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LASIK: Beyond Refractive Surgery, Part I

Cornea Donation

LASIK Shatters Assumptions

By Laura J. Rongé

In southern California, an eye surgeon prepared to perform a corneal transplant. The patient was anesthetized and the recipient eye readied for surgery, when suddenly the surgeon had to make an urgent call to the eye bank. Why? "I was in the middle of trephining a donor cornea, when it fell apart," he said.

"Fortunately, we were able to send a new cornea right away, and the surgeon finished the operation," said Ronald E. Smith, MD, medical director of the Doheny Eye Bank in Los Angeles. Later, back at the eye bank, researchers examined the ruined cornea and determined that it had had LASIK.

This anecdote, compounded by other reports in the press, may make cornea surgeons wonder: Should we be concerned about how the current keratorefractive surgery boom might affect the cornea donor supply?

Here, five cornea experts discuss the current trends and some protective measures for the future.

People who have had LASIK can't donate their corneas for use in human corneal transplants: How will this affect the supply of donor corneas?

The average age of LASIK patients is about 40. These people are not donating tissue at this time but might in the future, said Penny A. Asbell, MD. "I think eventually it is going to catch up with us and affect the supply."

Right now there is a good supply of donors for the number of transplants performed in the United States each year, Dr. Smith said. However, more than a million LASIK operations are done in this country each year. "If things stay as they are, we will lose more than 10 million potential donors over the next 10 years," he said.

James P. McCulley, MD, is not so sure. "On the surface it looks like, oh my

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gosh, millions of people are having keratorefractive surgery, and they are not going to be donors, my goodness," he said. However, in a population of 280 million, this is a relatively small percentage. And there is very little overlap in the demographics of patients having keratorefractive surgery and those who typify the cornea donor pool, he noted.

"That doesn't mean this isn't going to cause a real problem for us," he said. "Even if those two populations overlap only 2 to 5 percent, if we took two corneas from a patient who had had keratorefractive surgery and used them for corneal transplant, we would have two really bad problems."

Aside from a potential donor shortage, how else does LASIK affect corneal donation?

While Dr. McCulley is not worried about the cornea supply drying up, he is concerned that the occasional potential donor who has had keratorefractive surgery might not be screened out.

The other experts agree. "We don't have a way to identify a donor cornea that has had LASIK," Dr. Smith said. "In the case described above, the cornea did not look like it had had LASIK until after it fell apart."

In a living patient, one can usually detect LASIK with a slit-lamp exam or other clinical methods, Dr. Smith said, but once the cornea has been removed from the body, these techniques don't work.

"Even when we look at our patients with the slit-lamp exam, it looks so good I sometimes can't tell myself, and I did the LASIK," added Dr. Asbell. "We need a way to screen for LASIK, easily, inexpensively and without injuring the tissue." Screening today is done largely through family history alone, she said. However, a history from the family or friends of the individual, while helpful, is not always complete.

In Dr. Smith's case above, they did ask the family about eye surgery, and the family said no. "People may not tell anybody that they have had LASIK, or the family may forget," he said.

Will eye banks be able to continue to meet the needs of cornea surgeons in the United States and worldwide?

Since 1961, more than 700,000 people have undergone corneal transplants in this country, according to the Eye Bank Association of America, but it wasn't always as easy as it is today.

Just 20 years ago, people sometimes waited more than a year for a donor cornea, Dr. Smith said. There weren't enough eye banks or enough corneas, and corneas had to be used within 24 hours, compared with five to 10 days today.

In this country, there is a bit of shortage now, depending on time and geographic distribution, Dr. Asbell said. But people don't wait forever, as they do in other countries, where there are real shortages.

"Worldwide, eye banks cannot meet the demands for corneal tissue," Eduardo

C. Alfonso, MD, agreed. "And, in the United States, there is already a waiting period for available tissue anywhere from several weeks to months."

Indeed, many countries must rely on cornea supplies from the United States, Dr. Smith said. "In the near future, we will be all right in this country. The question is, What will it be like in 10 years if current trends continue?"

There are ongoing issues about meeting the need for transplantable tissue, Dr. Asbell said. "Keratorefractive surgery will add to that difficulty in getting the appropriate supply. It is another group [of potential donors] that we have to eliminate."

Regulations and restrictions are increasing, and cornea surgeons are concerned that the donor pool will decrease. In addition to the idea of LASIK affecting the supply, there is HIV, hepatitis C and most recently transmissible prion disease, such as Creutzfeldt-Jakob disease, in patients, Dr. Smith said.

Keratorefractive surgery will not cause a major shortage of corneas, Dr. McCulley added. "We have to screen more, and we will lose some corneas, but I think that the concern about transmissible prions is a greater risk to the donor pool than is keratorefractive surgery." He noted that laboratory screening for prions will be an expensive endeavor relative to screening the anterior corneal curvature for LASIK.

What solutions should be undertaken to avert a cornea shortage?

The experts make several recommendations:

- **Increase the donor pool.** We do need to increase the pool of donors, said Richard L. Abbott, MD, and ophthalmologists must continue to encourage organ and tissue donation and to provide education and awareness to the public for donation of tissue. But, he said, "We will obviously not discourage refractive surgery."

