



THE EYES HAVE IT

Or do they? Only time will tell if new eye surgery will be a boon or blind alley.

BY JOANNE SILBERNER

An elderly man lies on the operating room table with green sheets covering everything but his left eye. This lone spot of blue stares upward unfocused, the anesthetized brain failing to mark the bright glare, the surgical microscope or the masked faces of the people hovering above.

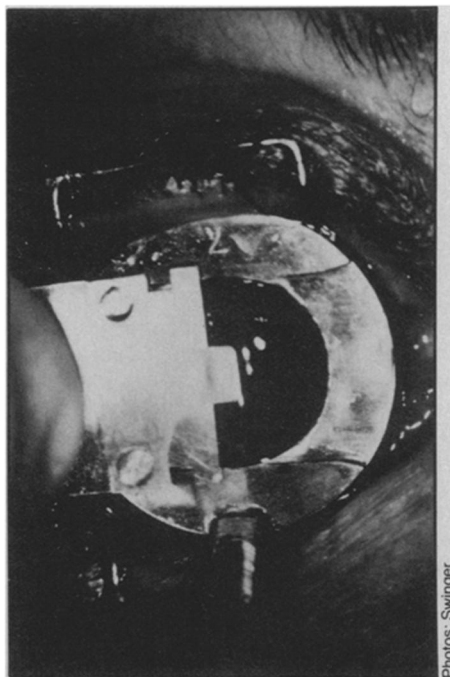
The eye is held still by a small stitch quickly made in the eye muscle. Looking through the surgical microscope, ophthalmologist Casimir Swinger then makes a tiny identifying scratch on the cornea, the clear protective tissue that overlies the pupil and iris. He speaks loudly to the patient: "You can relax. The operation's going well." The patient grunts and falls back into sleep.

A tiny horizontal guillotine is carefully rested on the center of the eye and a neat slice is made, severing a few tenths of a millimeter of cornea. The patient snores occasionally, apparently unperturbed by the goings on. Swinger gently slips a piece of donated cornea, previously frozen in liquid nitrogen and then carefully carved to exact proportions, under the slice. After checking the identifying scratch to make sure the patient's own cornea is still properly oriented, the ophthalmologist reattaches the tissue by tightening a single neat eight-pointed stitch, sandwiching the new donor tissue within.

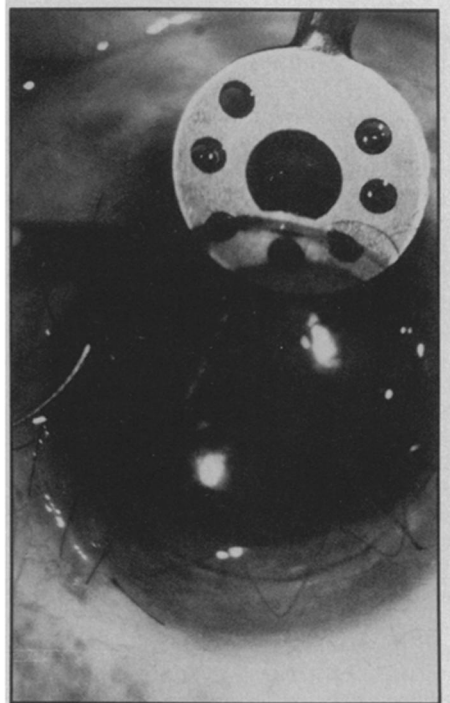
The procedure, called keratophakia (kerato = cornea, phakia = lens), is one of several operations that manipulate the corneal curvature to treat vision problems, taking advantage of the fact that the eye's cornea has even more refractive power than does its lens. Other such procedures include keratomileusis (kerato = cornea, mileusis = carving), in which the patient's cornea is sculpted; radial keratotomy, a series of radial cuts that flatten the cornea; orthokeratology, in which the cornea is remolded with contact lenses; and a variation of keratophakia that uses an artificial lens rather than a piece of donated human cornea.

These procedures have been introduced during the past few years, some of them accompanied by fanfare from the press. But none of them is conventional and none is backed by large, controlled studies. This last fact concerns the National Eye Institute, which has called for complete animal and clinical trials before the procedures, some of which require a great deal of training to perform, are widely adopted. Meanwhile, they are being done on a limited basis.

