Breast Brachytherapy

(Also known as Partial Breast Irradiation)
For
Early-Stage Breast Cancer

Using the

Savi® Brachy device
or
Multiple Interstitial Catheters

Cancer Center of Irvine

Kenneth M. Tokita, M.D.
16100 Sand Canyon Avenue, Suite 130
Irvine, California 92618
Phone 949-417-1100 *Fax 949-417-1165*

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At
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Introduction

This outline of Breast Brachytherapy is intended to answer commonly asked questions about Breast Brachytherapy. More and more patients want an alternative to the standard External Beam Radiation Therapy (EBRT) that is delivered after lumpectomy and sentinel lymph node biopsy. Accelerated Partial Breast Irradiation (Breast Brachytherapy) may be an option for select patients where the cancer is "early-stage," i.e., measures less than 2 inches (5 cm) in the lumpectomy specimen and has not spread to the lymph nodes. With standard EBRT, the entire breast is irradiated. In contrast, with Breast Brachytherapy, less than one inch of the breast around the lumpectomy cavity receives a high dose of radiation. With EBRT or Breast Brachytherapy, there is only about a 3-5% chance that a cancer will come back in the breast within 5 years. The rationale behind Breast Brachytherapy is that when breast cancers come back in the breast, they usually do so near the lumpectomy site. The primary advantage of Breast Brachytherapy is that it takes only one week. In contrast, EBRT takes 5-7 weeks. In addition, cosmetic results are better with Breast Brachytherapy than EBRT since only part of the breast is irradiated. Good to excellent cosmetic results have been observed in over 90% of Breast Brachytherapy patients at 5 years. Breast Brachytherapy can be performed using a single Savi Brachy device or Multiple Interstitial Catheters.

Historical Development of Breast Cancer Treatment:

Over the years, there has been a gradual improvement in the treatment of early-stage breast cancer, allowing women to keep their breasts.

At the turn of the century, there was no known cure for breast cancer. Dr. Halstead first showed it could be cured with a dramatic new operation called the Halstead Radical Mastectomy. This surgery involved removing the entire breast, underlying pectoral muscles and lymph nodes in the adjacent arm pit. As horrible as this sounds today, it was a dramatic step in showing that breast cancer was potentially curable.

The first major modification occurred in the 1950s. The major pectoral muscle was left intact with the Modified Radical Mastectomy. Cure rates were later proven to be identical to the Halstead Radical, but with a dramatic improvement in cosmetics and a decrease in complications. There was decreased lymphedema (arm swelling) and improved arm mobility. The cosmetic improvement was the ability to wear lower cut blouses and short sleeves. This sounds like modest improvements today, but they were huge improvements then.

Plastic Surgical Reconstruction: The early 1960s saw the introduction of Plastic Surgical breast reconstruction. Cosmetics became a very important factor. Physicians became

increasingly aware of the horrible psychological impact mastectomy was having on their surviving patients.

Lumpectomy (Breast-Conserving Therapy): The mid-1960s saw an innovative Surgeon, Oliver Cope, and a Radiation Oncologist, Sam Hellman, invent a dramatic, new procedure. Accepting for the first time that radiation could cure small amounts of cancer, they combined "limited" surgery with breast radiation to preserve the breast. This procedure is affectionately now called "Lumpectomy" (variations are "quadrant resection," "wedge resection," "wide local excision," etc.) and Radiation. Again, long-term studies showed equivalent cure rates to the Modified Radical Mastectomy, but dramatically better acceptance by patients with improvement in psychological healing.

External Beam Radiation Therapy (EBRT): EBRT was and still is accomplished with a linear accelerator (high-energy x-ray machine). Treatments are given daily, as an outpatient, Monday through Friday. Each treatment takes 10 to 15 minutes. EBRT is given over 5-7 weeks.

