Medical Xpress

FDA clears first implantable telescope for vision

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U.S. health officials have approved a first-of-its-kind technology to counter a leading cause of blindness in older adults - a tiny telescope implanted inside the eye.

The Implantable Miniature Telescope aims to help in the end stages of incurable age-related macular degeneration, a creeping loss of central vision that blocks reading, watching TV, eventually even recognizing faces.

The idea: Surgically insert the Implantable Miniature Telescope into one eye for better central vision, while leaving the other eye alone to provide peripheral vision. The brain must fuse two views into a single image, and the Food and Drug Administration warned Tuesday that patients need post-surgery rehabilitation to make it work.

There's little to help such advanced patients today aside from difficult-to-use handheld or glasses-mounted telescopes, while the new implanted telescope - smaller than a pea - can improve quality of life for the right candidate, said Dr. Malvina Eydelman, FDA's ophthalmic devices chief.

But it's only for a subset of the nearly 2 million Americans with advanced macular degeneration, Eydelman warned: Those 75 and older, with a certain degree of vision loss, who also need a cataract removed. In fact, the FDA took the highly unusual step of requiring that patients and their surgeons sign a detailed "acceptance of risk agreement" before surgery, acknowledging potential side effects - including corneal damage

and worsened vision - and the need for lots of testing to determine who's a candidate.

"We're not giving people back 20-year-old eyes," cautioned ophthalmic surgeon Dr. Kathryn Colby of Harvard and the Massachusetts Eye and Ear Infirmary in Boston. She helped lead manufacturer VisionCare Ophthalmic Technologies' study of the implant.

But by magnifying images onto more of the retina than its diseased center, someone who before couldn't see an entire face might now miss only the nose, Colby said.

In a 219-patient study, the FDA said 90 percent of telescope recipients had their vision improve by at least two lines on an eye chart, and three-quarters went from severe to moderate vision impairment.

Concern about damage to the inside lining of the cornea, the eye's clear front covering that helps focus light, held up FDA approval for several years. In that study, 10 eyes had serious corneal swelling, five that required corneal transplants. FDA's Eydelman said the company proposed candidate restrictions to minimize that risk, and will study how an additional 770 recipients fare after sales begin.

VisionCare, of Saratoga, Calif., is seeking Medicare coverage for the surgery and rehab costs, a package that it calls CentraSight. The company wouldn't estimate total costs but said the device itself costs $15,000.

More information: FDA: http://www.fda.gov
VisionCare: http://www.centrasight.com