

# The New York Times

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## A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

The initial accident report offered few details, except to say that an unidentified hospital had administered radiation overdoses to three patients during identical medical procedures.

It was not until many months later that the full import of what had happened in the hospital last year began to surface in urgent nationwide warnings, which advised doctors to be extra vigilant when using a particular device that delivers high-intensity, pinpoint radiation to vulnerable parts of the body.

Marci Faber was one of the three patients. She had gone to Evanston Hospital in Illinois seeking treatment for pain emanating from a nerve deep inside her head. Today, she is in a nursing home, nearly comatose, unable to speak, eat or walk, leaving her husband to care for their three young daughters.

Two other patients were overdosed before the hospital realized that the device, a linear accelerator, had inexplicably allowed radiation to spill outside a heavy metal cone attachment that was supposed to channel the beam to a specific spot in the brain. One month later, the same accident happened at another hospital.

The treatment Ms. Faber received, stereotactic radiosurgery, or SRS, is one of the fastest-growing radiation therapies, a technological innovation designed to target tiny tumors and other anomalies affecting the brain or spinal cord, while minimizing damage to surrounding tissue.

Because the radiation is so concentrated and intense, accuracy is especially important. Yet, according to records and interviews, the SRS unit at Evanston lacked certain safety features, including those that might have prevented radiation from leaking outside the cone.

The mistakes in Evanston involve linear accelerators — commonly used for standard radiation therapy — that were redesigned by the manufacturer, Varian Medical Systems, so they could also perform SRS. As the devices became more versatile and complex, problems arose when vital electronic components could not communicate with one another.

In the last five years, SRS systems made by Varian and its frequent German partner, Brainlab, have figured in scores of errors and overdoses, The New York Times has found. Some mistakes were caused by operator error. In Missouri, for example, 76 patients were overradiated because a medical physicist did not realize that the smaller radiation beam used in radiosurgery had to be calibrated differently than the larger beam used for more traditional radiation therapy.

Medical physicists say there is nothing inherently wrong with linear accelerators that deliver general radiation therapy, as well as SRS. And, they say, the overdoses might have been caught had users followed a more rigorous system of checks and double-checks.

“Tens of thousands of patients have been treated with protocols properly followed and no mistakes were made,” said Dr. Frank J. Bova, a medical physicist in Gainesville, Fla., and a pioneer in developing and enhancing the accuracy of SRS. “It has changed many difficult procedures, ones with high surgical risk, into one-day outpatient procedures.”

But radiation safety experts say the retrofitted devices made up of different companies’ products present a special challenge.

Dr. Howard I. Amols, chief of clinical physics at Memorial Sloan-Kettering Cancer Center in New York, said some problems appeared to be “a combination of user error, coupled with neither the manufacturers nor the F.D.A. being able to anticipate a potential safety flaw in a ‘mix and match’ treatment delivery system.”

Dr. William David Bloomer, chairman of radiation medicine at Evanston Hospital, said the mistakes happened even though medical personnel there had followed the manufacturer's instructions. "We rely on them to make sure the medical devices are safe," he said.

Varian, the world's leading manufacturer of linear accelerators, declined to be interviewed, but said in a statement that it has "deep concern" for accident victims and their families. "Our products include many built-in safety features, and we work continually to make them even safer," Varian said.

Brainlab denied any role in the accidents.

The accidents highlight shortcomings in the regulation of medical radiation.

Despite their complexity, the multipurpose devices are less regulated than their more simply designed competitor, the Gamma Knife, a device engineered specifically for stereotactic radiosurgery.

Linear accelerators, which generate radiation without using radioactive material, are overseen by the Food and Drug Administration, while the Gamma Knife is regulated by the Nuclear Regulatory Commission because it uses a radioactive isotope. The nuclear commission has more authority to investigate and publicize radiation errors.

The F.D.A. approved the retrofitted linear accelerators with little review on the grounds that they were mere extensions of existing technology.

But since there is no requirement that all mistakes involving linear accelerators be reported to a central database, getting a handle on how often SRS errors occur is difficult. "Everybody says these are isolated incidents," Dr. Bloomer said, "until you find out that maybe they are not so isolated."

### **Seeking Respite From Pain**

Before Marci Faber became a nursing home invalid at age 50, she had been leading a rich, full life. She loved musicals, country music and anything to do with her three daughters. When a mother was needed to oversee the sale of Girl Scout cookies, Ms. Faber was there.

"We go into a room and people really didn't care so much about me — Marci was definitely the person that people gravitated to," said Richard Faber, her husband. "She was gregarious, had a great smile. Her eyes light up the room."

Last March, Ms. Faber sought treatment for trigeminal neuralgia, a non-life-threatening condition that produces facial pain. While Ms. Faber's pain was intermittent, some cases become severe.