Brachytherapy Boost Radiation: Brachytherapy was originally accomplished by surgically inserting a number of needles through the breast in the area where the original tumor had been removed and where there may be residual cancer cells. The tubes were then "loaded" with a radioactive material called iridium-192 (Ir-192). Iridium is rice-sized pellets imbedded in plastic tubes. This "ribbon" of Ir-192 was slid into the hollow needles, delivered radiation at a low dose rate. This allowed for the delivery of radiation to cancer cells that may have been left behind by the surgeon. High dose rate brachytherapy is a newer approach that has been gaining in popularity since the year 2000. With high dose rate brachytherapy, the radiation treatment is given over about 10 to 15 minutes twice each day over 5 consecutive business days.

Subsequent Therapeutic Changes:

Many variations to radiation therapy have occurred. The first variation was to drop the brachytherapy and accomplish "the boost" with a linear accelerator using smaller radiation fields or a type of radiation that is available on newer accelerators known as electrons. Electrons only treat distances up to a few inches. Electron beam radiotherapy is the most commonly used "boost" done today.

This entire EBRT process typically involves anywhere from 25-35 treatments over 5-7 weeks. That's a lot of visits to the radiation department.

In an attempt to shorten this long course of radiation, some surgeons and radiation therapists have begun to apply the previous "Needle" brachytherapy to the breast as the only radiation. This is called "Partial Breast Irradiation" and does not involve any EBRT. This can be done safely in patients with:

- *a small, invasive tumor*. Ideally, the tumor should be less than 3 cm on mammogram, but up to 5 cm in the lumpectomy specimen is acceptable ("pT1" or "pT2"). A lobular carcinoma may be treated if an MRI scan shows no other evidence of cancer in the breasts.
- *a small, noninvasive tumor* known as ductal carcinoma in situ.
- *no lymph node metastases.* Ideally, there should be no evidence of cancer in lymph nodes, but a single lymph node "micrometastasis" up to 2 mm is acceptable ("pN0" or "pN1mi").

- *negative lumpectomy margins* (at least 1 mm between the tumor and the edge of the lumpectomy specimen is considered a "negative" margin by the National Comprehensive Cancer Network) and *adequate spacing* (at least 5 mm) from the skin.

New Brachytherapy Device*:* Recently a new brachytherapy approach has been approved by the FDA and now accepted by all major insurance programs and Medicare. This new procedure is accomplished by having a plastic balloon-like catheter bulb inserted into the cavity created by the surgeon as he or she removes the cancer. The catheter is placed in the cavity within 6-8 weeks of the lumpectomy. It is "loaded" with iridium-192 in up to 7 channels to irradiate the adjacent breast tissue. The trade name for the catheter is *Savi*.

All Cancer Treatments are Potentially Dangerous: With any type of cancer treatment, there is a risk of complications, sometimes severe. We are therefore always exploring ways to modify and improve our treatment and reduce treatment where we can. Breast Brachytherapy using a Savi catheter or Multiple Interstitial Catheters appears to be a wonderful new way to decrease the amount of breast tissue that is irradiated in select patients.

Who is This Treatment for?
This treatment is not for everyone. It is only for women in whom the cancer is caught early.

It is also important to realize that *Breast Brachytherapy treats only a portion of the breast surrounding the site of tumor removal. The standard radiation treats the whole breast. There is no way that Brachytherapy will control the whole breast as well as whole breast radiation. However, with careful screening and patient selection, we feel that the overall cure rates should be comparable and acceptable.*

The primary advantage is the accelerated overall course of radiation: one week versus 5-7 weeks.

Important Note: It is important for all patients to realize that we have 30 plus years of experience with standard External Beam Radiation Therapy (EBRT). In patients with early-stage breast cancer, we have achieved a 93% to 97% cure rate (no evidence of disease at 12-15 years).

We do not have 12-15 years of follow-up with Brachytherapy alone. Only time will tell if Brachytherapy is as effective in curing patients as standard EBRT. Each patient who picks this procedure must understand this and be willing to accept a potential difference in cure rates.

Obviously, we believe this treatment will be very close to EBRT, or we would not morally be able to offer this treatment as an alternative. The Cancer Center of Irvine is comfortable offering this treatment. We however would request all our patients, allow us to gather data on them, to further the body of knowledge needed regarding its effectiveness.

