

## Operative Vision

*Lens-weary patients and progressive ophthalmologists anxiously await FDA approval for sight-repairing surgery to be available in this country.—By Sigrid Bathen*

SUSAN WAGNER HAS worn glasses or contact lenses since she was 10. At 27, she works on a computer all day in the finance department of the City of Davis.

"It got to the point where I was helpless without my lenses," she says. "The contacts were becoming a nuisance, and I really felt that I wanted to be independent, not relying on having my glasses nearby or being sure I had saline solution for my contacts."

She even had special lenses in her goggles for scuba diving. "If the mask comes off," she says with some understatement, "I've got a problem."

Without correction, her vision was 20/400 in both eyes, 20/20 with glasses or contact lenses.

Two times last year, Wagner flew to San Diego, where she and several other eye patients were picked up and driven to a clinic just across the border in Tijuana. There, an increasingly popular form of laser surgery called photo-refractive keratectomy, or PRK, was performed on one eye in February and on the second eye in May.

"It was a very nice facility, and [the doctor] told me every step of the way what I was going to experience."

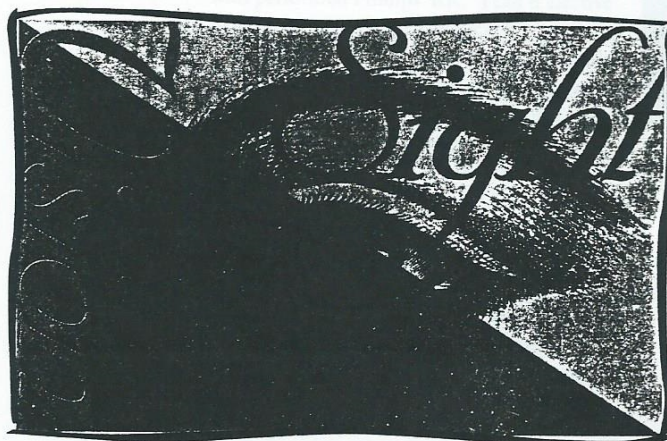
Wagner received a mild sedative and anesthetic eye drops before the procedure, which was completed in moments with no pain. "When the drops wore off, I had extreme sensitivity to light. They gave me dark glasses, but mostly I just wanted to stay in the dark for a day. There were slight, occasional twinges of pain for a couple of days, but nothing constant." After spending about two hours in the clinic, she flew back to Sacramento that afternoon.

"Admittedly, when I was first informed of the procedure and they said it was done in Tijuana, I was a bit concerned and asked about Canada," says Wagner. "But after seeing the facility in Mexico, I had no qualms about going back to have my second eye done. It was very state-of-the-art." The doctor who performed her surgery, Dr. Arturo Chayet, lives in Chula Vista and received his medical training at the University of California in San Diego.

Since the procedure, Wagner has 20/25 vision in both eyes.

Like many American patients, Wagner chose to go out-

side the country for a procedure not yet approved by the United States Food and Drug Administration, which many ophthalmologists and patients say is unnecessarily stalling a technique long used in other countries and first perfected in the U.S. with American technology. Other ophthalmologists are more cautious, even questioning the ethics of doctors who would circumvent U.S. medical standards designed to protect patients.



Refractive surgeries are considered cosmetic, so patients must foot the bill.

PRK is expected to win FDA approval soon, perhaps as early as this month, and American ophthalmologists are scrambling to outfit offices with the sophisticated—and expensive—equipment needed to perform PRK.

"I think it's a real tragedy," says KXTV news anchor Jennifer Smith, who had the procedure performed in Canada last January and covered it on the air in a first-person series that lit up the station's switchboard with calls from anxious potential patients. "It's American technology, and we can't use it."

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Before her surgery, which was performed by one of the pioneers in the field, Dr. Donald Johnson of New Westminster, near Vancouver, British Columbia, Smith's vision was 20/500 and 20/450 without contacts or glasses, which she'd had to wear since the second grade. Her overall vision is now 20/15 without glasses or contacts. Like Wagner, she is an extremely satisfied patient.

