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COVER
FEATURE

Laser-assisted cataract surgery **Balancing on the ethical edge with femtosecond cataract surgery**

by **Maxine Lipner** Senior EyeWorld Contributing Editor

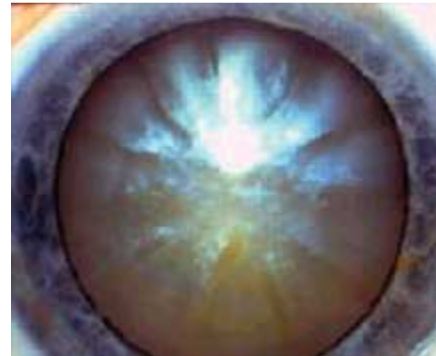
How to take the moral high-ground with the technology



It has become an ethical quagmire—what to do about the femtosecond laser for cataract surgery. While the femtosecond laser has wound its way into the cataract arena, a host of ethical issues abound, according to John D. Banja, Ph.D., professor in the Department of Rehabilitation Medicine and a medical ethicist, Center of Ethics, Emory University, Atlanta. Practitioners must of course abide by the Hippocratic Oath and "do no harm," but what ethical obligations do practitioners have when implementing a new technology such as the femtosecond laser for cataract surgery? "I think that the primary obligation is that one needs to act the way that a reasonable and prudent doctor is going to act with regard to this clinical situation," Dr. Banja said. One of the key ethical issues currently is the comparative benefit between the femtosecond laser approach and traditional cataract surgery. "Clearly, if we find out that the outcomes with the femtosecond are much better than they are with existing technologies, that's going to start to make a very strong case for implementing the femtosecond standard-of-care," Dr. Banja said. "The tricky part is determining how much better than the competition the femtosecond must be to persuade physicians to adopt it as the standard-of-care and to persuade Medicare to cover it."

Ethical dilemmas

Richard S. Hoffman, M.D., clinical associate professor of ophthalmology,



Dicing up a rock-hard cataract—such as the one pictured above—with the femtosecond laser may seem like an ethical no-brainer, but with softer cataracts weighing the cost, the advantages of the technology become more blurred

Source: Richard S. Hoffman, M.D.

AT A GLANCE

- Femtosecond technology for cataract surgery poses several ethical problems for practitioners
- Practitioners must weigh whether increased cost translates into increased benefit for patients when urging femtosecond use for cataract removal
- The ethics of up-charging for premium IOLs or PCRIIs to offset cost may in some cases be questionable
- When marketing femtosecond cataract surgery, it's important that practitioners resist the hype and not overstate the data

Oregon Health and Science

University, Portland, sees several femtosecond-related ethical dilemmas. "You've got a technology that's going to increase the cost of a procedure and you've got to look at whether the increased cost translates into an increased benefit," Dr.

Hoffman said. "For instance, when we went from radial keratotomy [RK] to photorefractive keratectomy there was an increased cost, but the benefit of that new technology made it worthwhile—in fact it was almost negligent, unethical, to perform RK when you had this other technology." Currently companies are trying to demonstrate a benefit for using the femtosecond technology for cataract surgery. However, it's also important to consider whether any increased benefit is worth substantial additional cost, Dr. Hoffman stressed.

He sees the ethical weight here as unfortunately falling on the surgeon's shoulders. "The companies are not really concerned about the ethical issues—they're concerned about the bottom line," Dr. Hoffman said. "I'd like to think that most surgeons are concerned about the ethical issues and the patient first, but when you've invested \$500,000, all of a sudden you're under a lot of financial stress to pay for that thing and then the goal boundaries get blurred and crossed."

The surgeon either needs to absorb that cost or pass it on to the patient. It is with some of the options for bypassing the problem that the real ethical dilemmas are arising. "Companies are saying that you can up-charge your premium IOL patients because that's something that is outside of Medicare," Dr. Hoffman said. The question, however, becomes: Is that ethical? "They're showing that there might be a slight improvement in effective lens position consistency if you have a perfect capsulorhexis," Dr. Hoffman said. But even if this is enough justification to use the femtosecond, the financial pool is limited. "Right now, the premium IOL channel only covers 7-10% of Medicare patients or patients that we're doing in general," Dr. Hoffman said.

