

# Cancer-busting balloon targets breast-tumor site

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When Terry Soffes had the second cancerous lump in her breast removed in December 2000, she wanted to avoid the traditional six-week course of external radiation.

Besides the hassle of daily trips to the hospital, she worried about long-term effects of radiation on tissue throughout her breast.

Seeking an alternative, Soffes enrolled in a trial at Mount Sinai Medical Center



testing the safety of a new device called MammoSite that allows doctors to irradiate only the tumor site.

MammoSite delivers targeted internal radiation through an inflatable balloon implanted in the breast — a twist on a technique called brachytherapy that has long

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**BALLOON DEVICE:** Dr. Martin Keisch, a radiation oncologist, holds MammoSite device. More health news, 3E.

# Cancer-busting balloon device can replace prolonged radiation

## ► BREAST CANCER, FROM 1E

been used in prostate cancer.

Since it delivers high-dose radiation from inside the breast to a single area, a full course of treatment takes just five days.

"There was nothing to it. It was just so easy," Soffes says. "You can run in, get it done, and run out."

MammoSite won approval from the Food and Drug Administration in May. At the time, Mount Sinai was the only hospital in Florida offering the treatment option. Since then, it has expanded to five Florida sites, including one at the Brachytherapy Institute of South Florida in Coral Gables. The University of Miami's Sylvester Cancer Center expects to begin offering MammoSite radiation in August.

Since the original study did not monitor the long-term success of MammoSite therapy, a larger trial has just begun that will track women receiving MammoSite radiation for five years. Mount Sinai is also participating in that study.

Dr. Martin Keisch, a radiation oncologist who headed the Mount Sinai portion of the original trial, says MammoSite promises to make it easier for some patients to keep their breasts intact following a breast cancer diagnosis.

"It's exciting. It really has changed the way we think about breast cancer," Keisch says.

## TREATMENT'S HISTORY

Currently, women whose breast tumors are small enough and caught early are offered lumpectomy — surgery that removes only the cancer — rather than the more disfiguring mastectomy that removes the entire breast.

Six weeks of external beam radiation that irradiates the entire breast follows.

But this process is arduous and often unrealistic for women who do not live near a

radiotherapy facility. Additionally, Keisch says, women worry about possible side-effects, such as scarring of the breast and the portion of the lung in the breast radiation field.

These worries cause a number of women to choose mastectomy over lumpectomy plus radiation, Keisch says.

Because around 95 percent of cancer recurrences are at the tumor's site, physicians adapted a technique, called brachytherapy, to deliver radiation solely to the tumor site. But it's used by only about 20 doctors nationwide in breast cancer treatment, Keisch says.

Brachytherapy involves implanting eight to 16 catheters, snaking through one side of the breast and out the other around the tumor site. The catheters must be placed evenly and the radiation "seed" must sit in a different place in each of the catheters to give the high dose of radiation to a precise location inside the breast.

## INFLATABLE BALLOON

Instead of the brachytherapy catheters, MammoSite uses one inflatable balloon placed precisely in the tumor's former site. Implantation takes about 10 minutes. The radiation goes into the catheter and is emitted through the balloon, that inflates to four to five centimeters.

"This is the same concept [as brachytherapy]. The only difference is that the balloon is easier to be placed and easier for the patient," says Cristiane Takita, a radiation oncologist at the UM School of Medicine.

"We get a lot of international patients who can't stay here for six weeks," Takita says. "If they are eligible for a short course of therapy, this might result in less mastectomy and more partial breast irradiation."

Keisch and Takita warn that MammoSite is designed only for a certain segment of breast

cancer patients, who are older than 45 and whose tumors are no more than 2 centimeters in diameter.

Keisch estimates that between 80,000 and 100,000 of the 240,000 breast cancers diagnosed each year are eligible for radiation treatment with MammoSite. Patients who think they might be eligible should discuss the options with their physicians.

## MAMMOSITE RESULTS

Keisch says none of the cancer patients who were part of the two-year MammoSite trial have had recurrences.

Patients who choose brachytherapy, he says, have a two to five percent cancer recurrence rate, roughly equivalent to the recurrence rate with traditional external radiation. But there have been no large-scale studies that randomly assign patients to groups to compare either brachytherapy or MammoSite radiation therapy with conventional external radiation.

As a result, the FDA required Proxima Therapeutics, the manufacturer of the MammoSite device, to include a warning that the "safety and effectiveness of MammoSite as a replacement for whole breast irradiation to treat breast cancer has not been established."

"This is not intended to scare people off, although it tends to have that effect," Keisch says. "It's intended to make it very clear that this an important point. It's clear to anybody using this what stage it's at."

Keisch thinks organizing a full-scale, random trial would be difficult. "Women are going to want one or the other to the point where study won't work well," he says. Keisch expects MammoSite to be received as an effective alternative.

But for Offes, receiving MammoSite radiation in that contained area was enough to make her feel comforted. "It just felt safer."