Keratophakia, for one, is used at only a handful of medical centers in this country, and mostly for persons who have had op-



In keratophakia and keratomileusis, the cornea is carefully sliced (above). Sculpted corneal tissue is slipped under the slice to increase the outer eye curvature during keratophakia (below).



erations to remove cataract-clouded lenses. Without their own lenses, these people must rely on "Coke-bottle" glasses, contact lenses or intraocular lens implants (artificial lenses placed within the eye, behind the iris) to restore their vision. But the thick heavy glasses magnify and distort, and often prove too cumbersome for comfort. Contact lenses are expensive, and many older persons are not capable of the delicate manipulations necessary for proper insertion and care. The intraocular lens implantation operation is still a matter of controversy because of the risk of infection and complications involved in implanting a foreign object within the eye. A National Institutes of Health consensus conference in September of 1979 called for more clinical trials and recommended against the use of intraocular lenses in both eyes, in younger patients, in patients with only one good eye and in patients with certain diseases.

Swinger favors the keratophakia operation over the lens implant procedure for most of his patients. "If it were my eye, I'd prefer it," he says. The advantage for the patient, he notes, is that the decision for the type of vision correction to be used does not have to be made before the operation. If intraocular lens implantation is the choice, it is done at the same time as the cataract removal. With keratophakia, the patient can first see if he or she can tolerate glasses or contact lenses before resorting to a surgical remedy.

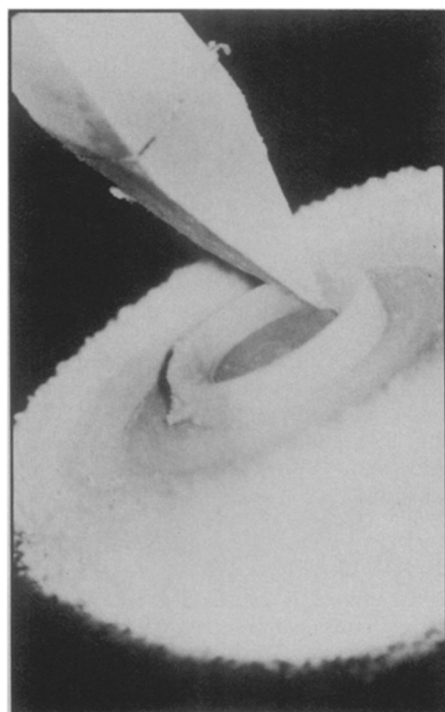
Keratophakia was developed by Jose Barraquar of Bogotá, Colombia, about 20 years ago. Swinger, who learned the procedure from Barraquar, says he has seen no eye loss or cases of rejection in the 60 or so keratophakia operations he has performed at the Beth Israel Medical Center in New York City, where he is the assistant director of ophthalmology. Cells within the corneal tissue are killed in the freezing process, and the foreign cornea is later colonized by native cells so rejection is unlikely, he explains.

A second procedure, keratomileusis, can be used to treat nearsightedness as well as farsightedness. In keratomileusis, a procedure also developed by Barraquar, a piece of the patient's cornea is removed, frozen, carved to a mathematically determined curvature and stitched back onto the cornea. The objective is the same as that of keratophakia—to change the outer curve of the cornea to affect the eye's refraction. Notes Swinger, "Keratomileusis is the first surgical procedure in history in which a part of the normal organ is removed from the body, surgically modified, and replaced to effect a beneficial change

in normal physiologic function." The procedure, said to provide near-normal vision, is more difficult than keratophakia. If the slice is too thin, it can't be carved, and if anything happens to it, a donor cornea has to be used.

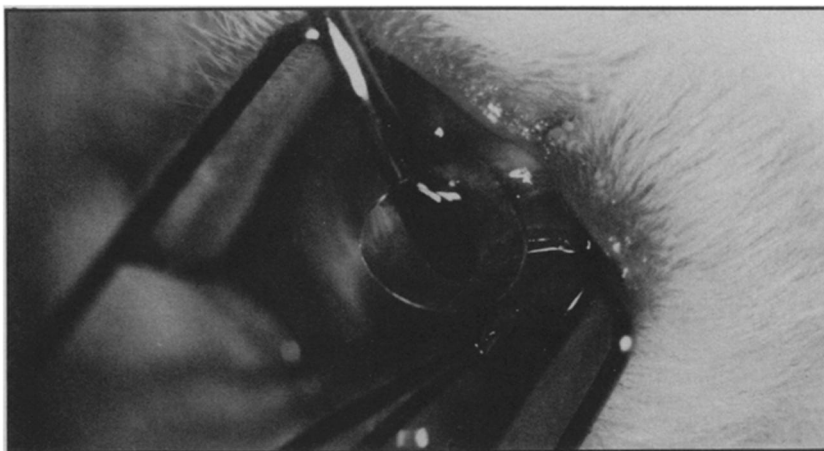
Keratophakia and keratomileusis are called refractive surgery because they physically change the light-bending and focusing quality of the eye. Other researchers are working on modifications of the procedures (see box). Swinger, a former aerospace engineer who does much of the complicated instrumentation involved in carving the corneas, is just now beginning to do keratophakia on persons other than cataract patients.

