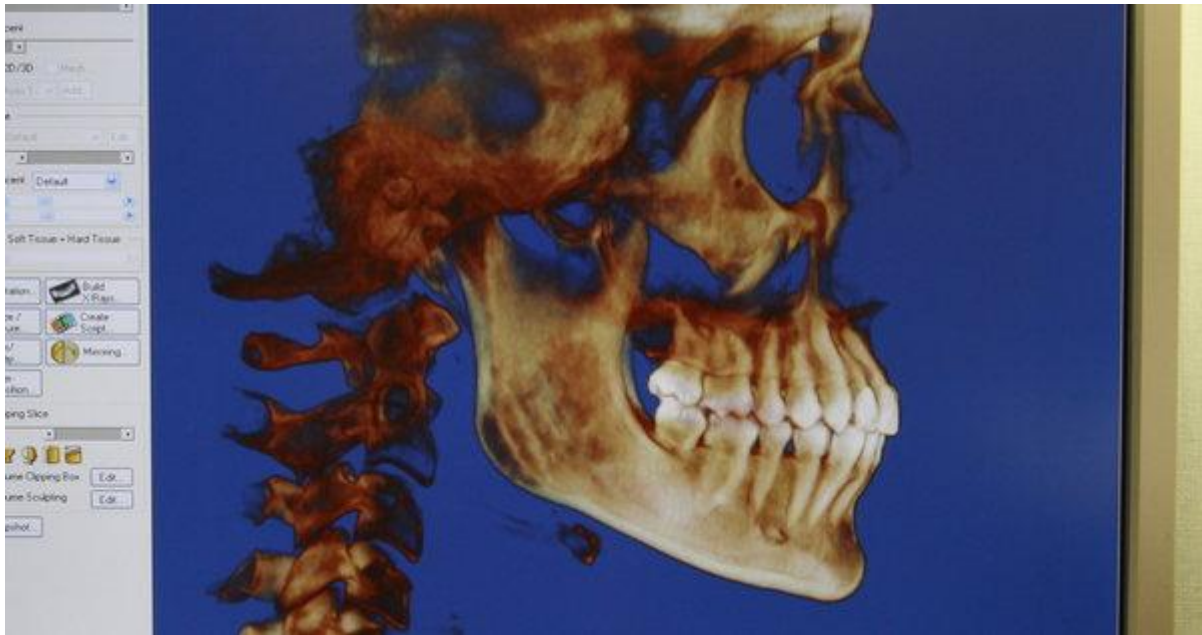


Radiation Worries for Children in Dentists' Chairs



An image from a cone-beam CT scanner used by dentists.

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Because children and adolescents are particularly vulnerable to radiation, doctors three years ago mounted a national campaign to protect them by reducing diagnostic radiation to only those levels seen as absolutely necessary.



Practices and Promotion Dr. Edward Y. Lin, at top, uses cone-beam scanners in Green Bay, Wis.

It is a message that has resonated in many clinics and [hospitals](#). Yet there is one busy place where it has not: the dental office.

Not only do most dentists continue to use outmoded [X-ray](#) film requiring higher amounts of radiation, but orthodontists and other specialists are embracing a new scanning device that emits significantly more radiation than conventional methods, an examination by The New York Times has found.

Designed for dental offices, the device, called a cone-beam CT scanner, provides brilliant 3-D images of teeth, roots, jaw and even skull. This technology, its promoters say, is a safe way for orthodontists and oral surgeons to work with more precision and to identify problems that otherwise might go unnoticed.

But there is little independent research to validate these claims. Instead, the cone beam's popularity has been fueled in part by misinformation about its safety and efficacy, some of it coming from dentists paid or sponsored by manufacturers to give speeches, seminars and continuing education classes, as well as by industry-sponsored magazines and conferences, according to records and dozens of interviews with dentists and researchers.

Last month, The Journal of the American Dental Association allowed one of the leading cone-beam manufacturers, [Imaging Sciences International](#), to underwrite an issue devoted entirely to cone-beam technology. That magazine, which the association sent to 150,000 dentists, included a favorable article by an author who has equated a cone-beam CT with an airport scan. In fact, a cone beam can produce hundreds of times more radiation, experts say.

Cone-beam CT scans can help dentists deal with complex cases involving implants, impacted teeth and other serious problems. But many experts in dental radiation have raised alarms about what they see as their indiscriminate use. They worry that with few guidelines or regulations, well-meaning orthodontists and other specialists are turning to a new technology they do not fully understand, putting patients at risk, particularly younger ones.

