MammoSite® Radiation Therapy System

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Whole breast radiotherapy is used in combination with lumpectomy for women with breast cancer that can be treated with breast-conserving therapy. Studies have shown that most breast cancer recurrences are located at the initial lumpectomy site, regardless of whether the patient has received whole breast radiation (Kuerer, 2003). Theoretically, radiation of the entire breast may not be necessary in most early-stage cancers and may add to complications or long-term sequelae.

The concept of partial breast irradiation (PBI) has been explored recently as a treatment option. PBI involves treatment of only the lumpectomy cavity and surrounding tissue, sparing the remainder of the breast. One method of PBI is the MammoSite® Radiation Therapy System (Proxima Therapeutics, Inc., Alpharetta, GA), which delivers high-dose radiation via a balloon catheter in a fraction of the time compared to conventional external beam radiation.

**Goal:** The goal of the MammoSite balloon is to facilitate delivery of high-dose rate radiation (HDR) therapy in a total of five days while irradiating the cells in the immediate lumpectomy or tumor site with little effect on the more distant surrounding tissue.

**Objectives:** To provide local control of breast cancer in patients following lumpectomy, minimize radiation therapy-related complications, and optimize cosmesis in the treated breast.

**Advantages:** The therapy is completed in five days and provides optimal cosmesis and concentrated doses of radiation in the area where the tumor was removed previously. The shortened therapy limits travel requirements and may improve patient quality of life and patient satisfaction. Because the duration of treatment is short, the radiotherapy can be given before starting a chemotherapy regimen, thus avoiding a delay in completing the local therapy.

**Disadvantages:** The remainder of the breast distal to the lumpectomy cavity does not receive therapy. The long-term effects of the treatment relative to local control of the breast cancer remain unknown. MammoSite balloon placement may require an additional procedure compared to conventional external beam radiation therapy.

**Patient selection:** Criteria for patient selection varies by institution and clinical trial guidelines. In general, patients who may be good candidates include women who are aged 40 and older with histologically diagnosed in situ and invasive T1 and T2 and N0 or N1 breast cancer treated with lumpectomy and sentinel lymph node or axillary node dissection (Dowlatshahi et al., 2004).

**Contraindications to the use of MammoSite balloon radiation therapy:** A patient may not be a good candidate if:

- She has a serious medical illness or condition that may affect the use of the MammoSite applicator (e.g., advanced diabetes, Parkinson disease).
- She is pregnant or breast-feeding.
- She has a collagen vascular disease, particularly dermatomyositis.
- Tumor pathology demonstrates an extensive intraductal component (more than 25% ductal carcinoma in situ).
- She has multilobular disease.
- If the distance from the lumpectomy cavity margin to the skin surface is less than 5 mm.
- She has a breast size smaller than a B cup.

**Coordination of care:** Multidisciplinary coordination of care is essential. Creating a flow sheet with all team members assists in communication and scheduling. Team members include the surgeon, schedulers, radiation oncologist, surgical and radiation nurses, and radiation and billing departments. Discussing patients at clinical case conferences helps to promote communication and coordination of care among team members.

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Digital Object Identifier: 10.1188/05.CJON.375-377
Documentation: Documentation should include the date the MammoSite is placed, lot number of the catheter, balloon volume, total balloon volume, dye volume, minimum skin bridge, dressing changes, and facility where the balloon was placed.

Description of the device: The dual-lumen (blue lumen and red lumen) catheter is approximately six inches long, with an inflatable balloon on one end. The balloon end is inserted into the lumpectomy cavity and inflated with saline through the blue lumen of the catheter. The catheter’s red lumen is used to attach the radiation cables to an HDR remote afterloader with an 192Ir seed. If catheters are connected to the wrong lumens, the HDR machine can be damaged permanently.

MammoSite placement: The surgeon performs an excisional lumpectomy with sentinel lymph node and/or axillary node dissection. The MammoSite is placed with the assistance of ultrasound after the pathology report confirms that the tumor size is adequate, margins are clear, and fewer than four nodes are positive for tumor.

Final verification of MammoSite placement to determine the skin bridge thickness (5–7 mm) and the degree of air and fluid pocketing in the lumpectomy cavity is made with a computed tomography (CT) scan. After the balloon is fitted properly, the patient proceeds to CT simulation and treatment with HDR therapy.

If the balloon does not fit the cavity properly (as determined by the CT scan), the patient will be sent back to the surgeon for further evaluation and possible balloon replacement. At that time, the healthcare team may determine that the patient is a better candidate for conformal PBI or whole breast irradiation. Air and fluid pockets or skin bridges sometimes can cause the MammoSite balloons to fit poorly in the cavity, which would result in an unbalanced radiation delivery.

High-dose radiation therapy: After the MammoSite balloon is fitted properly, the patient is scheduled for a CT simulation in the radiation therapy department. This allows the dosimetrist to construct the treatment plan.

Prior to each radiation treatment, the patient must have an x-ray (done on the simulation machine) to check for correct balloon placement. This is followed immediately by the HDR treatment.

The patient lies on a cushioned brachytherapy table. A cushion is placed under her knees for support. The nurse removes the MammoSite obturator and attaches the afterloader connector to the red lumen. The HDR cable then is attached to the afterloader connector. Visualization of the catheter during treatment via the monitor is essential. The patient is monitored on a video camera and can talk with the staff via an intercom.