Radial keratotomy, a more widely done and simpler surgical treatment for nearsightedness, has generated controversy and concern among ophthalmologists. Radial keratotomy was introduced as a treatment for nearsightedness by Soviet ophthalmologist Svyatoslav Fyodorov. In 1973 a schoolboy came to him following a



A frozen cornea is carved to computer-determined proportions by a cryolathe.

fight in which his glasses were broken, cutting into the cornea of one of his eyes. Not only did the injured eye heal after radial keratotomy was performed, but the boy's vision improved. The case suggested to Fyodorov a surgical treatment for nearsightedness. He developed a procedure in which 16 incisions radiating from the eye's central optical zone are made. Internal eye pressure causes the edge of the cornea to bulge, flattening the central portion of the cornea and moving the focusing point back, closer to where it should be on the retina. The depth and length of the cuts are dictated by a computer that has been supplied information on the shape of the



Sara Scholl/Emory Univ.

Physiologist Bernard E. McCarey at Emory University is working on an artificial lens for placement within the cornea. Instead of using a donated cornea as in keratophakia, he is using plastic, making the procedure more like placing a contact lens within the cornea. The lenses are new plastics that are up to 90 percent water. These lenses permit glucose and other nutrients to pass through, so the underlying cornea will still be nourished, McCarey says.

Implantation is done by making a 0.5-millimeter cut into the cornea, then reaming out a pocket with a tiny golf club-like device. The procedure takes about 20 minutes, McCarey says. So far

he has placed the lens in rabbits, cats and monkeys. In the seven months the lenses have been implanted, he has seen some rejection in rabbits, but none in monkeys. "The tissue does not stick to plastic at all," he says.

The advantage to intracorneal lens implants is that the hydrogels are easier to deal with than donor tissue and obviate the need for sophisticated lathe work on a patient's or donor's fragile cornea, he says. And by not going into the eye itself, the procedure avoids the problems of intraocular lens implantation. But whether the implant will prove to be a permanent, sterile contact lens, and whether it will hold up over time, remains to be seen.

eye and the degree of myopia.

Last May, the National Advisory Eye Council, an arm of the National Eye Institute, issued an advisory expressing "grave concern about potential widespread adoption" of radial keratotomy and called for carefully controlled human and animal trials before the treatment is made widely available. The American Academy of Ophthalmology also has expressed concern about possible abuse of the procedure by untrained surgeons. At the Academy's recent annual meeting, nearly 1,000 of the 8,000 or so ophthalmologists in attendance signed up for a session on the procedure, which was introduced at last year's meeting by Fyodorov. "The interest," says Norman Stahl, an ophthalmologist associated with the Creative Surgery Center in New York City, "is phenomenal and will grow."

Stahl, who learned the procedure from Fyodorov in Moscow last year, has done more than 100 radial keratomies in the United States since then. He says the operation can help "many to most" nearsighted persons, the limit being the degree of nearsightedness, the shape of the cornea and the amount of astigmatism. "We can't do it so precisely as to guarantee 20/20 vision," Stahl says, "but the majority of patients have been able to go without glasses full time or part time."

Side effects? "There is scarring," Stahl

notes, "and some patients, especially those who had the same complaint with contact lenses, complain about glare. But there have been no eyes lost, and I've seen no cases of infection." Radial keratotomy is useful only for nearsightedness, but some researchers are working on adapting the procedure for farsightedness by attempting to shrink the outer cornea with heat or electricity. This work is still in the animal phase, notes Stahl.

There's also a new nonsurgical procedure — orthokeratology. In principle, orthokeratology is to poor vision what orthodontics is to buck teeth. A series of hard lenses forces the eye into the proper shape. Complications include corneal scarring, and the procedure, says Swinger, cannot improve vision beyond 20/50. The National Eye Institute is not wild about the idea. "The safety and permanence of the changes orthokeratology effect remains a subject of controversy among eye specialists," they noted recently.

Despite such warnings, people will go to almost any lengths to regain lost vision. Some of the new techniques may not pan out, some may leave eyesight worse than before, some may restore precious vision. What remains to be seen from the upcoming clinical investigations and evaluations of keratophakia, keratomileusis, radial keratotomy and orthokeratology is whether the risk is worth it. □