Some orthodontists now use cone-beam CT scans to screen all patients, even though a number of dental groups in this country and in Europe have questioned whether the benefit of routine use justifies the added risk.

“All these different cone-beam CT scanners came out to a world that was unprepared,” said Keith Horner, a professor of oral radiology at the University of Manchester in Britain, who is coordinating a study of cone-beam scanners for the [European Commission](#). “They are just pushed out there by manufacturers with the message that a 3-D image is always going to be better than a 2-D image, and that isn't the case.”

One popular new brand of braces has helped cone-beam sales because it requires 3-D images, which doctors can obtain using either a cone-beam scanner with radiation, or a digital camera without it. Many orthodontists opt for radiation, because it is quicker.

Even those troubled by the widening use of cone-beam technology acknowledge that by itself, the risk from a single scan is relatively small. But patients often get more than one scan, and the lifetime risk increases with each exposure. Without a clear benefit, they say, there is only risk.

“So let me ask a question to the mother of a prospective orthodontic patient,” said Dr. Stuart C. White, former chairman of oral radiology at the [UCLA School of Dentistry](#). “Would you like me to use a tool that is entirely safe — a camera — to record the position of your child’s teeth, or another method that may rarely cause [cancer](#) so that we can save time?”

The cone-beam business is lucrative for manufacturers and dentists. According to one industry estimate, more than 3,000 scanners and about 30 different models have been sold, at prices up to \$250,000.

Dentists, some of whom charge several hundred dollars per scan, can profit by owning their own machines. “More profit per unit chair time,” promises Imaging Sciences, the cone-beam manufacturer.

Marketers increase interest in the technology by holding drawings for free cone-beam CT scanners and other gifts. A Washington State orthodontist, who gave an online lecture sponsored by Imaging Sciences, offers dentists coupons for free scans for their patients as a way to build referrals.

And then there is the “wow” factor, said Dr. Terry Sellke, an orthodontist in Illinois.

“Kids love to see that 3-D image,” Dr. Sellke said in a Webcast sponsored by Imaging Sciences. “They can go into our computer and look at their skull.” Another orthodontist talked about coloring 3-D skulls in green and purple. “Fun for the kids,” he said.

Dr. Allan G. Farman, president of the [American Academy of Oral and Maxillofacial Radiology](#), cautions doctors not to become overly enamored of the new technology, citing the example of how shoe stores once took X-rays of customers’ feet to see if shoes fit.

“At least the shoe merchants were ignorant of the effects of radiation,” Dr. Farman said.

Regulators are just now recognizing how ill equipped they are to oversee this new technology. “There is not a lot of radiation exposure data out there,” said Jerry Hensley, a state radiation protection official in California.

While protocols and guidelines exist for other types of imaging, Mr. Hensley said, “cone beams are off in their own land right now.”

‘A Lack of Understanding’

Even before cone-beam scanners, the dental profession had problems keeping radiation levels low.

For years, dentists have been advised to stop using slow, D-speed film for X-rays because it requires more radiation than faster film. Yet, most still use the slower film, which requires up to 60 percent more radiation, according to dental experts and government records.

Brian Smith, a spokesman for Carestream Dental, the market leader in dental film, said 70 percent of its film sales in the United States are D-speed. The percentage is lower globally, suggesting that dentists elsewhere do a better job of reducing radiation.

There is no excuse for not switching, the [Food and Drug Administration](#) said, because faster films offer the same quality for only pennies more.

Dr. John B. Ludlow, a [University of North Carolina](#) professor who has published widely quoted studies on dental radiation, said he suspects that some dentists avoid faster film because they mistakenly believe it is harder to process.

A check of state dental boards found none that were aggressively pressing dentists to use the faster film. Digital X-rays use even less radiation than film, but a minority of dentists use them.

One expert in dental radiation, Dr. Joel E. Gray, said he has found as much as a 500 percent difference in radiation levels because of sloppiness in developing film, including using chemicals that were degraded or at the wrong temperature. To get clearer images, dentists compensate by increasing exposure time — and radiation, said Dr. Gray, whose company, [Diquad](#), has contracts with three states, including California, to try to keep dental radiation in check.

New Jersey, which collects data on radiation exposure, found that 20 percent of its dental offices had high or “extremely high” radiation levels.