Eye banks often provide ophthalmologists with free literature on cornea donation for distribution to patients. (See "[Literature](#)".) However, Dr. Asbell said, "Most ophthalmologists are not involved in that effort."

We also need to inform the public that if they have had keratorefractive surgery, they are not potential cornea donors. "They can help us to screen themselves out," Dr. McCulley said. "In many states, we can designate body parts for donation on our driver's license. The driver's license could designate, for example, kidneys, heart but not corneas because of prior keratorefractive surgery."

- **Find alternative tissues.** "If we could take all corneal tissue from all potential donors, even those with unhealthy corneal endothelium, and seed corneal stromal tissue with corneal endothelium that has been grown in tissue culture, we could create a usable modular cornea from otherwise unusable corneas," Dr. McCulley said.

In addition to coating the posterior surface of the harvested corneal stroma with endothelium, one could coat the anterior surface of the cornea with corneal epithelium or amniotic epithelium, he added.

He and his colleagues continue to work on tissue culture of corneal endothelium, corneal epithelial stem cells and amniotic epithelium. "We have not solved all the problems, and we are not ready to transplant a reconstituted modular cornea directly into patients. But we are at the stage of transplanting amniotic epithelium onto the surface of diseased human corneas," he said.

The concept of growing organs has generated plenty of interest. "They are regrowing all sorts of organs, but we are far from an artificial cornea. I wouldn't bank on that any time soon," Dr. Asbell said.

- **Determine which corneas with LASIK are usable.** There may be a way to determine whether a cornea that has had LASIK is useful for transplant surgery, Dr. Smith said. "We think that one to three years post-LASIK, you can't use it. It might be that five or 10 years after LASIK, the cornea is OK. We need a way to determine if LASIK has been performed, and also if that cornea is still useful for transplant even if it has had LASIK."

In most clinical cases, using a cornea that has had a refractive procedure may not be a problem, Dr. Alfonso said. "The refractive power of the treated cornea may be just fine to compensate the refractive error of the recipient."

Will LASIK continue to be the procedure of choice for refractive surgery, or will it eventually be replaced by other procedures, which will present different challenges?

Dr. Asbell noted that although current designs of phakic intraocular lenses are less than perfect, with time they may become more compatible, easier and safer to use in the eye, making them a reasonable alternative to a laser procedure.

"Phakic IOLs will have the predictability of a machinemade object. Most surgeons are comfortable with cataract surgery, so they will already know how to do it, as an extension of their usual skill set, rather than learning a whole new procedure, as with LASIK," she said.

Of course, another idea is that of using wavefront analysis to detail every aberration of the visual system and then correcting each one to give people "perfect" vision. "One thing we have learned from this analysis is that every time you touch the cornea, you may be inducing aberrations rather than decreasing them. No matter how well you make the flap [during LASIK] and put it down again, you run that risk," Dr. Asbell said.

"As a result of these considerations, people are talking about LASEK, where you roll back the epithelium, laser the stroma and then roll the epithelium back into place, without creating a flap," she said. "The point is that we don't know what the procedure of the future will be."

How to Identify Corneas With Refractive Surgery

Most of our examination methods fall short in identifying LASIK in postmortem corneas:

- **A slit lamp** will show some types of refractive surgery, even in a cadaveric

eye. One can see radial keratotomy. One can see PRK with haze, assuming that the corneal epithelium is not so unhealthy as to mask it. If a person has had PRK and does not have haze, they will be difficult to screen out. "I certainly would still do a careful, thoughtful slit-lamp examination of the cornea, which will catch some keratorefractive surgery," Dr. McCulley said.

- **Screening** of potential donors for prior keratorefractive surgery must be developed so that it's more cost effective and efficient. Specular microscopy is not going to demonstrate it, Dr. McCulley noted. One might consider measuring corneal thickness, but if a patient has had a low degree of correction, not enough tissue is removed to reveal corneal thinning. Plus, death leads to corneal swelling, so assessment of corneal thickness probably is not going to work.

- **Topography** is a possibility, but eye banks are not set up to do that, Dr. Asbell added. "Once you handle the tissue in sterile conditions and put it in solution, people will not want to take it out to do anything more with it. The question is, how would you set that up?"

- **A handheld keratometer** to measure anterior corneal curvature before the corneal scleral rim is removed may be the answer. Dr. McCulley and his colleague published a study that showed the technique is feasible.¹ The instruments are widely available, but acceptance of the technique has been small. "It adds another step, and the instrumentation that was available to us at that time must be made much more user friendly. The eye bank technicians did not find it easy to do and therefore just repeatedly forgot to do it," Dr. McCulley said.

The challenge is to develop an easily used instrument that will allow surgeons to get photographic documentation of the corneal curvature. A reusable instrument should cost only a few thousand dollars and should last for many years. "It will add minimally to technician time in removing the cornea. With that, we can easily screen out the majority of the patients who have had keratorefractive surgery," Dr. McCulley said.

1 *Cornea* 1994;13:379–382.

Literature

If you would like to receive patient information literature on cornea donation, please contact:

Eye Bank Association of America

1015 18th St., Suite 1010
Washington, DC 20036
202-775-4999

<http://www.restoresight.org>

The Tissue Banks International

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410-752-3800

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