There's also the possibility of using the femtosecond laser to perform peripheral corneal relaxing incisions (PCRIs) because this is not a Medicare-covered benefit. "Again, you have to ask the question that has not been answered yet: Is performing PCRIs with a femtosecond laser that much more accurate than doing it manually?" Dr. Hoffman said. "Can you justify passing those significant charges on to your patient to have a femtosecond laser [peripheral corneal] relaxing incision rather than a manual one done with a diamond knife?"

Dr. Hoffman worries that some surgeons may begin blurring the lines of who really needs PCRIs to offset financial woes. "Some surgeons may, under financial stress, be pushing the envelope of who gets a limbal relaxing incision," he said. "Ordinarily we might not do a PCRI on someone who has a diopter or less of astigmatism, but if you're under stress to pay for this laser, you might start offering that to patients who you might not ordinarily offer it to if you were not 100% ethical, in my mind."

Kevin M. Miller M.D., Kolokotronis Professor of Clinical Ophthalmology, Jules Stein Eye Institute, David Geffen School of Medicine, University of California, Los Angeles, pointed out the importance of being up front with patients about charges. While practitioners can't legally charge more to remove a cataract using a laser, any refractive work done, such as a PCRI, is fair game. "It should be disclosed to patients who have a femtosecond laser-based cataract operation that they're getting the cataract portion basically for free, but being charged for the refractive

portion," Dr. Miller said. "None of the companies have 510(k) approval to perform astigmatic keratotomy at this time, but several have approval to make peripheral corneal incisions. So companies can say, 'PCRIs are an off-label use of the laser.'" Ophthalmologists can tell their patients that off-label use is common in clinical practice.

Dr. Miller is also concerned that practitioners may overstep on what they tell patients about femtosecond cataract surgery. "I worry that practitioners might say to their patients they will get a better result with a laser and, if they want the better result, they will have to pay for it," he said. "But there won't be any data to support that it produces better outcomes other than it makes a rounder CC, which probably doesn't mean anything."

He stressed that practitioners may find themselves in hot water when it comes to Medicare fraud if they tread over that ethical line. "What you hear at the meetings right now, especially from some of the frontrunners, is, 'Patients will pay more for laser-based cataract surgery when you tell them the benefits—it's a win-win,'" he said. "It's a win except that it's illegal—it's Medicare fraud if you participate in the Medicare program."

Questionable marketing

From a marketing perspective, Dr. Banja likewise stressed that it's important not to overstate what the data has shown. "You must resist the hype," he said. "Hype is a very real temptation because obviously the manufacturer has a financial interest, and possibly the researchers who developed this technology have a financial interest and may also have a self-esteem issue—this is their baby and it's easy for them to become so enamored with what they have produced."

When marketing this new approach, Dr. Hoffman urged practitioners to stick to the facts. "I think the way that physicians can remain safe about this is to market it as laser cataract surgery," he said. "I think that if surgeons advertise that they have this technology, once in the room, they can explain to a patient, 'This has some potential benefits, although in your case there may not be much of a difference.'"

Advertising that you have a technology that's superior, however, is pushing the ethical boundary, Dr. Hoffman thinks. Some practitioners may consider taking the gamble. "What's pushing a lot of this technology right now is fear—there's fear from surgeons that the guy down the street is going to get one of these and is going to start advertising, and they're going to lose all of their cataract patients," Dr. Hoffman said.

Going forward, Dr. Miller would like to see the situation evolve akin to what happened with premium lenses with Medicare offering a special exemption. "But we'll have to prove that there's a tangible benefit with improved clinical outcomes," he said. "Right now we don't have that data."

Dr. Miller hopes that early adopters follow an ethical standard beyond reproach. "I hope early adopters do everything above board and ethically so that the whole house of cards doesn't come down," he said. This happened to one province in Canada with premium lenses when it became apparent that fees were all over the map. After an investigation, the government stepped in and set a rate. "The same could happen here in a heartbeat," Dr. Miller said. "The government could decide if you want to use a laser you can charge an additional \$169—and that will put the whole thing out of business."

Editors' note: *Drs. Banja and Hoffman have no financial interests related to their comments. Dr. Miller has financial interests with Alcon (Fort Worth, Texas).*

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