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*Health*

## Reading the Fine Print

*A variety of emerging treatments are tackling problems with close-up vision, but a cure remains elusive*

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As she approached 40, Beverly Ingram realized she was losing her close-up vision. "I couldn't get my makeup on, I quit sewing because I couldn't thread the needle, and I wore my hair up in a bun because it was easier," says the Fullerton, Calif., businesswoman.

She stuck reading glasses on a chain around her neck, but her scarves and jewelry kept getting caught. "I really felt frumpy," she says. "It was a mess."

The problem was presbyopia, an age-related condition that affects 110 million Americans, usually beginning in their 40s, according to the research firm Market Scope LLC. Presbyopia, which means "aging eyes" in Greek, occurs when the crystalline lens of the eye hardens and is unable to change shape and focus on objects near at hand, according to the common theory. The symptoms are the same as farsightedness, but the cause is different: Farsightedness, which is often hereditary, occurs when the eyeball is too short or the cornea too flat.

Traditionally, people have dealt with presbyopia with reading glasses, bifocals or contact lenses. Now, convinced that aging baby boomers represent a billion-dollar market, companies are experimenting with an array of surgical presbyopia treatments, from replacement lenses to laser treatments to implants that stretch the white part of the eye. Ms. Ingram tried one of those new procedures in June 2003: conductive keratoplasty, or CK, which uses radio waves to reshape the cornea to improve close-up vision.

"I couldn't believe it," says Ms. Ingram, now 57. "I feel like I reinvented myself." She started playing cards with her friends again and donated her reading glasses to the Lion's Club.

### Looking Forward

There are big caveats for these new methods. "None of these things is a cure," says Terrence O'Brien, the director of refractive eye surgery and professor of ophthalmology at Johns Hopkins University School of Medicine in Baltimore. "They are really methods to cope with presbyopia. We're still trying to understand the underlying mechanisms."

Moreover, some of the new treatments, such as CK, have to be repeated to keep close-up vision clear, and others carry a risk of complications. In most cases, the procedures aren't covered by insurance.

CK, the treatment Ms. Ingram used, is the first procedure approved by the Food and Drug Administration to compensate for the vision problems caused by presbyopia. The method, which works best for people with excellent distance vision, was initially approved by the FDA in 2002 for extreme farsightedness. It was cleared last March for presbyopia-induced problems. Last year, largely thanks to that new FDA approval, the number of CK procedures performed more than doubled to 47,000.

How does it work? First, a bit of background about the parts of the eye, and how they work together. When light enters the eye, it first strikes the cornea, a clear covering that bends the rays and directs them through the pupil and onto the retina at the back of the eye. There, they are converted to electrical impulses and sent off to the brain.

The lens, which is behind the pupil, acts as a fine-tuner, ensuring that the light on the retina is in focus. Muscles in the eye contract or expand so the lens can focus on objects at varying distances.

As the lens ages, it becomes stiffer and thicker, and grows in size, says Daniel Durrie, an ophthalmologist in Overland Park, Kan., and a clinical investigator for Refractive Inc., of Irvine, Calif., which markets CK. The changes to the lens cause presbyopia by creating "a mismatch between the optics of the cornea and the optics of the lens," he says. "CK creates a better optical relationship."

Doctors use a tiny probe to apply radio waves in a circular pattern on the edges of the cornea, thus shrinking the collagen, a protein found in the eye. That creates a constrictive band that increases the cornea's curvature, allowing it to focus light more precisely. CK doesn't directly correct the problems with the lens that cause presbyopia, Dr. Durrie says; instead, it adjusts the cornea to compensate for the lens, and therefore the near vision is better.

CK takes only a few minutes, requires an eye-drop anesthetic and usually is performed on only one eye. The other eye is left untreated to handle distance vision. The cost: about \$1,500 to \$2,000. And because it doesn't involve any cutting or removal of tissue, CK has a very low risk of complications.

Steve Graves, a 56-year-old resident of Weston, Mo., who works as a financial analyst for Citibank, got CK last July. "When I realized I didn't need glasses anymore, it was a great feeling," he says.

### **Another Perspective**

But CK is far from perfect. "Some people will be able to cope with it, and some won't" because it treats only one eye, says Dr. O'Brien of Johns Hopkins. This creates what's known as monovision, in which one eye handles distance and the other focuses on near objects. Monovision can cause dizziness, nausea or other discomfort in some patients, as well as affect depth perception. Dr. O'Brien urges some patients considering CK to try wearing one lens for a while to see if they can adjust to monovision.

