

Ink-A-Dink-A-Don't!

One Radiation Therapist is Out to Correct Tattooing Procedures with Invention

BY KELLEY DEVEREAUX

James Matera, BS, RT(R), is in some ways an unlikely inventor.

His hair's not tousled like Albert Einstein's. He doesn't make a habit of falling asleep at his desk night after night like Thomas Edison. He didn't have to put up with public opposition to his ideas like Henry Ford. But like these and other famous inventors, Matera came up with an idea that no one else had before him and he had faith in its merit to change the way people work and live.

He discovered his idea through his career as a radiation therapist in Saint James, N.Y.

"I have been in the field for over 10 years—as a student, as a therapist, a chief therapist and as a supervisor/administrator. I began to recognize that at the many places I have worked, the procedure for tattooing was different everywhere I went and the reason is that there is not really any good device or tool out there made specifically for radiologic tattooing," Matera explained in a recent interview with *ADVANCE*.

That bothered Matera, a graduate of Nassau Community College in Garden City, N.Y. Not only are there no sterile devices for tattooing, there are also no regulated and sterile procedures for delivering the ink to the patient. "After researching, I decided to contact the Center for Devices and Radiologic Health (CDRH) and the Food and Drug Administration (FDA) about tattooing in the field of radiation oncology. I found out that it was never really regulated, nor is it regulated for the public, when people get tattoos on their own," he said. "It's just not an area that has a lot of requirements."

But that didn't stop Matera. In fact, it gave him more kindling for the flame of invention just beginning to fuel in his mind. "I wanted to raise it [radiologic tattooing] to a higher standard of quality—just because it's not a strictly regulated procedure doesn't mean you don't have to do it to the highest level of competency for the patient's sake," he said.

Tattoos in Radiation Therapy

For the unfamiliar, the idea of being tattooed may bring to mind images of a burly Harley Davidson motorcycle rider or a rebellious teenager on spring break away from home for the first time. Those are the kinds of people who get tattoos, right? Not always. In this case, the use of tattooing is a medical procedure used to

aid in the precise delivery of radiation treatments for cancer patients.

Tattooing is used in radiation therapy to deliver a consistent treatment to any particular area of the body over a long period of time (usually six to seven weeks). Ink is used to mark the exact area where treatment was delivered the first time, so that subsequent treatments can be given in the same spot. It is important to make sure the radiation is directed to the same precise location each time in order to ensure a greater rate of success. "That's the whole basis of giving radiation—to be precise every day," Matera said. Tattoos mark the area where the tumor lies beneath the skin to an extreme degree of accuracy and thus are an ideal method of marking, he said.

Usually, the tattoo is about the size of a freckle and can be fairly inconspicuous, especially if the color of the tattoo ink complements the patient's skin tone. In most cases, the tattoo is not recognized as such by anyone other than the patient and the radiation therapist. Unlike darker, larger marks from semi-permanent inks, which are sometimes used in place of a tattoo, the small and permanent nature of the tattoo allows the patient more privacy. It's small enough that no one would notice it, nor would they inquire about its presence on the body. Often, the tattoo blends in well with freckles, moles and other skin markings.

These tattoos, like any other, are permanent. But, they provide a helpful tool for both the patient as well as the provider. If the patient were to move to a new city or change treatment centers, for example, his or her new radiation therapist would know exactly where to deliver the

treatment because of the presence of the tattoo. Also, if the patient were to need treatment again several years after the initial round of therapy, there would be no question as to where the radiation was previously delivered on that patient's body. Tattoos also help physicians and radiation therapists to more quickly deliver emergency care, should it be necessary. "Permanent tattoo ink is better than using regular ink," Matera said. "You know it will always be there and it won't rub off or cause any confusion for the patient or the therapist."

Sterility Overlooked

With all these benefits of tattooing in radiation therapy, it's hard to imagine room for invention. But that's where Matera's 10 years of experience in the field came into play. He noticed a small but important overlooked detail that might not be obvious to someone outside the field. As a radiation therapy student, he had learned from day one the importance of maintaining a sterile environment and delivering sterile proce-

'I wanted to raise
[radiologic tattooing] to a
higher standard of
quality—just because it's
not a strictly regulated
procedure doesn't mean
you don't have to do it to
the highest level of
competency for the
patient's sake.'

—James Matera, RT(R)

dures to prevent any possible complications from contamination of any kind. But, because there is no standard procedure for radiologic tattooing across the board, methods of delivery vary from hospital to hospital and from state to state. Sometimes, the ink is not even stored in a specified and sterile environment, and in many cases, the ink is not made to be used on humans, Matera said. In the medical community, sterility is imperative. Matera thought radiologic tattooing should not be an exception to this ideal. "If I was the patient, I would like to think that everything being done to me was completely sterile," he said.