Using sophisticated computerized techniques and high-tech instrumentation, refractive surgeries—and there are several different types—alter the shape of the cornea, and hence the way it focuses. Refractive surgeries are not to be confused with orthokeratology, a nonsurgical technique performed by optometrists (who are not licensed to perform surgery) using contact lenses to change the shape of the eye.

The most common refractive surgical procedure is radial keratotomy, or RK, in which small incisions are made in the cornea to change its curvature. While lasers are approved for use in the United States for treating or correcting such conditions as glaucoma and certain cataract-related conditions, they have not been approved for treating nearsightedness. And, although refractive surgeries are generally regarded as elective or cosmetic by insurance companies, and thus patients must foot the bill themselves, many patients say their lives and even their livelihoods are often at stake.

"It's not cosmetic when you can't see," says Smith. "I could only leave my contacts in for the half-hour I was doing the news. I would get makeup under them, or something. If I was covering a fire, I'd get something in my eyes."

After the procedure, Smith says, she had some pain initially, but that was managed with pain killers. "The next morning [a Saturday], my vision was not very good, and I thought, 'Oh, my God, what have I done?' But they had warned me, and by Monday, my husband was driving me to the eye doctor in Sacramento, and I had 20/20 vision. He was wearing glasses and couldn't see some of the street signs, but I could."

Smith, who also had astigmatism, says a slight difference in improved vision between both eyes—"one eye is a little bit better than the other"—caused her some annoyance. "But it evened out. I did have some blurriness at night and when my eyes got tired. Still, in low light, there is some blurriness around the edges, some smearing of light at night. But it doesn't affect my ability to drive."

The Canadian procedure cost \$2,000 per eye plus transportation and lodging. Wagner's PRK cost \$1,650 per eye in Mexico plus

transportation. Both costs include follow-up with coordinating physicians in Sacramento—Smith with Drs. Robert Griffin and Brent Reed, Wagner with Dr. Richard Meister of the Center for Sight in Sacramento.

Despite her severe myopia and the occupational hazards of her contacts and glasses, Smith had long avoided RK because of the required corneal incisions. "I'd heard some horror stories about RK," she says, "and I didn't like the notion of my eye being sliced."

Many RK patients praise the procedure, however. Ken Phillips, a lieutenant in the Placer County Sheriff's Department in Auburn, opted for RK last November. Given the demands of the work, particularly for patrol and street duty, eye doctors say law enforcement officers are often prime candidates for corrective vision surgery.

"I've helped a lot of law enforcement and corrections people who need to have uncorrected visual acuity of 20/60 or better, particularly if they're involved in some sort of altercation," says Meister, the Sacramento ophthalmologist who performed Phillips' RK. "I call it elective [surgery], rather than cosmetic."

While Phillips said his nearsightedness (20/200 and 20/80 uncorrected, plus astigmatism) did not affect his work, he found glasses and contacts a nuisance. "I like outdoor activities, backpacking. It was more of a convenience thing for me. It [RK] was affordable, and it was safe. The only down side was that I may need reading glasses."

Phillips is now 20/40 in both eyes, which means he can drive legally without glasses, though he has a pair for night driving, when his vision goes down to 20/50. He says as many as 20 sheriff's department employees, including his partner, have had RK, and none has been dissatisfied. "It's nice to be able to look up and see things," he says.

Nanci Price, 50, is an accountant who owns a Santa Clara plastics business. Ztech Machine, with her husband. They divide their time between their Santa Clara business and a home in Lake Tahoe. Born without an optic nerve in her left eye, Price has no vision in that eye and had 20/200 vision in her right.

On Aug. 25, she took a major medical step and opted for RK on her one good eye. "As the years go by, I sit at a computer, putting my glasses on and taking them off. I couldn't see small, medium or large without putting them on. I've lived with blindness all my life. I requested [the surgery]. Dr. Meister told me all the risks, that in all the keratotomy, only one man lost an eye completely, that he got an infection and didn't go to the doctor. They cautioned me that if there was ever anything in my eye. . . ."



## The Latest Techniques

Meister, who performed the surgery, said he was "not anxious" to do it because of Price's blindness in one eye, and made certain she understood all the possible complications. Price was determined.

"It was the easiest thing I had ever experienced. As a one-eyed person, I'm very aware that 50 percent is gone. For me to give my eye to somebody, I had to have a lot of confidence. It took eight minutes. There was zero pain. I was very impressed." Price's "good eye" now sees at 20/40 uncorrected.

