

FDA Expected to Approve New Corrective Eye Surgery

**Implantable Lenses Offer Hope
To the Very Nearsighted;
A Potential Rival for Lasik**

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Paving the way for yet another entrant to the increasingly crowded field of corrective eye procedures, the Food and Drug Administration is expected in coming days to approve implants that would allow severely nearsighted people to shed their glasses.

In the latest procedure, a tiny corrective lens is implanted directly in the eye. Doctors expect the FDA to approve the first of these new lenses any day now. A second competing lens could get a green light soon, too.

It is likely the FDA will initially approve the procedure for severely myopic patients, though it is unclear what range of impaired vision will be included. These patients can't have laser eye surgery, because it would destroy too much of their corneas. There are about three million people who are severely myopic, or nearsighted.

But over time, eye doctors predict that use of the procedure will spread to people with more mildly impaired vision, putting the implants into direct competition with laser surgeries such as Lasik, the popular vision-correction procedure in which corneal tissue is reshaped with a laser.

For now, the new eye surgery won't be approved for people with astigmatism, in which an oblong-shaped cornea causes blurred or distorted vision. There are tests under way on so-called toric lenses that could extend the new procedure to people with astigmatism within a year or so.

The eye implants join a broad range of other developments in the fast-changing field of eye surgery. Among the most popular innovations are wavefront technology, which maps the eye and creates a customized laser treatment, as well as conductive keratoplasty, or CK, which uses radio waves to reshape the cornea. The FDA approved CK this year for hard-to-treat presbyopia, the reading-vision handicap that develops with age.

Unlike Lasik, implant surgery must be done in a sterile operating room. One eye is treated at a time, with patients waiting a matter of weeks or even months between eyes. In Lasik, they usually are both done the same day. The implants can be taken out if a patient isn't satisfied with them.

The implants will generally cost more than Lasik. Ophthalmologists who are gearing up to offer the procedure say they will charge several hundred dollars

more per eye for the intraocular surgery than for Lasik, putting the cost of the new procedure at between \$2,000 and \$3,500 an eye. Like Lasik, it won't be covered by insurance.

If there is a complication from lens implantation, it could be more serious than with Lasik because the interior of the eye is involved. One concern is that cataracts can form if a patient's natural lens is knocked during surgery. The rate of complications in the clinical trials by the lens manufacturer was very low, but it isn't unusual for more problems to emerge once a new medical procedure gets marketing approval and more physicians start using it.

Still, the risks of complication from implantation are small enough that they may be acceptable to patients whose natural vision is so poor that they can barely see their hands or recognize their friends without glasses or contact lenses. Each of the two competing lenses underwent a three-year trial that included several hundred patients. Patients in the FDA tests reported that their vision after surgery was as good as, or sometimes even better than, their corrected vision beforehand.

Elizabeth A. Davis, a surgeon at Minnesota Eye Consultants in Minneapolis, which has been testing the devices, says she initially was skeptical about the eye implants. But the group has successfully treated more than 200 patients, she says. "No one has said they didn't want it in the second eye; no one has asked to have an implant removed."

The surgery "hurt less and was less troublesome than having my teeth cleaned," says David Ash, a 48-year-old real-estate investor in Los Angeles. Now, "I wake up without glasses, I drive without glasses. The astigmatism bothers me a little bit more at night," he says. Mr. Ash plans to get a Lasik touchup to get rid of the astigmatism as soon as he is released from the FDA study.

Julie Fournier, a 33-year-old software saleswoman in Minneapolis, underwent the surgery three years ago. Her vision used to be so bad that she couldn't read an alarm clock on a bedside table. Contact lenses made her eyes bloodshot. She loved whitewater rafting but worried about losing a lens in rapids. That fear finally propelled her into a doctor's office.

Her corneas were too thin and her correction too steep to safely undergo a laser procedure. Instead, Dr. Davis suggested the experimental lens. She spent about two hours at the surgery center each time, including 30 minutes of surgery. "I took the patch off the next day and was able to see 20-20 for the first time," Ms. Fournier says.

Eye doctors long have treated patients with cataracts -- a clouding of the eye's natural lens -- by removing the lens and implanting a new, artificial one. But in this surgery, doctors don't disturb the natural lens.

To implant the new lenses, an incision is made in the eye, and the lens is inserted through the incision. The two competing lenses are set in different

places in the eye. The Verisyse lens, to be sold by AMO Inc., sits behind the cornea and in front of the iris, far from the natural lens that is vulnerable to cataracts, while Starr Surgical Inc.'s Visian lens is positioned right in front of the eye's natural lens.

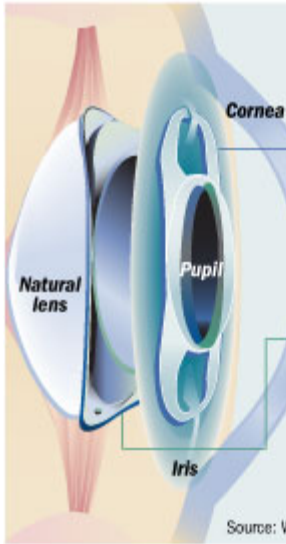
Surgeons, many of whom are lining up behind one lens or the other, cite pros and cons for each product. (The surgeons who are most familiar with the lenses tend to be paid consultants who have participated in one or both of the companies' FDA tests.) The Visian lens is made from a soft, foldable material that is easier for surgeons to insert, as it requires only a three-millimeter incision.

The Verisyse lens is made of hard plastic and requires a much larger incision. It also has small arms that clasp the back of the iris, the colored part of the eye. But the lens has a long track record in Europe, where it has been sold for more than a decade under the Artisan brand name.

The Verisyse lens -- which likely will be the first to be approved by the FDA -- already has been implanted in about 100,000 eyes in Europe, so U.S. surgeons have had a chance to "piggyback onto the European learning curve," says Kerry Assil, an ophthalmologist in Santa Monica, Calif. Dr. Assil has implanted both lenses and says they are both "good alternatives." The Verisyse lens has been more popular in Europe.

The FDA data don't show a significant difference between the lenses in the rate of cataract formations, says John Vukich, an eye surgeon at the Davis Duehr Dean Center for Refractive Surgery in Madison, Wis. He attributes the Artisan's higher European sales numbers to its "home-field advantage."

The Artisan lens has been sold by the Dutch company Ophtec BV for 13 years. AMO, based in Irvine, Calif., acquired rights to sell it in the U.S. under the Verisyse name a few years ago. Staar Surgical is based in Monrovia, Calif. Ophtec's lens was known as the "Worst claw" lens for many years -- a reference to the inventor and an aspect of the lens design -- a nickname that probably didn't help spread the product's appeal in English-speaking countries.




Assisting the Eye

To improve vision, a tiny corrective lens can be implanted in the eye. Two different kinds of lenses are awaiting approval.


Verisyse
Positioned behind the cornea and in front of the iris

- Sits far from the natural lens
- Made of hard plastic
- Requires a 6-millimeter incision in the eye



Visian
Positioned between the iris and the natural lens

- Sits next to the natural lens
- Made from a soft foldable material
- Requires a 3-mm incision in the eye



Source: WSJ research