Treatment length depends on how much the source has decayed but usually takes 5–15 minutes. Patients typically are in the department for approximately one hour with each treatment.

At the completion of treatment, the treatment cable retracts the iridium source so that no active radiation is released except during the actual treatment. The nurse then can unfasten the cables from the MammoSite catheter and replace the cap. After the patient’s dressing and vital signs are checked, she is discharged.

Dose: The dose delivered is 34 Gy in 10 fractions over five days.

Daily treatment program: An x-ray is taken before each treatment to confirm that the balloon remains inflated. Patients receive HDR treatments twice a day, with a minimum of six hours between fractions on the same day. They are allowed to return home between treatments. Scheduling is simplified if treatments are Monday through Friday for five days, for a total of 10 treatments.

Adverse effects: This treatment is associated with a number of possible acute and long-term side effects.

• Acute: Following the radiation treatment, patients may experience minor breast-related side effects, such as redness, bruising, and pain. These are common side effects of breast surgery or radiation therapy and usually last for only a short time. Some patients have drainage from the catheter insertion site, which is normal and will decrease over time. Patients also should be monitored on a regular basis for signs and symptoms of infection.

• Long term: Patients may experience chronic skin changes, rib injury, radiation pneumonia, pericarditis (for left-sided treatment), and lymphedema of the arm or breast on the treated side.

Complications: This treatment may cause the following complications.

• The balloon may rupture, requiring a new catheter and repeat CT simulation before continuing treatment.

• The catheter site may become infected, requiring antibiotic therapy and delayed or aborted therapy if sepsis occurs.

Facility and staff requirements: The facility must be certified by the state department of health to do HDR therapy and have the appropriate equipment and space. Surgeons are encouraged to complete a certification course for MammoSite placement. Nursing staff should be experienced in HDR therapy procedures.

Care of the site: The nurses should inspect the dressing daily and change it as needed. Changing it too often can lead to displacement of the balloon, resulting in treatment delays. If the dressing becomes saturated with fluid, it may be changed twice daily. The catheter exit site should be cleaned with hydrogen peroxide or povidone iodine, antibiotic ointment applied, and the area covered with a clean gauze dressing.

The catheter site should be kept clean and dry at all times. Patients should be instructed to take a tub or sponge bath and keep the catheter site clean and dry.

The catheter is removed in the radiation or surgical oncologist’s office. After the catheter has been removed, the catheter exit site should be cared for in the same manner until the site has closed and no longer drains.

If the color or character of drainage changes, or if the patient experiences breast swelling, redness, or fever, a physician should be notified.

Use of prophylactic antibiotics: The catheter manufacturer recommends using antibiotic prophylaxis at the time of implanting the MammoSite device. Cephazolin is recommended as a one-time dose 30 minutes prior to implanting the device. Clindamycin or vancomycin can be used in place of the cephalaxin in patients with penicillin allergies.

Follow-up care: Patients are recommended to see the radiation oncologist or surgical oncologist one month after the completion of radiotherapy with the MammoSite balloon, then every six months for three years, and annually after the third year. Visits can be alternated between the radiation oncologist and the surgical oncologist.

Patient education: Patients must understand their treatment options prior to beginning therapy, particularly the difference between standard care and new technologies. Patients should be educated about normal radiation skin changes and general care of the catheter site.

Reimbursement: Medicare and most major insurance companies reimburse for the catheter. Some insurance companies may require a physician letter describing the procedure to obtain coverage. This should be considered prior to MammoSite placement.

Research and clinical trials: A number of trials currently are under way to evaluate this treatment.

• The American Society of Breast Surgeons developed and managed a national prospective registry program to track the progress of patients treated with MammoSite. The registry is closed to patient accrual.

• A clinical trial sponsored by Proxima Therapeutics is under way to investigate MammoSite as the sole radiation therapy
technique for ductal carcinoma in situ. It is a phase II, nonrandomized trial being conducted at 10–15 centers nationwide to evaluate the efficacy, performance, and safety of MammoSite in this specific population. Target enrollment is 125 patients.

- A clinical trial sponsored jointly by the National Surgical Adjuvant Breast and Bowel Project and the Radiation Therapy Oncology Group will be initiated this year. This phase III trial will examine whether PBI is equivalent to whole breast radiotherapy for local tumor control following lumpectomy. It also will assess quality of life in patients receiving whole breast radiotherapy and PBI. The study will allow the use of MammoSite as well as other forms of PBI, interstitial brachytherapy, and three-dimensional conformal external beam radiotherapy. The projected enrollment is 3,000 women.

**Key teaching points:** In adopting this therapy option, healthcare providers should take the following into account.

- Consider the number of patients that the radiation facility can manage at one time, remembering that patients must be treated twice a day with visits at least six hours apart.
- Ensure that patients understand all of their treatment options.
- Develop a pathway to assist in the flow of patients and coordination of care.
- Coordinate scheduling among the team members, particularly between surgical and radiation oncology.
- Select “point people” for specific functions so that all team members know whom to contact about specific functions.
- Promote cooperation and teamwork among everyone involved with the care.

**Resources:** Visit MammoSite Radiation Therapy System at www.mammosite.com and Cancer Treatment Centers of America at www.brachytherapy.com. Information about the registry can be obtained from the American Society of Breast Surgeons at www.breastsurgeons.org.

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