“There is a lack of understanding of the radiation in dental offices,” Dr. Gray said.

That has become even more important with the emergence of cone-beam CT scanners. When first introduced in the United States about a decade ago, they were viewed mostly

as a cheaper, lower-radiation alternative to big, medical CT scanners that were often needed to diagnose serious ailments of the mouth and face.

But through aggressive marketing and technological improvements over the last several years, their use has rapidly expanded into other areas, including orthodontics. For many teenagers, getting scanned is now part of the ritual of getting braces.

“The parents of these children,” said Dr. Nicholas Dello Russo, a Boston periodontist who teaches at [Harvard](#) Dental School, “have no idea about the amount of radiation used in these CT scans, and even more frightening, neither do the dentists.”

Quick and Easy

In October, 26,000 people gathered in Orlando, Fla., for the annual conference of the American Dental Association.

The presence of cone-beam CT scanners could be seen and heard at every turn. There was the 3-D imaging center, cone-beam exhibits, demonstrations and continuing education lectures.

An open forum on cone-beam imaging was co-moderated by Dr. Michael Glick, editor of the Journal of the American Dental Association. Of the four panelists, one was a founder of Imaging Sciences, another was a consultant to the company’s distributor and a third was a paid speaker for another cone-beam company.

Cone-beam scanners are quick, easy to use, versatile and do not require much space. In most models, the patient sits in a chair for less than a minute while a small scanner circles the head. Enthusiasm for the technology is echoed by dentists around the country.

Dr. Steven A. Guttenberg of Washington said he uses the scanner “for every single implant that I do.” Dr. Rik Vanooteghem of Sunnyvale, Calif., added: “I really feel blindfolded if I don’t use it.”

Dr. Bradford Edgren of Greeley, Colo., said his scanner had found hidden teeth — among other things. “I found a rock in one child’s ear,” Dr. Edgren said. “Now she can hear and her grades have gone up.”

A California lawyer, Arthur W. Curley, suggested that dentists might even face legal liability for not using 3-D imaging. “Negligence may be the failure to incorporate new technologies that meet well-defined legal standards,” Mr. Curley said in a Web presentation.

Mr. Curley, along with Drs. Vanooteghem, Guttenberg and Edgren, share more than their enthusiasm. They have all received speaking fees from Imaging Sciences.

At the A.D.A.'s conference last month, six manufacturers spent nearly \$290,000 to promote 3-D technology. And the A.D.A. said it had accepted somewhere under \$100,000 from Imaging Sciences and its sister company — a specific figure was not given — from Imaging Sciences for the cone-beam supplement that came out around the time of the conference.

The company's i-CAT scanner is one of the most popular on the market.

"I use my i-CAT for everything," one orthodontist, Dr. Edward Y. Lin, proclaimed in a full-page advertisement in one magazine.

"I cringe every time I see that ad," said Dr. Farman, the radiology academy president and a professor at the [University of Louisville](#) School of Dentistry. He calls the i-CAT an excellent device, but said there is not yet proof that it is better and safer than conventional imaging in all applications.

This month, the academy and the American Association of Endodontists issued a joint statement saying that cone-beam CT "must not" be used "for screening purposes in the absence of clinical signs and symptoms."

Another cone-beam manufacturer, Sirona Dental Systems, has promoted its devices as better for detecting [cavities](#) than conventional methods, according to Professor Horner, the European Commission study group leader. But Professor Horner and dental experts in the United States say that claim is unproven. A spokesman for Sirona, John Sweeney, said his company's reference to cavities appeared in an article several years old and was at the time the best information available.

Dr. Lee W. Graber, president of the American Association of Orthodontists, praises the technology and said dentists have worked to reduce radiation over the years. In his suburban Chicago practice, Dr. Graber has a machine capable of delivering both cone-beam scans and conventional images, but only uses the higher radiation method when necessary. "Our goal as clinicians is to try to minimize the risk," he said.

Vatech America, a cone-beam manufacturer, does not support using its scanner as a screening device, said Travis Harrison, the company's director of business development. "We don't want to just dose everyone with a CT," he said.

Imaging Sciences, a unit of the Danaher Corporation, a diversified manufacturing and technology company, declined repeated requests for interviews, saying it granted such requests only to trade publications, according to Dan Gagnier, a company spokesman.

