16 patients had skin bridge measurements by both ultrasound and CT. There was ≤1.0 mm difference in the measurements between these two modalities in seven patients and ≤2.0 mm in nine patients. In eight patients the CT measurement was greater than that made by ultrasound, whereas in six patients the ultrasound measurement was greater than the CT measurement. In only one patient did this difference in measurement result in late radiation morbidity.

Acute complications occurred in three patients, two of which were mild. One patient developed a local infection around the catheter insertion site. This resolved rapidly with local care and antibiotics. Another patient developed grade 1 acute radiation dermatitis, characterized by erythema around the surgical incision. It resolved rapidly following completion of therapy. This patient did not develop any late skin morbidity from her radiotherapy. The final patient developed both acute and significant late morbidity from treatment. This patient's "skin bridge" measured only 3.0 mm by CT scan despite measuring 7.0 mm by ultrasound. Acutely this patient developed grade 2 radiation toxicity with bright erythema and patchy moist desquamation of the skin overlying the treatment site. The overall cosmetic result in this patient was "fair," and this was the only patient with less than a good or excellent outcome (see below).

Fifteen of the patients were available for evaluation of late skin morbidity and overall cosmetic results. Late morbidity was evaluated using the Radiation Therapy Oncology Group (RTOG) and European Organization for Research and Treatment of Cancer (EORTC) late radiation morbidity scoring scheme (6). Overall cosmetic results were evaluated using the Harvard scale criteria (Table 2). Eighty percent of patients had either no change in the skin from baseline or slight change in skin pigment following irradiation. Level 4 skin toxicity, characterized by marked atrophy and superficial ulceration of the skin, was noted in one patient. Again, this was the patient with a skin-to-balloon surface distance of 3 mm. Figure 3 shows the typical appearance of the skin in a patient treated with MammoSite inserted through the center of the incision using the SET.

Table 2. Late Radiation Morbidity

Evaluation scale	Number of patients (%)
RTOG/EORTC	
0	5 (33)
1	7 (47)
2	2 (13)
3	0
4	1 (7)
Harvard Scale	
Excellent—treated breast looks the same as untreated breast	7 (47)
Good—minimal but identifiable effects of radiotherapy	7 (47)
Fair—significant radiotherapy effects	1 (7)
Poor—severe normal tissue sequelae	0

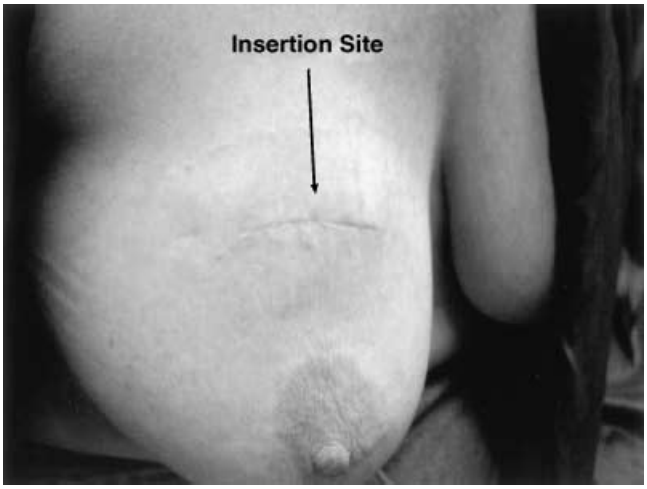

Figure 3. A patient 6 months after radiation therapy with the MammoSite inserted through the center of the incision.

DISCUSSION

Seventeen patients underwent accelerated partial breast irradiation as the sole radiation modality using the MammoSite device. More than 90% of the patients had either good or excellent cosmetic outcomes following use of the MammoSite to deliver radiation. When using the RTOG/EORTC assessment scale to evaluate skin toxicity, 75% of patients scored 0 or 1. The single patient with a score of 4 had radiation delivered despite a balloon-to-skin distance of 3 mm as measured by CT. It is recommended that this distance not be less than 5 mm.