Course of Therapy

Diagnosis: Most women are diagnosed by annual routine screening mammography or by feeling a mass. A mass may be discovered by Breast Self-Examination (BSE) or by a physician. Detection of a mass will lead to a Stereotactic (3-D guided) Biopsy.

Stereotactic Biopsies can be accomplished with a special mammographic machine or under ultrasound guidance. After a diagnosis of cancer is made, a patient is scheduled for appropriate consultations.

Pre-Operative Consultation with Dr. Tokita (Radiation Oncologists)*:* It is helpful for patients to have the opportunity to consult with Dr. Tokita prior to lumpectomy. From the mammogram and initial consultation, one can determine if Brachytherapy is an option. If the patient wishes to pursue this approach, Dr. Tokita will contact the referring surgeon. This will allow the surgeon to proceed in an orderly fashion, within the wishes and guidelines of the patients.

Surgery is then scheduled.

Lumpectomy: At surgery, the mass is removed (lumpectomy) with as wide a margin as needed to get clear (free of cancer) margins.

Sentinel Lymph Node Biopsy (SLNB): In the early to mid-1990s, Dr. Guiliano invented the 'Blue dye" Sentinel Lymph Node Biopsy (SLNB) procedure. It is now the standard procedure and involves injection of a blue dye (and now also a radioactive label) around the tumor before surgery to guide the surgeon to the set of nodes "draining" the cancer site. Its accuracy is superb and provides information to:

- cut down on the number of lymph nodes needing removal.
- decrease the incidence of lymphedema (postoperative arm swelling, which may never completely go away)
- decrease the pain post operatively.
- increase the accuracy of evaluating whether the cancer has spread to the lymph nodes.

So again, who is a candidate? The criteria for determining who is a candidate for Breast Brachytherapy have become broader over the years. In general,

- if the tumor is 5 cm or less in the lumpectomy specimen
- the margins are clear of cancer
- the cancer has not spread to the lymph nodes
- the patient does not want 5-7 weeks of radiation therapy

she is a candidate for Brachytherapy.

Catheter Implantation: The surgeon can prepare or "size" the lumpectomy cavity to accept the Savi catheter or Multiple Interstitial Catheters. Under direct visual exam, the surgeon can free up the surrounding tissue to allow for insertion of the catheter into the breast through a 1.5 cm incision in the skin. The lumpectomy site is closed and the end of the catheter sticks out of the breast by several inches. The end of the catheter can be secured against the breast using a sports bra.

For Multiple Interstitial Catheters, there is less of a need for re-exploring the previous surgical site. Needles are inserted through the lumpectomy site in a pre-planned pattern.

Dr. Tokita determine this pattern preoperatively. The patient is left with a series of plastic green tubes in the breast.

If the lumpectomy has already been performed, the catheters may be placed with a second surgery with the aid of ultrasound. This is up to the discretion of the surgeon.

Radiation: Postoperatively, the patients will go directly to the Cancer Center of Irvine, Radiation Therapy Department under the direction of Dr. Kenneth Tokita. In general, this appointment will be in the morning not long after catheter placement at the surgeon's office.

Examination*:* Dr. Tokita will examine the wound site and check the catheter.

- Drainage: One would expect a thin, pinkish to reddish drainage as long as the catheter is in place. Be aware that there should not be a lot of blood, pus or a foul odor.
- Bandages: The staff will teach the patient and family how to change the bandages.
- Symptoms: There should be no fever, chills, or sweats. There will be some discomfort at the surgical site and some tightness from the inflated balloon at the lumpectomy site.

Simulation and 3-D Conformational CT Scan*:* At the Cancer Center, a CT scan will be done of the chest without I.V. contrast. This will provide a detailed look at the catheter(s). The CT scan will be used to plan the Brachytherapy treatment plan.
Important parameters are:

- Tissue Conformance around the Balloon.
- Distance from the Balloon to the Skin (it should be at least 5 mm and preferably > 7 mm) and to the lung (preferably at least 10 mm).