Costs for RK in both eyes range from \$1,500 to \$3,000. The major criticism of the procedure has, until recently, been that there is no assessment of its effectiveness.

A landmark study released last fall, reviewing 10 years of RK surgeries throughout the country, concluded that, while the vast majority of RK patients have satisfactory long-term results, some patients' morning-to-evening vision "continued to fluctuate" 11 years after the procedure, necessitating glasses for some patients at certain times of the day. And some patients experienced a "long-term drift toward farsightedness," according to the study.

Ophthalmologists around the country are poised to perform PRK and related pro-

The following techniques are used to treat nearsightedness (some techniques are designed to treat astigmatism or farsightedness as well):



### NONSURGICAL

**Orthokeratology (Ortho-K):** A nonsurgical process, performed by optometrists, that uses a series of hard contact lenses to gradually flatten the cornea and reduce the refractive error. Optometrists say it is much like the way braces are used to shape teeth. It is "reversible," or temporary.

### SURGICAL

*All surgical techniques (listed below) must be performed by an ophthalmologist, a medical doctor specializing in the eye.*

**Radial Keratotomy (RK):** A common refractive surgery, practiced in the United States since 1978, in which small incisions are made around the center of the cornea, causing it to "flatten" and allowing light to focus differently, creating a clearer image. Widely used to treat nearsightedness and "free" patients from glasses or contacts. **Astigmatic keratotomy (AK)** is a form of RK used to treat patients with astigmatism.

### Lamellar Keratoplasty (LK):

Used for more severe nearsightedness and moderate farsightedness, a surgical technique in which a thin layer of the cornea is surgically fold-

ed back and a precise portion of corneal tissue removed, causing the cornea to flatten. For farsightedness, according to one description of the procedure, a "slightly thicker" layer of cornea is folded back, with pressure inside causing the cornea to "steepen."

**Photo-Refractive Keratectomy (PRK):** Using an excimer laser instead of a surgical device, and not yet approved for use in the United States, PRK is performed in many other countries, including Canada and Mexico. Using a laser to "vaporize" the central area of the cornea, the computerized procedure is more expensive than RK. Like RK, it changes the shape of the cornea to treat nearsightedness.

**Laser-Assisted in Situ Keratomileusis (LASIK):** Also known as laser intrastromal keratomileusis, a procedure combining LK and PRK to treat nearsightedness and astigmatism. Uses an excimer laser, and still undergoing FDA trials in the United States.

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cedures once FDA approval is granted.

Trials in the United States are also being conducted with a new laser procedure called laser-assisted in situ keratomileusis, or LASIK, also known as laser intrastromal keratomileusis—a procedure that involves surgically “folding back” a thin layer of the cornea (the corneal cap) and removing some corneal tissue with an excimer laser, which does not require stitches. As with other refractive procedures, LASIK causes the cornea to “flatten,” reducing or eliminating nearsightedness.

In an article headlined “Technique of the Week,” *Ophthalmology Times*, a publication of the American Academy of Ophthalmology, noted the complexities and pitfalls of the new LASIK technique: “Both the microkeratome [the surgical device used in many refractive surgeries, including RK and LASIK] and the excimer laser require high standards of maintenance. Microkeratome performance and function have direct bearing on complication rates and surgical outcome.” Translation: the equipment used in refractive surgeries requires meticulous and exacting care and maintenance to produce good results.