"It's no one's fault, it's just that there is no sterile device in widespread use for doing it," Matera said. "This is my way of improving the quality of care and raising it to a standard that is higher than what is recommended. I feel that if I am giving care to a patient, I am going to do the best I can. If there is a device that can allow me to do a sterile procedure that is not sterile at this point, I would want to use it."

Thus, the wheels of invention began to turn. While most people might stop there, never really giving the idea more than a passing thought, Matera took the discovery personally. It wasn't just something he was about to take for granted and let go. He started thinking about what could be done to ensure the proper ink was used and that it was sterile upon delivery.

From Idea to Reality

About five years ago, Matera started putting extra time in after work and on weekends researching a way to deliver sterile ink. Over the past year and a half, he really buckled down and, after much time and deliberation, came up with Steritatt—his name for the sterile, medical ink-delivering device. Made of plastic, individually sealed and sterile, Steritatt is shaped like a pen and filled with the appropriate tattoo ink. The radiation therapist would use the device to insert the needle, also contained in the pen-like tool, under the skin. In this way, the tattoo ink never comes in contact with the air. It goes directly from the Steritatt under the patient's skin, ensuring a safe and completely sterile delivery.

But, it was still just an idea. Matera knew he couldn't realistically market and manufacture the device on his own, and he'd need approval to do so anyway. He contacted the CRDH division of the FDA, which reviewed his product. In February, he was given approval to further market Steritatt and received an official owner/operator number and registration from the FDA.

"That's when things really started to get exciting," Matera said. "I'm just a radiation therapist like a lot of other people out there," he humbly admitted. "I just had an idea and I had a lot of people tell me that they thought it was a good idea, too, and that they would definitely be interested in using a device like this. I got a lot of support from the people I worked with."

Matera has even acquired a patent for his device and established Matera Technologies to allow for the manufacture of his idea. The road from idea to reality has not been without cost, however. Over the years, Matera has invested about \$20,000 of his own money in developing Steritatt. Things like patent lawyer fees, FDA clearance and manufacturing costs add up, not to mention the time he's put into it over the past five years. Most recently, he faced steep fees to develop a mold for the device, which he hopes eventually will be mass-produced.

"My intentions were not to spend any money at all. This is just something that we, as radiation therapists, need in order to improve the quality of care," he said. Unfortunately, medical device manufacturers Matera consulted in the early stages of development were not willing to front the money it took to get the product to where it is today. Now he's hoping they'll jump on board. "I've been talking with several manufacturers recently and I'm hoping that one of them will buy the idea and go with it," he said.

If all goes well, Matera hopes to begin production on Steritatt through a partnership with a medical company whose name he did not wish to disclose. He plans to introduce Steritatt to the market by this summer.

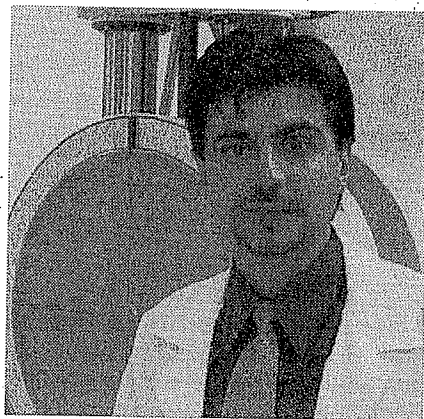
"If everything turns out, we should be at ASTRO [American Society of Therapeutic Radiation Oncologists] this year," he said. The device will likely come in boxes of 50 and will be available in three, four or five different colors of ink to match pigmentation. The idea is to use one Steritatt per patient per use and then to dispose of it, thereby maintaining sterility.

Besides the obvious monetary benefit of being an inventor, Matera has more altruistic aspirations, as well. "I just kept pursuing the idea because I really believed in it," he said. "Even to this day when I see tattooing being done, I just can't believe that no one has developed something for that procedure. You are introducing a needle under a patient's skin and as a patient I would hope that it is sterile. Unfortunately it is not necessarily done that way. This device would ensure that it is sterile. It could become a standard procedure, a standard device."

Matera already envisions his idea and his device becoming standard didactic protocol in radiation therapy classes across the country. It's an aspiration that might not be far from reality.

Matera said he would encourage all of his peers to believe in themselves as professionals and as potential inventors. "I came up with this idea because I have worked in radiation therapy for so long. When you're in the field day after day, things become obvious. We are the ones who know what needs to be changed or improved," he said. He encouraged his fellow radiation therapists to find the Einstein, Edison and Ford within themselves and just go for it.

For more information on Steritatt, contact James Matera at Steritatt@aol.com or write to him care of Matera Technologies, P.O. Box 2023, Saint James, N.Y. 11780. ■



James Matera, BS, RT(R) (photo/courtesy James Matera)

Tattoos and Hepatitis C

Getting a tattoo could be a key infection route for hepatitis C, according to research out of the University of Texas. See our Web site at www.advancedforRSP.com for details!

Kelley Devereaux is an assistant editor at ADVANCE. She can be reached at kdevereaux@merion.com.