Computed tomography and ultrasound measurements of the balloon-to-skin ratio were evaluated. Balloon-to-skin distances were within 2 mm of one another in 56% of cases. Moreover, CT estimated the skin bridge to be larger than that estimated by ultrasound in more than half the cases. Because excessive radiation to the skin depends upon the balloon-to-skin distance, it is our recommendation that both ultrasound and CT be used to evaluate this distance and that the smaller of the two distances be used to evaluate whether the MammoSite would be appropriate in each case.

The MammoSite balloon brachytherapy device was approved for use by the U.S. Food and Drug Administration (FDA) in May 2002. Keisch et al. (4) reported 2 years of results on the first 43 patients treated with the MammoSite prior to FDA approval, noting a 0% recurrence and good to excellent cosmetic results in 88%. Because long-term results for the MammoSite are not yet available, both the American Society of Breast Surgeons and American Brachytherapy Society have seen fit to make general recommendations regarding patient age, histology, tumor size, and nodal and margin status (Table 3) (7,8).

Table 3. Patient Selection Criteria for American Brachytherapy Society (ABS) and American Society of Breast Surgeons (ASBS)

	ABS	ASBS
Age	45 years	50 years
Diagnosis	Unifocal invasive ductal carcinoma	Invasive ductal carcinoma or DCIS
Tumor size	3 cm	2 cm
Surgical margins	Clear	Clear, 2 mm
Nodal status	N0	N0

There are currently two approaches to placement of the MammoSite device. The device can be inserted at the time of breast-conserving surgery or it can be inserted during the postoperative period. When inserting the device at the time of surgery, the balloon is inserted through a tunnel and the stem of the catheter is generally brought out lateral to the surgical incision. Postoperatively the cavity can be accessed via ultrasound guidance or directly through the surgical incision using the SET. In most instances, we have chosen to insert the MammoSite during the postoperative period. In our series, the MammoSite was inserted 3–6 weeks after lumpectomy (average is 3 weeks). As our experience with this procedure increased, we began to evaluate patients for adequate cavity size as early as 1 week after surgery.

With time, the walls of the lumpectomy cavity are likely to become more rigid and consequently it is more difficult to get good conformance of the balloon to the cavity. We have noted that in some patients the seroma cavity closes rapidly, and in several instances the cavity has been completely closed within 4 weeks. We would therefore recommend that when utilizing the SET, evaluation of the cavity should be carried out within the first 2 weeks following surgery and that every attempt should be made have the catheter implanted by 6 weeks.

The advantage of inserting the catheter at the time of surgery is that the cavity is most pliable and there is no chance for the seroma cavity to be rapidly absorbed. Conformance of the balloon to the cavity can also be assessed by direct vision. However, delayed implantation allows assessment of the final pathology report, including margins and node status. The SET is also performed in the outpatient setting. There is minimal if any discomfort on insertion and no sedation is required. Furthermore, because of the anisotropy of the radiation source (cylindrical) (9), the area of overlying skin closest to the source

will receive a reduced dose of radiation, potentially preventing skin complications in cases in which the skin bridge is marginal. Also, the psychological effect of having to remove the MammoSite prior to treatment because of margin involvement or node positivity should not be underestimated. Placement of the device after the final pathology report has been reviewed obviates this problem.

The long-term results using MammoSite are not known. A phase III randomized trial comparing various forms of accelerated partial breast irradiation and whole breast irradiation is currently in the planning stages. However, there are at least three studies of accelerated partial breast irradiation with a minimum of 5 years of follow-up using interstitial brachytherapy. Local recurrences in these trials range from 0.9% to 4.4%, comparing favorably with those reporting local recurrences following whole breast irradiation (3,5,10).

CONCLUSION

Seventeen patients underwent accelerated partial breast irradiation using the MammoSite balloon catheter. All 17 had the balloon device inserted postoperatively using the SET. Three patients had complications, including one case each of dry desquamation, radiation dermatitis, and catheter site infection. More than 90% of patients had good or excellent cosmetic results. There were no poor cosmetic results.

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