In a statement, the company said cone-beam scans give dentists “the ability to view patient anatomy more accurately” than conventional 2-D X-rays, making it easier to avoid nerves, avoid placing implants in bones that will not support them and improve orthodontic care — all at radiation levels below “a number of competing technologies.”

Weighing the Risks

On Nov. 10, more than 100 members of the Greater Philadelphia Society of Orthodontists met in the august, dark-paneled rooms of the Union League of Philadelphia.

They had come to hear Dr. James Mah, described by the society as one of the world’s foremost experts on 3-D technology, and to earn six continuing education credits. Dr. Mah, an associate clinical professor at [University of Southern California](#) and the [University of Nevada](#), Las Vegas, “has made over 100 presentations nationally and internationally,” according to his biography from a recent conference.

When a Times reporter showed up for the lecture, a representative of the society welcomed the coverage. But after the representative said he needed to consult a “vendor representative,” society officials reversed course. Because actual cases were to be discussed, the officials said, the reporter’s presence would violate federal patient privacy laws. Dr. Mah declined to be interviewed, and the reporter was escorted off the premises by security personnel.

Dr. Mah’s views on cone-beam technology are hardly a secret. In an online lecture this year sponsored by Imaging Sciences, he proclaimed, “In orthodontics, we image every patient.”

In that lecture — “Why Dentists Can’t Wait for Cone-Beam CT” — he played down health concerns, saying a cone-beam scan produces no more radiation than a whole-body scan at the airport.

Equating a cone-beam scan with an airport scan is “very wrong — by a lot,” said Dr. David Brenner, who directs the Center for Radiological Research at [Columbia University Medical Center](#). In fact, cone-beam scanners can be several hundred times as powerful, he said.

Yet in the special issue of the A.D.A. Journal underwritten by Imaging Sciences, Dr. Mah was the lead author on an article challenging the orthodontic association's position that a cone-beam scan "is not routinely required for orthodontic [radiography](#)."

Dr. Glick, the editor of the A.D.A. Journal, said that as long as authors can back up what they say with science, then he has no problem. "If they cannot back that up, then that's a different story," Dr. Glick said. He added that Dr. Mah's article was peer reviewed.

Critics say aggressive marketing has produced a distorted picture of the safety and efficacy of cone-beam scanners.

Writing in the International Journal of Oral and Maxillofacial Surgery last year, researchers concluded that the device's popularity "has resulted in numerous presentations at conferences, dozens of manufacturers' brochures and published papers resulting in an uncontrolled and non-evidence-based exchange of radiation dose values."

Some proponents of cone-beam scans say the radiation risk is no greater than what someone would experience flying cross-country or spending several days in the sun. They also minimize the risk by comparing radiation levels to imaging procedures not typically used in orthodontic care, such as medical CT scans done in hospitals and clinics.

"I don't like that comparison with how many days of daylight; I don't like that at all," said Dr. Christos Angelopoulos, the director of the division of oral and maxillofacial radiography at Columbia University College of Dental Medicine. "People still use it very frequently. That really in a way gives the feeling to the patient that it is not risky at all, whereas that's wrong."

Dr. Angelopoulos said radiation levels can vary greatly, depending on the scanner, its settings and scan time. "The numbers are all over the place," he said.

A report in the British Journal of Radiology last year concluded that cone-beam CT scans produced "significantly higher" levels of radiation than conventional dental imaging. The standard orthodontic scan for the i-CAT produces five times as much radiation as a 2-D panoramic scan, said Dr. Ludlow, the North Carolina radiation researcher. Depending upon the model and setting, other scanners produce 4 to 67 times as much as conventional X-rays, he added.

Whatever the radiation levels from a particular cone-beam scan, the risk is small, said Dr. Brenner, the Columbia University radiation researcher. But it is only worth taking, he said, if there is demonstrable benefit, particularly for young patients who are "typically 5 to 10 times more sensitive than adults."

Dr. Brenner said that a child faces up to a 1-in-10,000 chance of developing cancer from a single cone-beam scan. Yet orthodontic patients frequently get more than one scan during treatment and face a lifetime of additional X-rays, all of which scientists believe are cumulative. “You double the dose, you double the risk,” Dr. Brenner said.

And, Dr. Ludlow said, there is not yet scientific data to prove that the 3-D technology, sometimes known as volumetric imaging, produces better results.

“Until we have that data, and it’s going to take time, we just need to use common sense, good judgment,” he said. “And part of that good judgment is recognizing that the youngest are more sensitive to radiation than adults, and do we really — for an uncomplicated orthodontic case, where we are just going to move some teeth a little bit — do we really need volumetric imaging?”