"It's unimaginably bad and can drive some people to suicide," said Dr. Daniel Yoshor, chief of neurosurgery at St. Luke's Episcopal Hospital in Houston. "It's an awful, awful thing and the cause of it is not very well understood."

What is known is that the pain emanates from the tiny trigeminal nerve at the base of the brain. And stereotactic radiosurgery is one of the most effective methods of eliminating the source of the pain.

But treating trigeminal neuralgia "is probably the most technically demanding" form of radiosurgery, said Dr. Bova. "You are literally giving doses that are very, very high," he said, "and the machine has to be able to deliver the dose to the trigeminal nerve and stay off the brain stem, which is immediately adjacent to it."

Standard radiation therapy can involve dozens of treatments at lower doses, so one incorrect treatment might not cause much damage. But with SRS, there is often just a single potent dose requiring scalpel-like accuracy.

"It requires a little different mindset than when you are actually saying, I will give a little dose today, a little dose tomorrow and I will check it later," Dr. Bova said. "This has to be checked the first time you do it because there is not a second day."

For years, the Gamma Knife provided the necessary power and accuracy to accomplish its goal.

But many institutions could not afford it; the device costs upwards of \$3 million and requires its own room, and treatments take longer. There is also the added difficulty of handling and replacing radioactive material.

"It doesn't pay to have a Gamma Knife unless you have a large number of patients," said Dr. Amols.

By using linear accelerators retrofitted with cone attachments, hospitals expanded their pool of patients without having to buy an extra unit.

Radiosurgery appeals to patients because it is an alternative to surgery and can be performed as an outpatient procedure, often in a single day. In recent years, the use of these small beam treatments has soared, as doctors have begun using them on parts of the body other than the brain and spine.

When Ms. Faber entered Evanston Hospital in March 2009, she had every reason to believe that her treatment would put an end to her pain. Indeed, when she left the hospital her trigeminal nerve was no longer an issue.

### **Little Problems Get Bigger**

At first, Ms. Faber had no reason to be especially concerned. After her procedure, she experienced some vomiting, burning in her throat, and even a little weight loss. Swatches of hair began to fall out.

Still, the Fabers did not connect any of this to her radiation treatment.

But weeks later, as the hospital was on the verge of overradiating a fourth radiosurgery patient, its medical physicist caught the problem. He fixed it, and the patient received the correct dose.

But the hospital temporarily shut down its stereotactic radiosurgery program and began to investigate. What it found was deeply disturbing: three patients, including Ms. Faber, had been overradiated around the same time. All the victims were notified.

Evanston Hospital declined to discuss specific cases on privacy grounds, but a brief report sent to the F.D.A. in 2009 said one patient had been hospitalized three weeks after treatment with an irregular heartbeat, weakness, and changes in mental status; another was hospitalized for four days because of nausea, vomiting and dehydration; and the third, apparently Ms. Faber, was said to have experienced hair loss.

But about a year after her treatment, Mr. Faber said, his wife began losing her balance, falling occasionally and having memory problems. “I was sick to my stomach — scared,” he said.

Jordan Kagan, a family friend, said that when Ms. Faber attended his daughter’s bat mitzvah in April, she was mentally coherent but physically diminished.

Then, in what seemed like a blink of an eye, she disintegrated. “Four weeks later, she was like a vegetable,” Mr. Kagan said. “It was mind-boggling to see one person who was not elderly deteriorate that quickly.”

Now, she can only blink her eyes and lightly squeeze her husband’s hand. “It is very hard on the kids,” Mr. Faber said. “It has been hard on me but really nothing compared to what Marci is going through.”

Doctors who deal with her type of radiation injury say the prognosis for any meaningful recovery is poor.

At the hospital, officials had been scrambling to figure out what went wrong. While the software that drives the linear accelerator is complex, the mechanics of how the overdoses occurred is strikingly simple.

Linear accelerators can be adapted to perform stereotactic radiosurgery in two ways: with small computer-controlled metal leaves that shape the beam, or with a cone attached to the machine’s opening through which radiation is delivered. That opening is made smaller or larger by moving four heavy metal “jaws” that shape the beam into a square. When a cone attachment is used, the square beam must fit entirely within the circumference of the cone. If the square is slightly larger than the cone, radiation will leak out through the four corners of the jaws and irradiate healthy tissue. In the Evanston accidents, records show, the beam was four times too large.

Operators could not see this incorrect setting directly because a metal tray on which the cone is mounted hides the jaws, though the settings should have been displayed on a computer screen, according to people who have worked with this device. The mount also blocks a light field that could have shown where the radiation was to hit the patient.

But while the mount blocks light, it does not block radiation, which in the case of Ms. Faber and other Evanston patients went into healthy brain cells.

Determining that the jaws had been set wrong was the easy part. Then the hospital had to figure out how and why.

### **A Failure to Communicate**

Precisely why the jaws were open so wide is still in dispute. There is no indication that the State of Illinois or the F.D.A. has investigated the accident. No lawsuits have been filed. And Varian has declined to answer questions.