Treatment Planning: The CT images will be electronically forwarded to the Eclipse treatment planning computers. From these images, an individualized treatment plan will be developed. The Physicist and Doctor perform this planning. A computer program will then provide the necessary information for the High Dose Rate After-Loader to accomplish the "prescribed" treatment.
This complex and time-intensive process will take from 3-5 combined hours of the Physicist and the Radiation Oncologist.

Radiation Machine*:* The machine used is called a High Dose Rate (HDR) Remote Afterloader. This is a computer-controlled Ir-192 applicator. It allows for the remote insertion of a very strong Ir-192 source into the Savi device or Multiple Interstitial Catheters. The Ir-192 will be allowed to "dwell" for several minutes at specific points in the catheter(s). This machine allows us to deliver the dose in 10 to 15 minutes each treatment for a total of 10 treatments, which with the older Low Dose Rate applications would involve a single treatment over 2 days.

Orange County: **The Cancer Center of Irvine was the first facility in Orange County to perform partial breast irradiation and has one of the largest experiences in the country. There are only 15-20 centers in the United States with this much partial breast irradiation experience using HDR Brachytherapy**. In general, the number of Brachytherapy procedures performed by a Radiation Oncologist is an important factor in determining the quality of the treatment.

Treatments: Radiation treatments are delivered at the Cancer Center by appointment.

Personnel:

Dr. Tokita will be directing the therapy at all times.
A CT Technologist will obtain the initial CT scan and establish a protocol for daily, pre-treatment, quality assurance CT scans.
A Radiation Therapist will deliver the HDR Brachytherapy.
A Radiation Physicist helps to determine the optimal treatment plan.

Frequency: Brachytherapy treatments will be delivered twice a day, separated by at least 6 hours, over 5 consecutive business days for a total of 10 treatments.

Transportation*:* Patient will feel fine, so she may drive herself to the treatments.

Pre-Procedure*:* Prior to each treatment, a CT scan of the breast will be taken to verify proper balloon inflation and position.

Examination: The bandages and drainage will be checked before each treatment. If necessary, the bandages will be changed.

Pre-Treatment Checks*:* Prior to the patient coming in, the Radiation Therapist, Physicist and Radiation Oncologist go through a stringent checklist of equipment, safety precautions, emergency procedures, and quality assurance on the planned treatment.

Treatment: The patient will then be taken to the HDR room.

- A 3-feet long "transfer tube" will be attached to the catheter(s), and the other end attached to the HDR Remote Afterloader.
- The room will be evacuated (the patient will be in constant contact with the staff by 2 remote, closed-circuit TV cameras and an intercom system).
  - We can always see the patient and hear her at all times and can respond in seconds.
- The computer controlling the HDR Remote Afterloader is at the outside control console and has been programmed by the Radiation Physicist and checked by the Radiation Therapist and Radiation Oncologist.
- A final checklist of steps is taken, and the treatment is started.
- The patient will first feel a slight motion in the catheter, as a test wire will go through the machine and transfer tube into the catheter. This checks for any obstruction to the wire to be sure that there aren't any tight turns.
- The test wire will retract and be followed by the actual treatment wire. It will be left in place for several minutes. The time will vary slightly from each treatment as the Ir-192 source continues to get weaker over a period of months.
- Post-treatment, the physicist or technologists confirm that the Ir-192 source has retracted into the HDR Afterloader.
- The transfer tube will be removed and the "cap" replaced.
- Patient can now go home and return in 6 hours or the next day for treatment.

Number of Treatments*:* Ten treatments will be given over five business days. This could be Monday through Friday or may be broken up by a weekend.

***Time in Department**:* The patient should anticipate being in the department from an hour to an hour and a half for each treatment.

Post Implantation Care:

- Wear a cotton support bra, even while sleeping for comfort and protection of the catheter.
- Maintain normal activity as tolerated.
- No heavy lifting with the arm on the treatment side.
- Oral pain medication such as Tylenol #3 or Vicodin may be taken as needed.
- Antibiotics should be taken to help prevent an infection.
- Occasionally, the breast will stay tender and painful for a day or so. Take pain medicine as prescribed by your surgeon. If none was given, call Dr. Tokita. Catheter manipulation prior to the treatment can sometimes be painful. Holding the breast while we work around you markedly decreases the pain.