Moreover, the procedure has to be repeated anywhere from a year to five years after the initial treatment, and then again over time, to address the continued changes that the aging of the lens brings.

Some doctors wonder how many times the procedure can be repeated. "For patients 45 to 50, they can do it only two or three times, because after that they run out of room on the cornea," says Ernest Kornmehl, an ophthalmologist in Brookline, Mass.

Proponents say it's unfair to fault CK for not being a cure. "It's more of an anti-aging procedure," says Dr. Durrie. "If you get a wrinkle removed, it doesn't mean that you'll never get another one." He also says patients find CK-induced monovision much easier to tolerate than the kind created by using a contact lens in one eye.

Some doctors also use excimer-laser surgery, or Lasik, to treat presbyopia. This use of the procedure hasn't been directly approved by the FDA, although it is allowed as an "off-label" use: Once the FDA approves a drug or a procedure for one use -- in this case, treating nearsightedness and farsightedness -- doctors are free to use it for other purposes.

As in other laser eye surgery, the doctor cuts a flap in the cornea and uses a laser to reshape the tissues underneath. Only one eye is treated, and the result, as with CK, is monovision.

But that may change. The excimer laser is set to be tested in clinical trials to reshape both corneas, with the goal of enabling both eyes to see close, medium and far. Such studies have been going on in Canada and Britain and are getting under way at five sites in the U.S., including Johns Hopkins, according to Dr. O'Brien. Creating a multifocal cornea "would be a big advance," he says. "It's much more exciting than using monovision."

### **Replacing Lenses**

Another approach to presbyopia involves artificial lenses. Implantable lenses have long been used in cataract surgery to replace irreparably clouded natural lenses. Traditionally, however, the lenses were designed for distance vision, so reading glasses were still needed. Then, last November, the FDA approved the Crystalens,

described as the first "accommodative" lens. Equipped with tiny hinges, it moves back and forth in response to eye-muscle movements, and is designed to provide clear vision at all distances.

Crystalens, which is manufactured by eyeonics Inc., Aliso Viejo, Calif., was approved by the FDA for use in cataract patients. But some doctors are using it off-label to treat presbyopia in noncataract patients, a process called "clear-lens extraction," at a cost of \$4,500 to \$5,000 per eye. Some eye experts disapprove, saying the risks, which can include detached retinas and infections, can't be justified.

"I would never elect to have an artificial lens put into my normal eye," says Adrian Glasser, associate professor at the College of Optometry at the University of Houston.

Others disagree, saying that natural lenses aren't normal and healthy after age 40. "The lens gets more senile every day," says David Brown, an ophthalmologist in Fort Myers, Fla., who argues that there's no reason to wait until cataracts appear to replace the lens. He says the risks involved with clear-lens replacement are low, and are no different from those involved in regular cataract surgery.

Another approach to improving close-up vision is being tested in clinical trials by Refocus Group Inc., a Dallas medical-device company. The process, called the Scleral Spacing Procedure, is based on the controversial theory that presbyopia results from the continued growth of the lens, which leads to crowding and an inability to focus. That runs counter to the conventional view that a stiffening of the lens mainly causes the condition.

In the procedure, a physician makes four incisions in the sclera, or white part of the eye, and implants pieces of plastic about the size of a grain of rice. The sclera is thus stretched, giving the lens the room it needs to focus, proponents say.

Terry Walts, president and chief executive of Refocus Group, says the procedure takes about 30 to 40 minutes per eye under local anesthetic. Since the implants are under the conjunctiva -- the clear tissue over the white of the eye -- they can't be felt by the patient, the company says.

### **Seeing Change Overnight**

The procedure hasn't been approved in the U.S., but Kevin O'Brien, a 48-year-old surgical assistant and marketing director for an ophthalmology practice in Buffalo, N.Y., traveled to Mexico seven years ago to have it done. "The next day I woke up and was able to see to the very bottom of the reading card," he says.

Some physicians are skeptical of the procedure, and the company itself says FDA approval is at least three to four years away. It recently completed the first half of its Phase II clinical trial, and got favorable results, the company says.

Despite the high-tech alternatives on the horizon, some people are content with traditional vision aids. A few years ago, Naomi Karp, a 54-year-old attorney in Washington, started having trouble reading restaurant menus. But she says she's unlikely to give up her reading glasses for more drastic action.

"I'd have to know a lot more about the cost and invasiveness," she says. Though glasses can be annoying, she says, "they're easy enough to deal with. I talk to my ophthalmologist and he tells me what strength to get, and that's what I get."

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