But public records and interviews with doctors and others familiar with Varian's equipment point to a complicated matrix of computer systems and communication flaws that made such an accident more likely to happen.

That system is supposed to work this way: A treatment plan is developed on one computer, then transferred into another software system that, among other things, verifies that the treatment plan matches the doctor's prescription. The data is then sent to a third computer that controls the linear accelerator.

Several months after the Evanston accidents, Brainlab reminded customers to verify the correct jaw setting, specifically citing the possibility that treatment information could be altered as it passed "through a chain of devices."

Evanston Hospital had earlier encountered its own communication glitches after upgrading Varian software in December 2008. As a result, medical personnel had to load patient information onto a USB flash drive and walk it from one computer to another.

Then, three months ago, concerned that radiation might leak outside the cone, Varian warned customers that its software did not recognize cone attachments on the type of linear accelerator involved in the Evanston accidents.

To work around that problem hospitals needed to, as one medical physicist put it, essentially trick the machine into thinking it was using a different attachment, which it did recognize. To do that, users had to enter additional data into the SRS system.

Similar communication problems affected three other Varian brands of linear accelerators.

"If you weren't careful, you could give the wrong treatment," said Dr. Subhash C. Sharma, chief physicist at Parkview Comprehensive Cancer Center in Fort Wayne, Ind.

Last year, Varian promised to devise, among other things, a decidedly low-tech solution: a decal to stick on the machines, warning operators to be extra careful in setting the radiation field.

Dr. Bloomer, the radiation oncologist at Evanston Hospital, said the manufacturer had not answered the hospital's questions about why the overdoses occurred there. "We haven't gotten an adequate response," he said.

Dr. Amols, the Sloan Kettering physicist, said he believed several factors could have contributed to the accidents.

"Arguably, the physicist or radiation therapist should have noticed that there was a mismatch," Dr. Amols said, "and arguably there should be stricter laws regulating the 'mixing and matching' of complex medical equipment from different manufacturers. But at present there's no legal requirement for different companies to make equipment integration transparent to the end user — i.e., the hospitals."

After the accidents at Evanston, Brainlab and Varian this year released a software fix that will restrict the jaw size, so similar accidents will not occur, said David Brett, a Brainlab official. So far, 75 percent of the affected machines have incorporated the fix, the company said.

### **Dozens Are Overradiated**

While Evanston and its suppliers were dealing with the fallout of the overdose cases there, a different problem involving the retrofitted linear accelerators had been unfolding at CoxHealth, a hospital in Springfield, Mo.

Earlier this year, CoxHealth announced that it had overradiated 76 patients, most of whom had brain cancer, during SRS treatments. The overdoses had continued for five years because the hospital did not realize that its radiation therapy equipment had been set up incorrectly.

The hospital's medical physicist, who was apparently accustomed to calibrating larger radiation beams, did not realize that smaller beams needed to be handled differently, radiation experts say.

A hospital spokesman said the physicist used the wrong calibration tool to set up the machine, causing the overdoses.

"They were supposed to have switched over to a smaller detector," said Dr. Brad Bradshaw, a lawyer, who represents many of the overdosed patients. "The larger detector gave them a false reading."

Terri Anderson, 54, was overradiated at Cox last year while undergoing SRS treatment for a benign tumor. After her treatments, she began experiencing facial spasms. “I started having 12 to 14 of those a day,” Ms. Anderson said. She says she also developed balance and memory problems.

Dr. Bradshaw, who represents Ms. Anderson, said parts of her brain had received overdoses ranging from 25 percent to 100 percent.

A similar calibration problem involving a Brainlab and Varian unit was discovered in April 2007 at a hospital in Toulouse, France, where overdoses — smaller than those in Missouri — had occurred for a year, affecting 145 patients. These SRS treatments used tiny metal leaves to shape the beam.

“There were strong similarities between what happened in Missouri and what happened in Toulouse,” said Dr. Ola Holmberg, who heads the radiation protection unit for patients at the International Atomic Energy Agency.

But without a requirement that accidents and near-misses be reported, other hospitals cannot learn from these mistakes, Dr. Holmberg said.

“There is no effective way now of sharing the information or learning in a systematic way,” Dr. Holmberg said. “If something happens, such as Evanston, I would have wanted to know about it at the time.”

That point was echoed by Dr. Benjamin Movsas, chairman of the department of radiation oncology at Henry Ford Health System in Detroit. “I was not able to find any information about Evanston,” Dr. Movsas said. “It’s frustrating. We didn’t know there was a problem.”

Earlier this year, the American Society for Radiation Oncology called for the establishment of the nation’s first central database for the reporting of errors involving linear accelerators. So far that hasn’t happened.

“The system does need to change,” Dr. Movsas said. “Reporting needs to be transparent and mandatory.” He added: “We need regulations — that has to happen. It’s better for me and it’s better for my patients.”