The after-school rush was about to begin, and Dr. Edward Y. Lin used a final moment of calm on a recent day to show a visitor the 3-D images of a former patient’s teeth and bone structure. “So we put her braces on right here — it was April 27, 2007,” he said. “And there’s the finished smile.”

It was a complicated case involving implants, Dr. Lin said, but with 3-D technology and a computer-assisted method of attaching braces, he was able to do the job better and many months faster.

Dr. Lin and his partners run a popular orthodontic practice in and around Green Bay, Wis. A visit there illustrates some of the factors involved in deciding whether to use cone beam and how it fits into the economics of a practice.

For several years, Dr. Lin has been using technology called SureSmile where a robot, guided by 3-D images, bends wires that move the teeth into desired positions. The technology is able to mold metal wires to a patient’s teeth with great precision.

The 3-D image can be taken with either a tiny camera, which uses light, not radiation, or a cone-beam scanner.

The nonradiation method is “really no different than taking a series of still pictures like you would with a digital camera,” said Dan De Silva, vice president of marketing for OraMetrix, the Texas company that owns SureSmile. From those pictures, computers create a 3-D image.

A cone-beam scanner is quicker, and he says that about a third of his customers either own or have access to one.

Dr. Lin estimates that all of his roughly 800 SureSmile patients received cone-beam scans, some as many as four scans. Dr. Lin said he uses several techniques to keep the radiation as low as possible.

Dr. Lin said he started using the nonradiation method, but found that it took a half-hour or more to complete and could be uncomfortable for the patient. He says his i-CAT scanner takes only seconds, offers a better view of roots and often detects hidden problems that might complicate treatment. “It’s not the exception,” he said. “It happens on a routine basis.”

One of Dr. Lin’s satisfied patients is Tomek Miaskowski, 18, who just had his braces removed. “Today was probably the greatest day of my teenage life,” the patient said.

Mr. Miaskowski said he got two cone-beam scans. Radiation was not an issue for him. “I trust the doctor— that’s what you have to do,” he said.

Shorter treatment time makes the patients, their parents and the orthodontist happy. “We now attribute a significant portion of our revenue to the frequent use of our cone-beam machine for diagnostics, records and our SureSmile scans,” Dr. Lin said in a 2009 article he wrote for a dental publication.

In the article, Dr. Lin broke down the economics of his scanner, which cost about \$200,000. “We calculated the value of each clinical minute at our practice at approximately \$5,” he wrote, and using the cone beam instead of the camera cut each appointment by at least 30 minutes. “That’s \$150 in savings,” he wrote. “For 1,000 possible new appointments for braces yearly, that’s \$150,000 in savings.”

Using the cone-beam scanner, Dr. Lin wrote, he treats the same number of patients “in a three-day clinical week that we used to in a four-day week, which reduces our staff requirements.”

Little Regulation

Cone-beam CT scanners, like most radiological devices in medicine, are lightly regulated.

“Some states have in effect no inspections of dental X-ray units,” said Dr. G. Donald Frey, professor of radiology at the Medical University of South Carolina and a past president of the American Association of Physicists in Medicine. While inspectors generally evaluate machine performance, few attempt to measure the overall radiation risk to the patient’s organs.

“States tend not to want to regulate the practice of medicine or dentistry,” Dr. Frey said.

Most states require dentists to earn continuing education credits for re-licensure, but for the most part do not assess the content of the courses, trusting dentists to select and complete suitable courses.

The quality of these courses varies widely, The Times has found.

Dentists, for example, can earn two continuing education credits by reading about cone-beam technology in a new magazine, *Orthodontic Practice — US*, and then answering 10 simple questions appended to the end.

The article's author is Dr. Lin, who said he has been a paid lecturer for Imaging Sciences for three years. He said the company did not pay him to write the article or to appear in its full-page advertisement in the same issue.

Dr. Lin said he speaks on behalf of the company because he believes the i-CAT is the best machine around.

Imaging Sciences has benefited from other favorable coverage by the magazine's publisher, MedMark of Scottsdale, Ariz. A recent issue of MedMark's "*Implant Practice — US*" included continuing education articles and a corporate profile of Imaging Sciences, titled "A company of innovation, quality and service."

The article's praise was hardly surprising. According to the publisher, Imaging Sciences wrote it.