

Taken from The Wall Street Journal Online

HEALTH

New Treatment May Help Reduce The Number of Mastectomies

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DOW JONES NEWSWIRES

April 28, 2004

CHICAGO -- Melanie Reuler has had breast cancer twice and she has tried two methods of radiation treatment.

The first time, 10 years ago, she underwent six weeks of radiation. The treatment, delivered to her entire breast via an external beam, burned her skin and left her feeling tired.

When Ms. Reuler developed breast cancer again last year, she received a treatment called partial breast irradiation delivered through a catheter directly to the site where her tumor was, and spent only one week in therapy, going twice a day for about half-hour sessions.

"The emotional toll with full breast irradiation was much greater," said Ms. Reuler of Dallas. "I basically cried every day when I left there. That didn't happen at all this time. If you have to go through it, it wasn't such a bad experience."

Ms. Reuler, 51 years old, experienced less fatigue, no burning and just a tiny round mark on her breast. "You couldn't tell I'd had anything done to my breast. I feel great," she said.

Closely held Proxima Therapeutics is in the vanguard with this technology, and many doctors think the company's product could lead to a drop in the number of mastectomies, or surgical removal of the breast. Proxima's Mammosite device, approved by the Food and Drug Administration two years ago, has been used thousands of times, doctors say, and will be part of a 3,000-patient study to be funded by the National Cancer Institute this year comparing partial breast irradiation with whole breast irradiation.

"One of the most compelling arguments for partial breast irradiation is to reduce the number of mastectomies," said Tim Patrick, president and chief executive of Proxima Therapeutics.

He noted that many women with breast cancer who are told they need radiation treatment can't get it -- either because they live too far away from the treatment

center to go daily for the six or seven weeks required, or because their job keeps them from making that kind of time commitment. Sometimes, these women choose mastectomy over radiation. "It's sad," said Pamela Benitez, a breast surgeon at William Beaumont Hospital in Royal Oak, Mich., who has treated dozens of patients with the Mammosite method.

Others who reject radiation treatment because of logistics don't get a mastectomy or radiation, and stand a much higher risk of recurrence.

But with partial breast irradiation's one-week treatment course, women can get a hotel room, miss a week of work, get their treatment and be done.

"I do believe it will cut down on the number of mastectomies," said Dr. Benitez, who receives an honorarium from Proxima Therapeutics for teaching other doctors how to use Mammosite but has no other financial relationship with the company.

Partial breast irradiation is for patients who have had a lumpectomy -- or surgical removal of a tumor from the breast. After a lumpectomy, surgeons thread a catheter into the original tumor site. The catheter is inflated and a small dose of radiation is directed into the area using computer-controlled sensors. The traditional radiation treatment for breast cancer is to use an external beam to irradiate the entire breast.

Partial breast irradiation makes sense, said Richard Fine, former president of the American Society of Breast Surgeons and director of the Breast Center in Marietta, Ga., because 95% of the time when there is a recurrence of cancer, it occurs in the region of the lumpectomy. So there is no reason to treat the entire breast when just a small part is at risk.

By directing radiation right to the tumor site, Dr. Fine said, doctors can reduce the side effects of radiation, improve the cosmetic outcome and potentially reduce recurrence of cancer.

Eventually, Dr. Fine said, some form of partial breast irradiation will replace external beam radiation, or whole breast radiation. A course of treatment with Mammosite costs \$10,000 to \$15,000, roughly the same as treatment with external radiation, and it is covered by some private insurance companies and Medicare.

The American Society of Breast Surgeons keeps a registry of patients treated with partial breast irradiation, and says so far, none of the 1,100 or so patients on the registry has had a recurrence. Cosmetic results have been very good.

But the American Cancer Society wants to see longer-term data.

"There has been no real long-term randomized control trial," said Herman Kattlove, a medical editor with the American Cancer Society. "You want to look out several years before you say it's as good as standard treatment. On the other hand, it could be a benefit for women because it doesn't entail going [for treatment] every day for seven weeks. Hopefully it will turn out to be as good at preventing recurrence. We're waiting for the data. Until then, standard radiation is still the one that has the evidence behind it."

With standard radiation treatment, recurrence is between 5% and 10%.

About 270,000 American women develop breast cancer each year, and 40,000 die from it. Around half of breast-cancer patients receive a lumpectomy, and the majority of those patients receive radiation therapy.

Proxima Therapeutics has raised \$50 million in venture capital since its formation in 1996, and both **Boston Scientific** Corp. and **Johnson & Johnson** have made small investments in the company.

More than 400 facilities around the U.S., or about 20% of all facilities that provide radiation for breast-cancer patients, now offer Mammosite, Mr. Patrick said. More than 2,000 doctors are trained on the device.

The main competition for Mammosite -- besides that from traditional external beam radiation devices -- is from a new treatment that involves using an external beam to radiate a smaller portion of the breast.

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