Post- implant Education:

- There may be breast tenderness and occasional sharp pains. These gradually diminish over a period of months.
- A small amount of reddish drainage is expected.
- There is usually a mild breast swelling.
- There may be bruising from the surgery.
- Do not remove any of the caps on the catheter(s).
- Do not change the dressings until instructed by your surgeon or Dr. Tokita. Once instructed, one can change the dressings based on the amount of drainage.

Call us if: (phone numbers on last page of packet)

- There are signs of a breast infection:
  - The breast becomes increasingly warm, red, and swollen.

  The patient notices moderate to severe breast pain or a fever (above 100.5 °F).

Removal of the Savi Device or Multiple Interstitial Catheters: The catheter(s) will be removed shortly after the tenth treatment. There may be some pain. If the patient wishes, she can take Tylenol #3 or Vicodin 30 minutes before the last treatment.

Post Treatment Education:

There may be temporary side effects after treatment:

- Mild breast redness
- Possible infection
- Breast swelling
- Skin dryness. She can apply any personal choice of moisturizing creams.
- If the skin on the breast peels or becomes moist, the patient should call Dr. Tokita for an examination and instructions.
- Tiredness. This is very common after any treatment for an illness as serious as cancer and may be the normal let-down and "recharging of the patient's battery."

Follow-Up Visits:

The first follow-up visit will be one day after catheter removal. The next follow-up visit will be after about 2 weeks. The third visit will be after 1 month if there are specific problems that need checking. Otherwise, the third visit will be after 3 months. If the patient is being followed up by other physicians, for example, by a Medical Oncologist

who is monitoring her hormonal therapy, then she may subsequently be seen at the Cancer Center of Irvine on an annual basis. This schedule may be shared with your surgeon or medical oncologist, so as not to overburden the patient with appointments.

- ***Assessments:*** Checks will include:
  - Toxicity or side effects
  - Exit site evaluation
  - Cosmetic results
  - Possible cancer recurrence
  - Overall well-being

- ***Possible Complications:***
  - Infection (occurs in about 3% to 11% of patients. When an infection develops, it usually does so within the first month of treatment).
  - Seroma (a fluid-filled cavity develops in about 3% to 15% of patients)
  - Fat necrosis (breakdown of a small amount of fat in the breast usually does not cause symptoms and develops in about 11% of patients)
  - Fibrosis (scarring at the site of the lumpectomy and radiation develops in about 5% to 15% of patients)
  - Telangiectasia (the appearance of very tiny blood vessels in the skin at the radiation site develops in about one third of patients by 5 years)
  - Hyperpigmentation (darkening of the skin at the site of the radiation gradually diminishes over months)
  - Breast pain (occasional, sharp pains in the breast gradually diminish over months)

Device-Related Adverse Events

Breast edema (swelling)
Dry skin slough (desquamation)
Dry skin
Seroma (fluid-filled cavity)
Pruritis (itching)
Skin redness or discoloration
Induration (firmness)
Rash
Blister
Skin irritation
Eschar (scab formation)
Moist skin slough (desquamation)
Serosanguineous leak (red drainage)
Fibrocystic breast
Mastitis (inflammation of breast)
Ecchymosis (bruise)
Infection

Cosmetic Evaluation Results

Ninety-five percent to 99% of patients achieve good to excellent cosmetic results at 5 years. Using the "Harvard criteria," this means that there are only minimal but identifiable radiation effects in the treated breast. Fair to poor cosmetic results are uncommon. A fair cosmetic result means that there are significant radiation effects that are readily observable. A poor cosmetic result means that there are severe radiation effects.

Most Common Adverse Events

Erythema (redness of the skin)
Breast tenderness/pain
Catheter site drainage

Important Contacts and Phone Numbers*:*

During the week*:*

Dr. Kenneth M. Tokita	Office Phone	(949) 417-1100
Physicist: Albert Mesa	Office Phone	(949) 417-1100

Weekends or evenings*:*

Dr. Tokita	Home Phone	(949) 502-5445
	Cell Phone	(949) 677-5886