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Danbury's TOPEX at forefront of X-ray technology

BY BOB CHUVALA



Anthony Pellegrino is committed to building a better X-ray machine.

Back around 1984, Pellegrino began assembling a group of Ph.D.s to help him design a next-generation mammography X-ray machine that was integrated, compact and used the latest in high-power electronics.

"We didn't invent it," Pellegrino said of the LORAD digital mammography unit that is world-famous in medical circles. "We just made a much more compact machine. We improved the technology and everybody else followed us. We became the world leader in mammography."

Pellegrino hopes to do something similar with his newest company and latest effort -- improving existing and antiquated X-ray radiation machines that treat certain types of skin cancers without the need for surgery.

Last month, the U.S. Food and Drug Administration approved the Danbury company's mobile, low energy, superficial radiotherapy treatment system Pellegrino has developed over the past several years and, within the next 35 days, the first TOPEX Inc. unit will operate at the Maimonides Medical Center in Brooklyn, N.Y.

What Pellegrino hopes to tap into is the medical market for treating skin cancer, the incidence of which is growing at an alarming rate.

During the 1930s, one in 1,500 people developed skin cancer. That rose to one in 600 in 1960, to one in 66 in 2000. Now, according to the National Cancer Institute, one out of every seven people is at risk for developing some form of skin cancer in his or her lifetime. Exposure to the sun without protection and a decreasing ozone layer are considered the chief causes of the increase.

Despite the increase, however, X-ray-treatment technology is stuck in the past.

The old technology consists of several large components that are bolted to walls or floors.

"What I did was compact everything and put it onto a mobile base, so there is no permanent installation," Pellegrino said. "It gives a lot of flexibility for placing the machine in existing facilities. You just roll it in the treatment room."

Proven cure rate

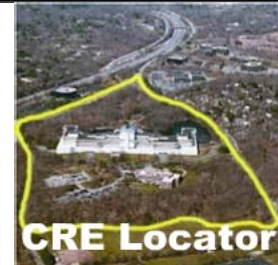
The unit also gives dermatologists and oncologists an alternative to surgery, especially when the skin cancer is on an eyelid or ear, Pellegrino said.

"That would be an ideal time to use this radiation treatment, because the cure rates are just about the same for surgery and radiation treatment," he said.

Despite its proven cure rate, radiation treatment is giving way to surgery, because "nobody has been making the machines for this application."

The older systems are between 30 and 50 years old, said John Brenna, president of TOPEX. He was president and chief operating officer of LORAD Corp. when Pellegrino was chief executive officer, bringing the company from \$65 million in revenues to \$125 million in about four years. He left when LORAD was sold to Hologic Inc. in 1999, and rejoined Pellegrino in 2003 at TOPEX "to get the company up and running."

The old superficial therapy units have successful cure rates, but they are labor and maintenance intensive and parts are getting harder to come by, Brenna said. There



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are thousands of them in use around the world that need replacing, "and we are looking to take this unit to nursing homes, where residents have a very high incidence of skin cancer."

It takes many years for skin cancer to develop and generally shows up in older people, he said. "Better than 50 percent of the population that has skin cancer is over 55," and all skin cancers are treatable if caught early, including melanoma, the most dangerous.

The TOPEX unit is designed to treat the less lethal basal cell and squamous cell cancers with superficial radiation therapy that eliminates the pain, swelling and sometimes poor cosmetic outcomes of surgery, Brenna said. "Eighty percent of all skin cancers are in the head and neck area, so it makes sense to use this type of therapy to treat them."

The radiation doses are concentrated in a small spot delivered from a counterbalanced arm similar to the arm on a dental machine, Pellegrino said. The radiation is given in a series of 10 treatments. "The malignant tissue does not recover as quickly as the healthy tissue, so the healthy tissue regenerates."

Establishing a market

"It's very hard to say how many units we're going to sell," Brenna said, "but in the United States alone, more than 1 million cases of skin cancer are diagnosed annually. Worldwide, it's 2.5 million to 3 million cases annually, especially in places like Australia and New Zealand," where the depleted ozone layer is more problematic.

Still, there's "not a huge market right now," Pellegrino said. "Part of what we're trying to do is redevelop the market in phases. The ready market is not very big right now, so we're trying to increase the market. We have to establish awareness of this procedure. Even mammography needed awareness development."

TOPEX's 10 employees are already assembling the X-ray units in a 3,000-square-foot facility about a half mile from LORAD's facilities.

"We design everything, send it out to outside contractors for fabrication, and that comes back here for assembly," Pellegrino said. "We've been making them in pilot-production mode for about a year."

As for the future, "it's hard to put a specific figure on growth," he said. "No matter what kind of plan you come up with, I can guarantee that's not the way it's going to work. It's a matter of what we run across in the future. Other opportunities will grow out of this and will spread to other applications we're working on."

"I think we'll have a sizable company, just as we did before, probably 50 or 100 people -- maybe even more -- in another few years."

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