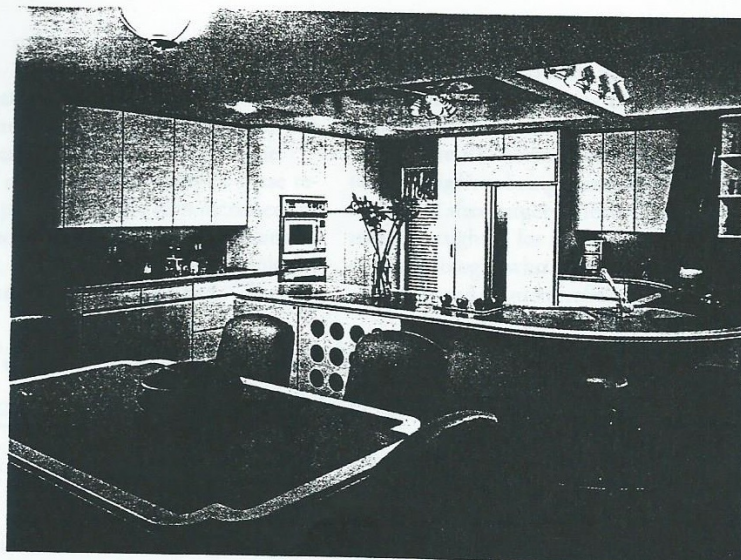
Serious complications from refractive surgeries are relatively rare, but there are horror stories. In one recent front-page article examining the new laser surgeries in the *Wall Street Journal*, a Michigan woman who went to Canada for PRK said her vision got “much worse” after the surgery. “When she looked at a straight line, it curved,” the paper reported. “Her depth perception was so bad, she began walking into things. Her body became spotted with bruises.”

She again had laser surgery to correct the condition, which continued to worsen. Ultimately, she switched surgeons and is now gradually regaining her vision.

Cases like hers have prompted the FDA to move with such deliberation. One member of the FDA panel reviewing PRK for introduction in the U.S. told the *Wall Street Journal* that the failure rate is “far too high” for elective surgery on essentially healthy eyes (the Michigan woman, a software engineer, had good vision with glasses but wanted to be free of them because they made her feel “handicapped”).

Dr. Ivan Schwab, a Sacramento ophthalmologist and professor at the University of California, Davis Medical School, supports the FDA approach and is critical of doctors who send patients out of the country for laser surgery. A specialist in the cornea and external diseases of the eye, he

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does not perform refractive surgeries "unless it's an eye that has a specific disease, and myopia is not a disease."

"I think this group of procedures is viable," he adds, "and they do work. The laser works even potentially better than RK over the long term. My approach is that it is an area I did not want to participate in. I view the eye as basically healthy. I didn't feel I wanted to work with people who have normal eyes, and do harm. [There have been] negative results from refractive surgery. I see the complications, and these are referred to me by the nature of what I do."

He believes the FDA "is appropriate in its concern" about the new laser surgeries. "As a society, we ask the FDA to protect us from avaricious practitioners and devices and compounds that may harm us. I think we know very little about this and are learning a lot about it. . . . This is a potential public health problem if there is a large number of people who may have problems."

Some ophthalmologists will say privately that "declining reimbursement" by in-

## Health

surance companies in this era of "managed care" means that some doctors are sent scrambling for new sources of revenue. Refractive surgery is such a source, and a potentially lucrative one.

"It is safe to say that many of these refractive procedures have seen increased interest because of declining reimbursement in other areas," said one ophthalmologist who asked not to be identified. "There is

In this era of managed care, refractive surgery could be a lucrative source of revenue.

great potential for abuse and claims that go beyond what these procedures can do."

Problems include infections of the surface of the eye, which can be difficult to treat because they may not respond to ordinary antibiotics. Incisions in radial keratotomy that are too close to the line of sight can result in glare. Done properly—particularly if a patient is very nearsighted—the RK incision must come close to the line of sight, requiring considerable surgical skill. Pro-

fessional opinions vary, but some ophthalmologists say there is room for abuse in the rush to refractive surgeries as a "cure" for nearsightedness.

The rare RK horror stories include patients going from being nearsighted to being farsighted after surgery. "You don't want to trade nearsighted for farsighted," said one ophthalmologist who is critical of the spate of elective and cosmetic refractive surgeries, as well as of doctors who send patients out of the country. "Then you need glasses for both."

Other problems after surgery include "irregular astigmatism," which can only be corrected with contact lenses—which can in turn cause further scarring that is difficult to treat. Critics add, however, that most problems have not resulted in marked loss of vision, and infections that cause loss of an eye are very rare.

"Most will do well, and patients are generally very satisfied [with refractive surgery]," says Schwab. "But patients need to be prepared. Planes crash, cars crash, and this kind of surgery can go wrong. As a physician, above all, [I pledge] to do no harm. I see potential harm, even though rare." ■



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